frontiers | Research Topics

Ethical considerations for digital public health

Edited by
Denise Veelo, David Černý, Josef Kure and Stephen Roberts

Published in
Frontiers in Public Health

ISSN 1664-8714
ISBN 978-2-8325-5537-8
DOI 10.3389/978-2-8325-5537-8

About Frontiers

Frontiers is more than just an open access publisher of scholarly articles: it is a pioneering approach to the world of academia, radically improving the way scholarly research is managed. The grand vision of Frontiers is a world where all people have an equal opportunity to seek, share and generate knowledge. Frontiers provides immediate and permanent online open access to all its publications, but this alone is not enough to realize our grand goals.

Frontiers journal series

The Frontiers journal series is a multi-tier and interdisciplinary set of open-access, online journals, promising a paradigm shift from the current review, selection and dissemination processes in academic publishing. All Frontiers journals are driven by researchers for researchers; therefore, they constitute a service to the scholarly community. At the same time, the *Frontiers journal series* operates on a revolutionary invention, the tiered publishing system, initially addressing specific communities of scholars, and gradually climbing up to broader public understanding, thus serving the interests of the lay society, too.

Dedication to quality

Each Frontiers article is a landmark of the highest quality, thanks to genuinely collaborative interactions between authors and review editors, who include some of the world's best academicians. Research must be certified by peers before entering a stream of knowledge that may eventually reach the public - and shape society; therefore, Frontiers only applies the most rigorous and unbiased reviews. Frontiers revolutionizes research publishing by freely delivering the most outstanding research, evaluated with no bias from both the academic and social point of view. By applying the most advanced information technologies, Frontiers is catapulting scholarly publishing into a new generation.

What are Frontiers Research Topics?

Frontiers Research Topics are very popular trademarks of the *Frontiers journals series*: they are collections of at least ten articles, all centered on a particular subject. With their unique mix of varied contributions from Original Research to Review Articles, Frontiers Research Topics unify the most influential researchers, the latest key findings and historical advances in a hot research area.

Find out more on how to host your own Frontiers Research Topic or contribute to one as an author by contacting the Frontiers editorial office: frontiersin.org/about/contact

Ethical considerations for digital public health

Topic editors

Denise Veelo — Amsterdam University Medical Center, Netherlands

David Černý — Institute of Computer Science, Czech Academy of Sciences, Czechia

Josef Kure — Masaryk University, Czechia

Stephen Roberts — University College London, United Kingdom

Citation

Veelo, D., Černý, D., Kure, J., Roberts, S., eds. (2024). *Ethical considerations for digital public health*. Lausanne: Frontiers Media SA. doi: 10.3389/978-2-8325-5537-8

Table of contents

frontiers | Frontiers in Public Health

TYPE Mini Review
PUBLISHED 11 January 2023
DOI 10.3389/fpubh.2022.1118116

OPEN ACCESS

EDITED BY
Denise Veelo,
Amsterdam University Medical Center, Netherlands

REVIEWED BY
Christos Troussas,
University of West Attica, Greece

*CORRESPONDENCE
Marcel Pikhart
✉ marcel.pikhart@uhk.cz

SPECIALTY SECTION
This article was submitted to Digital Public Health, a section of the journal Frontiers in Public Health

RECEIVED 07 December 2022
ACCEPTED 23 December 2022
PUBLISHED 11 January 2023

CITATION
Klimova B, Pikhart M and Kacetl J (2023) Ethical issues of the use of AI-driven mobile apps for education. *Front. Public Health* 10:1118116. doi: 10.3389/fpubh.2022.1118116

Ethical issues of the use of AI-driven mobile apps for education

Blanka Klimova, Marcel Pikhart* and Jaroslav Kacetl

Department of Applied Linguistics, Faculty of Informatics and Management, University of Hradec Kralove, Hradec Kralove, Czechia

Nowadays, artificial intelligence (AI) affects our lives every single day and brings with it both benefits and risks for all spheres of human activities, including education. Out of these risks, the most striking seems to be ethical issues of the use of AI, such as misuse of private data or surveillance of people's lives. Therefore, the aim of this systematic review is to describe the key ethical issues related to the use of AI-driven mobile apps in education, as well as to list some of the implications based on the identified studies associated with this research topic. The methodology of this review study was based on the PRISMA guidelines for systematic reviews and meta-analyses. The results indicate four key ethical principles that should be followed, out of which the principle of algorithmovigilance should be considered in order to monitor, understand and prevent the adverse effects of algorithms in the use of AI in education. Furthermore, all stakeholders should be identified, as well as their joint engagement and collaboration to guarantee the ethical use of AI in education. Thus, the contribution of this study consists in emphasizing the need for joint cooperation and research of all stakeholders when using AI-driven mobile technologies in education with special attention to the ethical issues since the present research based on the review studies is scarce and neglected in this respect.

KEYWORDS

artificial intelligence, mobile apps, ethics, ethical principles, education

Introduction

At present artificial intelligence (AI) is an indispensable part of people's lives and affects all fields of human activity, including education where it helps to enhance personalized learning and thus makes learning more student-centered in the form of using exploratory learning, collaborative, automatic assessment systems (1, 2), mobile game-based learning (3, 4) or conversational chatbots for developing foreign language skills (5–7). However, there are many aspects of the use of AI that need to be researched as the lack of data in these areas is still an issue, such as the impact of AI-driven tools to enhance human cognition or second language acquisition. The facts we know are that the use of AI technology in classes not only contributes to students' learning but can also reduce in some respect a teacher's workload and can improve students' learning and their learning results (8–10). However, fortunately, AI-driven technology cannot replace

teachers' pedagogical work in any case (11) since AI technology does not know which methods suit best to meet students' learning needs.

Despite the undeniable benefits that AI technology brings for both students and teachers, there are certain risks and threats associated with ethical issues and these risks should be carefully evaluated by both conceptual and empirical studies that will clearly delineate where the potential threats could be. One of these major risks is privacy or the lack of it. AI technology based on algorithmic applications intentionally collects human data from its users and they do not specifically know what kind of data and what quantities of them are collected. Although legislatively (in many countries or geographical/political regions, such as the European Union) user consent is required before using any AI technology, the user actually does not know what is happening with his/her data in the system (12). Therefore, AI technology companies should minimize this data and aim to include only the information that can enhance student learning (1).

In addition, using, for instance, chatbots for developing foreign language speaking and writing skills, indicates another problem and that is monitoring students' ideas, which might consequently decrease student engagement in using this tool since s/he does not want to be tracked or even stalked for his/her ideas [cf. (13)]. This aspect is also related to students' autonomy, i.e., the ability to govern their own learning since the use of algorithms can make predictions about their actions based on provided information input by students (14). As Reiss (15) puts it, *within every AI system there are the fruits of countless hours of human thinking*. Furthermore, another risk is connected with gender bias, for example, when using machine translation tools (16) that could actually create an environment that is not considered fair from the gender perspective.

Therefore, to reduce these risks, the European Commission (17) in October 2022 published a set of ethical guidelines for primary and secondary teachers, as well as for school leaders in order to effectively integrate AI technology and data into school education and raise awareness of their possible threats. The ethical use of AI and data in learning, teaching, and assessment is based on four key ethical considerations, which include human agency, fairness, humanity, and justified choice. In addition, the document lists new competencies of educators for the ethical use of AI technology and data for educational purposes, such as being able to critically describe the positive and negative impacts of AI and data use in education or being able to understand the basics of AI and learning analytics.

Therefore, the aim of this review is to describe the key ethical issues related to the use of AI-driven mobile apps in education and draw the attention of the academic community to these issues that might be set aside in the quest for research outcomes. The following research questions were formulated:

1. *What are the major ethical issues that could be observed when using AI-driven mobile apps for educational purposes?*
2. *What are the future lines of research related to the given topic that can be obtained from the studies available?*

Methodology

To obtain the answer to the research question, the study strictly followed the PRISMA methodology for systematic reviews and meta-analyses. This analysis was used to delineate a major trajectory of the given topic so that further implications could be shown. The following inclusion and exclusion criteria were followed.

Inclusion criteria

- All studies focusing on the research topic.
- Published between January 2018 and December 2022, i.e., last five years.
- Scopus and Web of Science databases.
- Peer-reviewed and only English-written journal articles were included.
- Search terms were applied in the title, abstract, or keywords of the articles.
- Open access journals.

Exclusion criteria

- Published earlier than 1 January 2018.
- AI-driven apps that are not used for educational purposes.
- Other (less reputable) databases.
- Other languages.
- Other than open access articles (such as gold and hybrid access, etc.).

Search string

The following search string was applied to create a dataset of all relevant articles.

("AI" OR "artificial intelligence") AND education AND ethic*.

As the search string was rather wide, it was necessary to manually eliminate all nonrelevant articles to yield only those that significantly contribute to the topic. The initial search using this search string generated 118 documents from Scopus and 467 studies from the Web of Science. After applying all inclusion

and exclusion criteria and removing duplicates, 44 studies could be considered to be analyzed. The authors also conducted a backward search, i.e., they searched the references of detected studies for relevant research studies which could be missed during their research. This generated another 2 studies. Thus, altogether 46 experimental studies were identified for the full-text analysis. After this initial screening, all the studies were carefully checked for their relevance to the topic by the research team and only 8 documents remained to be included in this analysis as they all represented breakthrough ideas that pertain to the topic and bring a novel and unbiased approach.

Results

The following studies have been yielded as they contain a clear systematic approach to the topic and they fully focus on the ethical issues of AI in mobile apps (14, 18–24). The other detected texts only included more or less superficial comments on ethics, touching only on isolated issues, such as privacy [e.g., (25–28)]. These studies are interesting and important, however, they could not be included in this specific conceptual research frame.

The chosen studies can be further subdivided into those that address purely educational issues related to AI (19, 21, 22, 24) and those that discuss the use of AI in medicine (20, 23) and could also be included in this study, while Leimanis and Palkova (18) address ethical issues of AI in medical education. The remaining study (14) deals with the ethics of AI in various disciplines, with machine ethics, a subfield of the ethics of AI, as a focal point but it provides insightful comments related to education, therefore, it also had to be included in this review. The summary of the key findings are in Table 1.

From a theoretical point of view, the key areas of ethics are at least mentioned in the texts studied. Stenseke (14) explains that ethics asks questions about what is good in particular cases, which points to *applied ethics*, then proposes general norms, which is what *normative ethics* is for, and explores the nature of morality, which is the topic of *metaethics*. The most widespread ethical theories are mentioned in at least one of the examined texts. These include *deontology* (14, 20, 21), *utilitarianism* [(14, 20, 21), *consequentialism* (14), *virtue ethics* (14, 21)]. These conceptual clarifications seem relevant and provide the reader with a necessary theoretical background that can be further extended into a practical application of this theoretical framing.

In terms of ethical principles that most often relate to the ethics of AI, the analyzed texts [e.g., Solomonides et al. (23) list the four prima facie ethical principles of beneficence, nonmaleficence, autonomy, and justice] include these that revolve around the following ones:

- *Beneficence* (beneficence, benevolence, nonmaleficence, do good, be good, goodness).
- *Accountability* (accountability, (risk) liability, responsibility, but also trust, explainability, interpretability, auditability, trustworthiness, transparency, sustainability, dependability).
- *Justice* (equality, justice, fairness, equity, no bias, no discrimination).
- *Human values* (human rights, dignity, freedom, autonomy, moral behavior, consciousness, rationality).

The texts studied bring some remarkable findings that seem to be very important to the understanding of the current situation. First, the most significant finding, included in six studies (14, 18–20, 23, 24), is that interdisciplinary, multi-stakeholder collaboration that takes into account different perspectives across disciplines is essential for establishing globally acceptable standards of AI ethics. These stakeholders include end-users and developers of AI systems, as well as other organizational and societal stakeholders, including manufacturers and indeed anyone who comes into contact with AI systems (23). Currently, there appear to be various barriers to such collaboration, as policies vary in content and application from institution to institution [e.g., Leimanis and Palkova (18)]. Perspectives also differ significantly from discipline to discipline (e.g., social science, philosophy, engineering, law) as ethicists and engineers rarely find common ground (14).

Javed et al. (21) studied the disciplinary distribution of AI ethics course delivery by the department and argue that AI courses are mainly delivered by computer science and humanities departments, but also by law departments, and some courses are multidisciplinary, i.e., offered by at least two different departments. The same authors recognize three basic approaches to teaching AI ethics, namely Build (engineering and technical aspects—trustworthy technical solutions), Assess (multidisciplinary teams focused on philosophy and application—judgments based on fundamental principles), and Govern (humanities and law disciplines focused on developing general knowledge—stakeholder protection). They add that holistic teaching that removes disciplinary, topic-oriented, and other barriers should be pursued (21). In the same vein, Stenseke (14) emphasizes the importance of avoiding a narrow disciplinary perspective by analytically understanding the different ways in which each discipline understands underlying concepts, conducts its research, and produces results.

Second, based on the texts studied, it can be assumed that the most promising areas for the development of AI ethics are *medicine, education, and engineering* (i.e., engineering directly related to AI). However, we cannot see these fields as necessarily strictly separated, but rather as overlapping or intertwined. This is especially so because interdisciplinary collaboration is seen as highly beneficial in the field of AI ethics as it is repeatedly supported by various research findings [see e.g., (14, 18–24)]. Engineering primarily encompasses the field of AI system manufacturing and includes all those involved in the entire AI

TABLE 1 An overview of the key findings from the detected studies.

References	Field	Objective	Ethical principles mentioned	Findings
Leimanis and Palkova (18)	AI ethical issues in healthcare education	Draw attention to ethics as an international problem and challenge global standards or ethical setting instruments	Seven key requirements that AI systems should meet in order to be deemed trustworthy: human agency and oversight, technical robustness and safety, privacy and data governance, transparency (the data, system and AI business models should be transparent), diversity, non-discrimination and fairness, societal and environmental well-being (AI systems should benefit all human beings, including future)	Numerous institutions create their own standards-the policies differ significantly in content and application; multi-stakeholder collaboration is required to optimize accountability, transparency, privacy, and impartiality to create trust.
Henry and Oliver (19)	Ethics of engaging with artificial intelligence (AI) in higher education—ethical and trustworthy AI	Show that ethics should not be understood only as abstract values or design decisions, but as socio-technical achievements—political and practical "doings," enacted in the practices of students, teachers, and corporations.	Restorative/reparative justice values such as obedience, the rule of law, and deterrence Fairness, accountability and transparency explicability, non-harmful use, responsibility and integrity	The ethics of using AI in education are political, involving the distribution of power, privilege, and resources. Immediate need for restorative justice against the slower temporality of systemic failure. Create new relationships between universities, students, businesses, algorithms, and the idea of academic integrity.
Hu et al. (20)	(Current barriers to) AI adoption in patient care (medicine)	Warn of the risks posed by AI due to its non-transparency and inherent potential for harm when used as a decision-making tool. Prove that the role of the physician (humans) likely remains paramount to (clinical) decision-making in the near future.	Deontology, nonmaleficence, utilitarian conflict, and beneficence. Utilitarian conflict of beneficence in deciding the extent to which it is acceptable to use an AI algorithm that may be more accurate and benefit certain subgroups at the expense of others. Deontological conflict to adhere to nonmaleficence. If we know there is a high likelihood of increasing disparity despite the beneficial aspects of AI, the application of AI would be unethical.	Substantial data bias may lead to unforeseen disparities in patient care as AI may stratify based on unintentional subgroups. Interdisciplinary collaboration between data scientists, data stewards, clinicians, and healthcare workers is crucial to developing a risk liability and quality improvement system before AI can serve as a medical decision-maker. AI is capable of identifying hidden features within data that can be leveraged to improve decision-making, but it is not without potential risk and needs to be deliberated by all stakeholders
Javed et al. (21)	Education: they analyzed 166 syllabi of AI ethics courses at 105 universities around the world.	Uncovers topics in teaching ethics in AI courses and their trends related to where the courses are taught, by whom, and at what level of cognitive complexity and specificity. Analyze patterns of teaching AI ethics and critically assess their implications.	Philosophy-related syllabi often include the study of classic ethical frameworks (e.g., utilitarianism, deontology, virtue-based ethics)	Department-wise disciplinary distribution of AI ethics courses: computer science, humanities, multidisciplinary, and law. An essential solution stressed for decades by educational, governmental, and industrial organizations for addressing problematic issues has been to incorporate ethics into teaching AI to tech professionals and future AI practitioners ranging from raising ethical awareness to developing concrete skills for the implementation of ethical guidelines.
Renz and Vladova (22)	AI in Education, learning, and teaching	Introduce the concept of human-centered AI (HCAI, i.e., AI under human control), which in line with human values without risks to humanity. It uses "design-for-values" approach (aims at making /incorporating moral values part of technological design, research, and development)	Human values, human rights, human dignity, and human freedom are at the center of AI design	HCAI teaming (integrating people with AI assistants) model of education. Now is the right time to consider value-conscious design principles in developing human-centered and responsible AI that addresses social, legal, and moral values prior to and during the technology development process.

(Continued)

10.3389/fpubh.2022.1118116

TABLE 1 (Continued)

References	Field	Objective	Ethical principles mentioned	Findings
Solomonides et al. (23)	American Medical Informatics Association's (AMIA) AI life cycle principles	Define and provide a rationale for principles that should guide the commission, creation, implementation, maintenance, and retirement of AI systems as a foundation for governance throughout the life cycle.	Requirements of practice and research in medicine and healthcare: beneficence (AI is designed explicitly to be helpful to people who use it, or on whom it is used, and to reflect the ideals of compassionate, kind, and considerate human behavior), nonmaleficence ("Do No Harm," every reasonable effort to avoid, prevent, and minimize harm or damage to any stakeholder), autonomy, and justice (equity in representation in and access to AI, data, and the benefits of AI; remedy in the event of harm resulting from the use of AI; the affirmative use of AI to support social justice) comes first. A set of principles follow from the creation and engineering of AI systems: explainability of the technology in plain terms; interpretability, that is, plausible reasoning for decisions; fairness and absence of bias; dependability, including "safe failure"; provision of an audit trail for decisions; and active management of the knowledge base to remain up to date and sensitive to any changes in the environment.	Introduce AI judiciously, in the appropriate environments, and in accordance with the principles outlined here. Principles require benevolence—aiming to do good through the use of AI; transparency, ensuring that all assumptions and potential conflicts of interest are declared; and accountability, including active oversight of AI systems and management of any risks that may arise. Stakeholders must be identified and consulted.
Shih et al. (24)	AI (including AI ethics) course for students with non-engineering backgrounds	Attempts to answer the following two questions: • Does the present situated-learning-based course have an effect on students' understanding of AI, AI teamwork, and attitudes toward AI? • Does the present course enhance students' awareness of AI ethical issues?	Ethical issues that arise in the use of AI include transparency, fairness, responsibility, and sustainability	Learning about ethical issues related to AI requires diverse perspectives from different fields of expertise. AI understanding and attitude toward AI can predict learners' awareness of AI ethical issues. The design of the course activities helped students pay more attention to the ethical issues.
Stenseke (14)	AI ethics across a diverse set of disciplines Machine ethics (ME)—a subfield of AI ethics—seeks to implement ethical considerations into AI systems	Explore the gap between ethics and technology and look for ways to reconcile the conflict between two discipline-specific approaches to machine ethics: the philosophical approach and the engineering approach Q: Whether and to what extent machines can or should be moral.	What is good; What does it mean to do good/to be good? Deontology, consequentialism (compared to utilitarianism, it does not specify the desired outcome). Determine what is moral in particular cases (applied ethics), advance general standards of what is moral (normative ethics), or explore the meaning and nature of morality (metaethics). Phenomena— e.g., moral behavior, moral cognition, moral values, or moral environments. Concepts like consciousness (phenomenal consciousness is central for the moral agency), autonomy (free will—Kantian tradition), and rationality are central to ME, Aristotle's animale rationale), "empathic rationality" capable of moral imagination and reflective equilibrium (Purves et al., 2015), Humean empiricism ("reason is the slave of passions"), and Kantian rationality (according to the law of the autonomous will) allegedly ethical machine?	Two main types of ME: (1) The philosophical approach to machine ethics (PME) weak obligation/advice—ethically justified—the conceptual exploration of what computer systems ought to do, and what systems ought to be built. (2) The engineering approach to machine ethics (EME) possibility-technically feasible—the exploration of what kind of morality can be implemented in computer systems, and what moral systems can be built. Work in machine ethics is propelled and shaped by conflicting disciplinary perspectives (philosophy and computer science) that lead to confusion on the prospect of machine morality—ethicists and engineers should strengthen and enrich their views with perspectives beyond their own discipline.

10.3389/fpubh.2022.1118116

system life cycle. It mainly covers the technical aspects related to the existence and use of AI. Medical ethics, because of its systematic nature and thoroughness based on a long tradition, carries the qualities necessary for the development of ethical theory and practice in the field of AI applied, among other areas, to education. Education actually brings all stakeholders together, because everyone can be educated in the ethics of AI. Education opens up new horizons for students, encourages them to ask new questions, and is aware of the different short-, medium- and long-term possibilities related to AI.

Third, there is a fundamental potential conflict within the ethics of AI. It consists in answering the question of whether to prioritize human-centered AI (HCAI, AI under human control) (22) or machine ethics (ME) (14). The former puts humans in the position of decision-makers, while the latter sees the future in (potential) AI being ethical in its own right without (unnecessary) human intervention. Stenseke (14) considers machine ethics as a subfield of AI ethics and adds that there are two types of machine ethics, namely the philosophical approach to machine ethics (PME) and the engineering approach to machine ethics (EME). While the former is based on weak *obligations or advice*—what AI *ought to* do and what AI systems *ought to* be created, the latter focuses on *possibilities or technical feasibility*—what morality *can* be implemented in AI and what moral AI systems *can* be created.

At least for now, we believe that AI should be controlled by humans. Although AI systems are (usually) designed for beneficial purposes, they can go awry and behave in ways that are unexpected, unclear, and counterintuitive from a human perspective (23). Nevertheless, theoretical discussions and research regarding artificial moral agents (AMAs, i.e., autonomous machines capable of making human-like moral decisions) are already underway (14).

Fourth, Solomonides et al. (23) and to some extent Renz and Vladova (22) consider the entire life cycle of AI systems. The main idea is that ethical considerations should provide ethical principles and guidelines for all activities related to the entire life cycle of AI systems, from the specification or commissioning to the creation and design, implementation, and maintenance, to the decommissioning of AI systems. Several key recommendations stem from this. One is the continuing engagement of identified stakeholders (23). Another is the application of an AI-specific ethical principle—algorithmovigilance, which is essentially the ongoing oversight of AI systems (23). Last but not least, social, legal, and moral values need to be consciously taken into account at all times (22).

Discussion

AI-related ethics, as a practical human endeavor that is studied with the help of theoretical insight, can provide very insightful comments and ideas that need further verification from a practical perspective. Moreover, it requires multi-stakeholder, interdisciplinary collaboration that embraces different perspectives because this is the only possible way how to obtain reliable results that could be further utilized in education, medicine, and other fields that utilize AI and other digital tools that can potentially pose a threat to the human mind and therefore they must be studied from various perspectives, one of them being ethics.

Fortunately, many authors (14, 18–20, 23, 24) are already aware of the need to respect and employ diverse perspectives on AI ethics when designing, programming and creating mobile apps for various purposes, including education. In the case of education, one must not forget that these tools will be widely used by children and the younger generation as they are in the process of formal and informal education and they will thus be massively impacted by these technologies. Despite the fact that they belong to the technologically savvy Gen Z and Millennials (29), they are still, or even more, vulnerable to the threats they are exposed to, such as surveillance or sexual harassment. It also seems that ethical-related issues will gain in their momentum when various kinds of virtual, augmented, and mixed reality will become an everyday part of our lives. For all these reasons, interdisciplinary interconnectedness seems crucial as it will be necessary to connect technological aspects with ethical considerations, which will enable our survival as a society and also the individual members of it (30).

Furthermore, when thinking about interdisciplinarity, Stenseke (14) suggest ways to make interdisciplinary integration and collaboration more effective by exploiting the possibilities of different perspectives while being aware of their limitations. Indeed, the perspectives differ based on disciplines, e.g., social science, philosophy, engineering, and law, but also based on time, i.e., short-term considerations as well as potential long-term risks (14). While all stakeholders can indicate various practical ethical problems related to AI and offer possible solutions, ethicists are there to refine all of this with respect to ethical theory and to point out possible pitfalls of a lay perspective. Still, even if there are (globally accepted) ethical guidelines for AI [e.g., Javed et al. (21) mention the ACM ethics guidelines—see https://ethics.acm.org/code-of-ethics/software-engineering-code/], they will not necessarily lead to the ethical functioning of AI. Businesses and institutions can abuse or misuse them as ethics-washing, i.e., a strategy to cover up unethical behavior (14).

The ethical functioning of AI also includes issues of AMAs and machine ethics. The question of whether and to what extent machines should/could be held accountable is extremely difficult to answer. We are leaning more toward human-controlled artificial intelligence, but technology is evolving so rapidly that it is almost impossible to predict what machines or artificial intelligence will be able to do in a few decades. Despite this, as long as stakeholders raise and discuss potential problems, AI

ethics should be able to come up with relevant solutions to the looming problems posed by human interaction with AI (31).

The major limitation of this study seems to be a lack of clear-cut empirical research into the topic of AI and its ethical issues in relation to education. There is a need for at least descriptive studies that could analyze the current situational issues related to ethical issues in mobile apps as they appear based on the authors' everyday observations when using them. The volume of data available is surprisingly extremely limited to draw any concise conclusion and many authors come to very daring and unjustified suggestions regarding the implementation of AI in all teaching practices without realizing its potential problems and dangers [such as (32)]. However, these conclusions, at least preliminary, are needed and they should be considered a must for further development of this vast area of AI in mobile apps for educational purposes. If we ignore the topic's urgency, we could easily put the whole generation of young users of these apps in danger and the risks related to them are unrepairable.

In conclusion, the research questions set at the beginning provide the following summary: *The major ethical issues that could be observed when using AI-driven mobile apps for educational purposes* include key four ethical principles that should be followed—beneficence, nonmaleficence, autonomy, and justice. In particular, the principle of algorithmovigilance should be considered in order to monitor, understand and prevent the adverse effects of algorithms in the use of AI in education [cf. (33)]. Furthermore, all stakeholders should be identified, as well as their joint engagement and collaboration to guarantee the ethical use of AI in education.

As far as the second research question is concerned, i.e., *the future lines of research related to the given topic*, first, the findings of this systematic review revealed that there was an impetus for further studies that have to be conducted, be it just descriptive studies at the beginning, and later developed into more experimental studies that could verify where we are now regarding the ethical threat there are when using AI in education. Second, it clearly shows that the AI-related issues in mobile apps for education are still a big unknown but it somehow suggests, when working with recent sources, what could the possible theoretical framing and practical consequences be of the AI-driven environment. And finally, it also stresses that the only possible perspective on the topic must always be multidisciplinary. The reason for this approach is that it can never be only evaluated by the information specialist, a designer, a teacher, or a user if the implementation of AI is relevant, dangerous, or beneficial, but it must always be a consensual evaluation of the status quo, and from this point, it is necessary to proceed further to ensure safety and security related to data, individuals and the whole society.

Thus, the contribution of this study consists in emphasizing the need for joint cooperation and research of all stakeholders when using AI-driven mobile technologies in education with special attention to the ethical issues since the present research based on the review studies is scarce and neglected in this respect.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Acknowledgments

This research is part of the Excellence 2023 project run at the Faculty of Informatics and Management at the University of Hradec Kralove, Czech Republic.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

1. Akgun S, Greenhow C. Artificial intelligence in education: addressing ethical challenges in K-12 settings. *AI Ethics.* (2022) 2:431–40. doi: 10.1007/s43681-021-00096-7

2. Holmes W, Bialik M, Fadel C. *Artificial Intelligence in Education: Promises and Implications for Teaching and Learning.* Boston, MA: Center for Curriculum Redesign (2019).

3. Krouska A, Troussas C, Sgouropoulou C. Applying genetic algorithms for recommending adequate competitors in mobile game-based learning environments. In: Kumar V, Troussas C. editors. *Intelligent Tutoring Systems. ITS 2020. Lecture Notes in Computer Science, 12149*. Cham: Springer (2020).

4. Krouska A, Troussas C, Sgouropoulou C. Mobile game-based learning as a solution in COVID-19 era: modeling the pedagogical affordance and student interactions. *Educ Inf Technol.* (2022) 27:229–41. doi: 10.1007/s10639-021-10672-3

5. Meunier F, Pikhart M, Klimova B. Editorial: new perspectives of L2 acquisition related to human-computer interaction (HCI). *Front Psychol.* (2022) 13:1098208. doi: 10.3389/fpsyg.2022.1098208

6. Smutny P, Schreiberova P. Chatbots for learning: a review of educational chatbots for the Facebook Messenger. *Comput Educ.* (2020) 151:1–11. doi: 10.1016/j.compedu.2020.103862

7. Troussas C, Krouska A, Virvou M. Integrating an adjusted conversational agent into a mobile-assisted language learning application. In: *2017 IEEE 29th International Conference on Tools With Artificial Intelligence (ICTAI)*. Boston, MA: IEEE (2017). pp. 1153–7.

8. Chrysafiadi K, Troussas C, Virvou M. Personalized instructional feedback in a mobile-assisted language learning application using fuzzy reasoning. *Int J Learn Technol.* (2022) 17:53–76. doi: 10.1504/IJLT.2022.123676

9. Kerr K. *Ethical Considerations When Using Artificial Intelligence-Based Assistive Technologies in Education.* (2020). Available online at: https://openeducationalberta.ca/educationaltechnologyethics/chapter/ethical-considerations-when-using-artificial-intelligence-based-assistive-technologies-in-education/ (accessed December 4, 2022).

10. Troussas C, Krouska A, Sgouropoulou C. Enriching mobile learning software with interactive activities and motivational feedback for advancing users' high-level cognitive skills. *Computers.* (2022) 11:18. doi: 10.3390/computers11020018

11. Johnson G. *In praise of AI's Inadequacies.* (2020). Available online at: https://www.timescolonist.com/opinion/geoff-johnson-in-praise-of-ais-inadequacies-4678319 (accessed December 4, 2022).

12. Stahl BC, Wright D. Ethics and privacy in ai and big data: implementing responsible research and innovation. *IEEE Secur Priv.* (2018) 16:26–33. doi: 10.1109/MSP.2018.2701164

13. Regan PM, Jesse J. Ethical challenges of edtech, big data and personalized learning: twenty-first century student sorting and tracking. *Ethics Inf Technol.* (2019) 21:167–79. doi: 10.1007/s10676-018-9492-2

14. Stenseke J. Interdisciplinary confusion and resolution in the context of moral machines. *Sci Eng Ethics.* (2022) 28:24. doi: 10.1007/s11948-022-00378-1

15. Reiss MJ. The use of AI in education: practicalities and ethical considerations. *Lond Rev Educ.* (2021) 19:5. doi: 10.14324/LRE.19.1.05

16. Klimova B, Pikhart M, Benites AD, Lehr C, Sanchez-Stockhammer C. Neural machine translation in foreign language teaching and learning: a systematic review. *Educ Inf Technol.* (2022) doi: 10.1007/s10639-022-11194-2

17. European Commission, Directorate-General for Education, Youth Sport and Culture. *Ethical Guidelines on the Use of Artificial Intelligence (AI) and Data in Teaching and Learning for Educators.* Publications Office of the European Union (2022). Available online at: https://data.europa.eu/

18. Leimanis A, Palkova K. Ethical guidelines for artificial intelligence in healthcare from the sustainable development perspective. *Eur J Sustain Dev.* (2021) 10:90. doi: 10.14207/ejsd.2021.v10n1p90

19. Henry JV, Oliver M. Who will watch the watchmen? The ethico-political arrangements of algorithmic proctoring for academic integrity. *Postdigit Sci Educ.* (2022) 4:330–53. doi: 10.1007/s42438-021-00273-1

20. Hu Z, Hu R, Yau O, Teng M, Wang P, Hu G, et al. Tempering expectations on the medical artificial intelligence revolution: the medical trainee viewpoint. *JMIR Med Inform.* (2022) 10:e34304. doi: 10.2196/34304

21. Javed RT, Nasir O, Borit M, Vanhee L, Zea E, Gupta S, et al. Get out of the BAG! silos in AI ethics education: unsupervised topic modeling analysis of global AI curricula. *J Artif Intell Res.* (2022) 73:933–65. doi: 10.1613/jair.1.13550

22. Renz A, Vladova G. Reinvigorating the discourse on human-centered artificial intelligence in educational technologies. *Technol Innovat Manag Rev.* (2021) 11:5–16. doi: 10.22215/timreview/1438

23. Solomonides AE, Koski E, Atabaki SM, Weinberg S, McGreevey III JD, Kannry JL, et al. Defining AMIA's artificial intelligence principles. *J Am Med Inform Assoc.* (2022) 29:585–91. doi: 10.1093/jamia/ocac006

24. Shih P-K, Lin C-H, Wu LY, Yu C-C. Learning ethics in AI—teaching non-engineering undergraduates through situated learning. *Sustainability.* (2021) 13:3718. doi: 10.3390/su13073718

25. Yang C, Lin C, Fan X. Cultivation model of entrepreneurship from the perspective of artificial intelligence ethics. *Front Psychol.* (2022) 13:885376. doi: 10.3389/fpsyg.2022.885376

26. Bamatraf S, Amouri L, El-Haggar N, Moneer A. Exploring the socio-economic implications of artificial intelligence from higher education student's perspective. *Int J Adv Comput Sci Appl.* (2021) 12:2021. doi: 10.14569/IJACSA.2021.0120641

27. Zhang H, Lee I, Ali S, DiPaola D, Cheng Y, Breazeal C. Integrating ethics and career futures with technical learning to promote AI literacy for middle school students: an exploratory study. *Int J Artif Intell Educ.* (2022). doi: 10.1007/s40593-022-00293-3

28. Blease C, Kharko A, Annoni M, Gaab J, Locher C. Machine learning in clinical psychology and psychotherapy education: a mixed methods pilot survey of postgraduate students at a Swiss University. *Front Public Health.* (2021) 9:623088. doi: 10.3389/fpubh.2021.623088

29. Pikhart M, Klímová B. eLearning 4.0 as a sustainability strategy for generation z language learners: applied linguistics of second language acquisition in younger adults. *Societies.* (2020) 10:38. doi: 10.3390/soc10020038

30. Zhang W, Wang Z. Theory and practice of VR/AR in K-12 science education—A systematic review. *Sustainability.* (2021) 13:12646. doi: 10.3390/su132212646

31. Alberola-Mulet I, Iglesias-Martínez MJ, Lozano-Cabezas I. Teachers' beliefs about the role of digital educational resources in educational practice: a qualitative study. *Educ Sci.* (2021) 11:239. doi: 10.3390/educsci11050239

32. Ahmad SF, Rahmat MK, Mubarik MS, Alam MM, Hyder SI. Artificial intelligence and its role in education. *Sustainability.* (2021) 13:12902. doi: 10.3390/su132212902

33. Varkey B. Principles of clinical ethics and their application to practice. *Med Princ Pract.* (2021) 30:17–28. doi: 10.1159/000509119

frontiers | Frontiers in Public Health

TYPE Perspective
PUBLISHED 04 May 2023
DOI 10.3389/fpubh.2023.1184971

OPEN ACCESS

EDITED BY
David Černý,
Czech Academy of Sciences, Czechia

REVIEWED BY
Priya Prahalad,
Stanford University, United States

*CORRESPONDENCE
Tomáš Holčapek
✉ holcapek@prf.cuni.cz

RECEIVED 13 March 2023
ACCEPTED 11 April 2023
PUBLISHED 04 May 2023

CITATION
Holčapek T, Šolc M and Šustek P (2023) Telemedicine and the standard of care: a call for a new approach?
Front. Public Health 11:1184971.
doi: 10.3389/fpubh.2023.1184971

Telemedicine and the standard of care: a call for a new approach?

Tomáš Holčapek[1,2]*, Martin Šolc[1,2] and Petr Šustek[1,2]

[1]Department of Medical Law, Faculty of Law, Charles University, Prague, Czechia, [2]Department of Civil Law, Faculty of Law, Charles University, Prague, Czechia

Telemedicine, understood as the provision of health care by a health professional to a patient who is physically not in the same location as the health professional, has many actual and potential benefits. It also has some disadvantages though, including a higher risk of misdiagnosis or another unfavorable outcome of certain remotely-provided services. In principle, the regime of legal liability for medical malpractice is the same for telemedicine as for traditional physical care. The general outline of the standard of care, which includes respect for medical science, the patient's individuality and objective possibilities, is abstract and flexible enough to be used for remote care without the need for redefinition. The quality of health care should be evaluated on the basis of the whole scale of risks and benefits it brings to a particular patient, including accessibility and comfort. In general, it should be permissible to provide a medical service remotely on the condition that its overall quality is at least as good as its comparable physical alternative. In other words, certain decrease in quality of some aspects of remote care can be compensated by other advantages. In terms of public health, support for telemedicine may bring a great improvement in the access to health care, and thus help significantly the individual members of the population. From the individual perspective, respect for personal autonomy implies that a patient should have every right to opt for a remote service, provided that there exists a true choice between meaningful options which is made on the basis of full information. If telemedicine is to fulfill its potential without sacrificing the protection of patients and their rights, reasonable guidelines for remote services need to be defined for particular medical fields, and for specific procedures within them. Among other issues, these guidelines must address the question of when it is necessary to refer the patient to physical care.

KEYWORDS

telemedicine, remote health services, standard of care, legal liability in health care, public health, health law

1. Introduction

Telemedicine has been a widely discussed topic in recent years, especially since the onset of the COVID-19 pandemic (1, 2). Digitization of health care is on the rise (3). Demographic changes (4, 5) and technological developments (4, 6) put a strain on the financial and human resources of health systems. New methods of diagnosis and treatment promise great benefits, yet at the same time, they make it difficult to maintain access to quality care for the general public. These powerful factors will almost certainly increase the importance of telemedicine in the foreseeable future.

If understood as remote provision of health services, telemedicine has been practiced for more than a century. In November 1879, just 2 years after the invention of telephone, Lancet published a mention about a physician who had been able to avoid an unnecessary midnight home visit by organizing care for a child with suspicious cough over telephone (7). Today, telemedicine is a much more sophisticated and broad field, ranging from the remote provision of medical advice similar to that in the 19th century (only via internet, instead of telephone) to high-tech continuous monitoring of vital functions, or the involvement of artificial intelligence (machine learning and deep learning systems; hereinafter "AI"). Its potential is accompanied by various problems though, including data protection (8), bias in data-driven AI systems (9, 10), and others. All these developments and challenges have an impact on the expected standard of care, and may give rise to legal liability should the care provided fall below this standard.

Some writers suggest to define a "new form of malpractice" for telemedicine (11), while others do not consider such a dramatic measure necessary (12). Arguably, there is no reason to completely remodel the common basic elements of legal liability, such as a breach of legal duty, the existence of harm, and a causal link between the two. What needs to be discussed, however, is their interpretation and actual application in cases involving telemedicine [see Koch (13) for a similar line of thought with respect to the Principles of European Tort Law]. In medical malpractice, the critical issues are typically whether the health service provider's conduct complied with the standard of care and whether it led to any harm suffered by the patient. The introduction of new technology, especially advanced software solutions and artificial intelligence, could make it particularly complicated to prove these elements of liability in a lawsuit. Some legal theorists (14) and legislative proposals, such as the recent proposal for an AI Liability Directive at the level of EU (15), aim to solve these problems by various legal techniques including rebuttable presumptions of non-compliance and causation, applicable in certain circumstances. But we shall leave procedural aspects aside in this paper, and rather focus on the effect of telemedicine on the content of standard of care.

2. The concept of telemedicine

The nomenclature for digital and remote health services has yet to be standardized. Nevertheless, several categories are usually distinguished. The following classification (16) offers a suitable set of definitions:

- **eHealth** is the broadest category and encompasses all systematic use of information and communication technologies (ICT) in health care. It serves to augment and connect every aspect of health care including the support of preventive care, diagnostics, treatments, and health care administration.
- **Telehealth** is a subcategory of eHealth. It denotes any efforts to prevent an illness and protect health via ICT means. While telemedicine focuses on clinical applications, telehealth also encompasses tools for education and promotion of a healthy lifestyle.
- **Telemedicine** is a subcategory of telehealth. EU authorities define telemedicine as *"the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location"* (17). These services may include e.g., remote consultations between a health professional and a patient, telemonitoring of health and diagnostic parameters, data transmission to a specialist, and remote consultations among health professionals in respect of a particular case.

In this paper, we discuss the standard of medical care, which assumes by definition that it is applied in clinical settings. Hence, our focus is on telemedicine.

3. Standard of care

The standard for assessing the conduct of a health professional in a particular case may have a different definition in each legal system, but often includes the following three components:

- **Compliance with the rules of science and acknowledged medical procedures**. The objective aspect of the standard requires health care providers to comply with scientific evidence embodied in guidelines, recommended procedures, medical protocols, scientific studies and papers in medical journals etc. These sources can have a crucial role in the judicial assessment of the provider's actions. Their form and content is not identical in all countries, but the fundamental principles of the practice of medicine apply universally (18). In its article IV. C.−8:104, the Draft Common Frame of Reference (19) describes the required care and skill as such *"which a reasonable treatment provider exercising and professing care and skill would demonstrate under the given circumstances."* An absolute consensus is probably unattainable in any profession. Hence, it is usually sufficient if a procedure is accepted by a relevant part of professionals in the particular field. For example, this principle was expressed succinctly in English common law decades ago in the judgment in *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582 (*"he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art"*) (20).
- **Respect for the patient's individuality**. Diagnostic and curative procedures must sometimes be adapted to suit the patient's unique biomedical, psychological, social, cultural or religious needs. Ignoring the patient's specific context might render the care suboptimal and possibly cause harm. Blind adherence to guidelines or protocols may be negligent in itself (21).
- **Regard to particular conditions and objective possibilities**. Nobody is obliged to do the impossible (22). While health service providers must comply with the prescribed equipment and staffing requirements, it is inevitable that the means and equipment available at particular health facilities will differ.

The number of staff on duty fluctuates (compare a shift on a workday to a weekend night). An extraordinary event, such as an outbreak of the COVID-19 epidemic, may cause periods of overload when the providers simply do not have enough resources for all the patients.

4. Applying the standard of care to telemedicine

On an abstract level, the three components of the standard of care described above can be applied to all types of health care, whether provided remotely or in traditional settings. It has been stated that telemedicine must be held against the same standards as physical care (23, 24). This also includes the ethical framework of telemedicine, which does not substantially differ from other clinical care (25, 26) and can be based on a modified theory of the four ethical principles of beneficence, non-maleficence, autonomy and justice (27).

This might not pose any problem: telemedicine already improves the quality of care in specific cases, as supported by primary evidence (28–33) as well as meta-analyses and systematic reviews (34–36). It may have further benefits in the future (37). In other situations, however, the physician is simply unable to utilize all the established procedures with respect to a remote patient. Some common steps, e.g., palpation or auscultation, are unavailable. An experienced physician is often able to discern a lot of information from the patient's locomotion and behavior, and may suspect a health issue even before the patient sits down in their office (38). These clues are likely to be neglected in the current practice of telemedicine. Physicians might then tend to mitigate the heightened risk of misdiagnosis (39) by overprescription of drugs (40).

These challenges should be reflected in education offered by medical schools (41, 42). In addition, unavailability of certain techniques in remote settings can be compensated otherwise. Artificial intelligence may ask the patients questions that could be omitted by a physician due to the lack of time they can spend interviewing a patient. In the case of certain illnesses, implantable devices may collect much more data and with a higher accuracy than is possible during an interview (43). Nevertheless, the physical constraints associated with telemedicine may still mean that care provided to a patient in a particular case remotely might be somewhat riskier or less effective than could be the case otherwise.

However, the overall quality of care should be evaluated on the basis of all its aspects including accessibility and comfort for patients, as these elements undoubtedly affect both its objective efficiency and perception by its recipients. The demand for health services has been increasing in modern world, which widens the gap between the need and the supply (4, 5). Telemedicine can help tremendously in addressing the problem of access to care, including shortened waiting times, partial substitution of professional workforce by AI (helping to resolve the problem of staff shortages), maintained availability of health care outside of large cities, and improved access to specialists and second opinions. The crucial question is whether the benefits that telemedicine might deliver with respect to the quality of health care, measured at the level of society as a whole, justify the use of a different standard for specific care provided remotely to a particular patient than that which would apply in other cases. In other words, the question is whether it is acceptable to interpret the abstract standard of care with such flexibility that telemedicine could be seen as complying with this standard even though it cannot utilize all the methods and techniques which would be available in traditional settings.

If this question is to be answered in the affirmative, the matter has to be considered from two points of view: public policy and individual autonomy.

4.1. Public policy and public health

The public policy aspect involves the promotion of public health, with the obvious line of reasoning being that implementing measures which improve health of the population as a whole will likely also benefit individuals. It is naturally not acceptable to use public health merely as a pretext for sacrificing the efficiency and safety of care for individual patients in order to obtain certain societal benefits. Such an approach would contradict the constitutional right to the protection of health in many countries. Similarly, Article 2 of the Council of Europe Convention on Human Rights and Biomedicine emphasizes the primacy of the interests and welfare of the human being over the sole interest of society (44). However, it may be in the legitimate interest of public health to modify (or interpret appropriately) the standard of care with respect to telemedicine in cases where it provides access to care that could otherwise be inaccessible (45). After all, complete unavailability of care would constitute a more serious violation of the right to protection of health than mere adaptation of its standard to allow for remote provision of care.

The legislator can use different tools to advance or suppress telemedicine. Regulating the standard of care is one of these tools, as it affects the willingness of health service providers to engage in this type of activity. Providers need to take potential legal liability into consideration, and as liability insurance is usually required, so do their insurers. Apart from liability considerations, the legislator's tools also include the powers to set the amount of reimbursements from the public health insurance system, and to regulate intellectual property rights and data protection. Telemedicine is helped by the processing (collecting, sharing, analyzing etc.) of large volumes of sensitive data. All stages of this process may be problematic from the perspective of privacy and cyber security. However, while data protection may arguably be connected with the standard of care in its broadest sense, it is a very complex issue on its own, beyond the scope of this paper (46, 47).

If providers are allowed to offer telemedicine, this also affects the relevant health service market. If they can specialize in telemedicine, i.e., without being simultaneously required to offer more traditional types of care, they can drive costs down and push less-specialized competitors out of the market. This, however, could then compromise the availability of health care. If, on the other hand, the legislator mandates that telemedicine can only be offered by providers who also operate traditional facilities, this might hinder the growth of remote services. These implications need to be carefully considered from the policy-making perspective.

4.2. Individual autonomy and informed consent

An important argument in favor of permitting telemedicine, even if it has certain disadvantages, consists in the patients' autonomy. A fully informed and competent patient is entitled to make almost any decision regarding their health care, including the refusal of life-saving care. A patient should arguably have the right to agree to a modified (and, in some aspects, lowered) standard applicable to remote care, and as a result, bear some of its heightened risks in exchange for greater accessibility, comfort or other benefits. If a remote service is a legally permitted alternative to traditional care, why should the patient not be entitled to choose between the two options? This is, of course, provided that the patient has been fully informed about their relevant advantages and disadvantages.

The patient's autonomy should not be routinely reduced to a mere choice between the two options (i.e., physical or remote care). Important clinical decisions should be reached via a shared decision-making process based on bilateral and continuous communication between the patient and the physician. This principle should motivate physicians to communicate meaningfully with patients and involve them in the guidance of their own care (48). Ideally, the patient should have the option to combine physical and remote services in a manner that optimizes the efficacy of care.

5. Adaptation of the standard of care for telemedicine

The standard of care, as outlined above on the abstract level, can be applied to telemedicine without any radical change. However, in order to have any practical value, abstract principles need to be translated into specific rules. Every procedure has its own specific standard in clinical practice. In addition, various ways to perform a certain procedure will usually differ in more than one aspect. If compared, each of them is often found to be better in some aspects and worse in others. The overall assessment is then based on the ratios of advantages and disadvantages. This distribution of benefits and risks may well be different in telemedicine as compared to physical care. The disadvantage related to the remote nature of care can be accepted if it is evened out–or even outweighed–by a certain advantage, such as better access to care or its greater comfort.

The ratio of advantages and disadvantages needs to be assessed with regard to every particular procedure. If no effort were made to strike the right balance, the principles applied would likely be too broad and cautious, such as "refer the patient to physical examination anytime there is a suspicion that remote service would not suffice to test all the possible diagnostic options." Such heavy-handed rules would effectively stop the development of telemedicine. The providers of telemedicine would only facilitate the first contact with the patient, but would then almost always refer the patient to physical examination since they would not be able to comply with the specific requirements posed by standards which never anticipated the existence of remote care. In this way, telemedicine would become effectively useless, prolonging the patient's medical journey rather than making it easier and more comfortable. It is hard to imagine that there would be any relevant demand for telemedicine under such conditions. As a result, telemedicine would never be practiced in any relevant scope. The same would be true if excessively detailed guidelines were used, requiring certain particular steps that cannot be done remotely even if they can be functionally replaced by technology.

To make it possible for telemedicine to live up to its potential, bring maximum benefits to patients and help keep health systems functional and efficient, the medical profession will need to define field-specific and procedure-specific guidelines for remote care (49). While certain guidelines and recommendations have already been issued in some medical fields (50), their further elaboration and expansion are vital.

Typically, the guidelines need to define cases in which patients should be referred to physical care. If remote health services are accepted as a permissible option, their inherent limitations form part of objective possibilities to be taken into consideration when assessing whether the care provided complied with the legally expected standard. The provider should not be held liable for any harm suffered by the patient as a result of such limitations.

6. Discussion

The dawn of telemedicine must not impair the overall quality of care. Nevertheless, inherent constraints or lower performance in some particular aspects do not necessarily render telemedicine impermissible. The standard of care needs to be judged on the basis of the comprehensive risk-benefit ratio of each procedure with regard to each particular patient, and interpreted accordingly. Some disadvantages of telemedicine (the consequences of lacking physical contact between the physician and the patient) may be outweighed by its benefits, such as increased comfort, speed and accessibility for the particular patient, as well as maintained accessibility and cost sustainability of health care at the level of the health care system as a whole.

Similar trade-offs are known from the daily practice of medicine: guidelines can be modified or even not followed if this suits the needs of the given patient, even though such an approach might be riskier in certain ways. On a similar note, telemedicine needs to be assessed on the basis of the whole complex of its benefits and risks. With exceptions, such as the state of necessity, telemedical services always require free consent of the patient, who has been adequately informed about all the relevant benefits and risks of remote care as compared to care provided in the traditional way.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Funding

The paper was written with the support of the Technology Agency of the Czech Republic in the project no. TL03000688 - Legal Tools in Support of Innovations in Medicine.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

1. Mandal S, Wiesenfeld BM, Mann D, Lawrence K, Chunara R, Testa P, et al. Evidence for telemedicine's ongoing transformation of health care delivery since the onset of the COVID-19: retrospective observational study. *JMIR Form Res.* (2022) 10: e38661. doi: 10.2196/preprints.38661

2. Vogt EL, Welch BM, Bunnell BE, Barrera JF, Paige SR, Owens M, et al. Quantifying the impact of COVID-19 on telemedicine utilization: restrospective observational study. *Interactive J Med Res.* (2022) 1:e29880. doi: 10.2196/29880

3. Kraus S, Schiavone F, Pluzhnikova A, Invernizzi AC. Digital transformation in healthcare: analyzing the current state-of-research. *J Bus Res.* (2021) 123:557–67. doi: 10.1016/j.jbusres.2020.10.030

4. De Meijer C, Wouterse B, Polder J, Koopmanschap M. The effect of population aging on health expenditure growth: a critical review. *Eur J Ageing.* (2013) 4:353–61. doi: 10.1007/s10433-013-0280-x

5. Schmidt S, Hendricks V, Griebenow R, Riedel R. Demographic change and its impact on the health-care budget for heart failure inpatients in Germany during 1995–2025. *Herz.* (2013) 8:862–7. doi: 10.1007/s00059-013-3955-3

6. Cinaroglu S, Baser O. The relationship between medical innovation and health expenditure before and after health reform. *Health Policy Technol.* (2018) 4:379–87. doi: 10.1016/j.hlpt.2018.10.001

7. Aronson SH. The lancet on the telephone 1876–1975. *Med Hist.* (1977) 1:69–87. doi: 10.1017/S0025727300037182

8. Tzanou M. *Health Data Privacy Under the GDPR. Big Data Challenges and Regulatory Responses.* Abingdon: Routledge (2021). p. 182. doi: 10.4324/9780429022241

9. Obermeyer Z, Topol E. Artificial intelligence, bias, and patients' perspectives. *Lancet.* (2021) 10289:2038. doi: 10.1016/S0140-6736(21)01152-1

10. Ribón Fletcher R, Nakeshimana A, Olubeko O. Addressing fairness, bias, and appropriate use of artificial intelligence and machine learning in global health. *Front Artif Intell.* (2021) 3:561802. doi: 10.3389/frai.2020.561802

11. Kramer GM, Kinn JT, Mishkind MC. Legal, regulatory, and risk management issues in the use of technology to deliver mental health care. *Cogn Behav Pract.* (2015) 3:258–68. doi: 10.1016/j.cbpra.2014.04.008

12. Kahn EN, La Marca F, Mazzola CA. Neurosurgery and telemedicine in the United States: assessment of the risks and opportunities. *World Neurosurg.* (2016) 89:133–8. doi: 10.1016/j.wneu.2016.01.075

13. Koch BA. The 'Principles of European Tort Law' in the digital age". In: Karner E, Magnus U, Spier J, Widmer P, editors. *Essays in Honour of Helmut Koziol.* Vienna: Jan Sramek Verlag (2020). p. 79–90.

14. Karner E. Liability for medical robots and autonomous medical devices. In: Karner E, Magnus U, Spier J, Widmer P, editors. *Essays in Honour of Helmut Koziol.* Vienna: Jan Sramek Verlag (2020). p. 57–77.

15. Proposal for a Directive for the European Parliament and of the Council on adopting non-contractual civil liability rules to artificial intelligence (AI Liability Directive).

16. Gütter Z. Úvod do problematiky, definice a vymezení pojmu. In: Táborský M, editor. *Digitální medicína 2022.* Prague: EEZY Publishing (2022). p. 19–35.

17. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.

18. Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine).

19. Principles, Definitions and Model Rules of European Private Law: Draft Common Frame of Reference (DCFR).

20. *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582.

21. Brazier M, Cave E. *Medicine, Patients and the Law.* Manchester: Manchester University Press (2016). p. 680.

22. Fellmeth AX, Horwitz M. *Guide to Latin in International Law.* Oxford: Oxford University Press (2009). p. 298.

23. Daniel H, Snyder Sulmasy L. Policy recommendations to guide the use of telemedicine in primary care settings: an American college of physicians position paper. *Ann Intern Med.* (2015) 10:787–9. doi: 10.7326/M15-0498

24. Medical Council. Regulatory Approaches to Telemedicine (2018). Available online at: https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/research-and-insight-archive/regulatory-approaches-to-telemedicine (accessed March 7, 2023).

25. Keenan AJ, Cert G, Dip G, Tsourtos G, Tieman J. The value of applying ethical principles in telehealth practices: systematic review. *J Med Internet Res.* (2021) 3:e25698. doi: 10.2196/25698

26. Černý D. Etika telemedicíny. Časopis lékařů českých. (2021) 7–8:282–6.

27. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics.* Oxford: Oxford University Press (2019). p. 512.

28. Rizas KD, Freyer L, Sappler N, von Stülpnagel L, Spielbichler P, Krasniqi A et al. Smarthpone-based screening for atrial fibrillation: a pragmatic randomized controlled trial. *Nat Med.* (2022) 9:1823–30. doi: 10.1038/s41591-022-01979-w

29. Parreño M, Di Lella FA, Fernandez F, Boccio CM, Ausili SA. toward self-measures in cochlear implants: daily and "homemade" impedance assessments. *Front Digit Health.* (2020) 2:582562. doi: 10.3389/fdgth.2020.582562

30. Nikniaz Z, Akbari Namvar Z, Shirmohammadi M, Maserat E. Smartphone application for celiac patients: assessing its effect on gastrointestinal symptoms in a randomized controlled clinical trial. *Int J Telemed Appl.* (2022) 2022:8027532. doi: 10.1155/2022/8027532

31. Kummerow Broman K, Gaskill CE, Faqih A, Feng M, Phillips SE et al. Evaluation of wound photography for remote postoperative assessment of surgical site infections. *JAMA Surg.* (2019) 2:117–24. doi: 10.1001/jamasurg.2018.3861

32. Barakat-Johnson M, Kita B, Jones A, Burger M, Airey D, Stephenson J et al. The viability and acceptability of virtual wound care command centre in Australia. *Int Wound J.* (2022) 7:1769–85. doi: 10.1111/iwj.13782

33. Galiano-Castillo N, Cantarero-Villanueva I, Fernández-Lao C, Ariza-García A, Díaz-Rodríguez L, Del-Moral-Ávila R et al. Telehealth system: A randomized controlled trial evaluating the impact of an internet-based exercise intervention on quality of life, pain, muscle strength, and fatigue in breast cancer survivors. *Cancer.* (2016) 20:3166–74. doi: 10.1002/cncr.30172

34. Snoswell CL, Chelberg G, De Guzman KR, Haydon HH, Thomas EE, Caffery LJ et al. The clinical effectiveness of telehealth: a systematic review of meta-analyses from 2010 to 2019. *J Telemed Telecare.* (2021). doi: 10.1177/1357633X211022907

35. Bashshur RL, Shannon GW, Smith BR, Woodward MA. The empirical evidence for the telemedicine intervention in diabetes management. *Telemed J E Health.* (2015) 5:321–54. doi: 10.1089/tmj.2015.0029

36. Kuan PX, Chan WK, Khoo Fern Ying D, Rahman MAA, Peariasamy KM, Lai NM. Efficacy of telemedicine for the management of cardiovascular disease: a systematic review and meta-analysis. *Lancet Digit.* (2022) 9:676–91. doi: 10.1016/S2589-7500(22)00124-8

37. Krittanawong C, Rogers AJ, Johnson KW, Wang Z, Turakhia MP, Halperin JL et al. Integration of novel monitoring devices with machine learning technology for scalable cardiovascular management. *Nat Rev Cardiol*. (2021) 2:75–91. doi: 10.1038/s41569-020-00445-9

38. Heneghan C, Glasziou P, Thompson M, Rose P, Balla J, Lasserson D, et al. Diagnostic strategies used in primary care. *BMJ*. (2009) 338:b946. doi: 10.1136/bmj.b946

39. Nittari G, Khuman R, Baldoni S, Pallotta G, Battineni G, Sirignano A, et al. Telemedicine practice: review of the current ethical and legal challenges. *Telemed E-Health*. (2020) 26:1427–37. doi: 10.1089/tmj.2019.0158

40. Hoffman LC. Shedding light on telemedicine & online prescribing: the need to balance access to health care and quality of care. *Am J Law Med*. (2020) 2–3:237–51. doi: 10.1177/00988588209 33497

41. Topol E. *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*. New York: Basic Books (2019). p. 400.

42. Yee V, Bajaj SS, Stanford FC. Paradox of telemedicine: building or neglecting trust and equity. *Lancet Digit*. (2022) 7:e480–1. doi: 10.1016/S2589-7500(22)0 0100-5

43. Bui AL, Fonarow GC. Home monitoring for heart failure management. *J Am Coll Cardiol*. (2012) 2:97–104. doi: 10.1016/j.jacc.2011. 09.044

44. Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine).

45. Nesher L, Jotkowitz A. Ethical issues in the development of tele-ICUs. *J Med Ethics*. (2011) 11:655–7. doi: 10.1136/jme.2010.040311

46. Slavíček K, Dostál O, Lieskovan T, Hajný J. Ensuring security of telemedicine project in compliance with GDPR. In: *2019 11th International Congress on Ultra Modern Telecommunications and Control Systems and Workshops (ICUMT)*. Dublin Ireland (2019). p. 1–4.

47. Bassan S. Data privacy considerations for telehealth consumers amid COVID-19. *J Law Biosci*. (2020) 7:lsaa075. doi: 10.1093/jlb/lsaa075

48. Černý D, Doležal A, Doležal T. "Informovaný souhlas v medicíně. Mýtus, pohádka, nebo pouhý právní požadavek?" In: Ptáček R, Bartůněk P, Mach J, editors. *Informovaný souhlas. Etické, právní, psychologické a klinické aspekty*. Prague: Galén (2017). p. 192–201.

49. Becker CD, Dandy K, Gaujean M, Fusaro M, Scurlock C. Legal perspectives on telemedicine part 2: telemedicine in the intensive care unit and medicolegal risk. *Perm J*. (2019) 4:18–294. doi: 10.7812/TPP/18.294

50. Gruska M, Aigner G, Altenberger J, Burkart-Küttner D, Fiedler L, Gwechenberger M, et al. Recommendations on the utilization of telemedicine in cardiology. *Wien Klin Wochenschr*. (2020) 23–24:780–800. doi: 10.1007/s00508-020-01762-2

frontiers | Frontiers in Public Health

TYPE Perspective
PUBLISHED 02 June 2023
DOI 10.3389/fpubh.2023.1186350

OPEN ACCESS

EDITED BY
David Černý,
Czech Academy of Sciences, Czechia

REVIEWED BY
Hanadi Hamadi,
University of North Florida, United States

*CORRESPONDENCE
Kriti Mittal
✉ kriti.mittal@umassmemorial.org

†These authors share first authorship

RECEIVED 14 March 2023
ACCEPTED 12 May 2023
PUBLISHED 02 June 2023

CITATION
Thomas E, Kennedy A, Walsh W, Carpentier M, Adeyinka H, Patel S, Gerber J, Cerny J and Mittal K (2023) Telehealth through the pandemic at a safety net hospital: observations and next steps for cancer care delivery. *Front. Public Health* 11:1186350. doi: 10.3389/fpubh.2023.1186350

Telehealth through the pandemic at a safety net hospital: observations and next steps for cancer care delivery

Erin Thomas[1†], Alice Kennedy[2†], William Walsh[2], Michelle Carpentier[3], Hannah Adeyinka[3], Shyam Patel[2], Jonathan Gerber[2], Jan Cerny[2] and Kriti Mittal[2*]

[1]Hospital Medicine, Massachusetts General Hospital, Boston, MA, United States, [2]Division of Hematology-Oncology, University of Massachusetts Chan Medical School, Worcester, MA, United States, [3]Division of Hematology-Oncology, University of Massachusetts Memorial Medical Center, Worcester, MA, United States

The COVID-19 pandemic revolutionized cancer care delivery leading to rapid adoption of digital technology for telehealth in the United States. In this study, we describe telehealth utilization trends across the three largest waves of the pandemic at a safety net academic center. We also provide a perspective on lessons learnt and our vision for cancer care delivery using digital technology in the near future. The integration of interpreter services within the video platform and its integration within the electronic medical record system is crucial for safety net institutes that service a diverse patient population. Pay-parity for telehealth, especially ongoing support for audio-only visits, will be critical in overcoming health disparities for patients without access to smartphone technology. Use of telehealth in clinical trials, widespread adoption of hospital at home programs, electronic consults for rapid access, and structured telehealth slots in clinic templates will be crucial in making cancer care more equitable and efficient.

KEYWORDS

telehealth, cancer care, pandemic, COVID-19, safety net hospital

1. Introduction

The risk of COVID-19 infection continues to pose unique challenges to healthcare delivery for oncology patients. Health safety concerns during the COVID-19 pandemic incentivized the adoption of existing digital technologies in the United States, and worldwide, for remote audio and video consultations. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic (1). According to several U.S. healthcare professional databases, by May 2020, in-office medical visits had declined by as much as 60–70% (2). Claims for oncology office visits fell by 30% in early April 2020 relative to pre-pandemic levels (3). Telehealth gained special importance for cancer patients due to their increased susceptibility to SARS-CoV-2 infection and its complications as oncology patients are often older, have multiple medical comorbidities, and suffer from immunosuppression-factors that are contributory to patients' propensity for severe disease (4, 5). Early studies of cancer patients with SARS-CoV-2, moreover, confirmed that active malignancy and prior exposure to chemotherapy independently increased the risk of death within 30 days of viral symptom onset (6). A large cohort study of 928 cancer patients with SARS-CoV-2 infection identified that those patients with active cancer, advanced age, smoking status, male gender, ECOG $\geq$ 2, number of comorbidities (2 vs. none), amongst others, were at heightened

risk of mortality at 30 days. It is also noteworthy that based on follow up data entry cut off as of May 7, 2020, residence in U.S.-Northeast region was associated with a higher 30-day mortality for patients with past or active diagnosis of cancer compared with those with residence in U.S.-Midwest (odds ratio 0.50; 0.28–0.90) or Canada (0.24, 0.07–0.84) (7).

Leveraging existing technologies and making use of expanded services allowable by federal guidelines therefore deserves undivided attention. Reimbursement has been the primary barrier in the past that limited adoption of telehealth technologies. To this end, the Coronavirus Aid, Relief, and Economic Security (CARES) Act broadened criteria for telehealth services billable as "full visits" under Medicare (8). Some private payers also announced similar expansions (9). Finally, the U.S. Health and Human Services Department decision not to enforce penalties for HIPAA non-compliance also encourages adoption of telehealth in oncology practices (10).

The COVID-19 pandemic has revolutionized cancer care delivery for both inpatient and outpatient oncology care. At the time of writing this article, telehealth has become ingrained in our daily clinic workflows, as well as inpatient consults for SARS-CoV-2 positive patients. Over the next 10 years, the number of cancer survivors living in the United States is expected to increase by 24% to 22.5 million (11). Lessons learned about effective implementation of telehealth for cancer patients during the COVID-19 pandemic, therefore, have important implications for improving care access and cost-savings for this growing population. Below we describe trends in outpatient tele-oncology at our safety-net hospital during the three initial waves of the pandemic, review lessons learned, and envision the next steps in this model of cancer care delivery in resource-constrained settings.

2. Methods

Data were collected in aggregate from workbench reports from EPIC electronic medical record system accounting for all outpatient hematology and medical oncology encounters at our primary academic site. Data for weekly statewide incidence of new COVID-19 cases were obtained from the Department of Public Health website (dph.gov) to provide an estimate of COVID-19 case burden in Massachusetts. Inpatient COVID-19 hospitalization metrics at our institution were obtained from our COVID Command Center, to reflect case acuity index of our local patient population. The three pandemic waves for purposes of data collection were defined as: wave 1 (3/2/2020–6/26/2020); wave 2 (10/3/2020–3/27/2021) and wave 3 (12/1/2021–3/4/2022). Telehealth utilization data from our cancer center were then superimposed onto trends of COVID-19 case burden, statewide and within our institution, to contextualize weekly telehealth volumes of the outpatient cancer clinic with the incidence of COVID-19 in our state.

3. Results

Prior to the March 2020, the Cancer Center at University of Massachusetts Memorial Medical Center (UMMMC) did not offer telehealth visits. During the first week of March 2020, COVID-19 cases began to present locally at our institution. Figure 1A demonstrates the trend in weekly total inpatient admissions at our site during the three largest waves of the pandemic in Massachusetts between 2020 and 2022. The uptrend in our institution's inpatient COVID-19 hospitalizations at the onset of wave 1 was consistent with the increase in statewide new cases of COVID-19. During the first wave, the incidence of weekly institutional COVID-19 admissions peaked at 147 in the week of 4/27/2020–5/3/2020 before down-trending to 29 at the end of wave 1. In parallel, statewide new COVID-19 cases peaked at 15,393 during wave 1 in the week of 4/13/2020–4/19/2020. Telehealth use, as a proportion of total clinic encounters peaked a few weeks prior during the week of 4/6/2020–4/12/2020 when 60% of patient visits were conducted via telehealth. At the tail end of wave 1, telehealth continued to be utilized in lieu of in-person visits by 34% of patients. During waves 2 and 3, the rate of institutional weekly hospitalizations at our site consistently correlated with the statewide incidence of new weekly cases. As clinic volumes recovered during wave 2, the relative proportion of telehealth visits as a percentage of total encounters varied from 10 to 25%, peaking during the week of 12/14/2020–12/20/2020, preceding the peak statewide new case incidence by 3 weeks. At the onset of wave 3 in December 2021, healthcare workers as well as oncology patients had widespread access to COVID-19 vaccines. During this wave, the percentage of telehealth utilization varied from 5 to 26%. The average utilization of telehealth for clinical encounters during waves 1, 2, and 3 was 39, 15, and 15%, respectively.

Figure 1B demonstrates the differential utilization of audio vs. video visits for telehealth encounters. At the onset of the pandemic, audio-visits constituted the vast majority of clinical encounters prior to 4/27/2020 (94–100%). Starting 4/27/2020, a new telehealth platform was adopted system wide that greatly reduced logistical barriers to video consultations and integrated within our electronic medical record system. The conduct of video-visits rose exponentially after implementation of this new platform during wave 1, increasing from 24% of all telehealth visits to 57% at the tail of wave 1. During waves 2 and 3, the use of video visits consistently exceeded the use of audio-only visits. At the tail of wave 3, 73% of telehealth encounters remained video based.

4. Discussion

The COVID-19 pandemic accelerated the adoption of novel models of care delivery in oncology, propelling telehealth to the forefront of cancer care since 2020. Some organizations, such as the U.S. Department of Veterans Affairs, expanded the use of pre-existing telehealth initiatives to expand cancer care for rural areas (12) and others developed models for in-home cancer treatments with remote monitoring (13). Given the global nature of the pandemic, it is not surprising that many centers of the world reported changes in practice, incorporating telehealth for up to 75% of cancer care (14–16). The American Society of Clinical Oncology (ASCO) evaluated the adaptations made to cancer care delivery and research in response to this pandemic and published a comprehensive report outlining recommendations on how to make both high quality cancer care and oncological research more accessible, equitable, and efficient going forward (17).

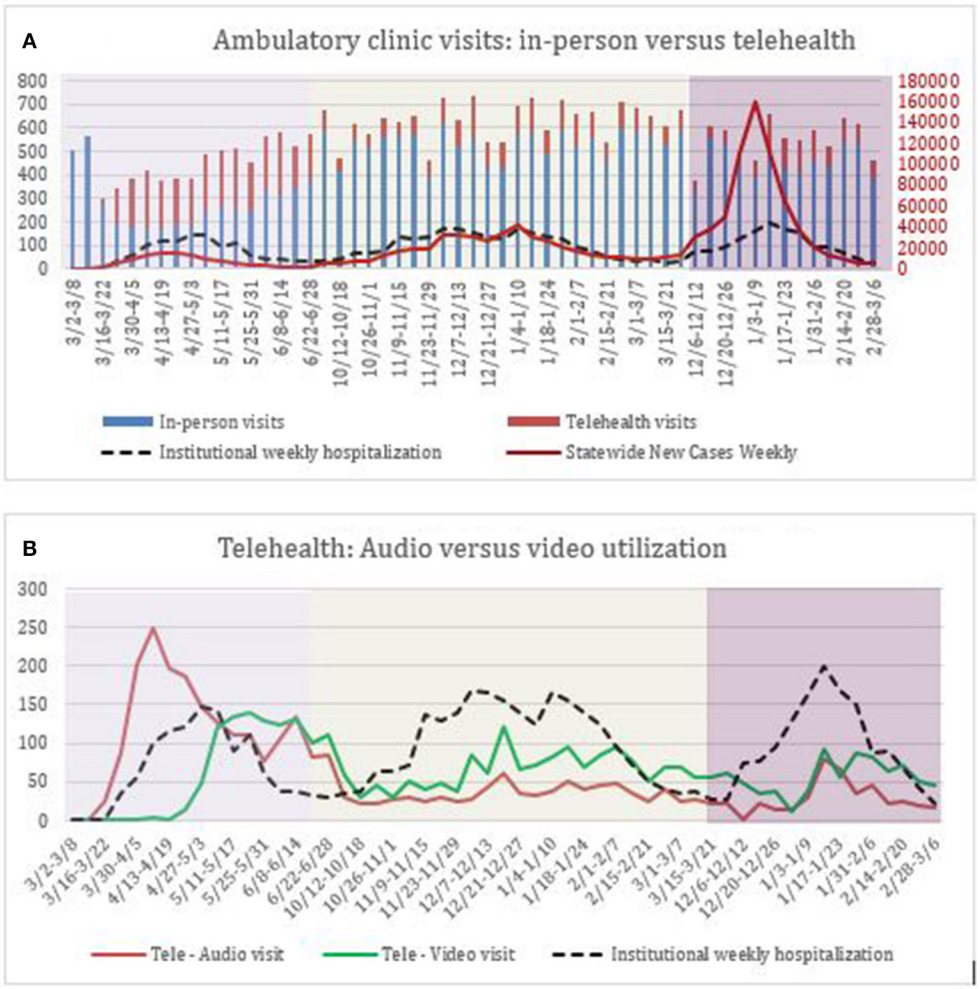


FIGURE 1
(A) Demonstrates weekly visits by type during three waves of the COVID-19 pandemic. *Y*-axis on the left depicts total number of weekly in-person, telehealth oncology visits as well as absolute number of institutional weekly hospitalizations related to COVID-19. *Y*-axis on the right depicts total number of weekly statewide new COVID-19 cases. **(B)** Demonstrates absolute numbers of audio vs. video telehealth visits by week during three waves of the COVID-19 pandemic, with institutional weekly hospitalization rate provided as a reference.

As a safety net academic hospital, our institution serves a county where 10% of the population lives in poverty (18). MassHealth patients account for 26% (internal data) of our clinical volumes. Safety net hospitals, while providing oncologic care to a large number of underserved patients and ethnic minorities, face unique challenges due to resource constraints (19). Our institution's response to local COVID-19 cases included the adoption and implementation of telehealth visits which were previously not offered at our cancer center. Consistent with local demographics (18), 15–20% of oncology patients are non-English speaking and we provide in-person, telephone and video-based interpretation services for all our patients. The integration of interpreter services within our video platform and the electronic medical record system was imperative to successful roll out of telehealth at our site. After the basic workflow was developed by our health informatics team, intensive physician training was conducted, led by a core of volunteer medical students who provided individual and group training as well as elbow support. Continued use of telehealth even after widespread availability of COVID-19 vaccines was noteworthy- with average utilization of 15% in both waves 2 and 3, with peak utilization rate of 25 and 26% during wave 2 and 3, respectively. While patient level data for adoption of telehealth are not available, nonetheless, these trends suggest that this modality remains an important vehicle for cancer care delivery at our safety net site, with the potential to improve health equity by overcoming barriers of transportation access amongst underserved patients. Therefore, it is incumbent upon policy makers to advocate for continued approval of telehealth visits by insurance payers. A recent report of recommendations from the ASCO Global Webinar Series regarding the COVID-19 pandemic emphasized that if telehealth is to be utilized post pandemic, it will require the continued advocacy of specialty societies and bolstered payer and government relations (20).

Our institution implemented both video and audio telehealth modalities at the start of the pandemic. As displayed in

TABLE 1 Roadmap for tele-oncology post-pandemic.

Vision/investment	Barrier	Interventions	Returns
Long term pay parity for telehealth visits	Complex interplay between federal, state and private payor guidelines	Congressional intervention, "An Act of Congress"	• Patient convenience • Reduce patient exposure
Routine use of telehealth in clinical trials	Protocol regulations, IRB regulations, industry buy-in	IRB supported guidelines that allow remote monitoring of vitals, video visits, and local labs for select clinical trials	• Increase trial enrollment in rural areas with lack of access to tertiary care • Reduce disparities as patients with limited means to travel gain benefit from trial enrollment
Hospital at Home programs/at home infusion visits	Limited use at this time, primarily due to lack of awareness and resources outside of limited centers	Education and experience with operationalization for wide-spread establishment of "virtual beds"	• Overcome hospital bed shortage • Minimize patient exposure • Reduce cost of care • Minimize burden on ambulatory infusion chair time
Structured telehealth days	Currently in use at many centers but may have initial logistical/scheduling barriers	Modify clinician templates for dedicated tele-oncology slots	• Streamlined clinics • Availability of dedicated sick visit slots • Social distancing in clinic pods • Overcome room shortage • Helps with staffing shortage (front desk, medical assistants)

Figure 1B, there was a sharp increase in the use of video during the week of 4/27–5/3. This transition coincided with contracting a new telehealth vendor beginning on 4/24/2020, which helped avoid video technology pitfalls which previously caused numerous visits to be converted from video to audio health, demonstrating the importance of user-friendly digital platforms to facilitate telehealth. From this point onwards, most patients opted to conduct their telehealth visits via video. Barring issues with technology, we therefore report a preference for video communication for oncology visits. In its current format, there exists a direct interface between our electronic health record and our preferred telehealth platform. As mentioned in the ASCO Webinar series, interoperability between telemedicine software and the electronic health record has been crucial in efficiently conducting visits with real-time access to medical records and documentation as well as simplifying the scheduling process (20). The rapid adoption of telehealth in our oncology center reflected awareness of cancer patients' susceptibilities to COVID-19. This is a vulnerable population amidst this pandemic due to patients' immunocompromised status, frequent hospitalizations and office visits, and in some cases, poor performance status and transportation barriers.

The expansion in Medicare coverage through multiple stimulus packages in March 2020, including the CARES Act, facilitated the accelerated integration of oncology telehealth services. Prior to this, telehealth services were only covered in non-urban areas or areas with a shortage of healthcare providers. Due to the exceptions made during the pandemic, even new patient telehealth visits have been covered for reimbursement (9). Furthermore, it was decided that penalties for HIPAA violations made in good faith while utilizing telehealth would not be enforced, and remote supervision of oncology services by physicians was also made permissible (10). Together, these factors allowed for the use of both audio-only visits and video visits at the start of the pandemic. Going forward, it remains to be seen what the reimbursement structure will be for telehealth visits, especially for audio-only visits. This will likely be a factor in deciding the longevity of telehealth. Looking ahead, it is predicted that there will be an almost 50% increase in cancer care demand by 2050 due to increasing cancer rates in an aging population and increased survivorship of cancer patients (21). Simultaneously, there will be a shortage of oncologists to meet this need as existing oncologists retire (22), and the pandemic has threatened to exacerbate staffing gaps due to increased clinician burnout (23). Telehealth shows promise in helping to meet this demand by increasing accessibility and efficiency, and in turn, decreasing physician burnout.

It is also pivotal to leverage telehealth in elimination of healthcare disparities in our underserved communities. Advanced age, low literacy, access to video technology, primary language are all potential factors that may conversely impact utilization of telehealth. A recent ASCO report on insights from the pandemic outlines the need for further research into how to optimize technological implementation for telemedicine visits, the need for broadband expansion to provide access for underserved populations, and the importance of adopting new, effective communication styles with patients in the absence of traditional tools like body language in person (17). An early study at UCSF Comprehensive Cancer Center showed that as the proportion of video visits increased as high as 72%, there was not a disparity found based on race/ethnicity, primary language, or payor (24). Finally, we have a responsibility to our patients to make sure that limited direct contact in the office does not fracture the doctor-patient relationship during a vulnerable time in their lives, and the integration of patient surveys could provide helpful insight going forward.

In rural areas, it seems telehealth has improved access to specialty care. Thirty three percent of veterans in the Veterans Health Administration (VHA) system live in rural areas, and the expansion of telehealth has led to decreased wait times to be seen by a specialist, as well as reduction in travel costs and days off from work for patients and caregivers (12). It would be interesting to see if this accessibility has led to decreased disease severity on presentation.

Telehealth may also have long-term adverse effects on clinical trials. An ASCO survey from March 2020 reported that amongst 32 respondents representing both academic and community based programs, about 60% of respondents' programs stopped screening and/or enrollment for certain clinical trials and about 60% halted

research-only visits besides those that provided cancer treatment (25). Respondents reported that it was difficult to adhere to clinical trial enrollment guidelines and protocols because of decreased in-person patient visits. With the ongoing use of tele-oncology, it will be important to monitor the impact on experimental therapeutics in oncology in the coming years and perhaps utilize telehealth in the consent, enrollment, and remote monitoring of patients in clinical trials.

How do we envision improvements in tele-oncology to impact cancer care in the next 5 years? Based on the challenges we encountered delivering cancer care in a safety net academic institution during the pandemic, and incorporating lessons learnt in the last 3 years, we propose a potential roadmap in Table 1 to allow for continued adoption of tele-oncology post-pandemic. Anticipated barriers and possible interventions to overcome these barriers are included, Pay-parity for telehealth, especially ongoing support for audio-only visits, will be critical in overcoming health disparities for patients without access to smartphone technology. Industry and co-operative group trials currently do not routinely support trial consents during telehealth visits, and larger conversations around this are ongoing. Our site has successfully rolled out the use of a hospital-at-home program using telehealth, and oncology patients have benefited from this method of care delivery. The use of structured telehealth days and electronic-consults may also help overcome barriers to subspecialty consults for cancer patients.

5. Conclusion

The sustained utilization of telehealth in oncology during the three initial waves of the pandemic at our safety-net academic site offers several unique insights and thought-provoking questions for the future of telehealth. In this study, we show that implementation of a new telehealth platform system-wide, in response to the COVID-19 pandemic, and that was integrated into our electronic heath record, greatly reduced logistical barriers to video consultations and allow improved access to healthcare. This may serve as a model that can be translated nation-wide. While the pandemic has undoubtedly left an indelible impact on the practice of oncology, we hope that ongoing development of telehealth technology will improve the framework of cancer care at an international level.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

ET, AK, KM, and JC: conception and design. ET, AK, KM, MC, and HA: collection and assembly of data. ET, AK, and KM: data analysis and interpretation. All authors: manuscript writing, final approval of manuscript, and accountable for all aspects of the work.

Acknowledgments

We acknowledge the leadership of Dr. Kathy Edmiston in the roll-out and implementation of telehealth during the pandemic. We also acknowledge the support and guidance of Dr. Eric Alper in implementing digital health solutions at the Cancer Center.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. AP News. *WHO Declares Coronavirus a Pandemic, Urges Aggressive Action.* (2020). Available online at: https://apnews.com/article/united-nations-michael-pence-religion-travel-virus-outbreak-52e12ca90c55b6e0c398d134a2cc286e (accessed November 3, 2022).

2. Commonwealth Fund. *The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges.* (2020). Available online at: https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits (accessed August 11, 2020).

3. IQVIA. *US Thought, Leadership team: White Paper: Monitoring the Impact of COVID-19 on the Pharmaceutical Market - IQVIA* (2020).

4. Fung M, Babik JM. COVID-19 in immunocompromised hosts: what we know so far. *Clin Infect Dis.* (2020) 72:340–50. doi: 10.1093/cid/ciaa863

5. Robilotti EV, Babady NE, Mead PA, Rolling T, Perez-Johnston R, Bernardes M, al. Determinants of COVID-19 disease severity in patients with cancer. *Nat Med.* (2020) 26:1218–23. doi: 10.1101/2020.05.04.20086322

6. Horn L, Whisenant JG, Torri V, Huang LC, Trama A, Paz-Ares LG, et al. Thoracic cancers international COVID-19 collaboration (TERAVOLT): Impact of type of cancer therapy and COVID therapy on survival. *J Clin Oncol.* (2020) 38:LBA111. doi: 10.1016/S1470-2045(20)30314-4

7. Kuderer NM, Choueiri TK, Shah DP, Shyr Y, Rubinstein SM, Rivera DR, et al. Clinical impact of COVID-19 on patients with cancer (CCC19): a cohort study. *Lancet.* (2020) 395:1907. doi: 10.1016/S0140-6736(20)31187-9

8. Courtney J. *H.R.748 - 116th Congress (2019-2020): CARES Act.* United States Congress. (2020).

9. CMS: Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19. (2020). Available online at: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf (accessed August 22, 2020).

10. OCR announces notification of enforcement discretion for telehealth remote communications during the COVID-19 nationwide public health emergency. (2020). HHS.gov. Available online at: https://www.hhs.gov/about/news/2020/03/

17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html (accessed August 22, 2020).

11. American Cancer Society. *Cancer Treatment & Survivorship Facts & Figures 2022-2024*. Atlanta: American Cancer Society (2022).

12. Jiang CY, El-Kouri NT, Elliot D, Shields J, Caram ME, Frankel TL, et al. Telehealth for cancer care in veterans: opportunities and challenges revealed by COVID. *JCO Oncol Pract.* (2021) 17:22–9. doi: 10.1200/OP.20.00520

13. Laughlin AI, Begley M. *Accelerating the Delivery Of Cancer Care at Home During the Covid-19 Pandemic*. (2020). Available online at: https://catalyst.nejm.org/doi/pdf/10.1056/CAT.20.0258 (accessed March 11, 2022).

14. Tsamakis K, Gavriatopoulou M, Schizas D, Stravodimou A, Mougkou A, Tsiptsios D, et al. Oncology during the COVID-19 pandemic: challenges, dilemmas and the psychosocial impact on cancer patients. *Oncol Lett.* (2020) 20:441. doi: 10.3892/ol.2020.11599

15. Gill S, Hao D, Hirte H, Campbell A, Colwell B. Impact of COVID-19 on Canadian medical oncologists and cancer care: Canadian association of medical oncologists survey report. *Curr Oncol.* (2020) 27:71. doi: 10.3747/co.27.6643

16. Chazan G, Franchini F, Alexander M, Banerjee S, Mileshkin L, Blinman P, et al. Impact of COVID-19 on cancer service delivery: Results from an international survey of oncology clinicians. *ESMO Open.* (2020) 5:e001090. doi: 10.1136/esmoopen-2020-001090

17. Pennell NA, Dillmon M, Levit LA, Moushey EA, Alva AS, Blau S, et al. American society of clinical oncology road to recovery report: Learning from the COVID-19 experience to improve clinical research and cancer care. *J Clin Oncol.* (2021) 39:155–69. doi: 10.1200/JCO.20.02953

18. U.S. Census Bureau. *U.S. Census Bureau Quickfacts: Worcester County, Massachusetts*. (2022). Available online at: https://www.census.gov/quickfacts/worcestercountymassachusetts (accessed April 18, 2023).

19. Hefner JL, Hogan TH, Opoku-Agyeman W, Menachemi N. Defining safety net hospitals in the health services research literature: a systematic review and critical appraisal. *BMC Health Serv Res.* (2021) 21:278. doi: 10.1186/s12913-021-06292-9

20. Jazieh AR, Chan SL, Curigliano G, Dickson N, Eaton V, Garcia-Foncillas J, et al. Delivering cancer care during the COVID-19 pandemic: recommendations and lessons learned from ASCO global webinars. *JCO Glob Oncol.* (2020) 6:1461–71. doi: 10.1200/GO.20.00423

21. Weir HK, Thompson TD, Stewart SL, White MC. Cancer incidence projections in the United States Between 2015 and 2050. *Prev Chronic Dis*. (2021) 18:210006. doi: 10.5888/pcd18.210006

22. Yang W, Williams JH, Hogan PF, Bruinooge SS, Rodriguez GI, Kosty MP, et al. Projected supply of and demand for oncologists and radiation oncologists through 2025: an aging, better-insured population will result in shortage. *J Oncol Pract*. (2014) 10:39–46. doi: 10.1200/JOP.2013.001319

23. Lim KH, Murali K, Thorne E, Punie K, Kamposioras K, Oing C, et al. The impact of COVID-19 on oncology professionals-one year on: lessons learned from the ESMO Resilience Task Force survey series. *ESMO Open*. (2022) 7:100374. doi: 10.1016/j.esmoop.2021.100374

24. Lonergan PE, Washington Iii SL, Branagan L, Gleason N, Pruthi RS, Carroll PR, et al. Rapid utilization of telehealth in a comprehensive cancer center as a response to COVID-19: cross-sectional analysis. *J Med Int Res.* (2020) 22:e19322. doi: 10.2196/19322

25. Waterhouse DM, Harvey RD, Hurley P, Levit LA, Kim ES, Klepin HD, et al. Early impact of COVID-19 on the conduct of oncology clinical trials and long-term opportunities for transformation: findings from an american society of clinical oncology survey. *JCO Oncol Pract*. (2020) 16:417–21. doi: 10.1200/OP.20.00275

frontiers | Frontiers in Public Health

TYPE Brief Research Report
PUBLISHED 17 July 2023
DOI 10.3389/fpubh.2023.1142062

OPEN ACCESS

EDITED BY
Rudra P. Saha,
Adamas University, India

REVIEWED BY
Cristian Timmermann,
University of Augsburg, Germany
Nicholas L. Rider,
Liberty University, United States

*CORRESPONDENCE
Amelia Katirai
✉ a.katirai.elsi@osaka-u.ac.jp

RECEIVED 11 January 2023
ACCEPTED 27 June 2023
PUBLISHED 17 July 2023

CITATION
Katirai A (2023) The ethics of advancing artificial intelligence in healthcare: analyzing ethical considerations for Japan's innovative AI hospital system.
Front. Public Health 11:1142062.
doi: 10.3389/fpubh.2023.1142062

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

Amelia Katirai*

Research Center on Ethical, Legal, and Social Issues, Osaka University, Suita, Osaka, Japan

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

TABLE 1 Coding framework created from the WHO Guidance.

Code	Item
1	Protecting human autonomy
1.1	Does not undermine human autonomy (humans should remain in control)
1.2	Ensure that providers have the information necessary to make safe, effective use of AI systems
1.3	People understand the role that such systems play in their care
1.4	Protection of privacy and confidentiality
1.5	Valid informed consent obtained through appropriate legal frameworks for data protection
2	Promoting human well-being and safety and the public interest
2.1	Should not harm people
2.2	Should satisfy regulatory requirements for safety, accuracy and efficacy for well-defined use cases or indications
2.3	Measures of quality control in practice and quality improvement are available
2.4	Should not result in mental or physical harm that could be avoided by use of an alternative practice or approach
3	Ensuring transparency, explainability, and intelligibility
3.1	Should be intelligible or understandable to developers, medical professionals, patients, users, and regulators
3.2	Transparency – sufficient information published or documented before the design or deployment of an AI technology
3.3	Transparency – information facilitates meaningful public consultation and debate on how the technology is designed and how it should or should not be used
3.4	Explainable – explained according to the capacity of those to whom they are explained
4	Fostering responsibility and accountability
4.1	Clear, transparent specification of the tasks that systems can perform – stakeholders ensure that they can perform those tasks and that AI is used under appropriate conditions
4.2	Human warranty – evaluation by patients and clinicians in the development and deployment of AI
4.3	Regulatory principles applied upstream and downstream of the algorithm through human supervision
4.4	Accountability – appropriate mechanisms for questioning and redress for individuals and groups that are adversely affected by decisions based on algorithms
5	Ensuring inclusiveness and equity
5.1	Designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, sex, gender, income, race, ethnicity, sexual orientation, ability or other characteristics protected under human right codes
5.2	Should be shared as widely as possible
5.3	Should be available for use not only in contexts and needs in high-income settings but also in the contexts and for the capacity and diversity of LMIC
5.4	Should not encode biases to the disadvantage of identifiable groups, especially groups that are already marginalized
5.5	Minimize inevitable disparities in power that arise between providers + patients, between policy-makers and people, between companies and governments
5.6	Monitored and evaluated to identify disproportionate effects on specific groups of people
5.7	Should not sustain or worsen existing forms of bias and discrimination
6	Promoting AI that is responsive and sustainable
6.1	Continuously, systematically, and transparently assess AI applications during actual use
6.2	Determine whether AI responds adequately and appropriately and according to communicated, legitimate expectations and requirements
6.3	Consistent with wider promotion of the sustainability of health systems, environments, and workplaces
6.4	Designed to minimize environmental consequences and increase energy efficiency
6.5	Consistent with global efforts to reduce the impact of human beings on the Earth's environment, ecosystems, and climate
6.6	Governments and companies to address anticipated disruptions in the workplace, including training for health-care workers to adapt to the use of AI systems and potential job losses

references to all components of a particular principle, to allow for comparison in the frequency of reference to each principle. It is noteworthy that neither the WHO Guidance nor its principles were directly referred to at any point in the Plan. Instead, all references tabulated here were indirect references to the principles. The results of this analysis are reported below, with all translations by the author.

3. Results

In total, there were 101 references to aspects of the WHO principles in the SIP Plan, but attention to the principles was notably uneven. The number of references to each aspect of the principles is reported in Table 2. Each principle will be examined in turn below, in order of frequency.

TABLE 2 Frequency of references to principles in the WHO Guidance.

Code	Item	Frequency	Total by principle
1.0	Protecting human autonomy	0	14
1.1	Does not undermine human autonomy (humans should remain in control)	0	
1.2	Ensure that providers have the information necessary to make safe, effective use of AI systems	0	
1.3	People understand the role that such systems play in their care	0	
1.4	Protection of privacy and confidentiality	14	
1.5	Valid informed consent obtained through appropriate legal frameworks for data protection	0	
2.0	Promoting human well-being and safety and the public interest	43	44
2.1	Should not harm people	0	
2.2	Should satisfy regulatory requirements for safety, accuracy and efficacy for well-defined use cases or indications	1	
2.3	Measures of quality control in practice and quality improvement are available	0	
2.4	Should not result in mental or physical harm that could be avoided by use of an alternative practice or approach	0	
3.0	Ensuring transparency, explainability, and intelligibility	0	12
3.1	Should be intelligible or understandable to developers, medical professionals, patients, users, and regulators	0	
3.2	Transparency – sufficient information published or documented before the design or deployment of an AI technology	3	
3.3	Transparency – information facilitates meaningful public consultation and debate on how the technology is designed and how it should or should not be used	7	
3.4	Explainable – explained according to the capacity of those to whom they are explained	2	
4.0	Fostering responsibility and accountability	0	13
4.1	Clear, transparent specification of the tasks that systems can perform – stakeholders ensure that they can perform those tasks and that AI is used under appropriate conditions	0	
4.2	Human warranty – evaluation by patients and clinicians in the development and deployment of AI	13	
4.3	Regulatory principles applied upstream and downstream of the algorithm through human supervision	0	
4.4	Accountability - appropriate mechanisms for questioning and redress for individuals and groups that are adversely affected by decisions based on algorithms	0	
5.0	Ensuring inclusiveness and equity	5	18
5.1	Designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, sex, gender, income, race, ethnicity, sexual orientation, ability or other characteristics protected under human right codes	0	
5.2	Should be shared as widely as possible	12	
5.3	Should be available for use not only in contexts and needs in high-income settings but also in the contexts and for the capacity and diversity of LMIC	0	
5.4	Should not encode biases to the disadvantage of identifiable groups, especially groups that are already marginalized	0	
5.5	Minimize inevitable disparities in power that arise between providers + patients, between policy-makers and people, between companies and governments	0	
5.6	Monitored and evaluated to identify disproportionate effects on specific groups of people	0	
5.7	Should not sustain or worsen existing forms of bias and discrimination	1	
6.0	Promoting AI that is responsive and sustainable	0	0
6.1	Continuously, systematically, and transparently assess AI applications during actual use	0	
6.2	Determine whether AI responds adequately and appropriately and according to communicated, legitimate expectations and requirements	0	
6.3	Consistent with wider promotion of the sustainability of health systems, environments, and workplaces	0	
6.4	Designed to minimize environmental consequences and increase energy efficiency	0	
6.5	Consistent with global efforts to reduce the impact of human beings on the Earth's environment, ecosystems, and climate	0	
6.6	Governments and companies to address anticipated disruptions in the workplace, including training for health-care workers to adapt to the use of AI systems and potential job losses	0	
	Total	101	101

Overall, there was the most attention ($n = 44$) to Principle 2, "Promoting human well-being and safety and the public interest," through statements focused on the expectations that AI could benefit stakeholders. For example, among the 43 coded items, there were 16 references (pp. 1, 2, 3, 7, 10, 13, 22, 28, 33, 34, 37, 42, 49) to the expectation that AI would reduce burden—primarily the burden experienced by HCPs, but also that of patients—4 references to increased efficiency (pp.10, 22, 26, 42), and 4 references to the benefits of AI in healthcare in a super-aging society (pp. 1, 10, 11, 42). Moreover, there were notable references to AI as a resource in times of disaster (p. 8), and to the socio-economic benefits of improved patient health and its knock-on effects on the labor force (p. 11). A representative example is Extract 1 below:

> *In addition, these technologies will be used to reduce the burden on healthcare professionals, including doctors and nurses, in hospitals, and to increase the efficiency of medical expenses, thereby contributing to overcoming various issues in a super-aging society, and to economic development.* Extract 1 (p. 1)

This situated AI within the broader context of the problems faced by the Japanese health system and positioned it as a potential solution to these issues. However, the focus on efficiency and burden reflected a narrow representation of the issues in the healthcare system. Moreover, its subcodes (see Table 1), including the risk of direct or indirect harm—particularly forms of harm that could be avoided by using alternatives to AI—were insufficiently addressed. There was also a lack of attention to regulatory requirements or measures of quality control.

Principle 5 ("Ensuring inclusiveness and equity;" $n = 18$) was the next most frequent, though here again, coverage of the items was uneven. 4 instances were coded under Principle 5 more broadly (pp. 16, 19, 21, 25), as they primarily addressed ensuring linguistic inclusivity through Natural Language Processing systems. Also coded under Principle 5 were calls to expand the reach of the AI systems by making them available for use outside of Japan, with 5 references to this (pp. 6, 7, 19, 35, 50). However, it is unclear whether the motivations for this were based on ethical ideals, or due to the potential commercial benefits of such initiatives, as in Extract 2 below:

> *At the end of the project, this model will be used as a basis for industrialization through overseas expansion, etc.* Extract 2 (p. 35)

Though the need to avoid creating inequality of access and of quality was acknowledged, sharing technologies with resource-poor locales globally, such as with low-and middle-income countries, went unaddressed. Moreover, there was little consideration of the potential for bias and discrimination, apart from two references to using AI to prevent inequity in the quality of healthcare (pp.3, 28).

There were 14 references to Principle 1, "Protecting human autonomy," the references to which focused solely on the "protection of privacy and confidentiality." Within this, in turn, privacy and confidentiality were narrowly dealt with, focusing primarily on ensuring secure systems. This does not sufficiently reflect how privacy and confidentiality are conceptualized as duties which are a part of respect for autonomy, and instead reflects a narrow approach to both autonomy, and to privacy itself, given that there was little consideration of other aspects of autonomy such as patient centeredness or control in decision-making (15). The Plan referred to the European General Data Protection Regulation and to potential differences between Japan and other contexts where the systems may eventually be applied, but without framing from the perspective of autonomy (Extract 3).

> *When international expansion is in view, the handling of the sensitive information of international persons will be considered according to international standards; it is important that our country retain control of collaboratively developed platforms without being overly concerned with competitiveness.* Extract 3 (p. 4)

A notable absence in this area was around ensuring that appropriate consent is gained for the use of patient data. For example, diagrams (pp. 17, 18) which depict the flow of patient data into databases and their retrieval for use did not depict patient consent being obtained. Interestingly, though one aim in the SIP was to use AI to help facilitate informed consent for medical procedures, there was little attention to consent for data used for the systems themselves.

Similarly, though there were 13 references to Principle 4, these were concentrated in one area: "providing human warranty through evaluation by patients and clinicians in the development and deployment of AI." This included ensuring evaluation of the systems developed through the Plan both prior to their development, at the end of each fiscal year, and a final evaluation at an unspecified time, which would include evaluation of necessity, efficiency, and efficacy (p.48). It is noteworthy as well that one component of this was the establishment of a board to consider the Ethical, Legal, and Social Issues (ELSI) of the technologies (pp. 5, 15, 44, 48; Extract 4). However, specifics about the board were not provided in the Plan, and online searches have not yet yielded easily accessible details at this time.

> *In addition to self-evaluation and PD and sub-PD evaluations, an oversight committee, an evaluation committee made up of third-party members, an intellectual property oversight committee, and a committee for evaluation of research and development from the perspective of Ethical, Legal, and Social Issues (hereinafter referred to as the ELSI Committee) as well as a Project Management Office (PJMO) will be established to evaluate and manage the PDCA cycle internally and externally.* Extract 4 (p. 5)

It was unspecified how accountability and responsibility for the systems would be handled, and if provisions would be made in advance for this.

There were 12 instances in which Principle 3 were addressed. Compared to the other categories, these were more evenly distributed among the subcomponents. Commitments were made to share information about the development of the technologies covered by the project, (e.g., pp. 41, 48), as well as a commitment to ensure patient understanding of the technologies (e.g., pp. 28, 32). However, this was not directly linked to the public more broadly (Extract 5).

> *In addition, by appropriately including the opinions of patients and users, and establishing an organization to consider system design optimized to society and regulations that pose obstacles, hearings and negotiations will be conducted with relevant government ministries and agencies.* Extract 5 (p. 45)

It is also noteworthy here that regulation was described in the extract above as a potential obstacle.

There were no instances reflecting Principle 6, "Promoting AI that is responsive and sustainable." It is notable that some aspects of the principle—namely, evaluation of "whether AI responds adequately and appropriately and according to communicated, legitimate expectations and requirements"—overlap with other aspects of the principles, such as providing for human warranty and evaluation by patients and clinicians (Principle 4) and meeting regulatory requirements (Principle 2). However, there were no references to these points in the Plan from the perspective of sustainability or responsiveness. And finally, there was no attention given to: the environmental impact of the technologies; considering possible impact of new technologies on employment; considering potential disruptions in healthcare workflows; or educational or other provisions to equip HCPs to handle these changes.

4. Discussion

Close attention to the ethics of AI in healthcare is imperative, as evidenced by the creation of the WHO Guidance itself (13). The results of this study have brought to light an uneven approach to ethics in the SIP Innovative AI Hospital System Research Plan, and a narrow conception within the Plan of the potential ethical issues of the technologies it proposes. The strongest focus in the Plan is placed on how the proposed technologies can promote "human well-being and safety and the public interest" (Principle 2). Yet, this is narrowly defined and primarily concentrated on reducing burden on HCPs, and on increasing efficiency. Given Japan's "super-aging society" (2), these are undoubtedly key goals for the medical system, but this emphasis on efficiency may impose further pressure on already overworked healthcare professionals HCPs.

Moreover, the Plan reflects a narrow and optimistic focus on the positive impact of the technologies, with little delineation of how this will be reached. For example, the Plan did not specify how the introduction of the technologies will directly link to reduced burden for HCPs, and how reduced burden will in turn bring benefits to HCPs and their patients. It also disregards the new skills that HCPs may need in order to effectively work with AI and side-steps the question of from where these skills will be obtained and how, and the potential for this to create additional burden.

Furthermore, it is unclear from the Plan how the proposed technologies were selected for such focused implementation, and whether the areas of development are indeed top priorities for Japan's medical system. Topol (3) and Keane and Topol (17) problematize the promotion of technologies for healthcare without ensuring that they bring clinical benefit and improvements to the status quo. There is a particular need for close examination considering the prevalence of "vaporware" —technologies which do not exist and/or do not perform as intended—among proposed uses of AI (18). The positive approach in the Plan further suggests a technological solutionist approach to the problems of healthcare, which expects that the introduction of new technologies can resolve fundamental issues, particularly in relation to overburdened healthcare workers and a lack of sufficient resources (1). Rather, the claims made for AI in healthcare should be critically examined, alongside consideration of what other societal shifts may be needed to support healthcare workers, beyond the introduction of new technologies (19).

In addition, there was little consideration of the potential direct or indirect harm which could occur as a result of the use of AI, as called for under Principle 2. There is a need for the consideration of proportionality, through which the application of new technology should be commensurate with its potential risks, particularly in relation to long-term social, economic, and environmental sustainability (20).

Bias in AI systems may lead to significant harm and discriminatory outcomes (Principle 5). This was not addressed sufficiently in the Plan. There was no description of attempts to ensure the reduction of bias or to avoid discriminatory outcomes. This is problematic in light of the discriminatory impact of AI in healthcare, which can affect patient well-being and mortality (21, 22). In the United States, for example, the use of AI has resulted in the allocation of resources along racial lines, disadvantaging already vulnerable populations (21). These oversights are particularly worrying in Japan, given that it "has the lowest percentage of foreign-born residents in the world among developed nations, suggesting far fewer cases and thus less experience working with non-nationals" (2). Thus, algorithms developed in and based on data from the Japanese context can be expected to lack sufficient diversity, and risk perpetuating healthcare inequality for minorities. Moreover, though the Plan includes provisions for securing access to patient data, the development of the systems it calls for appears to be moving forward without consideration of the need for such data to be representative. Thus, explicit provisions to avoid bias and discriminatory outcomes are necessary but lacking in the Plan. This is especially important if technologies are exported to other contexts, as described in the Plan itself. Here, it is important to note that one of the goals of AI implementation described in the Plan is to make healthcare more accessible to non-Japanese speakers, by reducing potentially fatal language barriers (23). If expanded further, this could bring benefits to immigrants and non-Japanese populations, particularly given that immigrants continue to face barriers to access for "ambulatory and emergency care," even with insurance coverage (23).

Autonomy (Principle 1) is another area where the Plan takes a narrow focus, as the preservation of human autonomy as stipulated in the WHO principles was not addressed in the Plan beyond limited consideration of data security and privacy, with a notable lack of consideration about the need for appropriate consent. Although, as stipulated by the WHO, "[r]espect for autonomy also entails the related duties to protect privacy and confidentiality and to ensure informed, valid consent by adopting appropriate legal frameworks for data protection," the Plan focuses primarily on data security, without consideration of the need to preserve patient autonomy. By situating privacy concerns under Principle 1, "Protecting human autonomy," the WHO Guidance points to how privacy and confidentiality ensure human autonomy on both sides of clinical interactions, which is critical to well-functioning healthcare systems (19). However, the protection of privacy is not synonymous with autonomy, which can be understood as the ability to act "in accordance with one's goals and values" (24) It is noteworthy that research in other settings has also found that narrower issues of data security and privacy are often more frequently addressed in considerations of AI ethics than principles such as autonomy (25). In this case, the absence of direct attention to

autonomy in the Plan may be grounded in an expectation in the Japanese context that AI-based systems remain supplemental to human HCPs, providing for the "override" on decisions as called for in the WHO Guidance (2), but does not necessarily ensure patient autonomy. Moreover, in light of recent work by Kodera et al. (26) which suggests that this HCP-centric approach may change, it is essential that stipulations to preserve autonomy be clearly put forward.

Care is needed in the handling of patient data, given the risks presented by rising numbers of cyber-attacks against healthcare facilities (27). Davis (27) highlights the risk of "function creep," through which data collected for one purpose comes to be used for another. Data breaches can reveal sensitive healthcare data, which may be used against data subjects in consequential settings including employment and for insurance judgments (28). This highlights the need for consideration of privacy issues. Patient consent for the use of data is also relevant here. Facilitating informed consent is presented in the Plan as an end goal for the development of AI, rather than to ensure that the data used for AI itself is ethically obtained.

Accountability is additionally a major issue in relation to healthcare, particularly given the black-boxed nature of many algorithms (3). How accountability would be handled and who would be responsible for potential issues that arose—such as when problematic decisions were influenced or made by AI—were insufficiently addressed. Research further suggests that these are important considerations for patients in relation to their willingness to engage with AI in healthcare (29, 30).

There were provisions in the Plan for consultation with direct stakeholders, including patients, which reflects trends towards the democratization of healthcare, and recognition of the value of patient involvement in healthcare (31–33). However, this did not extend to the level of broader "public consultation and debate" on the technologies, called for in the WHO Guidance. Caution is needed in this area, as there is the risk that consultation with limited stakeholder groups can lead to a form of "participation-washing" (34), in which the perspectives of small numbers of participants are overgeneralized to represent public perspectives. In this area as well, provisions for including the perspectives of minority users of healthcare would be desirable.

And finally, there was a significant lack of consideration of Principle 6, and especially for ensuring the sustainability—broadly defined—of healthcare. As discussed above, social sustainability was insufficiently addressed, and the Plan lacked provisions to offset potential disruptions in healthcare, such as through adequate training or education. Moreover, the environmental consequences of AI implementation raised in Principle 6 were not considered. Van Wynsberghe (35) describes the development of AI ethics as occurring in three waves. In this model, the current second wave of AI ethics is concerned with the potential for the amplification of existing biases in healthcare, while the coming, third-wave of AI ethics is concerned with the sustainability of AI systems. As Van Wynsberghe (35), Crawford (36), Brevini (37), and Jaume-Palasi (38) have argued, AI creates a substantial environmental burden across its life course, ranging from extracting materials such as rare earth metals and lithium used in the hardware, to the carbon emissions in creating and using systems and their data centers. Given the urgency of the breach of planetary boundaries and the extreme degradation of the global environment, all projects, including this one, must include consideration of their environmental impact.

4.1. Limitations and future directions

Ultimately, this exploratory analysis highlights significant oversights and a need for greater awareness of the potential ethical issues around AI in healthcare in the SIP, which are insufficiently considered despite the scale and governmental backing of the SIP. Although the Plan did provide for the outsourcing of ethical consideration through the creation of an ELSI Committee, lack of attention to the risks of bias and discrimination, of privacy and consent, and of the sustainability of the proposed technologies were problematic oversights in the context of broader debates on the ethics of AI. Plans for the development of AI in healthcare must contain explicit consideration of and provisions to offset a range of ethical issues. Though this study focused on a Japanese case, it highlights a need for similar, critical examination of plans set in other contexts. Japan's status as a front-runner for the implementation of AI into healthcare allows it to serve as an exemplar, enabling other countries to avoid possible pitfalls through lessons learned from the Japanese case.

This study was an exploratory analysis of ethical considerations in the Plan. It is noteworthy that the frequency of reference to a particular principle is just one possible metric and does not necessarily imply that a principle is perceived to be important or unimportant. Moreover, given the complexity of ethical principles and their application, reference to a principle in the Plan does not necessarily reflect the extent to which it is acted on in practice. Furthermore, is possible that further ethical consideration may have been conducted under the purview of the ELSI Committee described above, or within the design and implementation of the individual technologies called for in the Plan. Indeed, given that the Plan promotes the necessity of the technologies, the omission of direct attention to ethical considerations may strengthen the perceived merit of the technologies. Yet, consideration of the ethics of emerging technologies is essential in ensuring the longer-term social acceptance, trustworthiness, and beneficence of the proposed technologies. Particularly as the period allotted for the SIP draws to a close, further research may build on this exploratory study to examine the extent to which ethical issues were considered in the actual execution of the Plan and explore whether plans for AI in healthcare developed in other contexts share similar oversights.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

The author confirms being the sole contributor of this work and has approved it for publication.

Funding

This work was funded by the Japan Science and Technology Agency Research Institute of Science and Technology for Society Grant Number JPMJRX19H1.

Acknowledgments

The author wishes to express thanks to Professor Beverley Yamamoto, Sinai Harel, and Yan Li, and gratitude for the comments received during the review process.

Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

1. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. *Nat Med*. (2019) 25:44–56. doi: 10.1038/s41591-018-0300-7

2. Ishii E, Ebner DK, Kimura S, Agha-Mir-Salim L, Uchimido R, Celi LA. The advent of medical artificial intelligence: lessons from the Japanese approach. *J Intensive Care*. (2020) 8:35. doi: 10.1186/s40560-020-00452-5

3. Topol E. *Deep medicine: How artificial intelligence can make healthcare human again*. New York: Hachette Book Group (2019).

4. Fogel AL, Kvedar JC. Artificial intelligence powers digital medicine. *NPJ Digit Med*. (2018) 1:5. doi: 10.1038/s41746-017-0012-2

5. Panch T, Mattie H, Celi LA. The "inconvenient truth" about AI in healthcare. *NPJ Digit Med*. (2019) 2:77. doi: 10.1038/s41746-019-0155-4

6. Dalton-Brown S. The ethics of medical AI and the physician-patient relationship. *Camb Q Healthc Ethics*. (2020) 29:115–21. doi: 10.1017/S0963180119000847

7. Chen Y, Stavropoulou C, Narasinkan R, Baker A, Scarbrough H. Professionals' responses to the introduction of AI innovations in radiology and their implications for future adoption: a qualitative study. *BMC Health Serv Res*. (2021) 21:813. doi: 10.1186/s12913-021-06861-y

8. Nakamura Y. Japanese cross-ministerial strategic innovation promotion program "innovative AI hospital system"; how will the 4th industrial revolution affect our health and medical care system? *JAMA J*. (2022) 5:1–8. doi: 10.31662/jmaj.2021-0133

9. Cabinet Office (2022). Society 5.0 [internet]. Available at: https://www8.cao.go.jp/cstp/english/society5_0/index.html [Accessed November 21, 2022].

10. Japan Cabinet Office (2022). 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 [innovative AI hospital system research plan] [internet]. Available at: https://www8.cao.go.jp/cstp/gaiyo/sip/keikaku2/10_aihospital_1.pdf [Accessed December 3, 2022].

11. National Institutes of Biomedical Innovation, Health and Nutrition (2021). AIホスピタルプロジェクトとは [what is the AI hospital project?] [internet]. Available at: https://www.nibiohn.go.jp/sip/about/outline/ [Accessed August 17, 2022].

12. National Institutes of Biomedical Innovation, Health and Nutrition (2023). Innovative AI hospital system [internet]. Available at: https://www.nibiohn.go.jp/en/sip/ [Accessed January 9, 2023].

13. WHO (2021). Ethics and governance of artificial intelligence for health [internet]. Available at: https://www.who.int/publications/i/item/9789240029200 [Accessed August 17, 2022].

14. McLennan S, Fiske A, Tigard D, Müller R, Haddadin S, Buyx A. Embedded ethics: a proposal for integrating ethics into the development of medical AI. *BMC Med Ethics*. (2022) 23:6. doi: 10.1186/s12910-022-00746-3

15. Karimian G, Petelos E, Evers SMAA. The ethical issues of the application of artificial intelligence in healthcare: a systematic scoping review. *AI Ethics*. (2022) 2:539–51. doi: 10.1007/s43681-021-00131-7

16. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. (2005) 15:1277–88. doi: 10.1177/1049732305276687

17. Keane PA, Topol EJ. With an eye to AI and autonomous diagnosis. *NPJ Digit Med*. (2018) 1:40. doi: 10.1038/s41746-018-0048-y

18. Elish MCboyd danah. Situating methods in the magic of big data and AI. *Commun Monogr*. (2018) 85:57–80. doi: 10.1080/03637751.2017.1375130

19. Pasquale F. *New Laws of robotics: Defending human expertise in the age of AI*. Cambridge: The Belknap Press of Harvard University Press (2020).

20. Karliuk M. (2022). Proportionality principle for the ethics of artificial intelligence. AI Ethics [Internet]. Available at: https://link.springer.com/10.1007/s43681-022-00220-1 [Accessed December 6, 2022].

21. Obermeyer Z, Powers B, Vogeli C, Mullainathan S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations.

22. Moreau JT, Baillet S, Dudley RW. Biased intelligence: on the subjectivity of digital objectivity. *BMJ Health Care Inform*. (2020) 27:e100146. doi: 10.1136/bmjhci-2020-100146

23. Ishii E, Nawa N, Matsui H, Otomo Y, Fujiwara T. Comparison of disease patterns and outcomes between non-Japanese and Japanese patients at a single tertiary emergency Care Center in Japan. *J Epidemiol*. (2022) 32:80–8. doi: 10.2188/jea.JE20200211

24. Calvo RA, Peters D, Vold K, Ryan RM. Supporting human autonomy in AI systems: a framework for ethical enquiry In: C Burr and L Floridi, editors. *Ethics of digital well-being: a multidisciplinary approach [internet]*. Cham: Springer International Publishing (2020). 31–54.

25. Morley J, Kinsey L, Elhalal A, Garcia F, Ziosi M, Floridi L. (2021). Operationalising AI ethics: barriers, enablers and next steps. AI Soc [Internet]. Available at: https://link.springer.com/10.1007/s00146-021-01308-8 [Accessed September 21, 2022].

26. Kodera S, Ninomiya K, Sawano S, Katsushika S, Shinohara H, Akazawa H, et al. (2022). 医療AIに対する患者の意識調査.

27. Davis SLM. The Trojan horse: digital health, human rights, and Global Health governance. Health hum rights. *Int J*. (2020) 22:41–7.

28. Veliz. *Privacy is power: Why and how you should take Back control of your data*. Brooklyn: Random House (2020).

29. Jutzi TB, Krieghoff-Henning EI, Holland-Letz T, Utikal JS, Hauschild A, Schadendorf D, et al. Artificial intelligence in skin Cancer diagnostics: the patients' perspective. *Front Med*. (2020) 7:233. doi: 10.3389/fmed.2020.00233

30. Musbahi O, Syed L, Le Feuvre P, Cobb J, Jones G. Public patient views of artificial intelligence in healthcare: a nominal group technique study. *Digit Health*. (2021) 7:205520762110636. doi: 10.1177/20552076211063682

31. Grotz J, Ledgard M, Poland F. *Patient and public involvement in health and social care research: An introduction to theory and practice*. Cham: Palgrave Macmillan (2020).

32. Katirai A, Kogetsu A, Kato K, Yamamoto B. Patient involvement in priority-setting for medical research: a mini review of initiatives in the rare disease field. *Front Public Health*. (2022) 10:915438. doi: 10.3389/fpubh.2022.915438

33. Japan Agency for Medical Research and Development (2019). 患者・市民参画(PPI)ガイドブック ~患者と研究者の協働を目指す第一歩として~ [patient and public involvement (PPI) guidebook ~ as a first step towards collaboration between patients and researchers~] [Internet]. Available at: https://www.amed.go.jp/ppi/guidebook.html (Accessed August 17, 2022).

34. Sloane M, Moss E, Awomolo O, Forlano L. (2020). Participation is not a Design Fix for Machine Learning 7.

35. van Wynsberghe A. Sustainable AI: AI for sustainability and the sustainability of AI. *AI Ethics*. (2021) 1:213–8. doi: 10.1007/s43681-021-00043-6

36. Crawford K. *Atlas of AI: Power, politics, and the planetary costs of artificial intelligence*. New Haven: Yale University Press (2021).

37. Brevini B. *Is AI good for the planet?* Cambridge: Polity Press (2021).

38. Jaume-Palasi L. Why we are failing to understand the societal impact of artificial intelligence. *Soc Res*. (2019) 86:477–98. doi: 10.1353/sor.2019.0023

frontiers | Frontiers in Public Health

TYPE Original Research
PUBLISHED 18 September 2023
DOI 10.3389/fpubh.2023.1227146

OPEN ACCESS

EDITED BY
Denise Veelo,
Amsterdam University Medical Center,
Netherlands

REVIEWED BY
Karen Carlisle,
James Cook University, Australia
Gabriel Gomes De Oliveira,
State University of Campinas, Brazil

*CORRESPONDENCE
Kumarasan Roystonn
✉ k_roystonn@imh.com.sg

RECEIVED 22 May 2023
ACCEPTED 04 September 2023
PUBLISHED 18 September 2023

CITATION
Roystonn K, AshaRani PV, Devi F, Wang P, Zhang Y, Jeyagurunathan A, Abdin E, Car LT, Chong SA and Subramaniam M (2023) Exploring views and experiences of the general public's adoption of digital technologies for healthy lifestyle in Singapore: a qualitative study.
Front. Public Health 11:1227146.
doi: 10.3389/fpubh.2023.1227146

Exploring views and experiences of the general public's adoption of digital technologies for healthy lifestyle in Singapore: a qualitative study

Kumarasan Roystonn[1]*, P. V. AshaRani[1], Fiona Devi[1], Peizhi Wang[1], Yunjue Zhang[1], Anitha Jeyagurunathan[1], Edimansyah Abdin[1], Lorainne Tudor Car[2,3], Siow Ann Chong[1] and Mythily Subramaniam[1,4]

[1]Research Division, Institute of Mental Health, Singapore, Singapore, [2]Department of Primary Care and Public Health, School of Public Health, Imperial College London, London, United Kingdom, [3]Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore, Singapore, [4]Saw Swee Hock School of Public Health, National University of Singapore, Singapore, Singapore

Objective: Little is known about the general adult population's adoption of digital technology to support healthy lifestyle, especially when they are expected to take greater personal responsibility for managing their health and well-being today. The current qualitative study intended to gain an in-depth understanding of determinants of digital technology adoption for healthy lifestyle among community-dwelling adults in Singapore.

Design: A qualitative study design, with thematic framework analysis was applied to develop themes from the data.

Setting: Semi-structured individual interviews were conducted with participants either face-to-face or online through a videoconferencing platform.

Participants: 14 women and 16 men from the general population who were between the ages of 22 and 71 years.

Results: Three major themes were developed: (1) digitally disempowered (2) safety and perceived risks and harm; (3) cultural values and drives. Adoption of technology among the general population is needs-driven, and contingent on individual, technological and other cross-cultural contextual factors.

Conclusion: Our findings highlight there is no one solution which fits all individuals, emphasizing the challenges of catering to diverse groups to reduce barriers to adoption of digital technologies for healthy lifestyle. Digital guidance and training, as well as social influences, can motivate technological adoption in the population. However, technical problems as well as data security and privacy concerns should first be adequately addressed. This study provides rich cross-cultural insights and informs policy-making due to its alignment with government public health initiatives to promote healthy lifestyle.

KEYWORDS

digital technology, healthy lifestyle, technology adoption, ethical considerations, digital public health, qualitative research

Introduction

According to the World Health Organization, non-communicable diseases have caused more than 41 million deaths worldwide each year (1), and the risk of developing these diseases are decisively affected by lifestyle choices (2, 3). Southeast Asia faces an epidemic of these chronic preventable diseases, now responsible for more than 60% of deaths in the region (4, 5). Physical inactivity, unhealthy diet, poor sleeping and other lifestyle behaviors are strongly associated with the development of major non-communicable diseases such as cancer, heart disease, stroke, and diabetes (5, 6). In addition to premature mortality, the associated morbidity of these modifiable risk factors including direct and indirect economic costs, exerts a substantial burden on societies and healthcare systems (6, 7). For example, physical inactivity was estimated to globally cost health-care systems US$53.8 billion, with US$13.7 billion in productivity losses due to premature deaths, and was responsible for 13.4 million disability-adjusted life-years (DALYs) worldwide (8). A recent study estimated that the national healthcare spending related to modifiable lifestyle behaviors amounted to US$730 billion in the US (9). In Singapore, healthcare costs increased from S$11.1 billion in 2019 to S$15.2 billion in 2020 (10), and is expected to increase to S$59 billion by 2030 (11). Healthcare is clearly undergoing a paradigm shift; from traditional healthcare treatment towards a person-centered management of health and healthier behaviors across many world regions and in Singapore to decelerate the overwhelming burden on health care systems (12, 13). Despite the great strides made in clinical care to identify individuals with known risk factors and prescribing timely interventions to lower the risk of disease development, the persistent burden of disease today suggests a much-needed emphasis on primary prevention of disease through health promotion (14). A general conclusion is that reducing modifiable dietary and lifestyle risk factors could prevent most cases of major non-communicable diseases among high-income populations. Active and healthy lifestyles may confer benefits for multiple health outcomes related to reduction in all-cause mortality rates and improvement in mental well-being (5). These findings are profoundly important, because they indicate that these diseases are not inevitable consequences of a modern society. Furthermore, low rates of these diseases can be attained without expensive medical treatment and facilities. Population-wide primary prevention targeted at encouraging health promoting lifestyle habits should thus be the overarching priority for the response to this global crisis. In recent years, the Ministry of Health (MOH) in Singapore has launched national health campaigns for getting the population to engage in healthy lifestyle behaviors; the largest in 2016 is known as, *War on Diabetes (WoD)* campaign (15). The WoD campaign comprised efforts to promote a healthy lifestyle among the general population in Singapore, which were aimed at associated modifiable risk factors including obesity, physical inactivity, and unhealthy diet. Yet, there is suboptimal adherence to active healthy lifestyle behaviors in the general population (16). The 2019–20 National Population Health Survey in Singapore revealed that between 2013 and 2020, the prevalence of obesity has been exponentially escalating from 8.6% to 10.5% and that of overweight (including obesity) in adults has drastically increased from 34.3% to 39.1% (17, 18). National nutrition surveys in Singapore suggest that overall, consumption patterns appear to be shifting modestly toward healthier options. Between 2010 and 2018, saturated fats intake among Singaporean adults (18–69 years) was slightly lower from 38% to 36% (19). The level of confinement and other severe restrictions implemented during the coronavirus pandemic may also have had a negative influence on active and healthy lifestyle behaviors (20).

Although there have been strategic shifts in national efforts to enable and empower individuals to live out a healthy lifestyle (e.g., WoD campaign) (13, 15), more needs to be done. The national population data suggest that besides intensifying existing public education campaigns and programs, novel approaches are needed to transform the promotion of health and prevention of disease in the general population. Digital technologies are able to better promote and sustain positive lifestyle habits (21). From a public health perspective, one of the most powerful levers for influencing population health lie today in digital technological innovations that make healthy living convenient and an accessible choice (22). Prior studies have demonstrated in Western populations, the use of digital innovations to encourage and increase healthy behaviors (physical activity, diet, mood, and good sleep quality) implemented with various smart tools (e.g., wearables/smart watches, *m*health apps, nutrition apps, fitness tracking) (23). Digital technologies can enable individuals to be active participants in their health maintenance, enabling people to manage their health and make better health and lifestyle related decisions (24, 25); and may be key to tackling the current and post-pandemic challenges on how to empower individuals to engage in healthier personal lifestyle choices (21, 26). Other research also suggest increasingly higher acceptance rates for the use of technology as a healthy behavior accompaniment, through digital innovations, which may be an efficient approach to foster active and healthy lifestyles (26). Access to such technology is increasingly available around the globe, with global internet penetration rates exceeding 90% in most developed nations (27). Indeed, in Singapore, internet penetration is as high as 92% and over 90% of all adults own a smart phone. A wide spectrum of players have begun leveraging digital technologies to nudge consumers to greater participation in healthy lifestyle promoting behaviors (28) —not only public healthcare incumbents like the government, but also private entrants such as insurance conglomerates and health consumer-technology giants. One such national movement in Singapore is ActiveSG (29); complimentary for all Singapore citizens and permanent residents to promote a healthy lifestyle through sports and sporting activities virtual or otherwise. Through this nationwide movement, physical activity and nutrition programs or courses are promoted to Singaporeans across all age groups. While available as a website, ActiveSG users can also use a mobile app to facilitate participation in physical or virtual healthy lifestyle activities (30). Another example is the Healthy 365 program introduced by the Health Promotion Board (HPB) of Singapore, which gamifies wellness by awarding redeemable health points on an app for health-promoting lifestyle practices (31). More recently, HPB expanded on this with *LumiHealth*, encouraging additional healthy lifestyle activities for smartwatch users (32).

While it is encouraging that there is a rapid growth in the number and sophistication of digital innovations for active lifestyles, it is only worthwhile if these are accepted by both the young and old, and used to improve their health outcomes. However, several researchers have found that unlike the younger generation, most older adults may be digitally estranged (33, 34). Other behavioral research highlights potential frustrations with new digital technologies, concerns about privacy, and lack of support, which may likely make individuals doubt

their ability to learn and adapt, and leave them unmotivated to even try the technology (35). However, the wealth of research on the use of digital technologies focused on healthy lifestyle activities are centered on Western populations.

The Technology Acceptance Model (TAM) provides a framework for understanding the adoption of technologies (36). This model structures technology acceptance on the basis of two main perceptions: namely, usefulness (the benefit from using the technology) and ease of use. Simply, consumers are more likely to adopt a new technology that is considered usable, desirable, and beneficial. TAM has since been successfully applied to other domains including healthcare (37, 38). The uptake of digital health tools and applications has also been evaluated with the TAM to good effect in other qualitative research (39, 40).

Taking into consideration the emerging evidence for digital innovations as one of the promising solutions which potentially allow easy, personalized, and accessible means to improve the well-being of individuals, we felt that it would be meaningful to examine personal experiences surrounding the determinants of digital technology adoption for promoting active and healthy lifestyle behaviors in the general population of Singapore.

Materials and methods

Study design and setting

A qualitative design was undertaken in the study to explore individual experiences with digital technology to promote healthy lifestyle. This study was part of a larger nationwide study that examined the knowledge, attitudes, and protective practices toward diabetes among the public in Singapore (41). The study comprised a quantitative survey, followed by a qualitative phase, to explore the barriers and facilitators of a healthy lifestyle in Singapore. The study methodology has been published in an earlier article (41). A disproportionate stratified sampling design (by age group and ethnicity) was used, where the 3 main ethnic groups (Chinese, Malays, and Indians) and 4 age groups (18 to 34 years, 35 to 49 years, 50 to 64 years, and 65 years and above) were sampled in equivalent independent proportions of about 30% and 20%, respectively. The participants for the qualitative study were recruited from among those who participated in the quantitative survey (41) and had provided written consent for re-contact for research. Briefly, eligible participants: (1) were Singapore citizens or permanent residents; (2) aged ≥21 years; (3) could speak either English, Chinese, Malay, or Tamil, and; (4) had no formal diagnosis for diabetes. Initially, participants were stratified according to age, gender, and ethnicity, and randomly selected with an online randomization software for recruitment into the qualitative phase. Subsequently, demographics of the sample were reviewed and subsequent invitations were targeted to ensure maximum variation sampling (42), with a relatively even spread across gender, age groups, ethnicities, and languages to obtain a wide representation of views across Singapore.

Written informed consent was obtained from all participants, and ethical approval for the study was granted by the relevant institutional review board, the National Healthcare Group Domain Specific Review Board (DSRB ref.: 2019/00926). This study is reported in accordance with the Consolidated criteria for Reporting Qualitative research guidelines (43).

Public and patient involvement

Patients were not involved in the design, recruitment or conduct of the study.

Interviews

The study period (from August 2020 to March 2021) coincided with the rapidly developing Covid-19 pandemic situation and therefore, interviews were conducted either in person or via the video conferencing platform Zoom, depending on the participant's preference. A semi-structured interview guide (see Supplementary material) aimed to explore participants' perspectives on healthy lifestyle; the barriers and enablers; technology for healthy lifestyle; and, programs and initiatives related to healthy lifestyle in Singapore. The main themes in the interview guide were explored with broadly open-ended questions, and prompts (e.g., "*Can you please tell me a little bit more about that?*," "*Could you give me an example of that?*") were used if necessary. At times, the interviews required a 'two-way process' (44), where interviewers also shared information about themselves and their families, which in turn drew out richness and depth in the personal accounts of participants and their experiences.

Data collection and analysis happened concurrently, allowing emergent themes to inform ongoing data collection. The team decided to end data collection when saturation was assumed to have been reasonably attained with no new themes arising from the data. Data were analyzed first from the English-language interviews before commencing with the other language (Chinese, Malay, and Tamil) interviews. This was to ensure that we had reached thematic saturation with data collection and to simultaneously observe and analyze the other language interviews for the emergence of new themes. A total of 30 interviews were conducted by experienced qualitative researchers from the study team; 20 interviews were in English, while four were in Chinese, and three were conducted in Malay and Tamil respectively. Interviews were audio recorded, and transcribed verbatim by an external provider of transcription services. These were then checked for accuracy by researchers in the study team.

Data analysis

Data analysis was facilitated by NVivo V.11. We relied on qualitative description (45, 46) for the study design because we wanted to generate a rich and straightforward description of participant experiences and perceptions that would inform policy (47). Using the Framework analytic method (48, 49) we took a combined approach to analysis, enabling themes to be developed both inductively from the accounts of our participants and deductively from existing literature (45). Framework analysis was considered to be a better choice than thematic analysis, because it emphasizes how both *a priori* issues and emergent data driven themes should guide the development of the analytic framework (50); this was something that suited the aims of our present study, in so far as we had certain pre-defined areas we wished to explore, but also wanted to remain open to discovering the unexpected. Regular team discussions facilitated our critical exploration and discussion of participant responses, and agreement on recurring themes.

Members of our research team (AR, FD, WP, ZY, AJ, MS, and KR) first thoroughly read and re-read each transcript, and listened back to the audio-recorded interviews familiarizing themselves with the contents of the transcripts. We found this familiarization process essential in cases where the researcher analyzing the data had not been present during the interview (48). The team then independently coded the data, which involved line-by-line analysis of the data and identification of elements that appeared important to the research questions.

Next, the researchers independently developed initial themes by further refining codes and adapting, merging and sorting them into a preliminary structure representing themes and subthemes. The researchers then met to discuss and review emerging categories and ideas to construct an initial analytical framework. Themes and subthemes were reviewed multiple times to ensure external heterogeneity and internal homogeneity. On reaching a consensus, a codebook was constructed which described each code, the inclusion and exclusion criteria, and exemplars from the transcripts to assist with reliable code application.

We applied this final analytical framework, the codebook, to each transcript using NVivo. We divided the transcripts among the researchers and imported them into NVivo ready for indexing. The semi-structured interviews were the unit of analysis. We then systematically went through each transcript, highlighting each meaningful passage of text and selecting and attaching an appropriate code from the codebook. We then used NVivo to share our indexed transcripts, ensuring that each researcher could access the whole data set for the next stage.

Once all the data had been coded using the analytical framework, we reviewed and summarized the data in a matrix for each theme using Microsoft Excel. The matrix comprised of one row per participant and one column per code. We abstracted data from transcripts for each participant and code, summarized it using verbatim words and inserted it into the corresponding cell in the matrix. We also highlighted references to potentially interesting quotations within respective cells in the matrix.

The themes for this study were generated from the data set by reviewing the matrix and making connections within and between participant and categories. This process was influenced both by the original research objectives and by new concepts generated inductively from the data. We tried to go beyond descriptions of individual cases toward developing themes which offered possible explanations for what was happening within the data. Ideas were generated, explored and fleshed out through discussions with the lead researcher (MS) on the team. Our participants' experiences and beliefs have been presented with minimally edited verbatims in the results section below.

Results

Participant characteristics

Thirty individuals from the general public participated in the study, of which 16 were male and 14 were female. The mean age of participants was 44.7 years (SD = 14.7), with ages ranging from 22 to 71 years. Forty percent identified their ethnicity as Chinese, 33.3% as Malay, 20% as Indian and 7% as Others. Majority of the participants reported being married (70%), employed (66.7%), and most had attained secondary level education or higher (86.7%). Table 1 presents the demographic details of all participants.

Local context of digital technology adoption for healthy lifestyle

Our participants reported that using digital technologies affected their health status and lifestyle in some way. These digital technologies promoting active and healthy lifestyle behavior were mobile applications (apps), wearable devices, social media platforms and websites. The most commonly used were mobile health apps, most times associated with a wearable fitness activity tracking device.

Most participants also shared that they used one or more types of digital technologies concurrently. Participants from ethnic minority groups (Indians and Malays) expressed a tendency to use digital technology for weight and nutrition related activities such as weight management, healthy food consumption, and nutrition or calorie information compared to the Chinese majority. While many reported downloading or accessing digital tools of their own volition, more than a third, on the other hand, also reported using digital technology infrequently or not at all after.

Determinants of digital technology adoption for healthy lifestyle

Table 2 presents the themes and subthemes relating to determinants of technology adoption for healthy lifestyle. Three broad themes (with up to three subthemes each) were developed: (1) digitally disempowered; (2) safety and perceived risks and harm; and (3) cultural values and drives. Each main theme and subthemes will be discussed in the following paragraphs.

Theme 1: Digitally disempowered

The theme "digitally disempowered" was used to describe a small but significant group of participants who believed their access and use of digital technology was hampered by a lack of capability or language barriers. This theme also captured those who believed they were hindered by poor technological design and quality to engage with these digital technologies.

Lack of capability

Most participants were challenged by a lack of, or an inadequate level of specific digital skills to access and use the variety of technological innovations available. In general, participants felt a significant barrier to digital technology use was their age. Among these participants, some shared that they felt the use of digital technology for active and healthy lifestyle required significantly higher levels of digital knowledge and skills which were too complex and demanding for them to learn today.

> "knowledge wise, you see if you take me at my age, I don't have that level of scientific knowledge, knowledge to use (technology) or all of these" – Male, 35–39 years.

Instead, some felt that there was a lack of guidance and training to acquire these digital skills in order to take advantage of available digital tools.

TABLE 1 Demographic characteristics of the participants.

Characteristics	Mean (SD) / Percentage (*n*)
Age (years)	44.7 (14.7)
Gender	
Male	53.3 (16)
Female	46.7 (14)
Ethnicity	
Chinese	40.0 (12)
Malay	33.3 (10)
Indian	20.0 (6)
Others	6.7 (2)
Marital status	
Single/Never married	23.3 (7)
Married	70.0 (21)
Divorced/Separated/Widowed	6.7 (2)
Education level	
Primary level & below	13.3 (4)
Secondary level	26.7 (8)
Diploma/Vocational or ITE/Pre-university level	26.7 (8)
University level & above	33.3 (10)
Employment status	
Employed	66.7 (20)
Unemployed	13.3 (4)
Homemaker	13.3 (4)
Student/Never employed	6.7 (2)

SD, Standard deviation; ITE, Institute of Technical Education.

TABLE 2 Themes and subthemes relating to determinants of technology adoption for healthy lifestyle.

Theme 1: Digitally disempowered
• Lack of capability
• Language barriers
• Poor technology design and quality
Theme 2: Safety and perceived risks and harm
• Security and privacy
• Distrust and discontentment
• Threat to health
Theme 3: Cultural values and drives
• Social norms
• Peer influences
• Self-directed motivation

> "for those who are new to going online, they still don't know. It may be an obstacle. Because I totally don't know; I don't know how to book or go see. That's what I mean. Then, if someone teaches, I will know, and it will be easy, like that" – Female, 55–59 years.

Interestingly, few older participants were among those who reported a lack of digital skills or training. Some older adults shared how they were capable, and currently engaging with digital technology to engage in active lifestyle behaviors.

> "sometimes we open to this YouTube right, has exercises; to follow healthy lifestyle kind of exercise. They show you how to do this or do that…we use YouTube a lot" – Female, 65–69 years.

Poor technology design and quality

Poor technology quality or otherwise ill-suited designs of digital devices and smart instruments were found to hinder the possibilities of use. Some participants felt the current quality of smart wearables was still sub-par and the ill-suited designs or poor affordances meant they were not convenient or led to unappealing personal costs and effort to have them fixed.

> "My friend wears a smartwatch, but mine is spoiled, so I didn't change it because it is too difficult…I stopped. Just like that" – Female, 55–59 years.

Other participants aired their grievances about how existing digital tools lack innovation and sophistication to circumvent what they felt were cognitively challenging experiences with digital technology promoting active and healthy lifestyle behavior. For instance, having to repeatedly look at digital screens while trying to follow physical exercises or the need for frequent playback to observe the exercises more closely in order to get them right. Many shared these experiences were too cumbersome and off-putting.

> "I really used it only for a few months now then gave up… it's very difficult because you will need to watch the screen as you do the exercise. For me, it's very difficult" – Female, 35–39 years.

Language barriers

Participants also felt that sometimes language was a challenge to using digital technology. Several participants who were not English-literate, felt there was a severe lack of digital tools, particularly mobile apps, in their native languages.

> "I mean, for us people who only speak or understand Tamil…A lot of us, who only know Tamil, we won't know a lot of things on because of this you see" – Male, 35–39 years.

Theme 2: Safety and perceived risks and harm

This theme, "safety and perceived risks and harm" was described by the participants as one of the important determinants for adoption of digital technology for healthy lifestyle. Our participants reported three key subthemes: security and privacy, distrust and discontentment, and perceiving threats to health.

Security and privacy

Security issues and a lack of trust complicated the adoption of technology particularly among consumers of technology. Many participants expressed safety concerns about the security of personal information shared with various health-promoting digital tools and platforms in order to receive personalized, authentic, and meaningful experiences. Participants felt that their fear and anticipation of consequences regarding misuse of their personal data led to their avoidance or discontinued use of the technology.

> "I'm not very comfortable with the idea of sharing such personal data with technology companies….I think that's really very scary to me. Yeah, taking over our lives. And what we can or cannot do. So yeah.…because they really do steal data from their own (users)" – Male, 20–24 years.

Distrust and discontentment

Digital technologies associated with physical activity, sleep, mood and weight management are very popular in the general population; however, the quality of the digital technologies and health information propagated on these are hard to assess for making informed health care decisions by users.

> "These are the biggest negative factors online, I feel, a lot of gimmicks, a lot of scams, a lot of these kind of people that claim to know what they're doing but they don't" – Male, 25–29 years.

Experiences of distrust of digital content also emerged from the interviews, as participants shared about how they grappled with the challenge of false, inaccurate, and misleading information in digital technology promoting healthy lifestyle.

> "So if a company wants to sell its product, it can really buy off a few YouTubers, popular YouTubers and tell them to sell their products. So I think this can really sway a lot of people…Basically, spread a lot of half-truths or misinformation" – Male, 20–24 years.

A number of participants felt dissatisfied particularly with mobile health apps. While most have a free version, it tends to be limited in functionality and often inundated with advertising. Participants also shared feeling deceived by 'premium' apps and 'paid' apps. They shared how it was difficult to find suitable and effective apps to achieve their lifestyle goals.

> "They are just traps to get you to spend money. So it is very difficult to like figure out which ones are legitimate and which ones are out to get your money… even for a paid app, it doesn't really guarantee results" – Female, 25–29 years.

Some participants felt most of the digital technology for active and healthy lifestyle were primarily targeted at consumers from Western populations. Participants felt that often these digital tools were not always culturally relevant, or worse, causing physical and psychological harm to uninformed users in non-Western populations.

> "I think relying on it may not be very helpful, or it can actually disadvantage you because your body is definitely very unique and different from others. So your body is probably very different from that of an average Westerner. So with Western companies telling us what we should or should not do or eat, it can be affecting us very differently" – Male, 20–24 years.

Threat to health

In addition to the above safety concerns, a substantial number of participants commonly described digital technology as potentially harmful to healthy living. While many acknowledged that digital technology was useful for promoting healthy living, they shared how it can also bring a lot of distractions which may jeopardize their plans to engage in healthy lifestyle behaviors.

> "I think when people are just stuck on their phones non-stop, it shows that technology is really not helpful for healthy living…a lot of people will end up just watching or using it for so long and it stops us…from doing our exercise" – Female, 60–64 years.

However, several participants reported that technology use as a distraction was in fact useful in motivating them to last longer during activities such as exercise. Thus, participants felt digital distractions can be a double-edged sword.

> "It's like oh I want to watch just another episode or something on Netflix and then after that, I will go (exercise)…But then because they are distracted by the show, they run a bit more. So it is really like a double-edged sword. It distracts you but it also helps you to do more of your fitness stuff because you are distracted" – Female, 25–29 years.

Theme 3: Cultural values and drives

The theme, "Cultural values and drives" was identified as another key determinant of technological adoption. There were three subthemes: Social norms, Peer influences, and Self-directed motivations.

Social norms

Traditionally, healthy lifestyle interventions have been in-person activities conducted individually or in a group. A group of participants held a keen preference for these methods over the use of digital technology, as the latter was not seen to provide an equivalent experience or beneficial one. Unlike the 'digitally disempowered' described earlier, whose technology adoption was predominantly hampered by accessibility issues, participants in this social group shared common values to do with the undesirability of digital technology for healthy lifestyle and an avoidance of it. In addition, security and privacy concerns were also rather common in this faction of non-adopters.

> "the best way, right, is through human to human. That's the best way because like, for my sister, she didn't get proper training on apps. So, it turns out she's not getting slimmer, she's getting bigger"– Male, 30–34 years.

Many of the participants shared challenges related to the nature of communication and poor interaction through the digital

environment, whereas in-person sessions were thought to reduce potential misunderstandings because they provided opportunities to clarify, ask questions, receive more accurate feedback, and enhance the experience. Additionally, participants felt it was considerably less personalized in the digital environment and had doubts about receiving quality services remotely.

> "Online thing is not very good. Some people might think, "I'm not sure whether am I doing correct or not though I'm following it,"… the instructor might have a hard time telling them what is the correct posture, what you should be feeling because they are not with them" – Male, 35–39 years.

Peer influences

Yet, peer influences surrounding an individual were found to affect participants' propensity to engage with digital technology for healthy lifestyle. Peer opinions carried significant influence and could affect one's personal attitudes to various digital innovations, based on the prevailing attitudes within the social network.

> "Sometimes like our friends they will send us online messages, "Sis, this or that exercise online is very good," so I will just follow from there just like that…" – Female, 65–69 years.

Self-directed motivation

Many participants felt that these digital technologies intentionally or inadvertently give us an edge, promoting healthy lifestyle activities. They shared how leveraging technology, such as fitness apps and online coaching platforms, provided them quick access and flexibility to take up one or more workout routines at their convenience, and adapt their fitness goals to suit a variety of fitness levels at any time.

> "during the circuit breaker, I downloaded a gym exercise app, and I did some gym, some weight training at home for the weight loss. And then recently, I changed to yoga from the same app. And then I did the running app. It was the app that was from couch to 5K (laughter)…and now I'm just continuing…" – Female, 45–49 years.

Participants also tended to agree on the importance of personal motivation in order to benefit from digital technology for healthy lifestyle.

> "I looked at my screen time, and my screen time was three hours on the phone. And I'm like, "Oh my god. What is this? This is such a great waste of time." …. And I said, "One hour out of that time, I could have used it for doing something probably, something useful." So then, yeah, I think it's just finding the motivation is probably the biggest obstacle" – Female, 45–49 years.

Discussion

This study was the first attempt to investigate the challenges experienced by the general population in using digital technology promoting healthy lifestyle. The themes (*Digitally disempowered; Safety and perceived risks and harm; and Cultural values and drives*) illustrated the key determinants of digital technology adoption as perceived and experienced by an ethnically diverse sample of adults in Singapore. In this discussion, we highlight our key research findings, a local conceptual model on digital technology adoption, discuss the limitations of our study and discuss directions for future research. We discuss our findings on the experiences and perceptions of digital technology through a technology acceptance (36) lens. TAM suggests that technology adoption can be explained by two main perceptions: namely, usefulness or the benefits derived from using the technology, and the ease of use.

Perceived utility of digital technology

Our findings suggest individuals felt there were several benefits from using digital technology for healthy lifestyle. These included descriptions of its flexibility and capacity to accommodate the rapidly changing needs of individuals, and the capability to engage and motivate users. Individuals in our study also found much value in the functions, features and content available in digital technology for fitness activity and health and nutrition information. Research has suggested that the performance expectations for digital and mobile applications have a strong correlation with behavioral intentions of technology adoption (51). Our results reaffirm one of the constructs of the TAM in that individuals who appreciate the value associated with digital technology are positively influenced in their behavioral intentions of use.

Perceived risks of digital technology

On the other hand, our results elucidate that trust and privacy concerns directly hold significant negative effects on intentions of use and the utility of digital technology among the general public in Singapore. Our findings revealed widespread concerns about the security and privacy of personal data in these digital tools and services for healthy lifestyle. Other cross-cultural researchers have reported similar barriers to technological adoption, that is, beyond the two main constructs posited by the TAM, privacy and security concerns reduce intentions to adopt healthcare technology (52, 53).

Collectively, besides improving technological functions, features, and content, it is important to consider these perceived risks of technology use and safety concerns related to inadequate protection of data and privacy (54, 55). Since the digital field is rapidly advancing, there may be a need for a neutral regulatory body for an up-to-date evaluation of digital technology, to inform consumers about reliable digital tools with data protection and privacy regulatory adherence. Local governments could provide a central database of high-quality digital interventions and services and could potentially consider involving the community in the co-ownership and management of such resources (56). This approach may help more individuals make better informed health care decisions confidently and to protect against misinformation and potential harm, effecting greater technological adoption. In general, technology adoption research tends to focus on drivers of usage intentions such as perceived usefulness, and perceived ease of use. However, our results suggest

perceived risks and harms in the context of using digital technology for healthy lifestyle is a potentially important determinant of technology adoption.

Personal norms and peer influences

As another point of departure from the TAM, our study findings uncovered the influence of peers and personal values among the Singaporean public as a major determinant that influences adoption intentions in this population. We found that members of one's peer network affect individuals' adoption of digital technology, as the opinions of these social contacts matter. Consistent with literature, our local population were positively influenced to adopt technology through their social contacts and personal referents, as well as external sources, such as media (57). Accordingly, it would be crucial for national public health program developers to bear this in mind, i.e., consider targeting the social or peer influence circles surrounding select individuals directly, to improve the uptake of digital innovations for promoting healthy lifestyle.

Personal norms represent one's perceptions of moral obligation or responsibility to perform, or not to perform a behavior (i.e., adoption of technology), beyond perceived social pressure (58). Likewise, our results illustrated a significant barrier to digital technology adoption among certain individuals who undervalued and disfavored digital technology for healthy lifestyle activities despite a largely positive societal attitude observed toward digitalization and technological adoption. This resistance toward digital innovations was seen among the same individuals who voiced strong concerns about the perceived risks associated with digital technology as discussed earlier in our article. Research suggests that the risks are construed as a subjective perception about engaging with anything digital or the Internet in itself, and invariably has a negative impact on their intentions to adopt technology. These suggest that it is important to first assess the level of digital readiness among these individuals, and further underscores the need for particular health promotion strategies to engage and incentivize people while mitigating potential threats to privacy and security to improve the uptake of digital tools for promoting a healthy lifestyle. Thus, future research in this area is urgently recommended.

Perceived ease of use of digital technology for healthy lifestyle

The results of our study revealed that a small but significant proportion of the general population were digitally disempowered and felt they were challenged by the ease of use of digital technology for healthy lifestyle for reasons including digital skills, language limitations and the complexity of digital innovations.

Inadequate digital skills and knowledge

According to the TAM, self-efficacy renders positive effects on the perception of usability of technology while lack of knowledge and experience negatively affects ease of use. Similarly, our findings indicate the most obvious personal barrier was issues related to digital skills and capabilities of individuals, particularly those who were among the digitally disempowered. A typical challenge for individuals, regardless of age, was that their current levels of knowledge and skills were inadequate. Other research has also discovered that the problem of a lack of digital skills has broad effects in a general population (59, 60) in terms of technological adoption. Further, our study participants were also facing other challenges, such as the lack of training and guidance, which is consistent with previous literature (61). Since 2017, a national exercise to build up basic digital skills and digital literacy has helped many individuals including older adults to embrace digital life and services including digital interventions promoting healthy lifestyle (62, 63). However, the training and voluntary support programs which had helped many to gain digital access, were discontinued or turned into digital events due to the COVID-19 health crisis; further alienating those who were already lacking basic digital skills from participating. Despite the steady rise in digital services for healthy lifestyle, support may still be lacking for certain groups of individuals in the general population and necessitate immediate attention to reduce the digital divide in the population.

Language limitations in digital tools

One unique and significant barrier negatively affecting perceived ease of use among our participants, was found to be due to language limitations. English tends to be used as the primary 'working language' digitally throughout the world, with a billion others speaking it as a second language (64). This has allowed for most digital tools to be built around English as the default language, even if the coding that provides the basis for final platforms and applications are in specific computer languages. This means those who can navigate the *lingua franca* can easily access and utilize such digital technology better, to the detriment of non-English speaking, less digitally-connected individuals. Researchers have highlighted that language difficulties pose significant challenges to the adoption of digital technologies, especially among ethnic minorities who may struggle with weak language skills (65, 66). Developing user-friendly digital technology for healthy lifestyle and improving physical infrastructure and support systems for troubleshooting continue to be common problems affecting one's technological adoption (67).

Dealing with complexity of digital innovations

Notwithstanding, inability for the end user to troubleshoot hardware and software increases the complexity of using the digital innovations which affects their perceived ease of use and has also been linked to the perception of usefulness. On the basis of the TAM, applying Roger's theory of the diffusion of innovations (68), current literature has confirmed innovativeness may significantly influence the intention and motivation to technology adoption, where users with high innovativeness are able to handle uncertainty and thus show greater acceptance and adoption of technology (69, 70). These findings suggest a need for constructive input from key stakeholders, namely the potential users, together with designers of digital health innovations. Some researchers have suggested that external variables including individual differences, social influences, and facilitating conditions such as technical infrastructure and support for use of the

technology should be taken into account (51). A multifaceted approach is required, which can address the full range of strategic and technical issues to enhance technology adoption for healthy lifestyle. Looking at these issues together, mitigating strategies such as developing digital capabilities and social support, and improving the remote support infrastructures for technology are vital to reduce the digital divide and improve access to and adoption of technology for health promoting activities (71).

Local conceptual model of digital technology adoption for healthy lifestyle

The development of a cross-cultural model in a plural Asian society such as Singapore, is imperative to public health policy and practice; keeping abreast of the digital impacts on one's health and health-promoting behaviors. The proposed exploratory model is architectured around the factors influencing the adoption of digital technology in the context of our rich, interview data. To this end, and to develop meaningful insights, a local conceptual model integrating unique constructs with constructs related to the technology acceptance model has been proposed (see Figure 1).

In Figure 1, *Perceived Benefits of Use*, the degree to which the consumer perceives that the technology is useful, is an original TAM construct and remains in effect. In our local context, the effortless use of the digital technology is also vital for technological acceptance and use and has been considered within *Digital Access and Capability* parameters of digital skills, language skills, and technology design and quality. Similar to the TAM, we acknowledge both perceptions of the benefits of use and the ease of access can directly and indirectly influence behavioral intentions to use digital technology for healthy lifestyle. Further, we extend the TAM by capturing two unique nuances in our model of determinants namely, "*Fear of Perceived Risks and Tolerance of Uncertainties*," and "*Cultural Values and Drives*." We propose that subjectively weighed perceptions of risks and tolerance of uncertainties such as security and privacy of data, as well as, trust of digital content affect attitude and intentions to use. Intuitively, we can argue that consumers will not perceive usefulness in a technology that is likely to invade their privacy or believed to cause potential harm. We argue it will affect perceived usefulness negatively and indirectly influence intentions to use. Additionally, in our local model, we consider the unique influence of social and personal norms as the other major factor that influences adoption intentions. The attitudes and beliefs of social groups and personal referents significantly influence value judgments on the utility of technology and intentions to use digital technology. This model explores the interactions and relationships among the factors emergent in our study as significant determinants of adoption of technology. These various factors interact with one another in this multi-dimensional model which underscores key opportunities and targeted strategies to intervene.

Practical implications

Based on the notable challenges experienced by the general public, it can be argued that several key areas for development are necessary to encourage the use of digital health interventions for active and healthy lifestyle behavior. Our results suggest that one of the major problems in accessing such digital technology is related to one's level of digital skills, although, this study identified significant challenges in other digital determinants as well. Continued efforts to improve basic digital skills and equitable digital access among underserved groups will be beneficial. Additionally, in future, it will be important to invest in information about digital health services through various channels because the opportunities and potential benefits of these services has not been disseminated widely enough to reach everyone. Increasingly, both public and private stakeholders have begun leveraging digital technologies to nudge consumers toward monitoring their health and lowering the long-term cost of care.

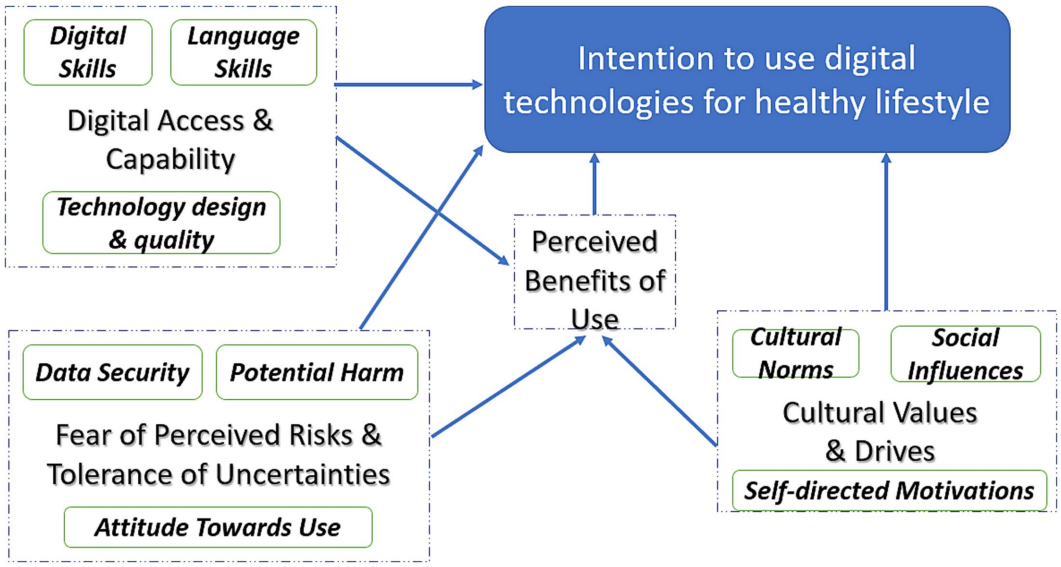


FIGURE 1
Proposed local conceptual model of digital technology adoption for healthy lifestyle.

Initial engagement with digital tools appeared to stem in most cases from self-directed motivations. Increased health consciousness and an uptake in technology means that there is likely to be a pressing need to examine how technology can reduce barriers and help people maintain the positive behavioral changes. This study hence further demonstrates the crucial need for additional support for on-going motivation and development of habitual routines for health-promoting activity. Investing in research and development for technologies such as digital conversational agents that explicitly motivate and support effective behavior change and habit formation could be a valuable public health strategy given the potential for maximizing reach in populations who may be disproportionately utilizing healthcare resources (72). Similarly, another potential avenue for this would be creating digital resources using participatory research or citizen science, which will help to ensure that the most pertinent digital tools and features are used in a way that will enhance engagement and the likelihood of behavior change (73). Moreover, it is wise to note that traditional face-to-face services for healthy lifestyle practices will continue to be important among certain groups in the population, and should still be maintained and provided alongside digital tools and services in a possible blended type of approach.

Study strengths and limitations

Our study has considerable strengths and few limitations. Strengths include the broad and diverse sample of participants interviewed, including males and females across age, ethnicity and language groups. Limitations of our study include the fact that our sample comprised participants who had volunteered to be contacted for this qualitative study and thus, our interviewed participants may have more positive experiences or be more willing to share their perceptions related to the topic. We interviewed participants in the midst of the rapidly developing coronavirus situation, and so it is not certain whether experiences would differ in the longer term. In addition, our sample comprised residents who lived in Singapore, spoke English, Chinese, Malay or Tamil, and had good to excellent Internet connectivity. Therefore, our findings in this study may not be transferable to those in other settings and in other countries.

Conclusion

In conclusion, the main objective of this study is to examine the general population's experiences and the factors influencing the adoption of digital technologies for healthy lifestyle. On the basis of TAM, this study found evidence for both perceived usefulness and the ease of use, but also contributed to new cross-cultural understandings of the phenomenon, with fear of perceived risks and cultural value and drives as potential antecedents of the adoption of digital technology. Participants appreciated the value of digital technology and mostly perceived the ease of use positively in Singapore which encourages digital technology for healthy lifestyle. However, despite efforts spearheaded by the Singapore Government, participants identified several barriers to technology adoption including a lack of digital skills, language barriers, and fear of perceived risks and harm on digital tools and platforms. On the other hand, social and peer influences emerged as a significant mechanism that can be leveraged to improve adoption of digital technology.

Future works

While future developments should invest more in usability research and the features of novel health-promoting digital tools, a much-needed consideration is to enhance data security research as well as to communicate a better understanding of private data use to allay concerns and improve the public adoption of digital innovations promoting healthy lifestyle. Future research should also examine if there is a paradigm shift in the population of how individuals engage with digital technology for healthy lifestyle purposes. The range of reasons for use and ways in which the resident population engage with digital tools to practice healthy lifestyle behaviors highlight there is no one solution which fits all individuals, highlighting the challenges of catering to diverse groups with varying engagement with digital technology. Factors influencing intentions to use digital technology may be different in long-term participation and maintenance of behavior. The processes and determinants could be more complex and require extensive investigation, particularly in this digitally-driven, post-pandemic future. Subsequent research should reveal the rich temporal process of engagement with digital technology promoting healthy lifestyle, that could not be possible in the current study.

Data availability statement

The datasets presented in this article are not readily available because restrictions apply to the availability of these data, which are not publicly available because of ethical and institutional regulations. Requests to access the datasets should be directed to MS, mythily@imh.com.sg.

Ethics statement

The studies involving humans were approved by National Healthcare Group Domain Specific Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

KR was the primary contributor to the writing of the article, conducted the interviews, and collaborated in data analysis. SC contributed to the design of the study and applied for the necessary approvals. MS contributed to the design of the study, conducted the interviews, collaborated in data analysis, and contributed to the writing of the article. PA, YZ, FD, PW, AJ, EA, and LC contributed to the writing of the article. All authors have made critical comments on the article, reviewed the article for its intellectual content, and approved the manuscript.

Funding

This study is supported by the Singapore Ministry of Health's National Medical Research Council under its Health Services Research Grant (NMRC/HSRG/0085/2018). The funders had no role in the

design of the study, collection and interpretation of data, or preparation of the manuscript.

Acknowledgments

The authors would like to thank the participants who contributed to this study.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1227146/full#supplementary-material

References

1. World Health Organization. (2022). Noncommunicable diseases. World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases

2. Gostin LO. Non-communicable diseases: healthy living needs global governance. *Nature*. (2014) 511:147–9. doi: 10.1038/511147a

3. Posadzki P, Pieper D, Bajpai R, Makaruk H, Könsgen N, Neuhaus AL, et al. Exercise/physical activity and health outcomes: an overview of Cochrane systematic reviews. *BMC Public Health*. (2020) 20:1724. doi: 10.1186/s12889-020-09855-3

4. WHO. (2023) Projections of mortality and burden of disease, 2004–2030. Available at: http://www.who.int/healthinfo/global_burden_disease/projections/en/index.html

5. World Health Organization. *WHO guidelines on physical activity and sedentary behaviour*. Geneva: World Health Organization (2020).

6. Dans A, Ng N, Varghese C, Tai ES, Firestone R, Bonita R. The rise of chronic non-communicable diseases in Southeast Asia: time for action. *Lancet*. (2011) 377:680–9. doi: 10.1016/s0140-6736(10)61506-1

7. Tan V, Lim J, Akksilp K, Chow WL, Ma S, Chen C. The societal cost of modifiable risk factors in Singapore. *BMC Public Health*. (2023) 23:1285. doi: 10.1186/s12889-023-16198-2

8. Ding D, Lawson KD, Kolbe-Alexander TL, Finkelstein EA, Katzmarzyk PT, van Mechelen W, et al. Lancet physical activity series 2 executive committee. The economic burden of physical inactivity: a global analysis of major non-communicable diseases. *Lancet*. (2016) 388:1311–24. doi: 10.1016/S0140-6736(16)30383-X

9. Bolnick HJ, Bui AL, Bulchis A, Chen C, Chapin A, Lomsadze L, et al. Health-care spending attributable to modifiable risk factors in the USA: an economic attribution analysis. *Lancet Public Health*. (2020) 5:e525–35. doi: 10.1016/S2468-2667(20)30203-6

10. Ministry of Health. (2023) Government health expenditure and healthcare financing. Available at: https://www.moh.gov.sg/resources-statistics/singapore-health-facts/government-health-expenditure-and-healthcare-financing

11. Ministry of Health, Singapore. (2022) Projected annual healthcare spending for next decade. Available at: https://www.moh.gov.sg/news-highlights/details/projected-annual-healthcare-spending-for-next-decade/

12. Asmat K, Dhamani K, Gul R, Froelicher ES. The effectiveness of patient-centered care vs. usual care in type 2 diabetes self-management: a systematic review and meta-analysis. *Front Public Health*. (2022) 10:994766. doi: 10.3389/fpubh.2022.994766

13. Ministry of Health, Singapore. (2022). Promoting overall healthier living while targeting specific sub-populations. MOH News Highlights. Available at: https://www.moh.gov.sg/news-highlights/details

14. Stock C. Grand challenges for public health education and promotion. *Front Public Health*. (2022) 10:917685. doi: 10.3389/fpubh.2022.917685

15. Ministry of Health. (2022) War on diabetes summary report. Available at: https://www-moh-gov-sg-admin.cwp.sg/docs/librariesprovider5/war-on-diabetes/wod_public_report.pdf

16. Pan S, Ren X, Vos S, Brombacher A. Digital tools to promote healthy eating for working-age individuals: a scoping review. In: *The Ninth International Symposium of Chinese CHI (Chinese CHI 2021)*. New York, NY, USA: Association for Computing Machinery (2022). 1–8. doi: 10.1145/3490355.3490356

17. Lee YS, Biddle S, Chan MF, Cheng A, Cheong M, Chong YS, et al. Health promotion board-Ministry of Health clinical practice guidelines: obesity. *Singap Med J*. (2016) 57:292–300. doi: 10.11622/smedj.2016103

18. Ministry of Health, Singapore. *National Population Health Survey 2019/20*. Singapore: Ministry of Health (2020).

19. Health Promotion Board Singapore. (2018). National Nutrition Survey 2018 shows gradual improvements in Singaporeans' dietary habits. Health Promotion Board Singapore. Available at: https://www.hpb.gov.sg/article/national-nutrition-survey-2018-shows-gradual-improvements-in-singaporeans-dietary-habits

20. Han SY, Jang HY, Ko Y. COVID-19-related anxiety and lifestyle changes. *Front Public Health*. (2022) 10:886137. doi: 10.3389/fpubh.2022.886137

21. Li X, Zhang M. How digital health technologies promote healthy life in the post-COVID-19 era: evidences from national survey on Chinese adolescents and youngsters. *Front Public Health*. (2023) 11:1135313. doi: 10.3389/fpubh.2023.1135313

22. Thomas Craig KJ, Morgan LC, Chen CH, Michie S, Fusco N, Snowdon JL, et al. Systematic review of context-aware digital behavior change interventions to improve health. *Transl Behav Med*. (2021) 11:1037–48. doi: 10.1093/tbm/ibaa099

23. Mendes D, Fonseca C, Lopes MJ, García-Alonso J, Murillo JM. *Exploring the role of ICTs in healthy aging*. Hershey, PA: IGI Global (2020).

24. Chatterjee A, Prinz A, Gerdes M, Martinez S, Pahari N, Meena YK. ProHealth eCoach: user-centered design and development of an eCoach app to promote healthy lifestyle with personalized activity recommendations. *BMC Health Serv Res*. (2022) 22:1120. doi: 10.1186/s12913-022-08441-0

25. Newbold JW, Rudnicka A, Cox A. Staying active while staying home: the use of physical activity technologies during life disruptions. *Front Digit Health*. (2021) 3:753115. doi: 10.3389/fdgth.2021.753115

26. Müller AM, Maher CA, Vandelanotte C, Hingle M, Middelweerd A, Lopez ML, et al. Physical activity, sedentary behavior, and diet-related eHealth and mHealth research: bibliometric analysis. *J Med Internet Res*. (2018) 20:e122. doi: 10.2196/jmir.8954

27. The World Bank. The World Bank data-ICT indicators database. Available at: https://data.worldbank.org/indicator/it.net.user.zs

28. Tan YWB, Tan ER, Sin KY, AshaRani PV, Abdin E, Roystonn K, et al. Acceptance of healthy lifestyle nudges in the general population of Singapore. *BMC Public Health*. (2022) 22:1297. doi: 10.1186/s12889-022-13668-x

29. Singapore Sports Council. (2020). ActiveSG – live better through sport. Singapore Sports Council, Sport Singapore. Available at: https://www.myactivesg.com/About-ActiveSG

30. Singapore Sports Council. (2020). ActiveSG virtual fitness. ActiveSG, Singapore Sports Council. Available at: https://www.myactivesg.com/Programmes/ActiveSG-Virtual-Fitness

31. Kwang K. HPB partners Fitbit to encourage Singaporeans to adopt healthier habits In: A Baur, H Yew and M Xin, editors. *The future of healthcare in Asia: Digital health ecosystems*. New York: McKinsey & Company (2019)

32. LumiHealth. (2021). A Healthier Everyday. Available at: https://www.lumihealth.sg

33. Wong PT. (2020). The big read: Digitally estranged, seniors struggle with sense of displacement in pandemic-hit offline world. Channel News Asia. Available at: https://www.channelnewsasia.com/news/singapore/big-read-covid-19-pandemic-senior-citizens-12697086

34. Low ST, Sakhardande PG, Lai YF, Long AD, Kaur-Gill S. Attitudes and perceptions toward healthcare technology adoption among older adults in Singapore: a qualitative study. *Front Public Health*. (2021) 9:588590. doi: 10.3389/fpubh.2021.588590

35. Bondaronek P, Dicken SJ, Singh Jennings S, Mallion V, Stefanidou C. Barriers to and facilitators of the use of digital tools in primary care to deliver physical activity advice: Semistructured interviews and thematic analysis. *JMIR Hum Factors*. (2022) 9:e35070. doi: 10.2196/35070

36. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Q*. (1989) 13:319–40. doi: 10.2307/249008

37. Holden RJ, Karsh BT. The technology acceptance model: its past and its future in health care. *J Biomed Inform*. (2010) 43:159–72. doi: 10.1016/j.jbi.2009.07.002

38. Gücin NÖ, Berk ÖS. Technology acceptance in health care: an integrative review of predictive factors and intervention programs. *Procedia Soc Behav Sci*. (2015) 195:1698–704. doi: 10.1016/j.sbspro.2015.06.263

39. Subramaniam M, Devi F, AshaRani PV, Zhang Y, Wang P, et al. Barriers and facilitators for adopting a healthy lifestyle in a multi-ethnic population: a qualitative study. *PLoS One*. (2022) 17:e0277106. doi: 10.1371/journal.pone.0277106

40. AshaRani PV, Jue Hua L, Roystonn K, Siva Kumar FD, Peizhi W, Ying Jie S, et al. Readiness and acceptance of eHealth Services for Diabetes Care in the general population: cross-sectional study. *J Med Internet Res*. (2021) 23:e26881. doi: 10.2196/26881

41. AshaRani PV, Abdin E, Kumarasan R, Siva Kumar FD, Shafie S, Jeyagurunathan A, et al. Study protocol for a nationwide knowledge, attitudes and practices (KAP) survey on diabetes in Singapore's general population. *BMJ Open*. (2020) 10:e037125. doi: 10.1136/bmjopen-2020-037125

42. Sandelowski M. Focus on quantitative methods: sample sizes, in qualitative research. *Res Nurs Health*. (1995) 18:179–83. doi: 10.1002/nur.4770180211

43. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. (2007) 19:349–57. doi: 10.1093/intqhc/mzm042

44. Kvale S, Brinkmann S. *InterViews: Learning the craft of qualitative research interviewing*. Thousand Oaks, CA: SAGE (2009).

45. Doyle L, McCabe C, Keogh B, Brady A, McCann M. An overview of the qualitative descriptive design within nursing research. *J Res Nurs*. (2020) 25:443–55. doi: 10.1177/1744987119880234

46. Sandelowski M. What's in a name? Qualitative description revisited. *Res Nurs Health*. (2010) 33:77–84. doi: 10.1002/nur.20362

47. Chafe R. The value of qualitative description in health services and policy research. *Healthcare Policy*. (2017) 12:12–8. doi: 10.12927/hcpol.2017.25030

48. Srivastava A, Thomson SB. Framework analysis: a qualitative methodology for applied policy research. *J Admin Gov*. (2009) 4:72–9.

49. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. (2013) 13:117. doi: 10.1186/1471-2288-13-117

50. Goldsmith LJ. Using framework analysis in applied qualitative research. *Qual Rep*. (2021) 26:6. doi: 10.46743/2160-3715/2021.5011

51. Wang Y, Wu M, Wang H. Investigating the determinants and age and gender differences in the acceptance of mobile learning. *Br J Educ Technol*. (2009) 40:92–118. doi: 10.1111/j.1467-8535.2007.00809.x

52. Dhagarra D, Goswami M, Kumar G. Impact of trust and privacy concerns on technology acceptance in healthcare: an Indian perspective. *Int J Med Inform*. (2020) 141:104164. doi: 10.1016/j.ijmedinf.2020.104164

53. Andrews L, Gajanayake R, Sahama T. The Australian general public's perceptions of having a personally controlled electronic health record (PCEHR). *Int J Med Inform*. (2014) 83:889–900. doi: 10.1016/j.ijmedinf.2014.08.002

54. Paganini S, Terhorst Y, Sander LB, Catic S, Balci S, Küchler A-M, et al. Quality of physical activity apps: systematic search in app stores and content analysis. *JMIR Mhealth Uhealth*. (2021) 9:e22587. doi: 10.2196/22587

55. McKay FH, Cheng C, Wright A, Shill J, Stephens H, Uccellini M. Evaluating mobile phone applications for health behaviour change: a systematic review. *J Telemed Telecare*. (2018) 24:22–30. doi: 10.1177/1357633X16673538

56. Keygnaert I, Dias S, Stock C, Frahsa A, Dietrich K. Editorial: how can we co-create solutions in health promotion with users and stakeholders? *Front Public Health*. (2021) 9:773907. doi: 10.3389/fpubh.2021.773907

57. Hsu MH, Chiu CM. Internet self-efficacy and electronic service acceptance. *Decis Support Syst*. (2004) 38:369–81. doi: 10.1016/j.dss.2003.08.001

58. Roos D, Hahn R. Understanding collaborative consumption: an extension of the theory of planned behavior with value-based personal norms. *J Bus Ethics*. (2019) 158:679–97. doi: 10.1007/s10551-017-3675-3

59. Melchiorre MG, Papa R, Rijken M, van Ginneken E, Hujala A, Barbabella F. eHealth in integrated care programs for people with multimorbidity in Europe: insights from the ICARE4EU project. *Health Policy*. (2018) 122:53–63. doi: 10.1016/j.healthpol.2017.08.006

60. Jeffrey B, Bagala M, Creighton A, Leavey T, Nicholls S, Wood C, et al. Mobile phone applications and their use in the self-management of type 2 diabetes mellitus: a qualitative study among app users and non-app users. *Diabetol Metab Syndr*. (2019) 11:84. doi: 10.1186/s13098-019-0480-4

61. Mežnarec NS, Bogataj D. Advanced health technologies require skills and influence the culture of education: literature review and research agenda. *IFAC-PapersOnLine*. (2021) 54:657–62. doi: 10.1016/j.ifacol.2021.10.526

62. Infocomm Media Development Authority. (2022). Digital skills for adults, seniors and persons with disabilities. Infocomm Media Development Authority. Available at: https://www.imda.gov.sg/for-community/digital-readiness/Digital-Skills-for-Adults-Seniors-and-Persons-with-Disabilities

63. Infocomm Media Development Authority. (2022). Public & Seniors – digital for life. Infocomm Media Development Authority. Available at: https://www.imda.gov.sg/Public-and-Seniors

64. Patel N, Ferrer HB, Tyrer F, Wray P, Farooqi A, Davies MJ, et al. Barriers and facilitators to healthy lifestyle changes in minority ethnic populations in the UK: a narrative review. *J Racial Ethn Health Disparities*. (2017) 4:1107–19. doi: 10.1007/s40615-016-0316-y

65. Acharya BB. A systematic literature review on immigrants' motivation for ICT adoption and use. *IJEA*. (2016) 8:34–55. doi: 10.4018/IJEA.2016070103

66. Yoon J, Huang H, Kim S. Trends in health information-seeking behaviour in the U.S. foreign-born population based on the Health Information National Trends Survey, 2005-2014. *Inf. Res.* (2017) 22

67. Kang HS, Exworthy M. Wearing the future-wearables to empower users to take greater responsibility for their health and care: scoping review. *JMIR Mhealth Uhealth*. (2022) 10:e35684. doi: 10.2196/35684

68. Rogers EM. *Diffusion of innovations. 4th* ed. New York, NY: Simon and Schuster (2010).

69. Yi MY, Fiedler KD, Park JS. Understanding the role of individual innovativeness in the acceptance of IT-based innovations: comparative analyses of models and measures. *Decis Sci*. (2006) 37:393–426. doi: 10.1111/j.1540-5414.2006.00132.x

70. Chalutz B-GH. Artificial intelligence (AI) acceptance in primary care during the coronavirus pandemic: what is the role of patients' gender, age and health awareness? A two-phase pilot study. *Front Public Health*. (2023) 10:931225. doi: 10.3389/fpubh.2022.931225

71. Shamim TM, Chiong R, Bao Y, Babur HM. Acceptance and use predictors of fitness wearable technology and intention to recommend: an empirical study. *Ind Manag Data Syst*. (2018) 119:170–88. doi: 10.1108/IMDS-01-2018-0009

72. Dhinagaran DA, Sathish T, Soong A, Theng Y-L, Best J, Tudor CL. Conversational agent for healthy lifestyle behavior change: web-based feasibility study. *JMIR Form Res*. (2021) 5:e27956. doi: 10.2196/27956

73. King AC, Winter SJ, Sheats JL, Rosas LG, Buman MP, Salvo D, et al. Leveraging citizen science and information Technology for Population Physical Activity Promotion. *Transl J Am Coll Sports Med*. (2016) 1:30–44. doi: 10.1249/TJX.0000000000000003

frontiers | Frontiers in Public Health

TYPE Opinion
PUBLISHED 13 October 2023
DOI 10.3389/fpubh.2023.1228212

OPEN ACCESS

EDITED BY
David Cerný,
Czech Academy of Sciences, Czechia

REVIEWED BY
Kashif Iqbal,
Shanghai Dianji University, China

*CORRESPONDENCE
Martina Anto-Ocrah
maa509@pitt.edu

RECEIVED 24 May 2023
ACCEPTED 25 September 2023
PUBLISHED 13 October 2023

CITATION
Anto-Ocrah M, Asiedu M, Rao S, DeSplinter L and Hollenbach S (2023) If you build it, they will come...or not. Considerations for women's health in the post-pandemic era of digital innovation. *Front. Public Health* 11:1228212. doi: 10.3389/fpubh.2023.1228212

If you build it, they will come...or not. Considerations for women's health in the post-pandemic era of digital innovation

Martina Anto-Ocrah[1]*, Mercy Asiedu[2,3], Simrun Rao[4], Lindsey DeSplinter[4] and Stefanie Hollenbach[5]

[1]Department of Medicine, Division of General Internal Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States, [2]Google, Mountain View, CA, United States, [3]Massachusetts Institute of Technology, Cambridge, MA, United States, [4]University of Rochester, Rochester, NY, United States, [5]Department of ObGyn, School of Medicine and Dentistry, University of Rochester, Rochester, NY, United States

KEYWORDS

digital health, women's health, FemTech, Africa, culture and information technology (IT)

Introduction

Culture has been defined as "an internalized and shared framework … through which both the individual and the collective experience the world" (1). Cultural processes shape social institutions, and mold—while in turn being molded by—members of a given cultural or subcultural group (1). The norms that are created by culture can have important implications for health outcomes. Take for example, the case of female genital mutilation, the "cultural" practice of partially or totally removing external female genitalia for non-medical reasons (2). This cultural practice, recognized by some as normal (3), has been associated with several obstetric and gynecological pathologies, and now recognized by the World Health Organization as a violation of human rights (2). This practice, deemed "normal" in one realm of society, is utterly unacceptable in another, and has sparked controversial clashes of belief systems and medical dilemmas which have been widely documented (4–6). At the root of these controversies however, is the fundamental question of "what does pathology mean to a group of people?" At what point does a biochemical change that progresses to pathophysiological change, translate to care-seeking? What forms of care-seeking do people engage in, and what are their reasons for choosing one care-seeking model over another? Are they financial? physical/geographic/infrastructural? (mis)trust? familiarity? racial/gender/cultural discordance? (7).

"Health" is defined by the WHO as "a state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity" (8). While health is sometimes interchanged with wellness, "wellness" is distinctly defined as pro-activity toward good health, and is "an active pursuit of activities, choices and lifestyle that lead to a state of holistic health" (9). Wellness, even more so than health, is highly subjective; and contextualized understandings of relevant wellness metrics and outcomes are important to understand. Does "wellness" mean the same to everyone, and if not, how does the notion of "wellness" differ by various demographics such as age, gender, race/ethnicity/cultural background, socio-economic status, and their intersectionalities? Digital health applications (apps) may cut across components of both health and wellness (10). These include multiplatform (web-based, native computer and smartphone-based, and basic mobile phones) components in health Information and Communications Technology (ICT), quantified self-care and wellness apps, gamification, metadata, sensors and wearable healthcare, electronic health records and medical imaging, telemedicine and personal genomics (10). These apps, when

used as interventions, have been successful in high-income countries. However, they have had limited success in low- and middle-income countries (LMICs), and among marginalized populations in high-income countries, even when they are provided at little to no cost (11–14).

In this era of democratization, without considering and understanding what the notion of health- as it relates to "disease" pathology- or "wellness" means to a group of people, digital health and wellness platforms risk falling short of their potential. Using Figure 1 as a guide, this article outlines considerations that should be taken into account as design anthropologists and developers take on the "social good" agenda of increasing digital access to a critical mass of people globally (15). We discuss notions of disease, wellness, care seeking decisions, competitors and acculturation across different cultures, offering digital health scientists some for food for thought in this post-pandemic era of digital innovation; particularly in women's health. We summarize the key points in Table 1, and conclude the commentary with recommendations for digital entrepreneurs to consider, on their paths to innovation.

Disease

The conceptualization of disease begins with an understanding of an individual or a society's interpretation of **what constitutes a diseased or pathological state that warrants care-seeking**; not merely the diagnosis of "disease" alone. As George Engel (1, 17), author of the biopsychosocial model of care proffers, "it is not necessarily because an individual has been diagnosed with a disease by a physician [or a laboratory examination] that that person [acknowledges that they are indeed sick], feels sick or is considered sick by their environment" (1, 18). In most resource-rich settings, insurance coverage and easier

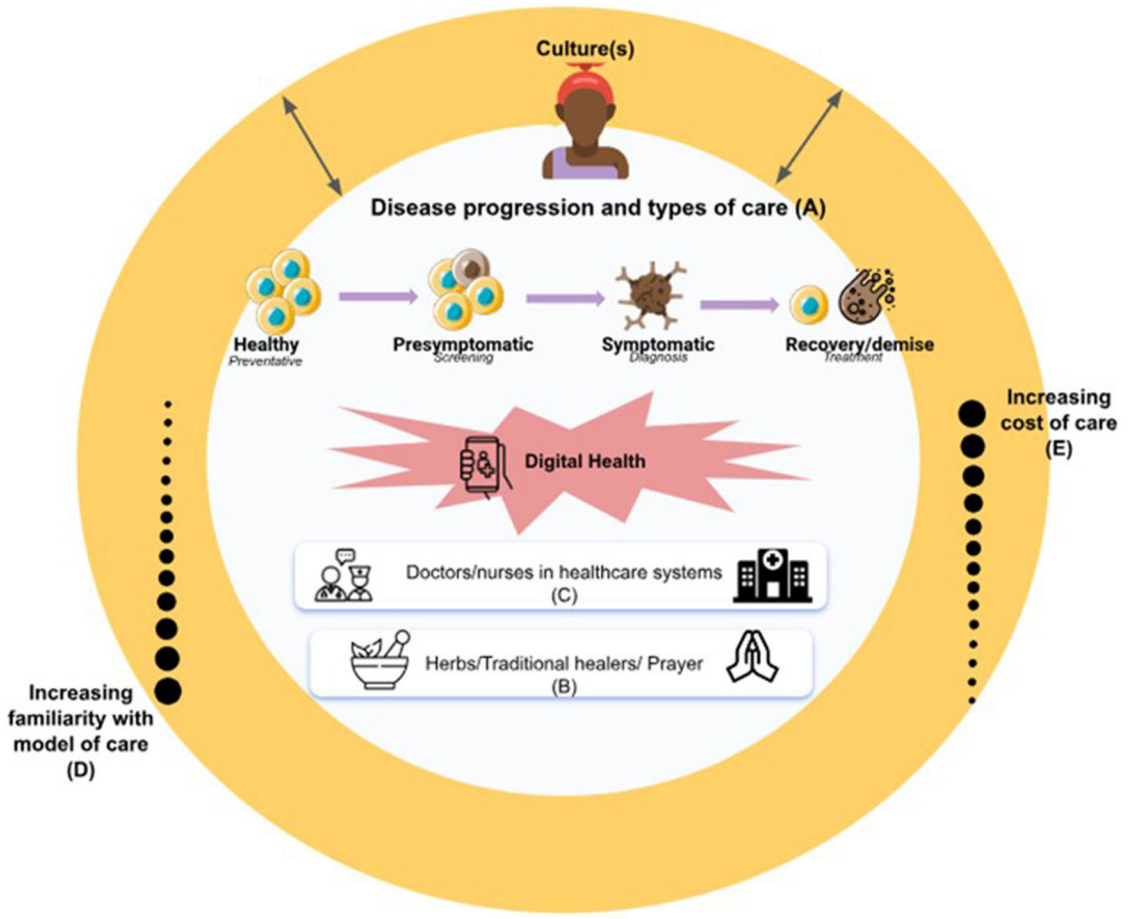


FIGURE 1
Considerations for digital innovators in achieving the goal of *AI for social good* (15). The availability of digital health tools gives individuals the opportunity to interact with care providers at any point during their pathology/disease progression- from the onset of laboratory diagnosis, to the acute and chronic phases of the disease (A); with the ultimate goal being to prolong optimal health and wellness as much as possible. Cultural normalization may impede a patient's acknowledgment of disease/pathology or "unwellness". Once acknowledged, treatment and care-seeking plans may involve "culturally acceptable" and familiar norms of care seeking that compete with digital solutions and include prayer (free), herbal remedies and traditional healers (affordable and familiar), and in-person care at medical facilities (less affordable but familiar to the population despite the transportation and geographic barriers) (B–E). Digital adoption requires acculturating people to digital health as another care-seeking option so it becomes familiar to the individual and their community (D).

TABLE 1 Similarities and differences in key factors affecting digital health innovations in Western and non-Western contexts.

	Similarities	Differences	The challenge for digital health innovation
Disease	"Disease" is generally understood as a pathological process that begins subclinically and if undetected/untreated could result in mortality.	In most resource-rich settings, greater access to preventative care services may "normalize" early disease detection whereas in cost prohibitive settings, "disease" may be recognized only when associated with debilitating symptomatology. Thus "normalization" of disease may be mediated by out-of-pocket expenses/extent of insurance coverage	Understanding that a one-size-fit-all approach may not work, and tailoring digital interventions to fit different notions of "disease" across cultures. E.g., Women in non-Western cultures may be less likely to own their own smartphone, purchase data, or access healthcare without the consent of their partners or in-laws (as dictated by cultural norms) compared to those in Western/resource-rich settings (16)
Wellness	Wellness is a subjective construct of taking care of one's self beyond a "diseased" state, and striving to live a fulfilled life.	"Wellness" is widely accepted in Western contexts as encompassing more than physical health and extending to mental, sexual, reproductive wellness, etc. In non-Western contexts, wellness is often limited to physical activity; with other aspects lagging behind.	Getting buy-in into the wellness revolution; given its subjectivity.
Care seeking behavior	Both contexts have health systems through which patients can seek care, and patients in both contexts do seek care, albeit at different time points. Care-seeking behaviors in both contexts, are driven by cost/insurance coverage/out-of-pocket expenses	In Western contexts, care-seeking is often an individual decision whereas in many non-Western contexts, the decision to seek care is made not by the diseased person solely, but in conjunction with their social institutions and community.	Integrating a "community" approach to the digital health care-seeking decision tree
Competitors, acculturation, and sustainability	Both contexts face issues with sustainability particularly pertaining to cost.	In non-western contexts, traditional, herbal and spiritual medicine, in addition to community-centered care provide sought-after alternatives to clinics and hospitals. In Western contexts clinics and hospitals offer primary sources of care. Pertaining to cost, in LMICs in non-Western contexts, financial burdens exist that impact investments in health and sustainability of health solutions. This is less so in Western contexts	Understanding that herbs and traditional forms of treatment, mixed with spiritual beliefs are at little or no cost to the non-Western populace, and proving that any digital innovation is superior to these.

access to preventative care services (beginning in pediatrics), has "normalized" annual physical examinations, mammograms and other preventative services, laboratory services, and frequent patient/provider interactions (7). However, in settings where cost is prohibitive, a biochemical change (indicated by a laboratory exam) must be associated with debilitating symptomatology and/or a sense of urgency before a person may be prompted to seek care (7). This could be further exacerbated by other barriers to care, such as travel time, transportation costs, and long wait times at hospitals (7). Patient/provider interactions may be infrequent, only utilized in emergency situations. While the advent of digital health in resource-limited settings may represent *a new healthcare ecosystem that is unfamiliar to the populace,* the availability of such digital health tools, give individuals the opportunity to interact with care providers at any point during their pathology/disease progression (depicted as "A" in Figure 1); from the onset of laboratory diagnosis, to the acute and chronic phases. The ultimate goal being to prolong "optimal health" as much as possible.

Wellness

First there is a need to differentiate disease prevention from wellness and wellness related activities. While disease prevention refers to efforts to stem occurrence and severity of a disease, wellness refers to *active efforts on the part of the individual to make choices for a healthy and fulfilling life* (9, 19). Wellness is meant to be holistic, involving physical fitness, nutrition, stress management, and environmental sensitivity (19). Given that wellness is a process toward all-encompassing health, it is even more subjective, and culturally specific than disease prevention. Several digital health tools like wearable fitness trackers, nutrition and dietary managements, stress management apps, and reproductive wellness apps have been—while potentially more accessible than traditional disease prevention tools—developed with the western context of wellness in mind, without much regard to how wellness is perceived in non-western cultures. For instance, what does "mental health wellness" mean in a culture where mental health is dismissed as a curse, or what does "reproductive wellness" mean in a culture were topics around sexuality are taboo? While digital health tools for physical activity are increasingly gaining popularity in non-Western settings, they are yet to extend beyond a small subset of the population and beyond exercise to other wellness areas (20).

The wellness journey

In Western contexts, wellness journeys typically work in the following stages (9, 19): (1) an acknowledgment that one is unhappy with their current state of wellbeing, mental, physically, emotionally or spiritually. (2) Focus and plans are developed for short or long term mitigation, via hiring an expert and/or utilizing

a digital health solution. (3) Tracking of some outcome metric over time through surveys, weight checks or changes in resting heart rate, and long term outcomes such as lower occurrences of disease and a holistic improvement in one's state is noted. The Ayurvedan wellness revolution taking place in the West serves as a great example (21, 22). Ayurveda, an ancient holistic health system originating from India, emphasizes the balance of mind, body, and spirit through personalized lifestyle practices, including dietary choices, herbal remedies, and mindful activities. This wellness approach aligns with the Ayurvedic principle of individual constitution or "dosha", which categorizes people into different mind-body types, guiding their wellness routines accordingly (22). As Western societies increasingly embrace holistic approaches to health, Ayurveda has gained traction as an alternative way to achieve overall wellbeing and prevent disease by fostering harmony within the individual (21).

In several cultures in Africa however, normalization of "unwellness" or a different perception of what wellness is (compared to the West) may impede a patient's acknowledgment of disease/pathology (7, 9, 19, 20). In cases where these are acknowledged, treatment options may involve religious or traditional solutions (e.g., herbs) that individuals are more familiar with, and/or are less costly than digital solutions (B–E in Figure 1). If a pathology is found in the process, the complex avenue of care seeking decisions, further detailed below, may come to play.

Care seeking decisions

The idea of digital health is modeled after the Western, individualistic model of care (further enforced by HIPAA laws), which centers disease as an individual experience. In many parts of the world however, the decision to seek care is one that is made not by the diseased person solely, but by their social institutions [partners/spouses, extended family (e.g., in-laws), or community] (7). It is important to note that a community is not a person and a person is not a community. Developing innovations for pregnant American women for example, should consider use cases by racial/ethnic background, as maternal mortality risks for Black women in the United States (US) is much higher than it is for their Caucasian peers, and worsens with acculturation due to social adversity (13). It is imperative to consider more nuanced backgrounds and target populations and incorporate community voices from those targets into any digital health innovation.

Any social good algorithm (15) must be inclusive, sensitive to, and respectful of all parties involved in the care-seeking decision tree of the digital tool. This is a critical step in the digital adoption process. If a patient chooses to seek "modern" forms of care in the healthcare setting (C in Figure 1), it is not only their personal experience that will shape future utilization, but the interactions that their partner, extended family, and community have with the physicians, nurses, and other care providers will also determine future utilization. The patient, and all parties involved in their care, must trust this "new" digitally-based model of care enough to deem it worthy of adoption. This trust-gaining experience is crucial for the (economic) sustainability of several digital interventions, and is the first step in the adoption and acculturation of the digital intervention for the individual's needs.

Competitors, acculturation, and sustainability

For a person to begin using healthcare digital technology the way it is intended for health (e.g., telehealth intended to bridge patient/provider gap by reducing time, transportation and geographic barriers to care) and wellness (e.g., using wearables to suggest physical activity or stress control), developers must (1) as discussed, first understand how people define and conceptualize disease and wellness (2) gain the user's initial trust then (3) acculturate the people to digital health as another care-seeking option (D in Figure 1). Developers must recognize that prior to this acculturation, they may be competing with other "culturally acceptable" and familiar norms of care seeking, that may range from prayer (free), herbal remedies and traditional healers (affordable and familiar), to in-person care at medical facilities (less affordable but familiar to the population despite the transportation and geographic barriers) (23, 24). For example, in a cross-cultural exploration of COVID-19's impact on antenatal healthcare-seeking behaviors in Ghana and the United States (US) (25), we asked a group of pregnant Ghanaian women if they would accept a telehealth appointment (over in-person) if offered. They all stated that despite the excessive measures they had taken to reduce their COVID exposure, they would forgo the telehealth option (25). As stated by a participant:

> *"If they are going to check on me via the telephone, how will they assess me? There are times I feel pain, abdominal pain, side pain, you go and complain and they take a look at it. . . Sometimes a scan is performed...If you stay home [and opt for telehealth], you wouldn't have access to the scan and all that stuff. I think I prefer going in [person]"* (25)

Their US counterparts were no different. Most of the pregnant women we interviewed expressed skepticism about telehealth: *it "just doesn't feel the same"* (25) stated a participant who voiced concern about the quality of care they would receive via telehealth, citing her lack of familiarity with the shorter, less-structured, and less intimate virtual visits (25).

In this era of rapid growth, digital health must convince the "naive user" of its utility, capabilities, cultural appropriateness, affordability, and overall fit in their own, personalized conceptualization of disease/pathology/wellness, and must aim to understand barriers to the form, function and deployment methods of digital health tools, in order to develop culturally specific solutions (26–28).

Culture and digital health, real world examples

Concrete evidence of the impact of culture on digital health platforms in women's health can be drawn from countries such as Bangladesh and India, where, in an effort to improve maternal health and wellness, Grameen Intel Social Business Limited designed a piece of wearable technology called the COEL bangle (which stands for Carbon Monoxide Exposure Limiter), a

smart wristband that is designed to resemble a piece of jewelry commonly worn by women in this region (16, 29, 30). Despite its unassuming exterior, the bracelet features a built-in speaker that educates women about their pregnancy by playing a series of pre-recorded messages in their local languages about diet and nutrition, prenatal environmental hazards in their vicinity, as well as antenatal appointment reminders. Designed with considerations of sociocultural and gender norms in rural Indian communities, the bangle was intended to give women more autonomy as a standalone wearable rather than a mobile app; as norms dictate that women seek permission from male family members or in-laws, in order to have mobile phone access. Thus the COEL bangle does not need to be paired with a smartphone, nor does it need internet connectivity to function. It also has a 10 month battery life (the span of a full-term pregnancy), and can be recharged for use postpartum.

MomConnect (31–33) is another maternal health innovation that was successfully designed and deployed with culture in mind. MomConnect (31) is a cell phone based technology, rolled out nationally by the South African National Department of Health to support maternal health via cell phone messaging. The innovation allows end-users to conveniently receive, access to shareable pregnancy-related educational information. Thus, information is not only accessible to the end-user, but also to whomever the end-user may want to share it with, such as the baby's father, their families, friends, or other mothers. The technology is free of charge to the user, making it more equitable and accessible to individuals of varying socioeconomic statuses across South Africa. MomConnect operates in the 11 official languages of South Africa, and has accumulated almost 2 million registered mothers across the country (31–33). The initiative was developed with key stakeholders and integrated into maternal and child health services already in place on a national scale. It has been lauded as a success story in the tale of digital health, women's health, and cultural adaptations.

Such innovations in women's digital health, designed with a culturally-tailored lens that ranges from the everyday bangle worn by the women, to language adaptations, are necessary to convince the end user of its utility and overall beneficence. The rapid adoption of the COEL bangle and MomConect demonstrate that they were created with not only a user-centered design, but also a culturally-centered framework. Unfortunately, both soon faced threats to their long-term sustainability and scalability due, mostly, to financial barriers. The bangle, for example runs between $12 and 15 US dollars, when the income of the target user is no more than $5 US Dollars a day (16). In the MomConnect model, the cost is absorbed by the service providers rather than the end user, making it free of charge for all end users (and their networks). However, the system requires about $1 million US dollars annually to maintain (33); an expense that is currently funded through public-private partnerships between South Africa's National Department of Health and private companies, including philanthropic donors, which are not guaranteed long-term (33). Thus both the COEL bangle, and MomConnect, lauded for their innovative, user-centered and cultural approaches to women's digital health, are challenged not by user adoption or engagement, but by financial barriers.

If governments are invested in the public's health, if they are invested in decreasing maternal morbidity and mortality, invested in reaching the Sustainable Development Goals of gender equality (Goal 5), good health and wellbeing (Goal 3), reduced inequalities (Goal 10), and sustainable communities (Goal 11), then, they must invest in women's digital health technology (34, 35). A self-sustaining digital model that considers (Figure 2) (26–28) cultural perceptions toward care seeking, cultural understanding of disease and wellness, cultural attitudes and norms around mobile phone use, and considerations for scale-up and sustainability must be designed from the onset.

Conclusion

Digital inclusion has been deemed a social determinant of health that, if not addressed, can further deepen health disparities (34). The purpose of the World Health Organization's Global Strategy on Digital Health is to promote healthy lives and wellbeing for everyone, regardless of geographic location (35). However, several digital health tools have been developed with Western conceptualizations of disease and wellness, without much regard of how these "states of being" are perceived in non-Western cultures. Even though innovations in the digital sphere are happening at unprecedented speeds, their adoption tends to be slow, their longevity short-lived, and their overall impact on health systems and people's wellbeing, questionable (36–38). As stated by the WHO, "To improve health and reduce health inequalities, rigorous evaluation of eHealth is necessary to generate evidence and promote the appropriate integration and use of these technologies…to ensure that such investments do not inappropriately divert resources from alternative, non-digital approaches" (36). Before we address issues of "digital inclusion," "digital literacy," and "digital access" (34), we must first understand what disease and wellness mean to the end user. For if, despite a pathology report, the end user does not deem themselves "diseased" or "unwell", a readily available laboratory portal, or a same-day delivery pharmacy prescription interface will be deemed useless. Digital innovations for women's health must also consider the socio-cultural norms imposed on women in their respective designs. Can a woman own a mobile phone? If yes, can she buy her own internet data for connectivity? If yes, can she afford the costs over the needs of her family? In many parts of the world, a woman's autonomy lies in the hands of her male partners and/or in-laws, not in her own. Lastly, a self-sustaining digital model-with government and financial stewardship and investment- must be designed from the onset. Plans for scale up and long-term sustainability must involve government buy-in and financial stewardship, lest these innovations, no matter how culturally appropriate they are, will die in their infancy.

Future work

In this commentary, we identify gaps in the cultural adaptation of digital health tools (Figure 1), and recommend a framework for digital health developers to consider for the development of culturally-specific digital health solutions

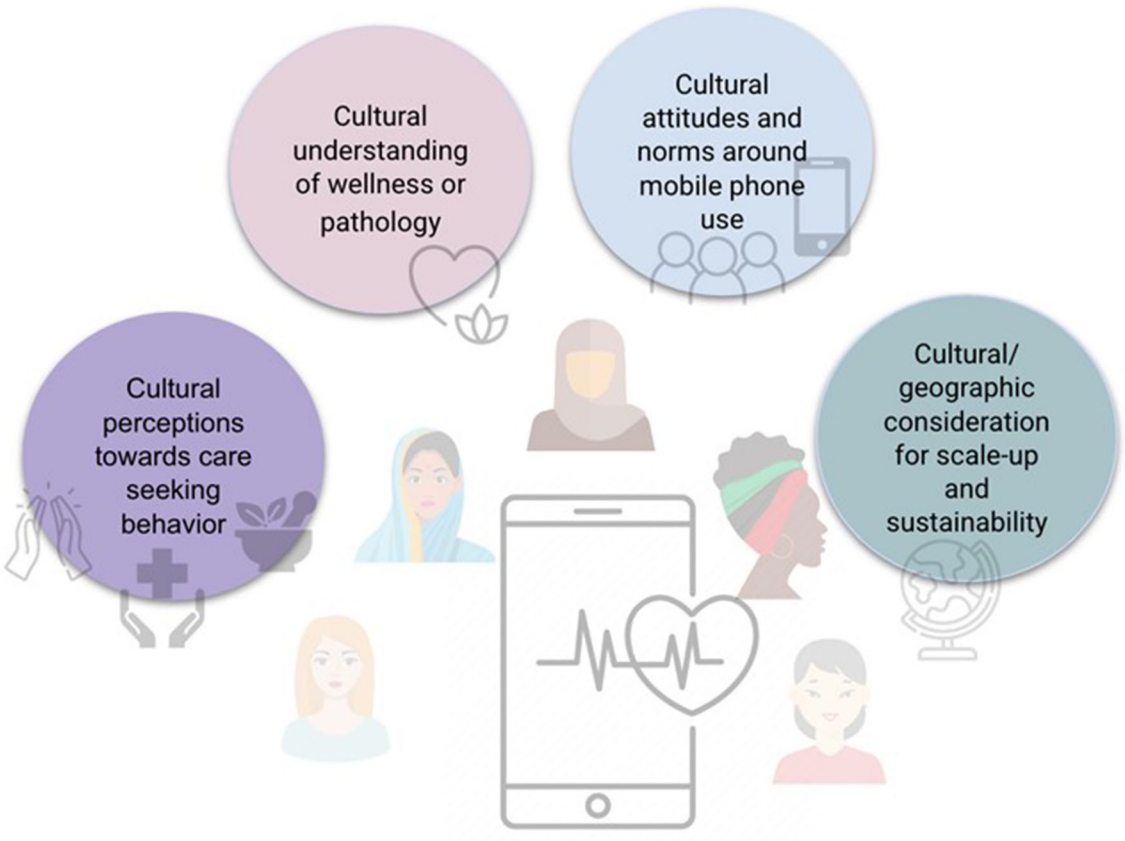


FIGURE 2
Recommendations and factors to consider for culturally-specific digital health interventions.

(Figure 2). This commentary is presented primarily from the perspectives of Ghanaian, Indian, and North American (USA) female clinical, public health, and digital health researchers, whose points of view reflect their own lived and research experiences. Future work would benefit from wider-spread examinations of interviews or focus groups on the adoption of digital health innovations in different cultural contexts.

Author contributions

MA-O: conceptualization and writing—original draft. MA-O, MA, SR, LD, and SH: writing—review and editing. All authors contributed to the article and approved the submitted version.

Funding

At the time of press, MA-O was funded by NIH NINDS Award #K01NS121199.

Acknowledgments

Thank you to Claire Couturier for your final touches to finalizing the manuscript.

Conflict of interest

MA was employed by Google.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. Shattuck EC. Networks, cultures, and institutions: toward a social immunology. *Brain Behav Immun Health.* (2021) 18:1–7. doi: 10.1016/j.bbih.2021.100367

2. World Health Organization. *Female Genital Mutilation.* (2022). Available online at: https://www.who.int/news-room/fact-sheets/detail/female-genital-mutilation (accessed October 17, 2022).

3. Morris R. The culture of female circumcision. *ANS Adv Nurs Sci.* (1996) 19:43–53. doi: 10.1097/00012272-199612000-00006

4. Richards D. Controversial issues: female genital mutilation. *Med Ref Serv Q.* (2000) 19:79–88. doi: 10.1300/J115v19n04_07

5. Gibeau AM. Female genital mutilation: when a cultural practice generates clinical and ethical dilemmas. *J Obstet Gynecol Neonatal Nurs.* (1998) 27:85–91. doi: 10.1111/j.1552-6909.1998.tb02595.x

6. MacReady N. AAP retracts statement on controversial procedure. *Lancet.* (2010) 376:15. doi: 10.1016/S0140-6736(10)61042-2

7. Anto-Ocrah M, Cushman J, Sanders M, De Ver Dye T. A woman's worth: an access framework for integrating emergency medicine with maternal health to reduce the burden of maternal mortality in sub-Saharan Africa. *BMC Emerg Med.* (2020) 20:3. doi: 10.1186/s12873-020-0300-z

8. World Health Organization. *Constitution.* (1946). Available online at:. https://www.who.int/about/governance/constitution (accessed November 27, 2022).

9. Global Wellness Institute. *What is Wellness?* Available online at: https://globalwellnessinstitute.org/what-is-wellness/# (accessed November 27, 2022).

10. Tambo E, Madjou G, Mbous Y, Olalubi OA, Yah C, Adedeji AA, et al. Digital health implications in health systems in Africa. *Eur J Pharm Med Res.* (2016) 3:91–3.

11. Adepoju OE, Chae M, Ojinnaka CO, Shetty S, Angelocci T. Utilization gaps during the COVID-19 pandemic: racial and ethnic disparities in telemedicine uptake in federally qualified health center clinics. *J Gen Intern Med.* (2022) 37:1191–7. doi: 10.1007/s11606-021-07304-4

12. Watts G. COVID-19 and the digital divide in the UK [published correction appears. *Lancet Digit Health.* (2020) 2:e395–6. doi: 10.1016/S2589-7500(20)30169-2

13. Patterson EJ, Becker A, Baluran DA. Gendered racism on the body: an intersectional approach to maternal mortality in the United States. *Popul Res Policy Rev.* (2022) 41:1261–94. doi: 10.1007/s11113-021-09691-2

14. Chitungo I, Mhango M, Mbunge E, Dzobo M, Musuka G, Dzinamarira T. Utility of telemedicine in sub-Saharan Africa during the COVID-19 pandemic. A rapid review. *Hum Behav Emerg Technol.* (2021) 3:843–53. doi: 10.1002/hbe2.297

15. Google AI. *AI for Social Good.* Available online at: https://ai.google/social-good (accessed November 27, 2022).

16. Pendrill K. *A New Smart Bangle is Designed to Prevent Pregnant Women from Dying in Rural South Asia.* (2017). Available online at: https://qz.com/india/987773/a-new-smart-bangle-is-designed-to-prevent-pregnant-women-from-dying-in-rural-south-asia (accessed August 18, 2023).

17. Engel GL. The need for a new medical model: a challenge for biomedicine. *Science.* (1977) 196:129–36. doi: 10.1126/science.847460

18. Konsman JP. So many faces, phases, and facets, sickness behavior beyond disciplines. *Front Psychiatry.* (2021) 12:630331. doi: 10.3389/fpsyt.2021.630331

19. Bharati K. *Health, Illness and Wellness: Essential Concept for a Holistic View of Life.* MedIndia (2020). Available online at:. https://www.medindia.net/patients/lifestyleandwellness/health-illness-and-wellness-essential-concept-for-a-holistic-view-of-life.htm (accessed October 17, 2022).

20. Arueyinzho O, Sanyaolu K. Digital health promotion for fitness enthusiasts in Africa. *IEEE.* (2022) 54–9. doi: 10.1109/ICDH55609.2022.00017

21. Mukherjee PK, Harwansh RK, Bahadur S, Banerjee S, Kar A, Chanda J, et al. Development of Ayurveda - Tradition to trend. *J Ethnopharmacol.* (2017) 197:10–24. doi: 10.1016/j.jep.2016.09.024

22. Gokani T. Ayurveda–the science of healing. *Headache.* (2014) 54:1103–6. doi: 10.1111/head.12363

23. Masters KS, Spielmans GI. Prayer and health: review, meta-analysis, and research agenda [published correction appears. *J Behav Med.* (2007) 30:329–38. doi: 10.1007/s10865-007-9106-7

24. Demeke CA, Woldeyohanins AE, Kifle ZD. Herbal medicine use for the management of COVID-19: a review article. *Metabol Open.* (2021) 12:100141. doi: 10.1016/j.metop.2021.100141

25. Norris KG, Huang PA, Glantz JC, Kodam RS, Anto-Ocrah M. A cross-cultural analysis of the COVID-19 pandemic's impact on antenatal healthcare-seeking behaviors in Ghana and the United States. *J Patient Exp.* (2021) 8:23743735211062392. doi: 10.1177/23743735211062392

26. van Stam G. Conceptualization and practices in digital health: voices from Africa. *Afr Health Sci.* (2022) 22:664–72. doi: 10.4314/ahs.v22i1.77

27. Alodhayani AA, Hassounah MM, Qadri FR, Abouammoh NA, Ahmed Z, Aldahmash AM. Culture-specific observations in a Saudi Arabian digital home health care program: focus group discussions with patients and their caregivers. *J Med Internet Res.* (2021) 23:e26002. doi: 10.2196/26002

28. Rabbani Z. *Mapping of Digital Service Providers in Bangladesh for the Aquaculture: Increasing Income, Diversifying Diets, and Empowering Women in Bangladesh and Nigeria Project.* WorldFish (2020). Available online at: https://hdl.handle.net/20.500.12348/4515 (accessed August 18, 2023).

29. Dareen S. *Women in India Can Soon Get Pregnancy Tips. From a Talking Bangle The Ladies Finger.* (2017). Available online at: https://yourstory.com/2017/05/smart-bangle-pregnancy-tips (accessed August 18, 2023).

30. Ashraf M, Hasin MM, Salahuddin ABE, Ahmed S, Ro SC, Ray P, et al. The potential scope of m-health initiative into Grameen renewable energy in Bangladesh. *Int Technol Manag Rev.* (2018) 7:144–50. doi: 10.2991/itmr.2018.7.2.3

31. MomConnect. *Department of Health Republic of South Africa.* Available online at: https://www.health.gov.za/momconnect/ (accessed November 27, 2022).

32. Barron P, Peter J, LeFevre AE, Sebidi J, Bekker M, Allen R, et al. Mobile health messaging service and helpdesk for South African mothers (MomConnect): history, successes and challenges. *BMJ Glob Health.* (2018) 3(Suppl. 2):e000559. doi: 10.1136/bmjgh-2017-000559

33. Jahan R, Zou P, Huang Y, Jibb L. Impact of MomConnect program in South Africa: a narrative review. *Online J Nurs Inform.* (2020) 24:211.

34. Sieck CJ, Sheon A, Ancker JS, Castek J, Callahan B, Siefer A. Digital inclusion as a social determinant of health. *NPJ Digit Med.* (2021) 4:52. doi: 10.1038/s41746-021-00413-8

35. World Health Organization. *Digital health.* Available online at: https://www.who.int/health-topics/digital-health/#tab=tab_1 (accessed October 17, 2022).

36. World Health Organization. *WHO Guideline Recommendations on Digital Interventions for Health System Strengthening.* (2019). Available online at: https://www.ncbi.nlm.nih.gov/books/NBK541902/ (accessed August 18, 2023).

37. Holst C, Sukums F, Radovanovic D, Ngowi B, Noll J, Winkler AS. Sub-Saharan Africa—the new breeding ground for global digital health. *Lancet Digital Health.* (2020) 2:e160–2. doi: 10.1016/S2589-7500(20)30027-3

38. Adepoju P. Africa turns to telemedicine to close mental health gap. *Lancet Digital Health.* (2020) 2:e571–2. doi: 10.1016/S2589-7500(20)30252-1

frontiers | Frontiers in Public Health

TYPE Original Research
PUBLISHED 23 October 2023
DOI 10.3389/fpubh.2023.1202182

OPEN ACCESS

EDITED BY
Josef Kure,
Masaryk University, Czechia

REVIEWED BY
Yunxi Zhang,
University of Mississippi Medical Center, United States
Mauro Iafrancesco,
Agostino Gemelli University Polyclinic (IRCCS), Italy

*CORRESPONDENCE
Jolana Kopsa Těšinová
✉ jolana.tesinova@health.cz

†These authors have contributed equally to this work and share first authorship

RECEIVED 07 April 2023
ACCEPTED 06 October 2023
PUBLISHED 23 October 2023

CITATION
Těšinová JK, Dobiášová K, Dušek Z and Tobiášová A (2023) Development of telemedicine in the Czech Republic from patients' and other key stakeholders' perspective.
Front. Public Health 11:1202182.
doi: 10.3389/fpubh.2023.1202182

Development of telemedicine in the Czech Republic from patients' and other key stakeholders' perspective

Jolana Kopsa Těšinová[1]*†, Karolína Dobiášová[1†], Zdeněk Dušek[2] and Alena Tobiášová[1]

[1]Institute of Public Health and Medical Law, First Faculty of Medicine, Charles University, Prague, Czechia, [2]Ernst & Young, s.r.o, Prague, Czechia

Telemedicine is a way to improve healthcare outcomes with greater efficiency for both patients and care providers. The great potential of digital technologies also lies in strengthening the patient-centered approach. The early successes and benefits of telemedicine in the Czech Republic, amplified by the COVID-19, have contributed to the fact that wider implementation of telemedicine is already generally supported at the expert and public levels. Our research focuses on the identification of key issues in the implementation of telemedicine and the challenges of telemedicine in the future, from the perspective of patients and other stakeholders. The study is based on a qualitative research approach, combining focus groups with key stakeholders, patient panels and expert panels (2021–2022). The lack of rules and uncoordinated development of various activities proved to be the main barriers to the integration of telemedicine in the health system. This regulatory uncertainty can generate a number of problems in the patient–doctor relationship in practice, including ethical ones, and can also lead to inequalities in access to healthcare and affect the overall quality of care provided. Furthermore, it has been shown that patients' interests in the implementation of telemedicine are: 1. a predictable and reliable framework that guarantees them certainty and security in the provision of telemedicine services, 2. telemedicine solutions that increase the availability and efficiency of the care provided while bringing comfort, and 3. user-friendly and simple solutions. At the same time, patients want to understand the new environment and be active participants in the process of digital innovation, including the practical implementation of telemedicine. The research team has developed recommendations for further developments in the implementation of telemedicine that reflect the patient's interest and can be implemented at three levels – the health system, institutional, and community level. In countries with a well-developed and institutionalized patient movement, the community level can be represented by patient organizations, thus becoming the link between telemedicine policy making and implementation at the individual level of healthcare provision. For the further development of telemedicine, the development of a national strategy involving all key stakeholders, including patients, in the implementation has proven essential.

KEYWORDS

development of telemedicine, patient organizations, community, patient and public involvement, patient interest, stakeholders, telehealth

1. Introduction

In the last two decades, health policy makers, influenced by a number of factors such as the demographic ageing of the population and the continuous increase in healthcare spending, have been trying to introduce new approaches in healthcare with a focus on digital solutions (1). Also contributing to this is the pervasive development and spread of information communication technology (ICT) and digital technologies in healthcare management and delivery (2). The COVID-19 epidemic also contributed to an unprecedented acceleration in the adoption and spread of ICT and digital solutions within health systems (3, 4).

Digital transformation was an important issue even before the coronavirus pandemic but, during the crisis, the development and implementation of various modern technologies accelerated, making the digitization of healthcare an overwhelming priority for most countries. In particular, there has been an increase in the use of telemedicine, which has become indispensable in ensuring continuity and accessibility of healthcare during epidemics (3).

In the Czech Republic, the legislative development of eHealth is only at the beginning, and despite the adoption of the Electronization of Healthcare Act (5), it is still among the countries with a lower level of digitization of healthcare processes, with the exception of partial aspects of digitization (e.g., e-prescription).

One of the decisive factors for the adoption of telemedicine by patients and healthcare providers is the reimbursement policy for telemedicine solutions (6–8). Considering that the healthcare system in the Czech Republic is based on compulsory health insurance, which guarantees equal access to healthcare and covers a wide range of services (9, 10), finding an optimal and sustainable way of its reimbursement from public health insurance is essential for the future use and development of telemedicine.

The main goal of health systems is to promote, restore, and maintain the health of the population, and therefore they should respond to the needs and expectations of the public. This is the reason why in the last decade there has been a growing effort to involve patients and the public (PPI) in health policy decision making processes (11). Different countries use a variety of tools, policies and interventions to systematically improve the position of the patient in the health system (11, 12).

In the Czech Republic, too, there has been a greater involvement of patients in health policy decision making in recent years. Since the 1990s, the first patient organizations were established, laying the foundation for the patient movement. There are currently around 140 patient organizations in the Czech Republic (13). The turning point for the development of PPI in the Czech Republic was the adoption of the Health Services Act in 2011 (14) which, for the first time, defined patients' rights at the level of national legislation (9).

The establishment of the PPI as a permanent part of the organizational structure of the Ministry of Health (Figure 1) in 2017 was crucial for the institutionalization of PPI (15). In the same year, the Patients' Council was established (16), which is a permanent advisory body to the MoH, with as its main mission to promote patients' rights, including participation in the legislative process. The Patients' Council currently has seven permanent working groups, one of which is explicitly dedicated to eHealth (Figure 1) (12).

Another important milestone of PPI was in 2021, when the patient organization was defined at the level of law and thus the involvement of patients in decision making processes was significantly strengthened (17). In the same year, the National Association of Patient Organizations (NAPO) was established, bringing together patient organizations focused on all types of diseases and disabilities in the Czech Republic. It carries out advocacy and awareness-raising activities and represents patients vis-à-vis state authorities. One of NAPO's main priorities is the digitalization of healthcare (13).

The aim of our research is to identify key issues in the implementation of telemedicine in the Czech Republic, and the challenges of telemedicine in the future from the perspective of patients and other stakeholders.

2. Methods

The study is based on an exploratory qualitative research approach with regard to the unexplored area of the implementation of telemedicine in the Czech Republic. The research was divided into four consecutive stages (see Figure 2).

2.1. Stage I

In stage I, a desk research was implemented, where team members worked with the literature, available statistical data, and health policy documents. In parallel, an analysis of legislation related to telemedicine in the Czech Republic in the context of European Union legislation was carried out. Based on the findings from this first stage of the research, a matrix of open questions was prepared for the follow-up stage 2 of the research.

2.2. Stage II

In stage II of the research, three focus group (FG) discussions (18) were conducted with key stakeholders of telemedicine implementation in the Czech Republic. Each FG had a different thematic focus (see Table 1). Informants were selected by purposive sampling to cover different areas of telemedicine implementation (19): physicians, patients, pharmacists, health care managers (of health insurance companies and health care facilities), officials of relevant government institutions (e.g., Ministry of Health). The institutional representation of informants is shown in Table 1. A total of 32 stakeholders were involved. The aim of the FG discussions was to identify problems related to the implementation of telemedicine in practice, to place them in the broader context of the Czech health system, to structure them, and to identify challenges for telemedicine in the Czech Republic in the future. All FG discussions were performed virtually in August 2021 using online meeting platforms Zoom and lasted approximately 2 h each. Online FG discussions allowed for a wider geographical coverage and a greater diversity of informants (20). At the beginning of each FG, all participants were briefed on the focus and objective of the research. With the consent of all participants, FG discussions were recorded. FG recordings were transcribed verbatim, anonymized, and subjected to thematic analysis (21). Based on the analysis of the FG discussions, the research team identified and described ten core areas of telemedicine implementation. The FG results formed the basis of the next stage of the research.

10.3389/fpubh.2023.1202182

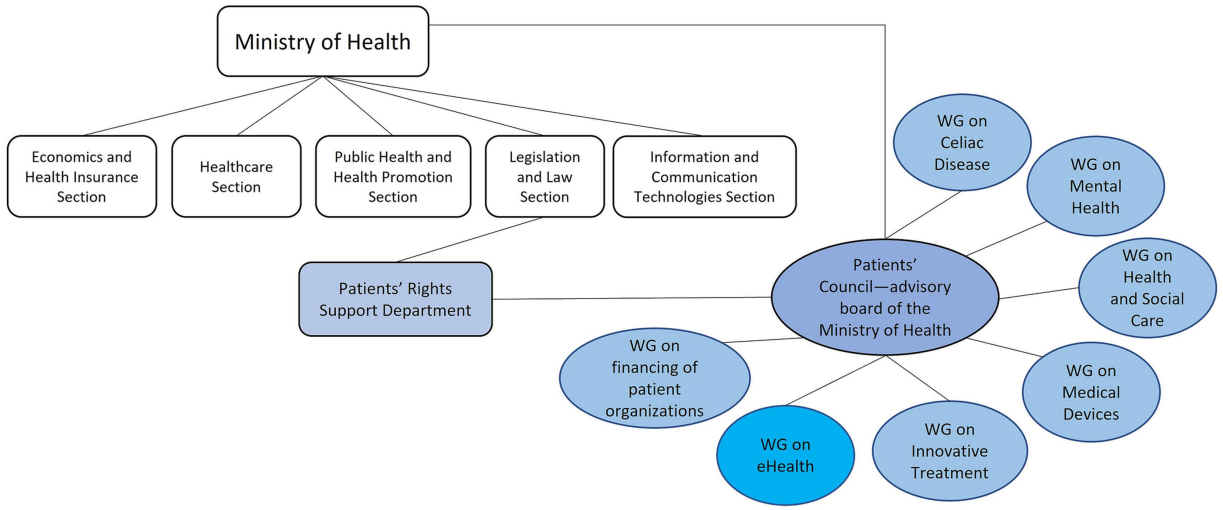


FIGURE 1
Patients' council and working groups.

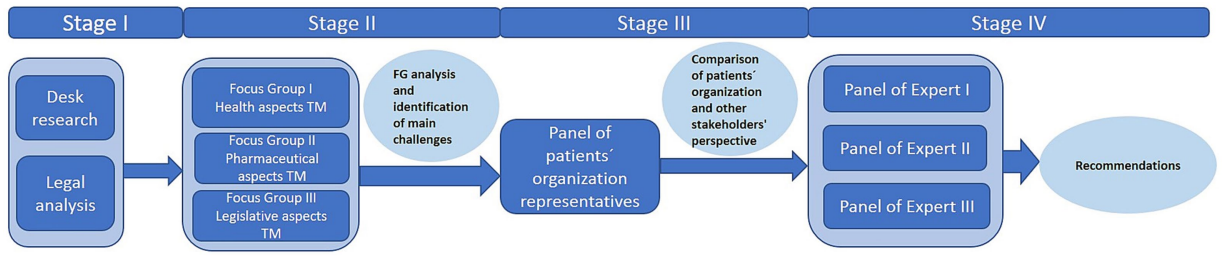


FIGURE 2
Exploratory qualitative research design.

TABLE 1 Institutional representation of stakeholders in focus group discussions.

Focus group I health aspects		Focus group II pharmaceutical aspects		Focus group III legislative aspects	
Informant	Institution	Informant	Institution	Informant	Institution
FG I-I1	University hospital	FG II-I1	State administration	FG III-I1	State administration
FG I-I2	Medical Institute	FG II-I2	Medical Institute	FG III-I2	Health insurance fond
FG I-I3	University hospital	FG II-I3	Pharmacist Society	FG III-I3	Health insurance fond
FG I-I4	Medical Society	FG II-I4	Pharmacy operator	FG III-I4	State administration
FG I-I5	Clinical center	FG II-I5	Pharmacist Society	FG III-I5	University hospital
FG I-I6	Medical Society	FG II-I6	Pharmacist Society	FG III-I6	University hospital
FG I-I7	Medical Society	FG II-I7	Patient organization	FG III-I7	Patient organization
FG I-I8	Patient organization	FG II-I8	Patient organization	FG III-I8	Patient organization
FG I-I9	Patient organization	FG II-I9	Pharmacist Society	FG III-I9	Medical Society
FG I-I10	Medical Society	FG II-I10	Pharmacist Society	FG III-I10	Pharmacist Society
FG I-I11	Medical Society			FG III-I11	Medical Society

2.3. Stage III

In stage III (September/October 2021) of the research, a panel of patient organization representatives was assembled to assess and supplement the results of FG discussions with stakeholders on the perspective of the patient. In recent decades, there has been a growing debate about patient and public involvement (PPI) in health care decision-making (11) and health research (22, 23). Various methods

are used to involve patients, such as patient panels, patient and public involvement panels, patient advisory boards, citizen juries, advisory committees, etc. (23). In addition, representatives of patient organizations, who usually have long experience in chronic disease management, can provide valuable information on what works and what does not work in practice. In addition, existing evidence shows that involving patients in the analysis, design and implementation of health policy increases patient confidence in and acceptance of new decisions. For these reasons the National Association of Patient Organizations (NAPO) was approached to help select members for the patient panel. Selected NAPO members were invited to become members of the patient panel. Here, patients did not figure as research participants but as partners of the research team (23). All panel members were made aware of the research objectives and agreed to participate as part of the patient panel. They were not remunerated for their participation in the panel. The patient panel included 6 representatives from various NAPO-affiliated patient organizations. All patient panel members had experience in the area of telemedicine implementation. One of the panelists was also a member of the Patient Council of the Ministry of Health, and two panelists were also members of the Patient Council e-health working group (see Figure 1). The patient panel received a report with the results of the focus groups with stakeholders in October 2021 for review. The Patient Panel discussed the results initially in the presence of the research team leader, who facilitated the discussion. The discussion lasted approximately 3 h. Subsequently, the patient panel met once more without an external facilitator, and members of the panel worked together to develop a patient perspective on the results of the focus groups. This position paper included both patients' concerns about some aspects of telemedicine implementation and patients' expectations for telemedicine in the future. Representatives of NAPO presented their position at a professional conference on telemedicine (24).

Members of the research team then compared the results of the FG discussions with the views of the patient panel, identifying areas where the patient's perspective differed from that of other stakeholders, and areas where it was consistent. This comparison formed the basis for the follow-up stage IV research.

2.4. Stage IV

The aim of stage IV of the research was to create recommendations for further development of telemedicine implementation in the Czech Republic, taking into account "the interest of patients." The members of the research team identified and invited experts from various fields who are extensively involved in the implementation of telemedicine in the Czech Republic. The Multidisciplinary Panel of Expert included 24 experts from different fields so as to represent a wide range of relevant opinions and expertise. Their institutional background is shown in Table 2. They included representatives of physicians and pharmacists, patient organizations, health care managers, representatives of insurance companies, lawyers specializing in health care, government officials and health policy makers, researchers, producers and distributors of drugs and health technologies. A total of three half-day (approximately 3 h) expert panel meetings were conducted in February, May and October 2022 in a face-to-face format. All experts were briefed in advance on the results of the research to-date (stage II and III), i.e., the findings of the focus group discussions and patient opinions. The experts were also presented with an overview of the implementation of telemedicine in selected countries and the status of domestic and EU legislation on telemedicine and e-health in the form of powerpoint presentations. This information was used as a stimulus for discussion. At each session, a number of open questions on telemedicine were presented to the panel of experts so that the patients' point of view was always reflected. The discussion was moderated by one professional moderator and two members of the research team. Two members of the research team took notes of the discussions. Based on the experts' discussion the research team formulated recommendations for the further development of telemedicine with respect to preserving "patients' interests" (Table 3).

TABLE 2 Background information on participants in the expert panel.

Institution	Number of experts
Society of Physicians	3
Health insurance companies	3
Drug and medical technology manufacturers	3
Consulting and advisory firms	3
Patient organizations	2
Pharmacists' societies	2
Hospitals	2
State administration	2
Treatment institutes	2
Academia	2

3. Results

3.1. Legal analysis

The research also included an analysis of the legal aspects of distance (remote) medicine using ICT reflecting the findings from the empirical data. It is apparent that the provision of health services in the Czech Republic is only possible on the basis of an authorization to provide them, which must correspond to the type and form of health care provided according to the Health Services Act (14).

The current concept of providing health services presupposes the personal (physical) presence of the patient in a health care facility, or the physical presence of the doctor in the patient's own social environment (e.g., in the context of home care). To some extent, consultations may be provided by remote access, but without being defined in more detail by law. This concept thus makes it considerably more difficult for healthcare to be provided by remote access via ICT, The provision of healthcare only through a 'virtual' provider who would not have a healthcare facility is completely excluded.

Despite the adoption of the Electronization of Healthcare Act (5), the field of remote care remains without direct legislative support. The same rules apply to telemedicine as to the provision of healthcare in general, i.e., it must be provided at the appropriate professional level (lege artis), i.e., according to the rules of science and recognized medical practices, respecting the individuality of the patient, taking into account the specific conditions and objective possibilities. The current legislation does not provide sufficient legal certainty for the provision of telemedicine services.

10.3389/fpubh.2023.1202182

TABLE 3 Identification of the "patient interest."

Key areas of telemedicine implementation	Focus group	Patient panel	Patient interest
	Identification of the problem/ challenges of TM	Identification of the problem/ challenges of TM	
Legislative environment	Lack of legislative definition of TM	Uncertainty if TM is legal	Responsibility of health service provider to be clearly defined
	Defining TM in law	Support for legislative definition	
Guidelines	Absence of guidelines	Concerns about whether the approach is professionally correct	(Published) guidelines available for patients (e.g., database)
	Development of guidelines by specialization	Support the development of best practices	
Technology and applications	Absence of rules for technological solutions	Concerns about invasion of privacy and safe provision of care	A database of safe technology solutions (health apps) available
	Define a standard and address the safe use of health applications	Promote a standard of secure technology solutions	
Communication and data sharing	Different perspectives on remote communication, with particular emphasis on formal and security aspects	Worries of suppressed autonomy of decision making, uncertainty of communication in a new and unfamiliar environment	A digital communication standard as a basis for communication between doctors and patients in an online environment
	Promote discussion among experts on remote communication	Support for the creation of rules for communication	
Organization of care and conditions of provision	The absence of rules for the inclusion of TM in the organization of healthcare and the conditions for the provision of remote care	Concerns about inconsistent and confusing settings between providers, concerns about the availability and ability to use technology for communication	Provider's awareness of TM interventions, enabling online bookings, making available guides for individual TM solutions and ensuring education from specific providers
	Define a time pool for remote care, support optional TM settings	Support for the organizational set-up and unification of TM conditions on the provider side, taking into account the specifics on the patient side	
Electronic pharmacy	Insufficient use of e-pharmacy tools and collaboration between doctors and pharmacists	Concerns about the limited availability of medicines for certain patient groups and their safe dispensing	Retaining autonomy in deciding how medicines are dispensed, enabling the whole remote end-to-end cycle online, and expanding it to include distance dispensing
	Support the development of e-pharmacy tools, redefine the relationship between doctors and pharmacists, lead the discussion on remote dispensing	Support for the development of e-pharmacy tools, support for remote consultation by pharmacists and remote dispensing of medicines	
Reimbursement of telemedicine solutions	Absence of conditions for TM entry into reimbursement	Concerns that providers will not be motivated to provide TM	Transparent process with the participation of representatives of patient organizations
	Define conditions for inclusion of TM in reimbursement, including with regard to their effectiveness	Support for TM to enter into reimbursement	
Education of healthcare professionals	Lack of training programs, low digital literacy of health professionals	Concerns about the safe use of digital technologies by healthcare professionals and the proper provision of remote care	To involve patient organizations in the education of health professionals
	Support training of health professionals and defining their new competences	Support the training of healthcare professionals and defining their new competences	
Patient education and awareness	Low health and digital literacy of patients	Concerns about poor access and quality of care due to lack of understanding of TM	Involvement of patient organizations in patient and public education in the field of TM
	Support for activities and programs to increase their literacy	Support for activities and programs to improve these	
Prevention and health promotion	Under-utilized potential of ICT in prevention and health promotion	Untapped benefits in terms of health and increased quality of life (comfort) for patients	To address in a systemic way in society
	Support for ICT tools that increase patient compliance	Support for use of ICT tools that increase patient	

10.3389/fpubh.2023.1202182

3.2. Focus groups with stakeholders

By analyzing the content of the transcripts of the focus group discussions, ten key areas for the implementation of telemedicine in the Czech Republic were identified: legislative environment; guidelines; technologies, applications and safe environment; communication and data sharing; organization of care and conditions of provision; electronic pharmacy; reimbursement of telemedicine solutions; education and competences of healthcare professionals; patient education and awareness; prevention and health promotion. Within these key areas, the research team focused on the main issues and challenges of telemedicine in the Czech Republic from the perspective of the interviewed stakeholders.

3.2.1. Legislative environment

The FG participants agreed that the legislative environment is a key factor for the successful development of telemedicine (25). They also pointed to the problematic current concept of health service provision in the Czech Republic, which, with exceptions (e.g., second opinion consultation), assumes the personal presence of the patient in the health care facility, or the physical presence of the health care professional in the patient's own social environment.

> *"Rather, it is assumed that the Health Services Act has been traditionally conceived as the very law that regulates the health care that we primarily knew in 2011, when it was passed. It is care that is provided in a health facility, with exceptions as a visiting service or a preventive service in the field." (FG III-I1).*

The field of telemedicine remains without specific legislation in the Czech Republic, despite the adoption of the Electronization of Healthcare Act.

> *"The Law on the Digitization of Healthcare rather introduces new elements for communication in the digital space to make it safe both in the technical sense and in the sense of who communicates with whom." (FG III-I1).*

Thus, the same rules apply to the provision of telemedicine services as to the provision of healthcare in general, i.e., they must be provided at the appropriate professional level (de lege artis). However, this regulation does not fully reflect the specificities of remote contact.

> *"Today, we do not have the word telemedicine in Czech law, but this does not mean that it is not regulated. It is regulated by general regulations both for medicine and for the provision of healthcare services, and more broadly for the use of IT tools, medical devices, privacy and cybersecurity." (FG III-I3).*

The stakeholders agreed on the necessity of defining a basic legislative framework for telemedicine and the use of ICT with gradual follow-up professional and other legal regulation.

> *"Giving the basic legal framework and testing where it makes sense to develop those services in the future, and where some follow-up regulation will be needed." (FG III-I1).*

> *"There is definitely a need for some further regulation to enter into this, both by legislation and, of course, by having medical experts define what type of healthcare is still Lex Artis. This must be done by experts in the field." (FG III-I3).*

At the same time, they expressed concerns about robust legislation that could hinder the development of telemedicine solutions.

> *"This legislation must not hinder progress." (FG III-I1).*

Therefore, minimalist legislation with broadly defined rules and a clear definition of responsibilities was preferred.

> *"The regulations must be minimalist and progressive. Gradual steps are, in my opinion, far better in this respect." (FG III I6).*

> *"It is necessary to address the responsibility for the outcome of the diagnosis made; where the limit for determining diagnoses is, that is a question for the doctor." (FG III-I5).*

In defining the rules of telemedicine, the need for cooperation between the Ministry of Health and professional societies was also emphasized (see Guidelines).

3.2.2. Guidelines

FG participants agreed that areas, disciplines and procedures appropriate for remote care must be described through clinically guidelines (professional standards).

> *"It is up to the experts to clearly declare what part of medicine is suitable to be implemented by this modern innovative tool, i.e., telemedicine." (FG III-I2).*

In the Czech Republic, the current guidelines only sporadically address telemedicine (26). All stakeholders agreed that the legislative anchoring of telemedicine in law should contribute to its greater development.

> *"There is no one area for telemedicine, and it depends on the field of medicine communicating with the patient. There will be different opportunities in oncology, different opportunities in GP. It is imperative that the option is there, but it will vary greatly by medical field and by specialization." (FG I-I6).*

They stressed, however, that the appropriateness of using telemedicine tools, even when the conditions implied by the guidelines are met, must be assessed by the physician on an individual patient basis.

> *"I would venture to say that it will probably always be at the discretion of the doctor. He/She must have the final say, whether this is something that can be dealt with remotely, or must be dealt with face to face." (FG I-I4).*

The development of clinical guidelines should serve as a basis for the development of innovative telemedicine interventions that can sustain quality of care in times of pandemic (or other crisis situations).

> *"Telemedicine is the future, but especially for chronic patients. In acute care, telemedicine is just a small addition that can be used in some crisis situations like a pandemic." (FG I-I5).*

3.2.3. Technology, application, and safe environment

The FG participants agreed that the creation of a digitally secure environment for communication, sharing and data compatibility, as well as their control, is a prerequisite for the wider implementation of digital technologies in health care models.

> *"For the most part, the focus should be on cyber security, which is still largely overlooked." (FG I-I3).*

They pointed out the absence of rules for technological solutions enabling communication with patients via remote access and its impact on practice.

> *"It is the lack of standardization and the absence of a law. Today, if those do not exist, there is no way to ask the patient to connect with each doctor differently. Each person uses what is nearest to them. If you know how to use WhatsApp, and you ask the doctor and you have his number, it is easier for him to send you something, or for you to send something to the doctor." (FG I-I3).*

Complicating matters in the Czech Republic is the possibility of legal clinical use of data from devices that are not approved medical devices. The issue of certification of data obtained from medical applications has not been resolved.

> *"It is supplementary data that we cannot yet consider certified, but it's just a matter of time. I'm sure legislation will include these more in the clinical process." (FG I-I3).*

Stakeholders agreed that systems (technologies) supported should be simple, safe and also affordable for providers and patients.

> *"We need to make sure that those systems are simple, secure, inexpensive, and also that the information systems operators open them up for inexpensive solutions." (FG I-I6).*

They recommended defining uniform technical and security standards for the use of digital platforms by individual healthcare providers.

> *"There should be some way of defining how the patient should connect with the doctor." (FG I-I8).*

They also recommended defining rules for the use of non-certified health apps, including rules for sharing data collected from these devices.

> *"Can I trust those values? There's going to be a problem with standardization. Those are obviously things we are going to have to address…" (FG I-I4).*

Creating a uniform and transparent environment for the use of telehealth services and setting up certification systems for telemedicine solutions is perceived by experts as a task for the state.

> *"We need to have a framework within which to operate. We perceive that the one who will set the framework will be the Ministry of Health." (FG III-I2).*

3.2.4. Communication and data sharing

Respect for patient autonomy is a key requirement of current ethical and legal codes (27). Fulfilling the principle of autonomy is only possible on the basis of proper patient education. FG participants agreed that communication in healthcare is a problem in the Czech Republic in general.

> *"It happened to me repeatedly: a patient who had come from a specialist telling me that I was the first one in six months to a year to listen to them. It's terribly important to put demands on the education of doctors in the area of communication with patients, not just the specialist component." (FG I-I11).*

They also agreed that telemedicine limits, or even negates, some forms of communication that are essential for determination of proper treatment.

> *"The physical presence of the patient in the office is extremely important. We can read the patient's posture, their attitude, assess their psychological aspects much more easily when we have them next to us. Of course, a flat screen is a kind of substitute, but, again, there are many things we cannot see." (FG I-I1).*

FG participants pointed out the possibility of using modern technology in educating the patient about possible treatment procedures.

> *"If the patient does not have a certain level of health literacy and, at the same time, is under a lot of stress, the amount of information at one time can be a big problem for them, and they may feel some discomfort and prefer not to express their opinion at that moment. And this is where modern technology can help a lot: presenting the patient with treatment options online first, and then, already specifically educated, discussing the most appropriate treatment with the doctor." (FG I-I2).*

Stakeholders pointed in particular to the risks associated with the security of personal data and the invasion of privacy in remote communication. They also expressed concerns about potential implications for legal liability in relation to poor communication, however without proposing solutions.

> *"There is a pronounced risk of misuse or invasion of privacy and abuse of data protection." (FG III-I1).*

> *"The responsibilities of the doctor and the patient when communicating remotely must be clearly established." (FG III-I5).*

3.2.5. Organization of care and conditions of providing

Successful implementation of telemedicine requires not only changes in the technological infrastructure, but also in the

organization of healthcare and the organization of healthcare professionals. FG participants agreed that the time pool of health care providers devoted to telecare during office hours should be clearly defined.

> *"At the moment, we cannot define the time that a doctor who wants to provide this service should schedule in his/her office. It should be about what the logistics of those services they will provide, as well as scheduling some visiting services. The doctor should, probably within their office hours, schedule teleconferencing to address their clients' problems." (FG III-I3).*

Telemedicine should not lead to unrestricted use of health care that would disproportionately increase the workload of physicians.

> *"In the context of telemedicine, anyone can write an email or a message to their doctor at any time. The amount of information that comes in this way is so vast. It's similar with phone calls. Some regulation is needed and we need to talk about how to regulate that." (FG I-I4).*

When incorporating telecare, the organizational capabilities and operational conditions of a particular health service provider should be respected.

> *"The problem with telemedicine is some division of working hours. There should just be some time pool that needs to be dedicated to it. The idea that a doctor is constantly online and constantly communicating with a patient and that he/she is basically available on call at any time, which is what a lot of patients imagine telemedicine to be, is completely wrong." (FG III-I5).*

Stakeholders agreed that the setting up of telecare by healthcare providers should be optional, not an obligation for all participants.

> *"We see providing this service as an option that we would not want to make mandatory; medicine is primarily about patients seeing doctors in person, but this is an option, and it will as such depend on the experience of the doctor and their willingness to provide this service." (FG III-I2).*

They also pointed out that new models of care using ICT may introduce new risks, exacerbate existing health inequalities and, for a certain segment of the population, reduce access to healthcare. Therefore, the specificities in terms of the patient's health status (e.g., immobility), their particular capabilities (e.g., availability of technology), but also their social background (e.g., cooperation of family members) should be taken into account.

> *"There are people who are socially vulnerable, people with disabilities, older adult, or maybe just less technologically adept, even some younger people. These people are there and we have to provide proper health care for them, and telemedicine is not going to be an appropriate way of providing health services for them." (FG III-I1).*

The setting, quality, and sustainability of telemedicine services must be consistent with the goal of universal access to health care and should also promote continuity, coordination of care and a multidisciplinary approach.

3.2.6. Electronic pharmacy

Digitization in the Czech Republic has long been in effect, mainly in the field of pharmacy and pharmaceuticals. The eRecept system as one of the components of e-health has proven its value, especially during the COVID-19 pandemic. The FG participants supported the development of other e-health tools.

> *"E-recipes are a huge simplification for us. But I would imagine there's even more to it. For example requests form for medical devices. "(FG II-I7).*

Stakeholders disagreed on regulations in the area of delivery-service dispensing of prescription drugs and related services of pharmacists.

> *"… with telemedicine or any digitization, the patient should be able to go through the whole process from start to finish, from a consultation, from a diagnosis to e-prescription, to eventually having the medicine delivered to their home." (FG I-I1).*

> *"I cannot imagine that we will start turning our pharmacists into couriers. This is not the route we want to go down." (FG II-I4).*

On the contrary, all agreed on the need to innovate the relationship between pharmacists, doctors and patients in the context of the introduction of telemedicine solutions. In particular, they supported the expansion of pharmacists' competences to include consultation services and closer collaboration with physicians.

> *"The pharmacist, together with the doctor as partner, caring about the patient's health, in order to solve the problem. It's about the doctor and pharmacist working together to benefit the patient's health." (FG II-I3).*

3.2.7. Reimbursement of telemedicine solutions

Healthcare digitalization tools can significantly contribute to the necessary higher cost-effectiveness of healthcare, and thus respond to long-term and current challenges not only in the Czech healthcare system. FG participants agreed that telemedicine interventions in terms of support for reimbursement from public health insurance must be defined with regard to their effectiveness, costs, and added value for providers and patients.

> *"Avoid a blanket introduction of telemedicine. Introduce specialized telemedicine where it counts, where it makes sense both from the patient's point of view and from an economic point of view." (FG I-I3).*

The introduction of telemedicine procedures into the public health insurance system should be allowed on the basis of standard procedure and opposition.

> *"Insurance companies, in cooperation with experts, but also with those who offer those particular types or particular ways of*

> *telemedicine solutions, should determine in what form they will enter into reimbursement." (FG III-I2).*

In relation to reimbursement from public health insurance or direct patient payment, a distinction should be made between telemedicine procedures that bring an improvement in patient comfort and those that bring a therapeutic benefit.

> *"Telemedicine is not only wanted by technology providers and producers. Patients want it too. And it has to be said that some of the care that patients choose to receive in this way will not be covered by public health insurance. For example, if they want a consultation in the evening." (FG III-I1).*

According to stakeholders, digital communication between health insurance companies and health service providers should also be supported as an important tool for an effective control system.

> *"To help find any inefficiencies in the system, reporting of healthcare or its provision from public health insurance, and it will also facilitate the auditing process to ensure that what should be covered is really covered." (FG III-3).*

3.2.8. Education and competences of health professionals

New models of remote healthcare require healthcare professionals to acquire the necessary ICT skills. FG participants agreed on the need to integrate telehealth and digital skills into the educational programs of health professionals in undergraduate and postgraduate education.

> *"We have a huge deficit in communication skills training in medical faculties. This cuts across all disciplines and it is terribly important that communication skills are developed with digital in mind." (FG I-I1).*

Stakeholders agreed that the use of ICT in health care provision also allows for a more active involvement of non-medical health professionals and recommended their greater involvement in the implementation of telemedicine.

> *"The issue of incorporating video consultations or those ways of providing healthcare into the work of healthcare providers. It does not always have to be physicians. Somewhere, general nurses or other types of health professions will suffice." (FG III-I6).*

A more active involvement of non-medical health professionals in telecare in the future will not be possible without defining their new competences. However, this will require changes in the law and in training programs for individual disciplines.

> *"One of the key issues is what a nurse can do and what a doctor must do. It will be very discipline-specific." (FG III-I6).*

> *"The unpreparedness of the Czech Republic is also in the competencies. So that some of the tasks within telemedicine can be done by a non-physician. But they cannot even do that because we have not prepared, for example, nurses to have the competence to do some things." (FG I-I2).*

3.2.9. Patient education and awareness

The use of remote healthcare using ICT requires a certain level of health and digital literacy from its users.

> *"Better health literacy is as much in the physical contact as it is in the delivery of a health service using digital technology. The patient needs a little more information and some better awareness of their rights to be able to possibly refuse the imposed use of digital technology in health service provision. In this sense, some patient education would be helpful." (FG III-I1).*

FG participants agreed that patients should be educated not only on how ICT can be used in healthcare delivery, including with regard to their safety, but also on what their rights and responsibilities entail.

> *"It's one thing that we need to have some technical standards set, but it's another thing that the patient, who is the recipient of that service, should be educated on how to use it, and that it all has some limits." (FG III-I1).*

Stakeholders also pointed to the important role of the state and the role of patient organizations in supporting patient education and increasing patients' digital skills in using ICT.

> *"Patient organizations, in particular, can disseminate information to their members through IT technologies and essentially make that information more available to patients and can convey it in a much more immediate and better way than patients having to look it up on the internet." (FG III-I8).*

> *"I think it's not just down to patient organizations and patients in general. It is also the role of the state, or perhaps the National Institute of Health, to make sure that awareness – and obligations – of patients' rights is as widespread as possible." (FG I-I8).*

3.2.10. Prevention and health promotion

The use of digital technologies, including health apps (mHealth), has a high potential for use in prevention and health promotion.

> *"The deployment of these technologies is precisely in the field of primary prevention as well as other prevention programs. In the future, I see the integration of these technologies with smart solutions, for example in the form of smart watches, which gives us hope that we will be able to rehabilitate some patients properly, for example after cancer treatment, to get them back to a better condition." (FG I-I2).*

FG participants agreed that telehealth solutions increase patients' compliance and adherence to treatment and strengthen their role in healthcare provision.

> *"The benefit of telemedicine is also in increasing compliance, if a patient has the information that the doctor has, then I suppose their curiosity will somehow get them more involved in the game for their own health." (FG I-I3).*

They also agreed that the use of health apps can also increase motivation for a healthier lifestyle, and serve as a general educational tool to increase health literacy.

> *"Telemedicine can be used to both educate the patient regarding their diagnosis and monitor their chronic or acute conditions. Further, there is definitely wide educational potential in personalizing the system through the patient's mobile app, and I mean very general education, like self-management, lifestyle." (FG I-I2).*

Explaining the meaning and importance of preventive examinations and supporting projects to use ICT in prevention is perceived by stakeholders as the role of the state. The systemic setting of ICT in prevention should also be supported by health insurance companies.

> *"I think that, in general, the need to take more care of ourselves should resonate more in society. This education should also come from insurance companies and from the Ministry of Health." (FG I-I11).*

3.3. Patient panel and comparison

3.3.1. Patient panel

Representatives of patient organizations generally support the development of rules and regulations for the development of telemedicine solutions at all levels of healthcare (24). However, they point out that this model of care brings new roles, relationships and responsibilities, and raises a number of uncertainties and associated expectations and concerns. Patients ask questions, the answers to which will have a major impact on their decision whether or not to trust telemedicine solutions. Representatives of patient organizations identified the following topics as key to the successful development of telemedicine: safe care, protection of confidentiality and privacy, communication in the new environment, uniform conditions for the organization of care, systemic support for telemedicine solutions and digital training for healthcare professionals and patients.

3.3.1.1. Safe care

The lack of a legislative anchor for telemedicine raises patients' concerns about the legality of care provided by remote access. The lack of development of guidelines for telemedicine increases their legal uncertainty about whether care is being delivered in a professionally correct way (lege artis). It is important for patients to be of sound health. It is also important for patients that the physician's responsibility for using a telemedicine solution is clearly established. Patients would like to have access to guidelines (information) so that they can learn about in which situations the use of telemedicine is appropriate and safe.

> *"What can I even address remotely? Is telemedicine safe? Will a telemedicine exam be as good as an in-office exam? Might the doctor miss something? Who is responsible for the care I choose?" (Questions from the patient panel).*

3.3.1.2. Confidentiality and privacy

Patients are concerned about the safety of the technology used, the security of the data transmission, and the quality of care provided if conditions (standard) are not set for the technical equipment. Clearly defined rules for the provision of telemedicine services are important to patients with regard to privacy and online access to their health data. Patients would welcome a database of secure technological solutions, including health applications.

> *"How is the transmission of my data secured? Where does the data from my measuring device go? What happens to my data? Who is my data shared with? Can it be misused? How will my privacy be secured on the provider side? Who else may participate in the telemedicine service?" (Questions from the patient panel).*

3.3.1.3. Communication in a new environment

Telemedicine increases demands on communication between doctors and patients. Patients are concerned that a lack of communication may lead to a lower quality of care. It is important for patients that there is a single standard for digital communication that they would like, with their doctors, to participate in creating. They consider it crucial that the rules for the provision of telemedicine services respect the autonomy of patient decision-making. They would welcome guidance and education on how to communicate with physicians in the online environment. They also support the practice of completing structured guidance questionnaires prior to an appointment, to enable them to better prepare for their appointment with the doctor.

> *"What should I say to the doctor and how? What should the doctor ask me? How will the telemedicine exam be different? How will the doctor identify me? How will the patient's informed consent be secured? How will my right to make decisions about my care be assured?" (Questions from the patient panel).*

3.3.1.4. Uniformly-set conditions for the organization of care

Different approaches and conditions between each of the providers in setting up and using telemedicine solutions make the system unclear for patients. Patients are concerned about providers mandating certain ICT configurations they will have to manage. It is important for patients that providers make information public on the scope of the telemedicine services to be provided. They would welcome user guides on technology solutions and plainly support online booking systems.

> *"Do I need to use telecare? I do not have the technical equipment that telemedicine requires, so will the service be unavailable to me? Will telemedicine work the same everywhere? Why will not my doctor answer the phone? Why do not booking systems work in*

> *health services? How can I find out which doctor provides telemedicine services?" (Questions from the patient panel).*

3.3.1.5. System support for telemedicine solutions

The absence of conditions for the entry of telemedicine solutions into reimbursement raises concerns on the part of patients about whether providers will be motivated to use them. Patient organizations clearly support the inclusion of telemedicine in health insurance reimbursement, and want to be part of a transparent process to set up a reimbursement system for telemedicine procedures and telemedicine solutions. Patients also want to decide how medicines are dispensed, and support systemic solutions to enable remote dispensing.

> *"Which telemedicine procedures are in the reimbursement system? How will the entry of telemedicine procedures into the reimbursement system be evaluated? Will patients (patient organizations) be able to influence which telemedicine procedure should be included in the system? If I have an e-prescription, why do not I have 'e-medicine'? Why cannot I get my prescription medication delivered to my home?" (Questions from patient panel).*

3.3.1.6. Digital training for healthcare professionals and patients

The low level of digital literacy of patients and healthcare professionals raises concerns about the safe use of ICT, and the poor accessibility, and the quality of remote healthcare. Patients support educational and motivational programs to acquire and expand their ICT skills. They stress that the patient's perspective should not be neglected in the education of health professionals. Thus, patient organizations want to be involved in programs to increase digital literacy of citizens, patients, and healthcare professionals.

> *"How can I learn to work with new technologies? What new skills will doctors and patients need to learn?" (Questions from patient panel).*

3.3.2. Comparison of patient's and other stakeholders' perspective

A comparison of the FG outputs and the patient panel's opinions showed that there is consensus between the stakeholder and patient conclusions in most of the key areas described by the research team. Both groups agree on the identification of key issues and challenges for the implementation of telemedicine in the Czech Republic.

In the area of communication and data sharing, patients came up with concrete solutions to eliminate their concerns about miscommunication or lack of communication in a new and unfamiliar environment. They propose the creation of rules (standards) for digital communication between patients and doctors, and also rules (standards) for shared decision making (informed consent) in the online environment.

It also showed that in each key area, another patients' perspective can be identified, which appropriately complements or even extends the stakeholders' conclusions on the process of telemedicine implementation. This perspective was identified (described) by the research team as "patient interest" (see Table 3).

3.4. Recommendation

The research team formulated recommendations that would strengthen patient and public confidence in telemedicine interventions, taking into account the possibilities of collaboration between patient organizations and healthcare professionals in the development of communication (online) strategies and their involvement in the processes of telemedicine implementation. Within the process of telemedicine implementation, the proposed recommendations can be used by individual stakeholders separately or interconnected at different levels of healthcare management.

- Involve patients in the development of telemedicine rules, decision-making, and evaluation processes for reimbursement of telemedicine solutions and certification of healthcare applications (support the development of patient involvement strategies).
- Ensure that patients have systematic (open) access to information on telemedicine interventions and their suitability and safe use for individual therapeutic areas, and safe telemedicine solutions including health apps.
- Provide patients with information on telemedicine interventions at the individual provider level, including the definition of a time pool for telemedicine by specific providers.
- Make user guides for telemedicine solutions available to patients by individual providers, including the provision of tech support.
- Promote collaboration between healthcare professionals and patient organizations to develop rules for safe and effective communication in the online environment (digital communication standards).
- Development, in collaboration with patient organizations, of targeted educational programs for patients and the public to increase the level of digital health literacy and a better understanding of the telemedicine care provided.
- Include patient interest in targeted interventions to educate health professionals on telehealth.
- Take into account technical inequalities and ensure wide accessibility of telemedicine services, while preserving patients' freedom of choice. Promote the ethical adoption of digital health technologies in the provision of remote healthcare.

4. Discussion

The successful implementation of any technology into the healthcare system depends largely on the trust of its end users, i.e., the public and patients (28). Telemedicine is a new service in healthcare, and therefore understanding the attitudes that patients have towards it is important to facilitate its adoption (29).

Similar to other authors (11, 23), we base our research on the premise that involving patients in implementation processes at all levels of the health system as key users of health services contributes to protecting their interests, improving the quality and safety of services, and making them patient-centered.

The greater experience with telemedicine in the Czech Republic, reinforced by the COVID-19 pandemic, has contributed to the fact that a wider introduction of telemedicine elements in different healthcare fields is already generally supported by patients (12, 30).

Our research also confirmed the high level of patient acceptance of telemedicine interventions, similar to the level of acceptance in foreign studies (31, 32).

Although use of telemedicine has declined from its peak during the pandemic, it remains well above pre-pandemic levels (33, 34). However, it appears that traditional health care regulation is not sufficient to address the (legal, social, and ethical) issues associated with innovative technologies (29). Thus, individual health systems are seeking a balance between in-person and virtual care delivery (32). Patients are also adapting to the new model of "hybrid care" (mixed care), and it is important to understand their concerns and feelings in order for telemedicine to continue to develop (35).

The results of our research have shown the unpreparedness of the Czech healthcare system to deliver ICT-enabled telemedicine services across the full spectrum of stakeholders [similarly (36)]. In agreement with patients, stakeholders identified regulatory uncertainty as the main barrier to telemedicine integration, leading to the incoordination of telemedicine implementation in the Czech Republic. Thus, the absence of legislative regulations and other (disciplinary and organizational) guidelines for telemedicine can generate a number of problems in the patient–doctor relationship (37, 38), including ethical ones (27, 39). This may also lead to inequalities in access to healthcare (3, 40) and affect the overall quality of care provided (41).

Involving patient organizations in our research allowed us to understand their values, beliefs, knowledge, experiences, motivations and attitudes in relation to telemedicine. Thusly, "patient interest" in all key areas of telemedicine implementation could be identified. With regard to patient interest, it became clear that patients want: 1. a predictable and reliable framework that provides them with certainty and security in the provision of telemedicine services, 2. telemedicine solutions that increase the availability and efficiency of the care provided and also bring convenience (e.g., in terms of time savings), and 3. user-friendly and simple solutions. At the same time, they want to understand the new environment.

It has been shown that patients want to be active participants in the process of digital innovation, including its practical implementation (e.g., collaborating with physicians to create rules for shared decision-making) (42). Telemedicine provides an ideal environment for shared decision-making, which is essential for building patient-centered care (43). Involving patients in collaboration with physicians can lead not only to improved communication in the delivery of online care, but also to improved quality of life, as well as empowerment of patients (44).

Recommendations developed by the research team that reflect the patient's interest can be implemented at three levels – at the health system level (policy), at the institutional level (providers, insurers), and at the community level (patient organizations, regions). The implementation of these recommendations at each level can intersect and influence each other.

In this context, Otto et al. (45) point out that communities play a key role in the successful scale-up of telemedicine interventions. The community can actively influence and encourage individuals to adopt telemedicine, for example, by conducting awareness campaigns or creating support programs for disadvantaged community members. However, the community itself is also affected by various factors (e.g., legal and regulatory constraints) that influence its readiness for telemedicine. In countries with a developed and institutionalized patient movement, including the Czech Republic, it is patient organizations that can represent the community level. Other authors, for example Zhang et al. (46), point out that telemedicine stakeholders should strengthen intersectoral collaboration to incorporate population preferences and entrench the service in the healthcare system.

The readiness of patient organizations for telemedicine initiatives, as one of the key communities, can help bridge the gap between individual patient decisions (attitudes) to adopt telemedicine and system-wide efforts to implement them (45).

Based on the results of our research, future studies could look more closely at the barriers and motivators to patient organization involvement in telemedicine adoption. Consideration of 'patient interest' in other phases of telemedicine implementation could also be explored, including with respect to individual telemedicine interventions at different levels of the health system.

5. Limits of the research

Our research involved a wide range of stakeholders, including patients. This gave us a comprehensive view of the implementation of telemedicine in the Czech Republic. A limitation of this study is the smaller number of patient panelists. We tried to eliminate this limitation by selecting patient representatives from an umbrella organization who have been active in the patient movement for a long time and also have experience with telemedicine at the individual and system level. Another limitation may be the subjective aspect in identifying "patient interest," which we tried to avoid by having it identified by a pair of team members. We avoided the subjectivity in making recommendations by involving the whole team in their formulation based on a panel discussion of experts.

6. Conclusion

In our research, the basic pillars of telemedicine implementation in the Czech Republic were defined. Specific activities within each pillar should be interrelated. Therefore, the development of a state-coordinated strategy and implementation plan for telemedicine is crucial for the further development of telemedicine. All stakeholders, including patients, should be involved in the development and implementation of this strategy for the development of telemedicine, allowing their needs, priorities and expectations to be taken into account. Involving patient organizations can be an effective way to involve patients in initiatives related to the development and implementation of telemedicine. Patient organizations can thus become the link between telemedicine policy making and implementation at the individual level of healthcare provision.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical review and approval was not required for the study of human participants in accordance with the local legislation and institutional requirements. All research participants provided informed consent to participate in this study.

Author contributions

JT and KD led the conception and design of this paper, collected and analyzed data, and solicited financial contributions. JT, KD, ZD, and AT formulated recommendations. All authors contributed to the article and approved the submitted version.

Funding

This output was supported by the NPO "Systemic Risk Institute" number LX22NPO5101, funded by European Union – Next Generation EU (Ministry of Education, Youth and Sports, NPO: EXCELES).

Conflict of interest

ZD was employed by Ernst & Young, s.r.o.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

1. Cannavacciuolo L, Capaldo G, Ponsiglione C. Digital innovation and organizational changes in the healthcare sector: multiple case studies of telemedicine project implementation. *Technovation*. (2023) 120:102550. doi: 10.1016/j.technovation.2022.102550

2. Mitchell M, Kan L. Digital technology and the future of health systems. *Health Syst Reform*. (2019) 5:113–20. doi: 10.1080/23288604.2019.1583040

3. Mann DM, Chen J, Chunara R, Testa PA, Nov O. COVID-19 transforms health care through telemedicine: evidence from the field. *J Am Med Inform Assoc*. (2020) 27:1132–5. doi: 10.1093/jamia/ocaa072

4. Garattini L, Badinella Martini M, Zanetti M. More room for telemedicine after COVID-19: lessons for primary care? *Eur J Health Econ*. (2021) 22:183–6. doi: 10.1007/s10198-020-01248-y

5. Act No. 325/2021 Coll., on the Electronization of Healthcare. Available at: https://www.zakonyprolidi.cz/cs/2021-325 (Accessed February 17, 2023).

6. Bajowala SS, Milosch J, Bansal C. Telemedicine pays: billing and coding update. *Curr Allergy Asthma Rep*. (2020) 20:60. doi: 10.1007/s11882-020-00956-y

7. Schinasi DA, Foster CC, Bohling MK, Barrera L, Macy ML. Attitudes and perceptions of telemedicine in response to the COVID-19 pandemic: a survey of Naïve healthcare providers. *Front Pediatr*. (2021) 9:647937. doi: 10.3389/fped.2021.647937

8. Dahlgren C, Spånberg E, Sveréus S, et al. Short- and intermediate-term impact of DTC telemedicine consultations on subsequent healthcare consumption. *Eur J Health Econ*. (2023) 23:1572. doi: 10.1007/s10198-023-01572-z

9. Alexa J, Recka L, Votapkova J, van Ginneken E, Spranger A, Wittenbecher F. Czech Republic: health system review. *Health Syst Transit*. (2015) 17:1–165.

10. Dlouhý M. Measuring geographic inequalities: dealing with multiple health resources by data envelopment analysis. *Front Public Health*. (2018) 6:53. doi: 10.3389/fpubh.2018.00053

11. Baumann LA, Brütt AL. Public and patient involvement (PPI) in health policy decisionmaking on the health system-level: protocol for a systematic scoping review. *BMJ Open*. (2021) 11:e043650. doi: 10.1136/bmjopen-2020-043650

12. Dobiášová K, Kotherová Z, Numerato D. Institutional reforms to strengthen patient and public involvement in the Czech Republic since 2014. *Health Policy*. (2021) 125:582–6. doi: 10.1016/j.healthpol.2021.03.011

13. NAPO. O NAPO. [About NAPO]. (2023) Available at: https://silapacientu.cz/o-napo/ (Accessed February 17, 2023).

14. Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision (Act on Health Services). Available at: https://www.zakonyprolidi.cz/cs/2011-372 (Accessed February 17, 2023)

15. Ministerstvo zdravotnictví. Pacientská rada. Portál pro pacienty a pacientské organizace [Ministry of Health. Patient's council. Patients and patient's organizations portal]; 2020. Available at: https://pacientskeorganizace.mzcr.cz/index.php?pg=pacientske-organizace–pacientska-rada (Accessed February 17, 2023). Czech.

16. Ministerstvo zdravotnictví. Statut a jednací řád pacientské rady ministra zdravotnictví. Příloha k příkazu ministra č. 15/2017 [Ministry of Health. Patient's Council's Statutes and Rules of Procedure. Attachment to ministerial direction no. 15/2017.]. Praha: MZ ČR; 2017. Available at: https://pacientskeorganizace.mzcr.cz/res/file/dokumenty/pacientska-rada-statut-jednaci-rad-20170727.pdf (Accessed February 17, 2023). Czech.

17. Act No. 371/2021 Coll. Amendment to Act No. 372/2011 Coll., effective from 1 January 2022. Available at https://www.zakonyprolidi.cz/cs/2021-371: (Accessed February 17, 2023)

18. Kitzinger J. (2006). Focus groups. C. Pope and N. Mays (Eds.), *Qualitative research in health care* (21–31). Blackwell Publishing; BMJ Books.

19. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*. (2006) 29:489–97. doi: 10.1002/nur.20147

20. Wilkerson JM, Iantaffi A, Grey JA, Bockting WO, Rosser BR. Recommendations for internet-based qualitative health research with hard-to-reach populations. *Qual Health Res*. (2014) 24:561–74. doi: 10.1177/1049732314524635

21. Clarke V., Braun V., Hayfield N. (2015) Thematic analysis. J.A. Smith, (Ed.), *Qualitative psychology: A practical guide to research methods*, SAGE Publications, London, 222–248

22. Price A, Schroter S, Snow R, et al. Frequency of reporting on patient and public involvement (PPI) in research studies published in a general medical journal: a descriptive study. *BMJ Open*. (2018) 8:e020452. doi: 10.1136/bmjopen-2017-020452

23. Koskinas E, Gilfoyle M, Salsberg J. Exploring how patients, careers and members of the public are recruited to advisory boards, groups and panels as partners in public and patient involved health research: a scoping review protocol. *BMJ Open*. (2022) 12:e059048. doi: 10.1136/bmjopen-2021-059048

24. Konference Digitální medicína (nejen) pro pacienty. [Conference Digital medicine (not only) for patients]. 1.LF UK. Akademie věd ČR, 30. 11. 2021, Praha. Available at: https://www.youtube.com/watch?v=T5Ig66OZdWo

25. WHO World Health Organization. (2021). Global strategy on digital health 2020–2025. Available at: https://apps.who.int/iris/handle/10665/344249 (Accessed January 7, 2023).

26. Mucha C, Býma S, Šonka P A kol. Telemedicína. Doporučené diagnostické a terapeutické postupy pro všeobecné praktické lékaře. [Telemedicine. Recommended diagnostic and therapeutic procedures for general practitioners]. Společnost všeobecného lékařství, (2020). Available at: www.svl.cz/files/files/Doporucene-postupy/2020/DP-Telemedicina.pdf (Accessed January 7, 2023).

27. Shaw JA, Donia J. The sociotechnical ethics of digital health: a critique and extension of approaches from bioethics. *Front. Digit. Health*. (2021) 3:725088. doi: 10.3389/fdgth.2021.725088

28. Adjekum A, Blasimme A, Vayena E. Elements of trust in digital health systems: scoping review. *J Med Internet Res*. (2018) 20:e11254. doi: 10.2196/11254

29. Landers C, Vayena E, Amann J, Blasimme A. Stuck in translation: stakeholder perspectives on impediments to responsible digital health. *Front. Digit. Health*. (2023) 5:1069410. doi: 10.3389/fdgth.2023.1069410

30. Lazárová M, Hlavinka A, Šulc P, Dodulík J, Václavík J. Využití telemedicíny u pacientů se srdečním selháním (the use of telemedicine in patients with heart failure). *Vnitr Lek*. (2022) 68:154–8. doi: 10.36290/vnl.2022.031

31. Eze ND, Mateus C, Cravo O, Hashiguchi T. Telemedicine in the OECD: an umbrella review of clinical and cost-effectiveness, patient experience and implementation. *PLoS One*. (2020) 15:e0237585. doi: 10.1371/journal.pone.0237585

32. OECD (2023), The COVID-19 pandemic and the future of telemedicine, *OECD Health Policy Studies*, OECD Publishing, Paris.

33. Chang JE, Lindenfeld Z, Albert SL, Massar R, Shelley D, Kwok L, et al. Video visits during COVID-19: safety-net provider perspectives. *J Am Board Fam Med*. (2021) 34:1103–14. doi: 10.3122/jabfm.2021.06.210186

34. Berry CA, Kwok L, Massar R, Chang JE, Lindenfeld Z, Shelley DR, et al. Patients' perspectives on the shift to telemedicine in primary and behavioral health care during the COVID-19 pandemic. *J Gen Intern Med*. (2022) 37:4248–56. doi: 10.1007/s11606-022-07827-4

35. Ftouni R, AlJardali B, Hamdanieh M, Ftouni L, Salem N. Challenges of telemedicine during the COVID-19 pandemic: a systematic review. *BMC Med Inform Decis Mak*. (2022) 22:207. doi: 10.1186/s12911-022-01952-0

36. Opatrný M, Šlegerová L, Táborský M, Bolcha P. Telemedicine services: barriers and the possible development in the Czech Republic. Working paper. (2022). Anglo-American University. Czech Republic. Available at: https://www.aauni.edu/. (Accessed January 7, 2023).

37. Agha Z, Roter DL, Schapira RM. An evaluation of patient-physician communication style during telemedicine consultations. *J Med Internet Res*. (2009) 11:e36. doi: 10.2196/jmir.1193

38. Pogorzelska K, Marcinowicz L, Chlabicz S. A qualitative study of primary care physicians' experiences with telemedicine during the COVID-19 pandemic in north-eastern Poland. *Int J Environ Res Public Health*. (1963) 2023:20. doi: 10.3390/ijerph20031963

39. Černý D. Etika telemedicíny. *The ethics of telemedicine Čas Lék čes*. (2021) 160:282–6.

40. Solimini R, Busardò FP, Gibelli F, Sirignano A, Ricci G. Ethical and legal challenges of telemedicine in the era of the COVID-19 pandemic. *Medicina*. (2021) 57:1314. doi: 10.3390/medicina57121314

41. Escobar O, Leone D, Malafronte P, Mele S. The effect of telemedicine on patients' wellbeing: a systematic review. *J. Innov. Econ. Manag.* (2021) 35:9–31. doi: 10.3917/jie.pr1.0098

42. Meskó B, deBronkart D. Patient design: the importance of including patients in designing health care. *J Med Internet Res*. (2022) 24:39178. doi: 10.2196/39178

43. Hartasanchez SA, Heen AF, Kunneman M, García-Bautista A, Hargraves IG, Prokop LJ, et al. Remote shared decision making through telemedicine: a systematic review of the literature. *Patient Educ Couns*. (2022) 105:356–65. doi: 10.1016/j.pec.2021.06.012

44. Pappas Y, Vseteckova J, Mastellos N, Greenfield G, Randhawa G. Diagnosis and decision-making in telemedicine. *J Patient Exp*. (2019) 6:296–304. doi: 10.1177/2374373518803617

45. Otto L, Schlieter H, Harst L, Whitehouse D, Maeder A. The telemedicine community readiness model – successful telemedicine implementation and scale-up. *Front Digit Health*. (2023) 5:1057347. doi: 10.3389/fdgth.2023.1057347

46. Zhang Y, Chandra S, Peña MT, Lal L, Summers RL, Swint JM. Framework for evaluating and developing sustainable telehealth programs. *Telemed J E Health*. (2023) 29:1421–5. doi: 10.1089/tmj.2022.0407

frontiers | Frontiers in Public Health

TYPE Original Research
PUBLISHED 08 January 2024
DOI 10.3389/fpubh.2023.1301949

OPEN ACCESS

EDITED BY
Lauren Moo,
United States Department of Veterans Affairs, United States

REVIEWED BY
Asos Mahmood,
University of Tennessee Health Science Center (UTHSC), United States
Wioletta Anna Medrzycka-Dabrowska,
Medical University of Gdansk, Poland

*CORRESPONDENCE
Federica Alemanno
✉ alemanno.federica@hsr.it

RECEIVED 25 September 2023
ACCEPTED 22 December 2023
PUBLISHED 08 January 2024

CITATION
Emedoli D, Houdayer E, Della Rosa PA, Zito A, Brugliera L, Cimino P, Padul JD, Tettamanti A, Iannaccone S and Alemanno F (2024) Continuity of care for patients with dementia during COVID-19 pandemic: flexibility and integration between in-person and remote visits.
Front. Public Health 11:1301949.
doi: 10.3389/fpubh.2023.1301949

Continuity of care for patients with dementia during COVID-19 pandemic: flexibility and integration between in-person and remote visits

Daniele Emedoli[1], Elise Houdayer[1], Pasquale Anthony Della Rosa[2], Alice Zito[1], Luigia Brugliera[1], Paolo Cimino[1], Jeffrey David Padul[1], Andrea Tettamanti[1], Sandro Iannaccone[1] and Federica Alemanno[1]*

[1]Department of Rehabilitation and Functional Recovery, IRCCS San Raffaele Scientific Institute, Milan, Italy, [2]Department of Neuroradiology, IRCCS San Raffaele Scientific Institute, Milan, Italy

Introduction: During the pandemic, the Cognitive Disorders Unit of San Raffaele Hospital (Milan, Italy) offered patients the opportunity to undergo neuropsychological evaluations and cognitive training through telemedicine.

Method: We conducted an investigation to assess how patients responded to this option and to determine if telemedicine could ensure continuity of care.

Results: Between October 2019 and May 2022, a total of 5,768 telemedicine appointments and 8,190 in-person outpatient appointments were conducted, resulting in an increase in the rate of telemedicine activity from 16.81% in January 2020 to 23.21% in May 2022. Peaks in telemedicine activity reached 85.64% in May 2020 and 83.65% in February 2021, both representing a significant portion of the total activity. Interestingly, there was a notable positive correlation between telemedicine activity and the worsening of the Italian pandemic ($r = 0.433$, $p = 0.027$).

Discussion: During the peaks of contagion, the total number of visits remained stable, highlighting that telemedicine effectively served as a valuable and efficient tool to ensure continuity of care for vulnerable patients. This was evident from the integration of remote visits with in-person appointments.

KEYWORDS

telemedicine, telerehabilitation, cognitive disorders, cognitive training, neuropsychology, COVID-19, continuity of care

Introduction

During the COVID-19 pandemic, issues related to discontinuing care have arisen due to hospitals needing to close numerous clinical departments and allocate most beds to COVID-19 patients. Furthermore, because of the emergency, many outpatient clinics were either closed for months or limited their services to emergencies only. To address these interruptions, the use of telemedicine was expanded, alongside digital solutions and advanced technology interfaces (1, 2). Telemedicine, along with tools rooted in artificial intelligence, big data analytics, and mobile tracing apps for surveillance, was extensively utilized globally for

diagnosing, preventing, monitoring, and treating individuals (3, 4). Concomitantly with the drastic reduction in outpatients appointments, there has been a surge in the utilization of remote consultations (5). Patients, caregivers and clinicians rated the use of telemedicine during the recent pandemic as highly satisfactory (6). Consequently, the majority of patients and healthcare providers expressed a willingness to continue using telemedicine even after the pandemic (7, 8).

In 2019, before the onset of the COVID-19 pandemic, the Cognitive Disorders Unit at San Raffaele Hospital (Milan, Italy) had established telemedicine services for conducting remote neuropsychological evaluations and cognitive training. This service was offered to patients already undergoing treatment at our Institute, primarily those receiving care for dementia and acquired brain injuries. Dementia currently stands as the seventh leading cause of death worldwide and significantly contributes to disability and dependency among older populations. The statistics regarding dementia and its impact on patients, their families, and the entire healthcare system are staggering (9). Evidence reveal escalating pressures on families and caregivers, both emotionally and financially, alongside substantial financial strains on the entire healthcare system (10). Hence, telemedicine services represent an innovative solution that lessens the burden on patients' support networks, is more environmentally friendly, and incurs reduced costs compared to in-person appointments (11–13). While further investigations are necessary to gauge the environmental impact and social costs, telemedicine has been reported as a feasible approach to assist individuals with dementia stay connected to their service providers amid the pandemic (14). The usability and efficacy of teleneuropsychology assessments and training have already been investigated (15–18). Data reported in the litterature showed good evidence for the validity of teleneuropsychology assessments in older adults and an efficacy of telecognitive rehabilitation at least as strong as face-to-face cognitive training. Additionally, prior studies have already indicated that both patients and clinicians found teleneuropsychology services satisfactory during the COVID-19 pandemic (8, 19). It is now accepted that telemedicine is useful but not sufficient and should not replace in-patient services but should complement traditional visits (7). More information should be collected regarding the integration of teleneuropsychology services into traditional care and how patients might respond to such offerings, especially in challenging situations like during a pandemic.

In this study, our primary objectives were to assess patients' receptiveness to telemedicine services provided by the Cognitive Disorders Unit during the COVID-19 pandemic, investigate potential disruptions in continuity of care due to the various pandemic waves, and determine patients' preferences continued telemedicine use versus returning to in-person outpatient care. This was particularly considered in light of the pandemic's reduced impact in Italy since spring 2022.

Materials and methods

Telemedicine and outpatients' clinic activity

We performed a retrospective analysis of telemedicine and outpatient clinic appointments administered by the Cognitive Disorders Unit at the San Raffaele Scientific Institute in Milan, Italy, between October 1st, 2019, and May 30th, 2022, as our primary outcome. Throughout this entire period, patients were given the option to receive care either in the outpatient clinic or through telemedicine. Despite the closure of numerous outpatient clinics and the reduced activity of others within our Institute, the Neuropsychology Service remained accessible to patients throughout the pandemic. The only prerequisite for patients to qualify for telemedicine was that they had previously undergone at least one neurological visit and one neuropsychological evaluation in the outpatient clinic. The telemedicine and outpatient clinic appointments considered in this study encompassed neuropsychological evaluations for patients' follow-up and cognitive training sessions.

Telemedicine appointments were conducted remotely using video-conferencing software provided by our Institute, ensuring utmost confidentiality and privacy in a designated private room. Notably, patients who had tested positive for SARS-CoV-2 within the last 14 days were temporarily restricted from accessing the outpatient clinic during this period to mitigate the risk of contagion. The study was approved by the local Ethics committee of the San Raffaele Hospital (protocol number: PROTECT-COVID).

Correlations with the pandemic severity

As a secondary outcome, we correlated the severity of the Italian pandemic situation, extracted from the number of symptomatic patients hospitalized with SARS-CoV-2 in Italy from February 2020 to May 2022 (20), with the numbers of telemedicine and outpatients' clinic appointments.

Statistical analyzes

First, we calculated the monthly percentage change (MPC) for both the outpatients and telemedicine activity time series with respective bootstrapped confidence interval (CI 95%) to explore the temporal trend of the two time series during the COVID-19 pandemic (February 2020 to May 2022).

Second, to test whether observed variations in the number of cases in the telemedicine activity series and the number of cases outpatient activity series shared any temporal association, a cross-spectral analysis was performed. A bivariate model was fitted to the time series during the COVID-19 pandemic (February 2020 to May 2022) to quantify the frequency-related squared coherence (i.e., the strength of dependency between the two time series at a particular period) and phase shift between in person medicine (the independent variable) and telemedicine (the dependent variable). The spectral estimates were smoothed with a Hamming window of width 5.

Third, a bivariate correlation analysis with bootstrapping ($n = 5{,}000$ samples) was run to assess the relationships between the volume of telemedicine appointments and the severity of the pandemic,. To ensure the validity of our analyzes, we also performed analyzes of variance with the Levene Test for Equality of Variances. Statistical significance was determined at a threshold of $p < 0.05$. All data analyzes were carried out using the commercially available IBM SPSS Statistics version 23 (IBM Corp. ©) software.

10.3389/fpubh.2023.1301949

Results

Between October 1st, 2019, and May 30th, 2022, 225 patients benefited from neuropsychological evaluations or cognitive training and were included in the analyzes (103 Female, mean age 71.53 ± 15.36 years). The patient's population consisted in post-traumatic disorders (8%), post-stroke patients (23%) and dementia patients (69%) (Alzheimer's disease, Mild Cognitive Impairment, Frontotemporal Dementia, Lewy Body Dementia).

A total of 13,958 treatments were included in the analyzes: 2,512 neuropsychological evaluations (18% of the total treatments) and 11,446 cognitive training (82% of the total treatments). Among these 13,958 treatments, 5,768 appointments were conducted in telemedicine and 8,190 in-person appointments were conducted in the outpatients' clinic.

During this period, the rate of telemedicine activity increased from 16.81% in January 2020 to 23.21% in May 2022. Peaks in telemedicine activity reached 85.64% in May 2020 and 83.65% in February 2021 (Table 1).

In-person appointments in the outpatients' clinic had a greater variability compared to telemedicine appointments, especially during the year 2020, as shown by the standard deviations analyzes (in-person appointments sd = 143.13 vs. telemedicine sd = 76.30, $p = 0.017$) (Figure 1).

The monthly percentage change index for the outpatients (mean percentage variation = 13.83; 95% CI: −8.58, 42.67) and telemedicine activity series (mean percentage variation = 5.14%; 95% CI: −6.43, 16.46) during the COVID-19 pandemic, shows a positive trend concerning telemedicine continuity and utility.

The bivariate spectral analysis yielded a significant common movement in the two series, with a significant peak involving a squared coherence of 0.421 ($p = 0.032$; phase angle, 3.03 radian) (see Figure 2),

TABLE 1 Telemedicine and outpatients' clinic activity, over time.

	Telemedicine		Outpatients clinic	
	Number of visits	Percentage of total activity (%)	Number of visits	Percentage of total activity (%)
October '19	40	8.47	432	91.53
November '19	60	11.67	454	88.33
December '19	80	17.13	467	82.87
January '20	80	16.81	396	83.19
February '20	160	24.92	482	75.08
March '20	161	38.80	254	61.20
April '20	201	72.04	78	27.96
May '20	310	85.64	52	14.36
June '20	183	74.09	64	25.91
July '20	123	64.40	68	35.60
September '20	128	33.16	258	66.84
October '20	132	29.01	323	70.99
November '20	168	42.00	232	58.00
December '20	270	71.05	110	28.95
January '21	302	74.02	106	25.98
February '21	440	83.65	86	16.35
March '21	280	76.09	88	23.91
April '21	228	71.47	91	28.53
May '21	192	65.31	102	34.69
June '21	242	48.21	260	51.79
July '21	122	27.60	320	72.40
September '21	142	33.18	286	66.82
October '21	166	34.87	310	65.13
November '21	263	52.29	240	47.71
December '21	286	48.31	306	51.69
January '22	181	30.83	406	69.17
February '22	206	33.17	415	66.83
March '22	180	29.80	424	70.20
April '22	186	29.15	452	70.85

corresponding to a Fourier period of 5.2 months and with a 2.5-month lead relationship between the two time series.

There was a significant positive correlation ($r = 0.354$, $p = 0.038$) between the number of telemedicine appointments and pandemic worsening expressed as the number of symptomatic patients hospitalized with SARS-CoV-2 in Italy (Figure 3).

The first two peaks of SARS-CoV-2 contagion (March 2020 and November 2021) were immediately followed by an increase in telemedicine appointments. Strikingly, patients were faster to switch from in-person to telemedicine appointments at the third worsening of the Italian pandemic situation. This was reflected by the rise in telemedicine activity preceding the third peak of the pandemic, in Italy (Figure 4).

Discussion

In recent years, teleneuropsychology has been recognized as a valid tool for patients' assessments (16, 21, 22) and cognitive training (17, 18). we demonstrated how patients with dementia transitioned between modalities, moving from face-to-face visits to telemedicine and back to face-to-face appointments, depending on the severity of the pandemic situation. This suggests that telemedicine has the potential to become an integrated component of clinical practice for neuropsychology services. Our results showed that patients preferred telemedicine appointments during the difficult times of the pandemic, as reflected by a significant squared coherence peak and phase angle in the spectrum, mirroring a significant jointly cyclical variation

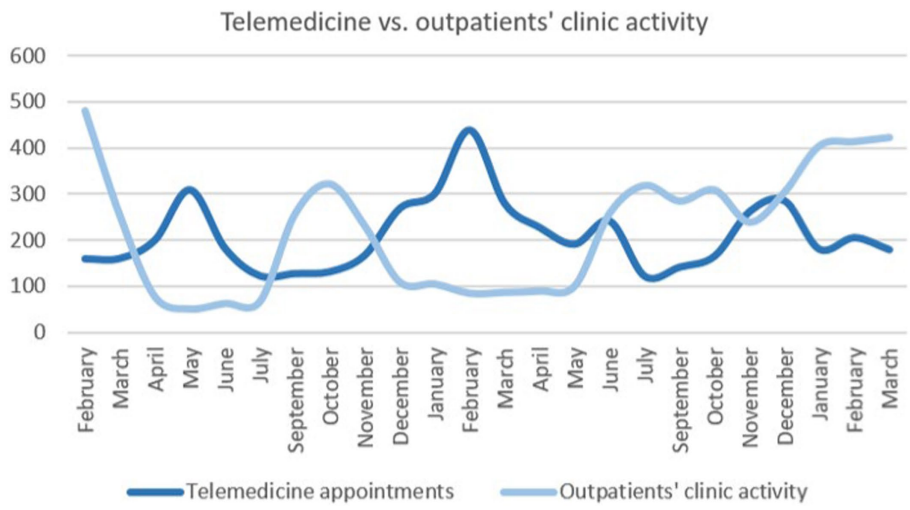


FIGURE 1
Telemedicine and outpatients' clinic activity. It shows the evolution of telemedicine appointments (dark blue) and outpatients' clinic activity (light blue) during the COVID-19 pandemic (February 2020 to May 2022).

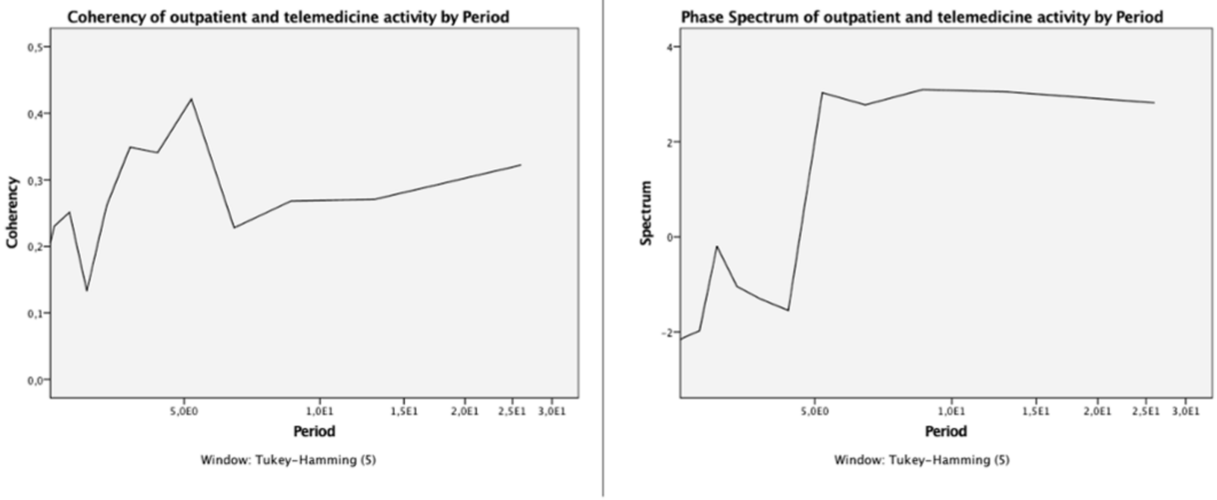


FIGURE 2
Coherency spectrum (left panel) and Phase Spectrum of outpatient and telemedicine activity during the COVID-19 pandemic (February 2020 to May 2022).

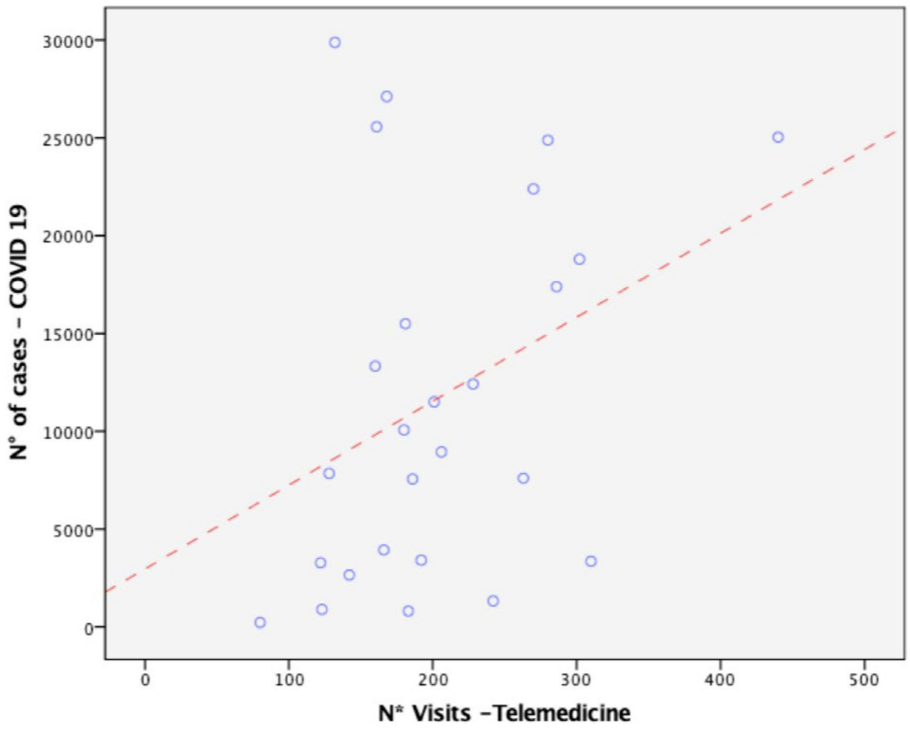


FIGURE 3
Positive association between telemedicine activity and the severity of the COVID-19 pandemic in Italy.

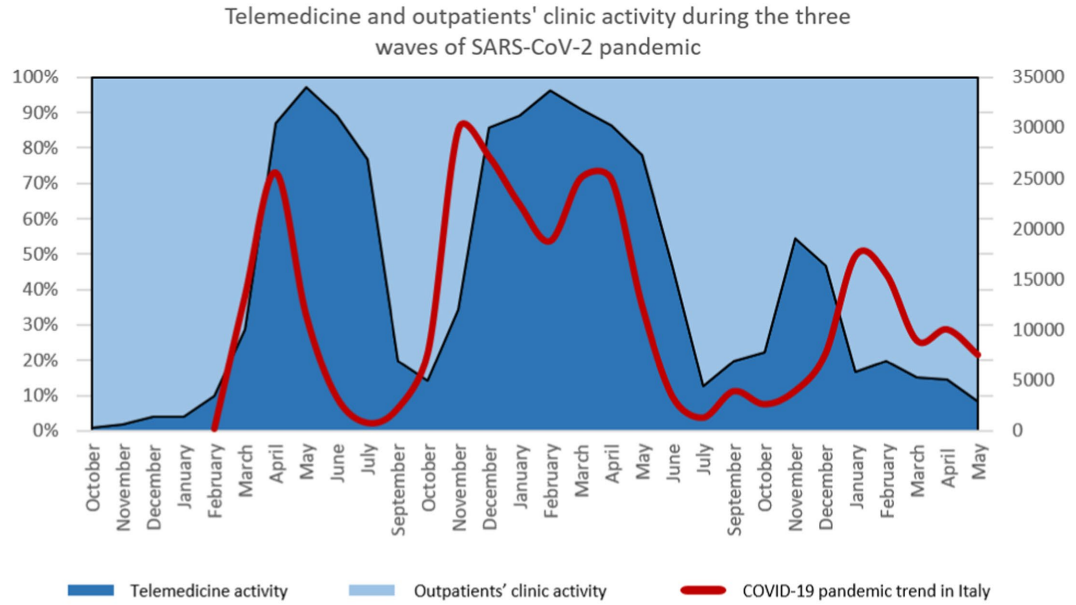


FIGURE 4
Telemedicine activity and pandemic trend in Italy. Percentages of telemedicine appointments (dark blue) and percentages of outpatients' clinic appointments (light blue) are expressed and superimposed with the pandemic trend in Italy (red line), expressed as the numbers of hospitalized COVID-19 patients with symptoms over the national Italian territory.

between outpatients' and telemedicine activity corresponding with the COVID-19 pandemic cycle. Importantly, our data revealed that the total number of patients under our Unit's care remained consistent over the past 2 years. This suggests that telemedicine can facilitate continuity of care for these vulnerable and aging patients, especially during challenging periods when accessing outpatient clinics becomes difficult. Telemedicine activity increased in parallel with the severity of the pandemic, as shown by the positive association between

telemedicine activity and the severity of the COVID-19 pandemic in Italy. Indeed, during the first two waves of the pandemic, the rise in telemedicine appointments immediately followed the pandemic curve. These data showed how fast the Cognitive Disorders Unit could propose alternative treatments' modality to patients and how patients positively responded to these offers. During the peaks of contagion, our Institute restricted access to outpatient clinics, but the Cognitive Disorders Unit remained open to patients throughout the pandemic. Patients were consistently provided with the option to choose between in-person and telemedicine appointments. Between the pandemic waves, patients notably preferred returning to the hospital, continuing their treatments in person at the outpatient clinic. These findings demonstrate that even during the pandemic, every patient was able to continue their treatment plan, and patients adapted effectively to the new system, ensuring a consistent continuity of care.

Interestingly, during the third wave of the pandemic in Italy, patients anticipated the increase in contagions. They made the decision, as soon as the pandemic curve began to rise again, to transition back to telemedicine appointments. This data indicates that telemedicine has become a natural choice for patients when deciding the modality of their visits (23). Nowadays, telemedicine should not be viewed merely as a replacement for outpatient visits; rather, it should be integrated into regular clinical practice, helping to provide a continuity of care and protection for vulnerable patients (7). In the patients' and healthcare professionals' minds, telemedicine was often perceived as an alternative or substitution of in-person appointments. Such dichotomie might create barriers in the clinical practice and might lead patients to mistrust this system. Telemedicine should be integrated as a supplementary element in clinical practice. The intensity, timing and specificity of the use of telemedicine should be personalized according to the patients diagnosis and condition. In the case of neuropsychological assistance of patients with dementia, our study suggests that telemedicine can be integrated with outpatients clinic activity. Study limitations lie in the fact that we did not investigate patients' and caregivers' satisfaction of the telemedicine services. Future studies should incorporate satisfactory questionnaires for both patients and caregivers, assessing the quality of neuropsychological services delivered via telemedicine and evaluating the usability of such services, including the telehealth technology.

Many efforts remain to be achieved by the healthcare systems to recognize this modality of treatment as such and implement reimbursements and payments for patients (23). Moreover, more studies are needed to define the best use of telemedicine according to the pathology being addressed. Our study showed how patients positively adhered to remote treatments for cognitive disorders. The manner in which patients transitioned back to outpatient clinic visits implies that telemedicine could be seamlessly integrated into patients' routine care alongside in-person visits, ensuring comprehensive continuity of care. However, it's essential to acknowledge that telemedicine might not be suitable for all conditions and there is still the need to define its best application.

Conclusion

Our study suggests that telemedicine might constitute an effective tool to promote continuity of care for patients with dementia during the pandemic. We showed that in a short period of time, patients fully adopted this modality of treatment, switching between telemedicine and outpatients' clinic depending on the pandemic situation. To facilitate healthcare systems in providing financial support to clinics and patients for promoting telemedicine, further studies are imperative. These studies should evaluate the amount of energy saving, the social contribution and the improvements in quality of life of patients and caregivers that might be correlated to the use of telemedicine.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Ethics committee of the San Raffaele Hospital. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

DE: Formal analysis, Writing – original draft. EH: Writing – original draft, Writing – review & editing. PR: Data curation, Writing – review & editing. AZ: Project administration, Writing – review & editing. LB: Writing – review & editing. PC: Writing – review & editing. JP: Writing – review & editing. AT: Writing – review & editing. SI: Conceptualization, Data curation, Investigation, Writing – review & editing. FA: Conceptualization, Data curation, Investigation, Methodology, Resources, Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. Arshad Ali S, Bin Arif T, Maab H, Baloch M, Manazir S, Jawed F, et al. Global interest in telehealth during COVID-19 pandemic: an analysis of Google trends™. *Cureus*. (2020) 12:e10487. doi: 10.7759/cureus.10487

2. Fiani B, Siddiqi I, Lee SC, Dhillon L. Telerehabilitation: development, application, and need for increased usage in the COVID-19 era for patients with spinal pathology. *Cureus*. (2020) 12:e10563. doi: 10.7759/cureus.10563

3. Golinelli D, Boetto E, Carullo G, Nuzzolese AG, Landini MP, Fantini MP. Adoption of digital Technologies in Health Care during the COVID-19 pandemic: systematic review of early scientific literature. *J Med Internet Res*. (2020) 22:e22280. doi: 10.2196/22280

4. Gunasekeran DV, Tseng RMWW, Tham YC, Wong TY. Applications of digital health for public health responses to COVID-19: a systematic scoping review of artificial intelligence, telehealth and related technologies. *NPJ Digit Med*. (2021) 4:40. doi: 10.1038/s41746-021-00412-9

5. Omboni S, Padwal RS, Alessa T, Benczúr B, Green BB, Hubbard I, et al. The worldwide impact of telemedicine during COVID-19: current evidence and recommendations for the future. *Connect Health*. (2022) 1:7–35. doi: 10.20517/ch.2021.03

6. Emedoli D, Alemanno F, Houdayer E, Brugliera L, Iannaccone S, Tettamanti A. Mobile application tool for remote rehabilitation after discharge from coronavirus disease-19 rehabilitation unit. *Healthc Technol Lett*. (2022) 9:70–6. doi: 10.1049/htl2.12033

7. Nanda M, Sharma R. A review of patient satisfaction and experience with telemedicine: a virtual solution during and beyond COVID-19 pandemic. *Telemed J E-Health Off J Am Telemed Assoc*. (2021) 27:1325–31. doi: 10.1089/tmj.2020.0570

8. Andrews E, Berghofer K, Long J, Prescott A, Caboral-Stevens M. Satisfaction with the use of telehealth during COVID-19: an integrative review. *Int J Nurs Stud Adv*. (2020) 2:100008. doi: 10.1016/j.ijnsa.2020.100008

9. Alzheimer's Association. 2009 Alzheimer's disease facts and figures. *Alzheimers Dement J Alzheimers Assoc*. (2009) 5:234–70. doi: 10.1016/j.jalz.2009.03.001

10. Grabher BJ. Effects of Alzheimer disease on patients and their family. *J Nucl Med Technol*. (2018) 46:335–40. doi: 10.2967/jnmt.118.218057

11. Pickard Strange M, Booth A, Akiki M, Wieringa S, Shaw SE. The role of virtual Consulting in Developing Environmentally Sustainable Health Care: systematic literature review. *J Med Internet Res*. (2023) 25:e44823. doi: 10.2196/44823

12. Ruggiero F, Zirone E, Molisso MT, Carandini T, Fumagalli G, Pietroboni A, et al. Telemedicine for cognitive impairment: a telephone survey of patients' experiences with neurological video consultation. *Neurol Sci Off J Ital Neurol Soc Ital Soc Clin Neurophysiol*. (2023) 44:3885–94. doi: 10.1007/s10072-023-06903-9

13. Patel KB, Turner K, Alishahi Tabriz A, Gonzalez BD, Oswald LB, Nguyen OT, et al. Estimated indirect cost Savings of Using Telehealth among Nonelderly Patients with Cancer. *JAMA Netw Open*. (2023) 6:e2250211. doi: 10.1001/jamanetworkopen.2022.50211

14. Elbaz S, Cinalioglu K, Sekhon K, Gruber J, Rigas C, Bodenstein K, et al. A systematic review of telemedicine for older adults with dementia during COVID-19: an alternative to in-person health services? *Front Neurol*. (2021) 12:761965. doi: 10.3389/fneur.2021.761965

15. Brearly TW, Shura RD, Martindale SL, Lazowski RA, Luxton DD, Shenal BV, et al. Neuropsychological test administration by videoconference: a systematic review and meta-analysis. *Neuropsychol Rev*. (2017) 27:174–86. doi: 10.1007/s11065-017-9349-1

16. Marra DE, Hamlet KM, Bauer RM, Bowers D. Validity of teleneuropsychology for older adults in response to COVID-19: a systematic and critical review. *Clin Neuropsychol*. (2020) 34:1411–52. doi: 10.1080/13854046.2020.1769192

17. Manenti R, Gobbi E, Baglio F, Macis A, Ferrari C, Pagnoni I, et al. Effectiveness of an innovative cognitive treatment and telerehabilitation on subjects with mild cognitive impairment: a Multicenter, randomized, Active-Controlled Study. *Front Aging Neurosci*. (2020) 12:585988. doi: 10.3389/fnagi.2020.585988

18. Cotelli M, Manenti R, Brambilla M, Gobbi E, Ferrari C, Binetti G, et al. Cognitive telerehabilitation in mild cognitive impairment, Alzheimer's disease and frontotemporal dementia: a systematic review. *J Telemed Telecare*. (2019) 25:67–79. doi: 10.1177/1357633X17740390

19. Parsons MW, Gardner MM, Sherman JC, Pasquariello K, Grieco JA, Kay CD, et al. Feasibility and acceptance of direct-to-home tele-neuropsychology services during the COVID-19 pandemic. *J Int Neuropsychol Soc JINS*. (2022) 28:210–5. doi: 10.1017/S1355617721000436

20. Dati COVID-19 Italia (2022). Presidenza del Consiglio dei Ministri - Dipartimento della Protezione Civile. Available at: https://github.com/pcm-dpc/COVID-19

21. Parks AC, Davis J, Spresser CD, Stroescu I, Ecklund-Johnson E. Validity of in-home Teleneuropsychological testing in the wake of COVID-19. *Arch Clin Neuropsychol*. (2021) 36:887–96. doi: 10.1093/arclin/acab002

22. Harrell KM, Wilkins SS, Connor MK, Chodosh J. Telemedicine and the evaluation of cognitive impairment: the additive value of neuropsychological assessment. *J Am Med Dir Assoc*. (2014) 15:600–6. doi: 10.1016/j.jamda.2014.04.015

23. Ahmed S, Sanghvi K, Yeo D. Telemedicine takes Centre stage during COVID-19 pandemic. *BMJ Innov*. (2020) 6:252–4. doi: 10.1136/bmjinnov-2020-000440

frontiers | Frontiers in Public Health

TYPE Opinion
PUBLISHED 08 January 2024
DOI 10.3389/fpubh.2023.1270450

OPEN ACCESS

EDITED BY
David Černý,
Czech Academy of Sciences, Czechia

REVIEWED BY
Weizheng Wang,
City University of Hong Kong, Hong Kong SAR, China

*CORRESPONDENCE
Plinio Pelegrini Morita
✉ plinio.morita@uwaterloo.ca

†These authors have contributed equally to this work and share first authorship

RECEIVED 31 July 2023
ACCEPTED 19 December 2023
PUBLISHED 08 January 2024

CITATION
Morita PP, Kaur J and Miranda PADSES (2024) Enhancing public health research: a viewpoint report on the transition to secure, cloud-based systems.
Front. Public Health 11:1270450.
doi: 10.3389/fpubh.2023.1270450

Enhancing public health research: a viewpoint report on the transition to secure, cloud-based systems

Plinio Pelegrini Morita[1,2,3,4,5*†], Jasleen Kaur[1†] and Pedro Augusto Da Silva E Souza Miranda[1†]

[1]School of Public Health Sciences, University of Waterloo, Waterloo, ON, Canada, [2]Department of Systems Design Engineering, University of Waterloo, Waterloo, ON, Canada, [3]Research Institute for Aging, University of Waterloo, Waterloo, ON, Canada, [4]Centre for Digital Therapeutics, Techna Institute, University Health Network, Toronto, ON, Canada, [5]Institute of Health Policy, Management, and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

KEYWORDS

UbiLab research environment, public health research, Personal Health Information (PHI), data governance in healthcare, cybersecurity standards for PHI, azure cloud-based research

1 Introduction

From smart devices to smart home technologies, Personal Health Information (PHI) is being collected on a previously unprecedented level (1–8). The individual and population metrics gathered can transform public health research, providing valuable insights into population health, disease trends, and effective interventions. Despite advancements in data availability, collection, and analysis (9–13), the use of PHI for research has been hindered by storage, cybersecurity, and data governance challenges (6–8, 14–18). PHI has traditionally been stored in local databases or filesystems which lack sufficient cybersecurity and data governance. This leaves sensitive health information vulnerable to unauthorized access and malicious attacks (3, 5, 19–28). Local databases also lack scalability, making it difficult to accommodate large volumes of data and perform computationally intensive tasks (10, 29–32).

Cloud-based solutions have emerged to address these challenges (33). Our rapid literature review (34–39) identified several frameworks such as InfusedHeart (34), I-Health (38), and Blockchain-Based Personalized Federated Learning (39), which leverage cloud computing for public health applications. While these solutions offer insights into the potential of cloud services, it's crucial to note that their compliance with healthcare standards such as PIPEDA (17), HIPAA (18), and GDPR (15) varies. Some may partially meet these standards, addressing certain aspects of Personal Health Information (PHI) management, but there remains a lack of a comprehensive solution fully aligned with all these regulatory requirements. This gap underscores the need for a tailored approach, such as the UbiSECE framework, which is specifically designed to address the complex requirements of PHI in public health research, ensuring full compliance with these critical healthcare standards.

Microsoft Azure (33, 40), a leading cloud platform, has gained popularity in public health research due to its robust infrastructure and compliance with industry standards (41). The Ubiquitous health technology lab (UbiLab) at the University of Waterloo has faced and addressed the challenges associated with the use of PHI for public health research (42). This paper aimed to share our experiences and insights gained in the adoption of UbiSECE, a cloud-based data governance framework. UbiSECE is based on Microsoft

Azure's governance architecture guidelines and incorporates NIST 800–53 compliance with healthcare standards such as PIPEDA, HIPAA, and GDPR (15, 17, 18, 40, 41). It also implements role-based access controls and centralizes data storage. The framework shared here serves as a blueprint for the field of public health research to create streamlined and efficient platforms for managing PHI. To assist readers, a Glossary of specialized terms and acronyms used throughout this paper, such as PHI, PIPEDA, HIPAA, GDPR, NIST and others, is provided at the end of the document. This Glossary aims to clarify key concepts and ensure a clear understanding of the technical aspects discussed.

2 Phases

2.1 Phase 1- local system

2.1.1 Scenario and benefits

In this initial phase, each UbiLab researcher operated independently, using their own system for research data and resources. This approach resulted in a spread of data across individual computers with minimal centralized storage. Despite the challenges this posed, there were implicit benefits in this setup. Researchers experienced a certain level of comfort and familiarity with their own systems, which might have allowed for ease of use and adaptability to individual working styles. Furthermore, this decentralized approach could have been perceived as more cost-effective initially, as it relied on existing resources without additional investment in centralized infrastructure.

2.1.2 Challenges

The limited utilization of cloud resources and data sharing created a fragmented landscape of resources, often leading to a "sandbox" effect between projects. This phase was marked by a lack of standardized data storage solutions, such as SQL or JSON databases, and an absence of unified data governance frameworks. Cybersecurity measures were not adequately established, leaving sensitive data potentially vulnerable. Additionally, the management of credentials was limited and primarily facilitated by the university's Information Systems & Technology (IST) department, indicating a reliance on external support for essential security processes. There was also a notable deficiency in the IT infrastructure necessary for effectively managing study participants' informed consent and re-consent, which are critical components of ethical research practices. Moreover, the detailed management of data processing costs was inefficient, leading to potential resource wastage and budgetary concerns.

2.2 Phase 2- UbiLab azure general environment

2.2.1 Scenario and benefits

In Phase 2, the UbiLab research team made a significant leap by upgrading to a unified cloud-based research environment utilizing Microsoft Azure. This strategic shift enabled the centralization of data storage and sharing within individual research project groups. Additionally, the team implemented enhanced data governance mechanisms, marking a pivotal change in the management and accessibility of research data.

The transition to a cloud-based architecture brought about several key benefits. Firstly, it facilitated improved access to Personal Health Information (PHI) and the utilization of big data, which are crucial for advanced public health research. Secondly, the cloud environment simplified collaboration with third parties and industry partners, making the sharing and analysis of data more efficient. Another significant advantage was the reduction in sandbox sharing of resources and data, which streamlined the research process and reduced redundancies. Moreover, the ability to collect informed consent and PHI remotely and automatically through the development of scripts and Application Programming Interfaces (APIs) was a noteworthy advancement. This not only enhanced the efficiency of data collection but also aligned with the evolving needs of digital health research.

2.2.2 Challenges

In Phase 2, while the transition to Azure improved certain aspects, several significant challenges persisted. Obtaining or producing high-quality, ongoing, or real-time datasets from Personal Health Information (PHI) remained a complex task. The IT management responsibilities, such as the development of scripts, APIs, and cloud-based pipelines for data transfer, continued to pose substantial barriers for public health researchers.

Furthermore, there were gaps in data governance frameworks, specifically in the alignment with standards like ISO/IEC 38500, as well as in cybersecurity standards and credential management. Another substantial challenge was the cost implications associated with each researcher establishing their resource group. This setup often involved unique virtual machines (VMs), storage accounts, Databricks instances, database servers, app services, and a variety of mostly underutilized resources. This not only led to inefficiencies but also contributed to increased costs.

In addition, there was limited IT infrastructure support for managing study participants' informed consent and re-consent processes, which is a crucial aspect of public health research. The cost management for processing the research data also remained inefficient, further complicating the overall effectiveness of the transition to the cloud-based environment.

2.3 Phase 3- UbiLab secure NIST environment

2.3.1 Scenario and benefits

In Phase 3, the focus shifted to enhancing cybersecurity and data governance within the cloud environment to manage Personal Health Information (PHI) more effectively. This phase saw the incorporation of comprehensive security recommendations outlined in the National Institute of Standards and Technology (NIST) Special Publication 800–171. Additionally, it integrated compliance with multiple key regulatory frameworks, including Ontario's Freedom of Information and Protection of Privacy Act, the Personal Information Protection and Electronic Documents Act (PIPEDA), the General Data Protection Regulation (GDPR), the Personal Data Sovereignty Inter-Organizational Governance

Framework for Public Health Research (43), and Azure's cloud governance framework. These integrations represented a significant advancement in the project's approach to data security and governance.

The introduction of these robust cybersecurity standards and data governance frameworks had a marked impact on enhancing the security and management of PHI. This development significantly improved trust with collaborators, as the enhanced security measures provided assurances for safer data exchanges. It also led to an increase in operational efficiency by effectively mitigating risks associated with unauthorized access. The alignment with international and regional data protection regulations further bolstered the framework's credibility and reliability, making it a more robust solution for managing sensitive health data.

2.3.2 Challenges

In Phase 3, as the use of Azure increased, several new challenges emerged. The implementation of a virtual private network (VPN) for resource access became necessary, which in turn required the installation of a firewall and various security and performance applications, including Azure's NIST 800–171 blueprint initiative. This shift led to a significant escalation in the costs and complexity of managing networks, controlling user access, and configuring resources.

Additionally, public health researchers at UbiLab often lacked the necessary expertise to navigate these complex technical systems. This gap in knowledge necessitated one-on-one meetings to assist each researcher through the VPN setup process, as the existing documentation proved inadequate due to its technical jargon. The limited internet access from Azure resources further complicated matters, leading to stalled workflows and prolonged wait times for issue resolution.

Another challenge was the complexity involved in configuring and maintaining the resources deployed in Azure. Each new resource required extensive documentation and security measures such as firewall protection, logging, tagging, and password management. These tasks were often inadequately performed due to a shortage of human resources, which added to the challenges of maintaining a secure and efficient cloud-based environment.

2.4 Phase 4- secure UbiLab environment with a centralized data ecosystem

2.4.1 Scenario and benefits

In Phase 4, the appointment of a dedicated cloud architect played a pivotal role. This specialist expedited the setup of VPNs and network configurations, significantly improving user support, resource configuration, and maintenance. Concurrently, there was a notable enhancement in cybersecurity measures. Additionally, a data governance program was established, featuring a committee composed of representative stakeholders. This committee was tasked with aligning UbiLab's data strategy with the internal objectives of stakeholders and developing a comprehensive data-sharing agreement.

The implementation of these measures in Phase 4 led to the creation of a secure, centralized cloud environment that is specifically designed for managing Personal Health Information (PHI) in public health research. A notable achievement during this phase was the reduction in Azure resource costs by ∼30%−40%, which was primarily due to decreased data redundancy costs. Additionally, the establishment of the data governance program significantly streamlined the process of collecting data from data custodians, effectively reducing obstacles, and enhancing the efficiency of data management overall.

2.4.2 Challenges

In Phase 4, the team faced a range of barriers related to data governance in healthcare, including concerns over user privacy, meeting data security requirements, setting appropriate data standards, and managing the intricacies of cross-institutional data collection and aggregation. The challenge of managing study participants' informed consent and the related costs was also significant.

To address these challenges, the team worked to establish semi-trusted relationships with stakeholders. This approach was supported by governance mechanisms such as clearly defined metrics, compliance monitoring, and auditing processes. These strategies were aimed at creating a robust and reliable framework for data governance, ensuring comprehensive management of all data aspects, from privacy to consent, in line with the broader objectives of the UbiLab project.

3 UbiSECE framework

The UbiLab Secure Cloud Environment (UbiSECE) was developed as the cumulative result of our experiential learning in PHI-based research (Phase 1–4). UbiSECE prioritizes data security; securely storing PHI data and providing controlled, role-based access defined by our cloud architect. Azure's governance functionalities enable us to define roles and responsibilities, monitor data usage and costs, and meet the traceability, accountability, auditability, and compliance needs of our stakeholders.

UbiSECE's Azure Architecture comprises four main environments: UbiLab External, UbiLab Production, UbiLab Internal, and UbiLab Research (Figure 1).

UbiLab_external: This environment hosts resources, applications, APIs, or other services that are externally accessible without the need for a VPN and user account. It is designed with the highest degree of access flexibility in mind, allowing for wider data collection and interaction with external systems. However, given the open nature of this environment, no PHI is stored here. Any data collected in this environment via user interactions or APIs are transferred securely via Azure's private links to our secure data storage, thus maintaining the integrity and security of our data.

UbiLab_production: This domain hosts resources ready for production, serving as the active interface for deployed applications. It may include Python scripts collecting data from user sensors or a Jupyter notebook for a data science project shared

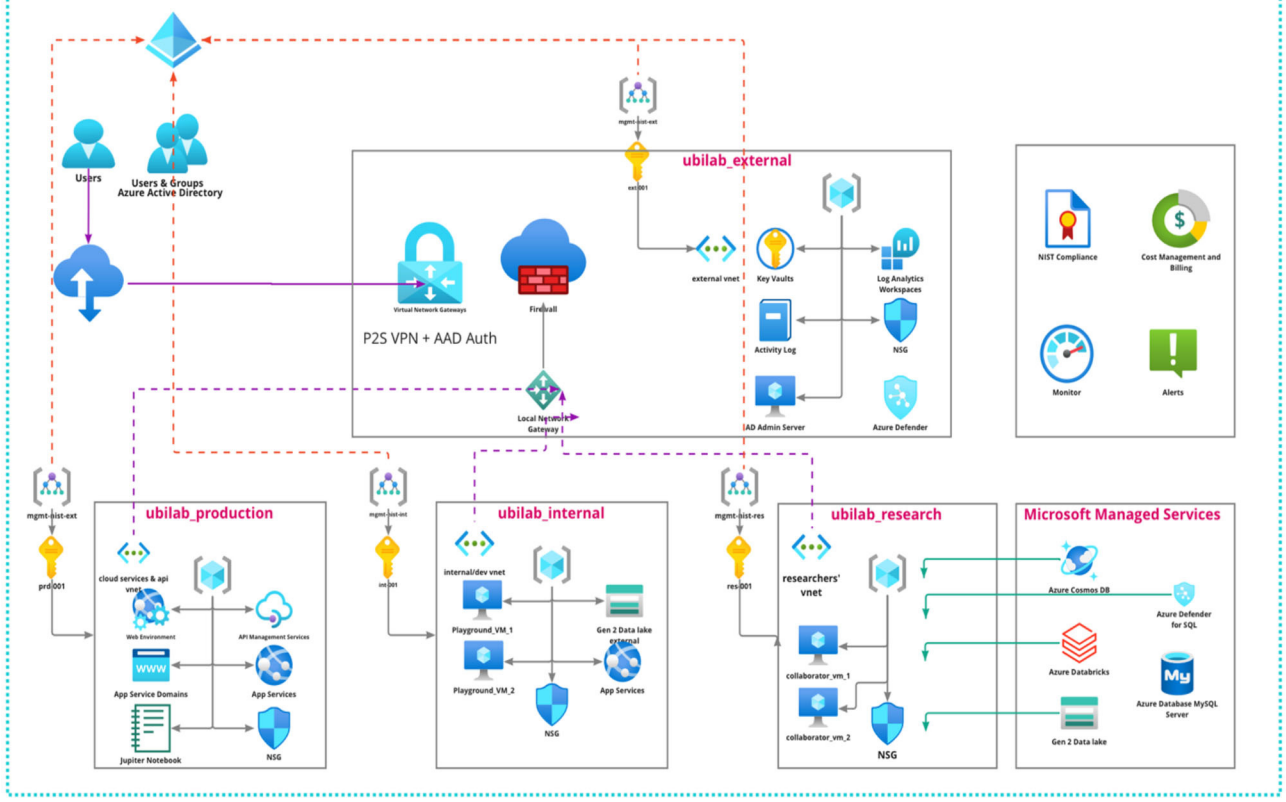


FIGURE 1
UbiSECE azure architecture for public health research.

with industry partners. This environment requires authentication and strict access control for any interaction. Only users with an Azure account, created and managed by our cloud administrator, can access these resources, ensuring that only authorized personnel can access these applications.

UbiLab_internal: This is a controlled environment where internal research projects are executed, hosted separately from the external and production domains. It's secluded from the Internet and does not involve industry partners. It offers collaborators controlled and cached access to portions of UbiLab's PHI data via virtual machines for research purposes. Direct access to centralized data storage is restricted, and any need for writing information into the central data storage requires specific privileges. As in the production environment, access requires passing through security layers and an Azure account created by our cloud administrator.

UbiLab_research: Dedicated to fostering academic research, this domain is exclusively reserved for UbiLab's Master's and Ph.D. students to conduct their thesis research. Although it shares the same restricted access controls as the internal and production environments, the UbiLab_research domain is distinct due to the nature of the work it hosts. It supports a wide range of academic activities, from experimental data science work to more structured, thesis-driven research projects. As in the other environments, access to resources in this domain is only possible through security layers and with an Azure account created by our cloud administrator.

4 Discussion

4.1 Strengths and scalability

Storing and managing Personal Health Information (PHI) is a major challenge in public health research. Here we outlined the progress toward the development of UbiSECE: a private and secure cloud-based data governance framework. UbiSECE employs role-based access controls to centralized data storage to ensure the security of PHI while enabling public health research.

One of the key strengths of our cloud-based solution is its scalability and accessibility. UbiSECE allows public health researchers to store and analyze large volumes of data efficiently and facilitates seamless collaboration among different teams. The UbiSECE framework also paves the way for future integration with PHR systems, enabling seamless sharing and utilization of medical records for research purposes. The scalability of the UbiSECE framework is twofold, encompassing both vertical and horizontal dimensions. Vertically, it can expand its capacity to accommodate larger datasets and more complex processing needs. Horizontally, the framework is designed to integrate emerging technologies and adapt to new research demands, ensuring its utility in the evolving landscape of public health research.

Another strength lies in the framework's compliance with healthcare standards and regulations including NIST 800–53, PIPEDA, HIPAA, and GDPR. The framework ensures that PHI is handled according to established security protocols and sets a

high standard for ethical and responsible data governance. Looking forward, UbiSECE is strategically positioned to evolve with the advancements in technology and the increasing demands for data in public health research. Its design and infrastructure are geared toward adaptability and scalability, ensuring its relevance and efficacy in the future.

4.2 Challenges in data access and security

Despite these benefits, managing data access for new collaborators or researchers remains complex. Currently, access is granted by cloud administrators through registered user accounts with limited privileges. Streamlining and automating this process could enhance collaboration and expedite research activities. Furthermore, although the framework ensures data security, ongoing efforts are needed to refine governance programs and fully comply with NIST-800–171 and NIST-800–52 standards. Continuous improvement and regular audits are essential to mitigate emerging cybersecurity threats and maintain the integrity of the cloud infrastructure.

4.3 Evaluation and feedback

In recognizing the importance of continuous improvement, our framework includes robust evaluation and feedback mechanisms. Weekly leadership meetings are conducted with researchers to discuss the functioning and efficacy of the UbiSECE framework. These meetings serve as a platform for researchers to provide feedback on their experiences, challenges faced, and suggestions for improvements. Adjustments to the system and processes are made as needed, based on this feedback. Additionally, monthly meetings are held with stakeholders to ensure their perspectives and requirements are effectively integrated into the framework. This iterative process of gathering and implementing feedback ensures that the UbiSECE framework remains responsive to the needs of its users and up to date with the latest developments in public health research.

4.4 Training and user support

UbiLab's transition to the UbiSECE framework is supported by training sessions conducted by our dedicated cloud architect. These targeted one-on-one sessions equip researchers with the necessary skills to navigate and utilize the cloud-based system effectively. These sessions cover a range of topics, from basic navigation of the Azure cloud environment to advanced data management and security protocols. Additionally, comprehensive user guide to provide ongoing support and address common technical queries were provided to the researchers.

4.5 Practical applications

In the context of UbiLab's current projects (44–52), the UbiSECE framework is actively employed in a variety of research areas, demonstrating its practicality and versatility. These initiatives include using IoT for monitoring climate change behaviors and chronic disease risks (45, 47), analyzing big data for public health studies on air pollution effects (51), and applying smart home technologies for older adult healthcare (52). This range of applications highlights UbiSECE's effectiveness in enhancing both research efficiency and data security, showing its potential as a key tool in public health research.

4.6 Ethical considerations

The transition to cloud-based systems for managing Personal Health Information (PHI) necessitates a comprehensive examination of ethical considerations that extend beyond informed consent. The adoption of cloud computing in healthcare brings to the fore critical questions regarding data ownership, patient confidentiality, and the potential for data misuse (53). To ensure patient confidentiality within cloud environments, robust encryption, and sophisticated access control mechanisms must be employed, alongside clear policies on data ownership that honor patient rights and adhere to legal standards. Moreover, the risk of data misuse—whether by intent or accident—necessitates the implementation of stringent governance frameworks and the conduction of regular audits. These steps are imperative to uphold compliance with ethical standards and legal requirements. Addressing these ethical dimensions is crucial to maintain trust in cloud-based healthcare systems and to safeguard the integrity of PHI.

4.7 Future directions and cost-effectiveness

Future research should explore advanced data analytics techniques and machine learning algorithms within the cloud-based framework to extract valuable insights from healthcare data. Azure's machine learning capabilities could be leveraged to develop predictive models and decision support systems for public health research. Investigating the interoperability and data exchange standards between different cloud platforms and PHR systems could facilitate data sharing and collaboration. Finally, continuous evaluation of the framework's performance and security measures and monitoring of emerging healthcare regulations and standards will ensure its effectiveness and adaptability in an evolving healthcare landscape.

Additionally, it's pertinent to note the financial aspects of the UbiSECE framework implementation. Initially, UbiLab incurred upfront costs for data migration, staff training, and system setup in adopting cloud technology. However, these were effectively balanced by long-term savings, including a ∼30%—40% reduction in Azure resource costs, primarily due to decreased data redundancy and enhanced operational efficiencies. The scalability of cloud solutions also mitigated the need for substantial future investments in IT infrastructure, further underscoring the cost-effectiveness of this transition.

The frameworks developed here can support interdisciplinary research and accelerate knowledge discovery while safeguarding public health information.

Author contributions

PMo: Project administration, Resources, Supervision. JK: Writing—original draft, Conceptualization, Methodology, Visualization, Writing—review & editing. PMi: Writing—original draft, Data curation, Methodology, Visualization, Writing—review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

1. Laplante PA, Laplante N. The internet of things in healthcare: potential applications and challenges. *IT Prof.* (2016) 18:2–4. doi: 10.1109/MITP.2016.42

2. Banerjee S, Hemphill T, Longstreet P. Wearable devices and healthcare: data sharing and privacy. *The Inf Soc.* (2018) 34:49–57. doi: 10.1080/01972243.2017.1391912

3. Ajunwa I, Crawford K, Ford JS. Health and big data: An ethical framework for health information collection by corporate wellness programs. *The J Law Med Ethics.* (2016) 44:474–80. doi: 10.1177/1073110516667943

4. Khoury MJ, Ioannidis JP. Big data meets public health. *Science.* (2014) 346:1054–5. doi: 10.1126/science.aaa2709

5. Tse D, Chow CK, Ly TP, Tong CY, Tam KW. The Challenges of Big Data Governance in Healthcare. In *2018 17th IEEE International Conference On Trust, Security And Privacy In Computing And Communications/12th IEEE International Conference On Big Data Science and Engineering (TrustCom/BigDataSE).* Piscataway, NJ: IEEE (2018), 1632–1636.

6. Dobson R, Wihongi H, Whittaker R. Exploring patient perspectives on the secondary use of their personal health information: an interview study. *BMC Med Inform Decis Mak.* (2023) 23:1–14. doi: 10.1186/s12911-023-02143-1

7. Winter JS, Davidson E. Governance of artificial intelligence and personal health information. *Digital Policy Reg Gov.* (2019) 21:280–90. doi: 10.1108/DPRG-08-2018-0048

8. Winter JS, Davidson E. Big data governance of personal health information and challenges to contextual integrity. *The Inf Soc.* (2019) 35:36–51. doi: 10.1080/01972243.2018.1542648

9. *Blockchain-Enabled Genomic Data Sharing and Analysis Platform and Semantic Scholar.* (2023). Available online at: https://www.semanticscholar.org/paper/Blockchain-enabled-genomic-data-sharing-and/d9d9e6240435eccb2d94ff0a53829edc529dd046 (accessed December 14, 2023).

10. Van Panhuis WG, Paul P, Emerson C, Grefenstette J, Wilder R, Herbst AJ, et al. A systematic review of barriers to data sharing in public health. *BMC Public Health.* (2014) 14:1–9. doi: 10.1186/1471-2458-14-1144

11. Jaiman V, Urovi V. A consent model for blockchain-based health data sharing platforms. *IEEE access.* (2020) 8:143734–45. doi: 10.1109/ACCESS.2020.3014565

12. Xia QI, Sifah EB, Asamoah KO, Gao J, Du X, Guizani M. MeDShare: Trust-less medical data sharing among cloud service providers via blockchain. *IEEE Access.* (2017) 5:14757–67. doi: 10.1109/ACCESS.2017.2730843

13. Lu Y, Wang W, Bhargava B, Xu D. Trust-based privacy preservation for peer-to-peer data sharing. *IEEE Trans Syst Man Cybernetics Part A Syst Hum.* (2006) 36:498–502. doi: 10.1109/TSMCA.2006.871795

14. Frost J, Massagli M. Social uses of personal health information within PatientsLikeMe, an online patient community: what can happen when patients have access to one another's data. *J Med Internet Res.* (2008) 10:e1053. doi: 10.2196/jmir.1053

15. *Art. 4 GDPR - Definitions - GDPR.eu.* (2023). Available online at: https://gdpr.eu/article-4-definitions/ (accessed December 14, 2023).

16. *Personal Information Protection and Electronic Documents Act.* (2023). Available online at: https://laws-lois.justice.gc.ca/eng/acts/p-8.6/FullText.html (accessed December 14, 2023).

17. *PIPEDA Fair Information Principles - Office of the Privacy Commissioner of Canada.* (2023). Available online at: https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/p_principle/ (accessed December 14, 2023).

18. *HIPAA Home and HHS.gov.* (2023). Available online at: https://www.hhs.gov/hipaa/index.html (accessed December 14, 2023).

19. Demchenko Y, De Laat C, Membrey P. Defining Architecture Components of the Big Data Ecosystem. In *2014 International conference on collaboration technologies and systems (CTS).* Minneapolis, MN: IEEE (2014), 104–12.

20. Dash S, Shakyawar SK, Sharma M, Kaushik S. Big data in healthcare: management, analysis and future prospects. *J Big Data.* (2019) 6:1–25. doi: 10.1186/s40537-019-0217-0

21. García S, Ramírez-Gallego S, Luengo J, Benítez JM, Herrera F. Big data preprocessing: methods and prospects. *Big Data Anal.* (2016) 1:1–22. doi: 10.1186/s41044-016-0014-0

22. *Data Privacy Issues in the Age of Data Brokerage: An Exploratory Literature Review* and *Request PDF.* (2023). Available online at: https://www.researchgate.net/publication/327779549_Data_Privacy_Issues_in_the_Age_of_Data_Brokerage_An_Exploratory_Literature_Review

23. *Privacy and Trust in Healthcare IoT Data Sharing: A Snapshot of the Users' Perspectives.* (2023). Available online at: https://uwspace.uwaterloo.ca/handle/10012/15333 (accessed December 14, 2023).

24. Heeney C, Hawkins N, de Vries J, Boddington P, Kaye J. Assessing the privacy risks of data sharing in genomics. *Pub Health Genomics.* (2010) 14:17–25. doi: 10.1159/000294150

25. *I Know What You Did Last Summer: Risks of Location Data Leakage in Mobile and Social Computing - Open Research Online.* (2023). Available online at: https://oro.open.ac.uk/90252/ (accessed December 14, 2023).

26. Farnden J, Martini B, Choo KKR. Privacy Risks in Mobile Dating Apps. *arXiv [Preprint]. arXiv:1505.02906* (2015). doi: 10.48550/ARXIV.1505.02906

27. IBM: cost of a data Breach Report 2019. *Comp Fraud Secur.* (2019) 2019:4. doi: 10.1016/S1361-3723(19)30081-8

28. Krishnamurthy B, Wills CE. On the leakage of personally identifiable information via online social networks. In: *Proceedings of the 2nd ACM Workshop on Online Social Networks.* Barcelona: ACM (2009), 7–12.

29. Takemiya M, Vanieiev B. Sora Identity: Secure, Digital Identity on the Blockchain In: *2018 IEEE 42nd Annual Computer Software and Applications Conference (COMPSAC).* Tokyo: IEEE (2018), 582–7.

30. Abaid Z, Shaghaghi A, Gunawardena R, Seneviratne S, Seneviratne A, Jha S. Health Access Broker: Secure, Patient-Controlled Management of Personal Health Records in the Cloud In: *13th International Conference on Computational Intelligence*

in Security for Information Systems (CISIS 2020). Advances in Intelligent Systems and Computing, Vol. 1267. Cham: Springer International Publishing (2021), 111–21.

31. *Dynamic Consent in Cybersecurity for Health*. (2023). Available online at: https://www.researchgate.net/publication/335161119_Dynamic_Consent_in_Cybersecurity_for_Health (accessed December 14, 2023).

32. *Cybersecurity and Healthcare Records: Tips for Ensuring Patient Safety and Privacy - Document - Gale OneFile: Health and Medicine*. (2023). Available online at: https://go.gale.com/ps/i.do?id=GALE%7CA507825663andsid=googleScholarandv=2.1andit=randlinkaccess=absandissn=19305583andp=HRCAandsw=wanduserGroupName=anon%7Ec20b9737andaty=open-web-entry (accessed December 14, 2023).

33. *Cloud Computing Services and Microsoft Azure*. (2023). Available online at: https://azure.microsoft.com/en-ca (accessed Januray 17, 2023).

34. Pandya S, Gadekallu TR, Reddy PK, Wang W, Alazab M. InfusedHeart: A novel knowledge-infused learning framework for diagnosis of cardiovascular events. *IEEE Trans Comput Soc Syst*. (2022) 12:1–10. doi: 10.1109/TCSS.2022.3151643

35. Nyatuka DR, De La Harpe R. Service design as a catalyst for patient-centered eHealth innovation: an architectural design framework for cloud-based maternal health information service in underserved setting. *IJISMD*. (2021) 12:62–85. doi: 10.4018/IJISMD.20210701.oa1

36. Yang WJ, Zhao HY, Li ZY. Research on public health information resource service system based on cloud computing. *Adv Mat Res*. (2014) 998:1215–8. doi: 10.4028/www.scientific.net/AMR.998-999.1215

37. Saxena D. Big Data for Digital Transformation of Public Services. In: K Sandhu, editor *Advances in Business Strategy and Competitive Advantage*. London: IGI Global (2021), 250–66.

38. Sarkar JL, Ramasamy V, Majumder A, Pati B, Panigrahi CR, Wang W, et al. I-Health: SDN-based fog architecture for IIoT applications in healthcare. *IEEE/ACM Trans Comput Biol Bioinf*. (2022). doi: 10.1109/TCBB.2022.3193918

39. Lian Z, Wang W, Han Z, Su C. Blockchain-based personalized federated learning for internet of medical things. *IEEE Trans Sust Comput*. (2023) 8, 694–702. doi: 10.1109/TSUSC.2023.3279111

40. *Azure Governance and Microsoft*. (2023). Available online at: https://www.microsoft.com/en-us/americas-partner-blog/2019/07/24/azure-governance/ (accessed December 14, 2023).

41. *National Institute of Standards and Technology (NIST) SP 800-171 - Azure Compliance and Microsoft Learn*. (2023). Available online at: https://learn.microsoft.com/en-us/azure/compliance/offerings/offering-nist-800-171 (accessed December 14, 2023).

42. *Home and Ubiquitous Health Technology Lab*. (2023). Available online at: https://uwaterloo.ca/ubiquitous-health-technology-lab/ (accessed May 26, 2023).

43. Da Miranda PA, Morita PP. A Proposed Personal Data Sovereignty Inter-Organizational Governance Framework for Public Health Research. In *2022 IEEE International Conference on Big Data (Big Data)*. Osaka: IEEE (2022), 1.

44. *Projects and Ubiquitous Health Technology Lab*. (2023). Available online at: https://uwaterloo.ca/ubiquitous-health-technology-lab/projects (accessed December 14, 2023).

45. Kaur J, Sahu KS, Oetomo A, Morita P. A Smart Thermostat-based population-level Behavioural Changes During the COVID-19 Pandemic in the United States: A Proposed Study. In: *Proceedings of the 2022 Workshop on Emerging Devices for Digital Biomarkers*. Portland Oregon: ACM (2022), 7–12.

46. Oetomo A, Kaur J, Wang K, Butt Z, Berry P, Morita P. The case for indoor temperature in heat health warning systems: deployment of a real-time indoor temperature data ecosystem in community housing. *Population Med*. (2023) 5:164245. doi: 10.18332/popmed/164245

47. Oetomo A, Kaur J, Wang K, Butt Z, Berry P, Morita P. Using indoor temperature in heat health warning systems: Deployment in community housing in Canada. *Eur J Pub Health*. (2023) 33:ckad160-848. doi: 10.1093/eurpub/ckad160.848

48. Miranda P, Kaur J, Morita P. UbiSeCEF: Ubilab's secure cloud environment framework for public health research. *Eur J Pub Health*. (2023) 33: ckad160.1209. doi: 10.1093/eurpub/ckad160.1209

49. Kaur J, Sahu K, Oetomo A, Chauhan V, Morita P. Public health monitoring of behavioural risk factors in USA: an exploratory study. *Eur J Pub Health*. (2023) 33: ckad160-574. doi: 10.1093/eurpub/ckad160.574

50. Miranda P, Kaur J, Morita P. UbiSecE: UbiLab's Secure Cloud Environment for Public Health Research in Microsoft Azure. In: *2023 19th International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob)*. Montreal, QC: IEEE (2023), 1–4.

51. Salim S, Zakir Hussain I, Kaur J, Morita PP. Air Pollution Surveillance System: A Big Data Approach to Monitoring Adverse Health Outcomes for Public Health Interventions. in 2022 *IEEE International Conference on Big Data (Big Data)*. Osaka: IEEE (2022), 6808–10.

52. Wang K, Nath P, Kaur J, Cao S, Morita PP. Cloud Native Remote Monitoring Data Ecosystem for Aging Population based on Commercial AAL Sensors. In *2023 45th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)*. Sydney: IEEE (2023), 1–5. doi: 10.1109/EMBC40787.2023.10340481

53. Atanda. Cloud computing in healthcare industry: a systematic literature review. *GJIT*. 13:64–71. doi: 10.18844/gjit.v13i2.8867

Glossary

Cloud Technology: Online computing services for data storage and processing.
PHI (Personal Health Information): Identifiable health and healthcare payment data of individuals.
Azure: A cloud computing service by Microsoft for app services and data management.
NIST 800-53: U.S. standards for information security in federal systems.
GDPR (General Data Protection Regulation): EU law for data protection and privacy.
RBAC (Role-Based Access Control): A system of managing user access based on roles.
HIPAA (Health Insurance Portability and Accountability Act): U.S. law for medical information privacy.
PIPEDA (Personal Information Protection and Electronic Documents Act): Canadian data privacy law for commercial sectors.
API (Application Programming Interface): Rules for software components interaction.
VPN (Virtual Private Network): A secure network connection over the internet.
NIST 800-171: U.S. guidelines for protecting non-classified information.
Data Governance: Management of data availability, usability, integrity, and security.
Cybersecurity: Protection of systems and networks from digital attacks.
Machine Learning: AI that enables software to predict outcomes more accurately.
Data Analytics: Analyzing raw data to find trends and insights.

frontiers | Frontiers in Public Health

TYPE Review
PUBLISHED 13 February 2024
DOI 10.3389/fpubh.2024.1347623

OPEN ACCESS

EDITED BY
Denise Veelo,
Amsterdam University Medical Center, Netherlands

REVIEWED BY
Saber Soltani,
Tehran University of Medical Sciences, Iran
David Alfredo Medina Ortiz,
University of Magallanes, Chile

*CORRESPONDENCE
Radha Ambalavanan
✉ radha@selfresearch.org

RECEIVED 01 December 2023
ACCEPTED 23 January 2024
PUBLISHED 13 February 2024

CITATION
Ambalavanan R, Snead RS, Marczika J and Malioukis A (2024) Epidemiological contemplation for a currently pragmatic COVID-19 health passport: a perspective. *Front. Public Health* 12:1347623. doi: 10.3389/fpubh.2024.1347623

Epidemiological contemplation for a currently pragmatic COVID-19 health passport: a perspective

Radha Ambalavanan*, R Sterling Snead, Julia Marczika and Alex Malioukis

Research Department, The Self Research Institute, Broken Arrow, OK, United States

The coronavirus disease 2019 (COVID-19) has caused a global pandemic that has wreaked havoc on the lives of millions of people around the world. Confinement measures aim to reduce the epidemic's spread and minimize the burden of morbidity and mortality. In response to the challenges caused by the pandemic, digital health passports have been developed exponentially. We highlight the latent epidemiological barriers to health passports to achieve standardized digital care platforms. This review paper not only highlights the epidemiological barriers but also articulates the possible infrastructure required to make the International Standard for a multi-factor authenticated and validated health passport.

KEYWORDS

SARS-CoV-2, COVID-19, health passport, health certification, COVID-19 status certification, digital health passport, epidemiological challenges

1 Introduction

At the start of 2020, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) belonging to the *Coronaviridae* family arose and led to coronavirus disease 2019 (COVID-19). This virus was first identified in Wuhan, China and has since spread worldwide. As of November 2022, more than 600 million cases of COVID-19 have been reported, with more than 6.5 million deaths (1–3).

The impact of the COVID-19 pandemic on mortality and morbidity is dramatically increasing over time. The consequences of COVID-19 are catastrophic, as the lockdown measures to contain the spread of the virus not only crippled the economy but also curtailed civil liberties and confined people to their homes. The devastating impacts of the COVID-19 pandemic accelerated the research, production, and distribution of new vaccinations, which occurred at a rate extraordinary in the history of humanity. Currently, millions of people around the world are being vaccinated against COVID-19; as of November 2022, more than 12 billion (12,885,748,541) vaccine doses had been administered (4, 5). It is believed that this vaccination measure will pave the way for economic recovery, restoration of people's social life, physical and mental well-being, and the reinstitution of freedoms. As a result, governments throughout the world have been looking into the prospect of health passports to allow more freedom of movement both within their countries and internationally (6–8).

1.1 Health passport for the COVID-19 vaccine to safely resume activities

According to the literature analysis by Karopoulos et al. (9) on the COVID-19 digital certificate, a significant number of countries have devised solutions that are either paper based or digital, validated by electronic means, and support at least one kind of vaccination proof, diagnostic test, or immunity certificate, as follows: (i) vaccination certificates, which state whether an individual is vaccinated or not; (ii) diagnostic test certificates, which report whether an individual has undergone a specific type of testing; and (iii) immunity certificates, also termed immunity passports, which authenticate an individual's past infection status and the development of antibodies. Digital health passes could become an important vector for post-pandemic life and prevention for subsequent pandemics (10, 11).

1.2 Domains for implementation and evaluation of health passports

The World Health Organization (WHO), the International Air Traffic Association (IATA), and the World Economic Forum have explored possible standards and mechanisms for implementing immunity passport solutions, which reflects the probability of their initial implementation being for international travel (12). In the COVID-19 pandemic setting, health passports are envisioned for these sectors: (i) international travel, (ii) returning to work (e.g., healthcare workers, teachers, people of the transportation crew, workers at ports of entry), (iii) education (e.g., academic institutions), (iv) attending athletic events, (v) attending mass gatherings, (vi) immigration, (vii) government agencies (which may include front-line workers, health department representatives, hospital staff), and (vii) government policy stakeholders (13). A vaccine passport should address specific issues based on each country's needs, logistics, and epidemiological determinants.

The main objective of this review is to contemplate the many epidemiological variables in successfully introducing health passports on a large scale. Apart from the assumed list of epidemiological barriers, our review highlights the infrastructure required to operationalize idea health passport and successfully overcome the inherent challenges.

To accomplish this, we conducted a thorough literature analysis from January 2020 to January 2023, utilizing PubMed, Medline, Google, Scopus, Google Scholar, and WHO websites. Our English language searches focused on epidemiological factors, testing barriers, immunity, vaccination, variants, data and research gaps, and COVID-19 health certificate validation. We used several keywords, including "COVID-19 passports", "digital health passport", "health certification", "vaccination passports", "vaccine verification", "vaccination campaigns", "testing requirements", "privacy and security", "health information exchange", "challenges", as well as "obstacles." The use of Boolean operators and snowballing approaches yielded 135 related articles. The study addresses identified gaps and presents a comprehensive overview of considerations for implementing COVID-19 health passports.

2 Scenarios for Covid-19 epidemiological variables—intrinsic overview

For crucial information on the spread of the pandemic, it is important to infer the transmission dynamics of COVID-19 in a variety of contexts, particularly in geographic areas with poor access to healthcare, dense populations, and a high prevalence of other neglected regional diseases (14). Heterogeneity remains broad in the modes of transmission and viral shedding, primarily through respiratory droplets, aerosols, fomites, other body fluids, and secretions, throughout the infectious period and including pediatric and asymptomatic infections as well. Highly infectious individuals shed tens to thousands of SARS-CoV-2 virions per minute through droplets and aerosols while breathing, talking, and singing (15–17).

2.1 Global strategies for disease containment through non-pharmaceutical interventions

From the beginning of the pandemic to this moment, public health counter measures have involved the use of already existing interventions to limit the spread of the virus (Figure 1) (18–23).

2.2 New variants change the herd-immunity equation

The race to vaccinate the world against COVID-19 is already facing significant challenges, with distribution and allocation issues compounding the problem. The new virus variants are adding to the woes, especially because they are more transmissible and resistant to vaccines. According to immunologist Ester Sabino at the University of São Paulo, Brazil, and her colleagues, more than 60% of individuals with COVID-19 had been infected by June 2020, a rate more than sufficient to achieve herd immunity. However, in January 2021, a massive resurgence in the number of cases occurred, and this spike happened because of the emergence of a new SARS-CoV-2 variant, P.1., which undoubtedly shows that previous infection and immunity never provided any protection.

Ferrari, an epidemiologist at Pennsylvania State University Center for Infectious Disease Dynamics, states that higher immunity rates could increase pressure on sustainable herd immunity favoring variants that can infect already immunized people. Therefore, there is an excellent reason to build and infrastructure to monitor novel variants in the setting of vaccination that can produce new variants in response to evolutionary pressure (24).

A potential framework was developed for identifying and estimating community-wide immunity to COVID-19 using data

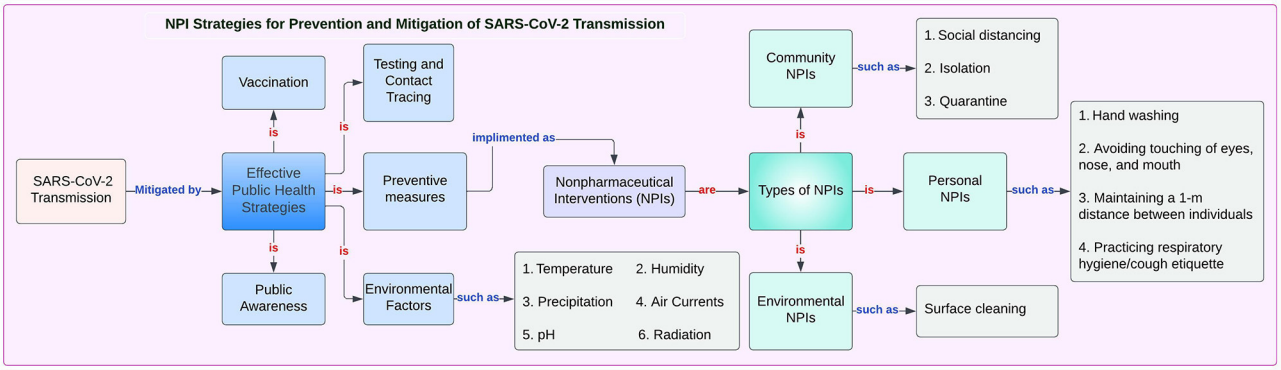


FIGURE 1
NPI Strategies for Prevention and Mitigation of SARS-CoV-2 Transmission.

reportable to local public health authorities. However, biological factors and changing behavioral contributors, as well as context-specific factors make it hard to determine specific geographical thresholds for herd immunity (25).

2.3 Significance of knowing the incubation period and clinical features together with disease severity

During an outbreak, knowing the incubation period of an infectious illness—defined as the time between exposure to the causative agent and the symptom onset can provide crucial information, such as when infected persons will be symptomatic and are most likely to spread the disease. Due to the fact that the symptom onset reflects the pathogen growth, replication rate, and toxin excretion, the incubation period provides insight into the etiology and origin of a disease when these elements are unknown, leading to potential treatment strategies. Active monitoring during the incubation period requires exposed persons to report their status to local health authorities on a daily basis (26, 27).

In a scoping review of the literature, Zaki and Mohamed (28) report that the average incubation period for the virus is around 7.8 days, whereas WHO and European Center for Disease Prevention and Control (ECDC) reported an incubation period of 0, 14 days and 212 days, respectively. Infection with COVID-19 can occur in three stages: (i) an early infection, marked by a viral response; (ii) a pulmonary phase; and, finally, (iii) a hyper-inflammation phase, marked by an inflammatory response from the host.

The early stage of infection is generally associated with fever, a dry cough, and mild constitutional symptoms. The pulmonary phase involves shortness of breath with or without hypoxia. The hyper-inflammation phase involves acute respiratory distress syndrome, shock, and cardiac failure (29).

Clinical symptoms of COVID-19 are similar to those of the common cold; remarkably, however, the fatality rate with COVID-19 remains at 2%—3% for individuals with either health complications or previous comorbidities, and especially among older adults. The specific comorbidities include cardiovascular disease, diabetes mellitus, chronic respiratory disease, hypertension, and cancer; notably, lifestyle factors such as smoking and obesity are associated with adverse outcomes (30). Acute respiratory distress syndrome is the primary complication in patients with severe illness and may develop shortly after the onset of shortness of breath. Other complications include arrhythmias, acute cardiac injury, and shock. Thromboembolic complications, including pulmonary embolism and acute stroke, have also been reported. Some patients had laboratory evidence of an enduring inflammatory response that was associated with critical and fatal outcomes.

The SARS-CoV-2-related morbidity and mortality are considerably lower among young children and adolescents, and children may be less vulnerable to infection (31). Although asymptomatic infections have not been systematically studied, some studies estimate that approximately 20%—50% of infections are asymptomatic, with significantly higher rates of asymptomatic infections among children (32).

TABLE 1 COVID-19 vaccines: types and descriptive overview.

Category	Description
Genetic vaccines	Utilize SARS-CoV-2 specific DNA/RNA sequences to stimulate an immune response.
Viral vector vaccines	Use alternative viruses as carriers for SARS-CoV-2 genes.
Whole virus vaccines	Based on the presence of an inactivated form of the virus.
Protein-based vaccines	Incorporate select virus spike proteins.
Repurposed vaccine	The Bacillus Calmette-Guérin vaccine is repurposed to stimulate the immune system.

2.4 COVID-19 vaccination as a pathway for trustworthy protection

Numerous vaccines were developed worldwide against SARS-CoV-2 and approved by various countries (33). Table 1 summarizes types and descriptive overview of COVID-19 vaccines.

This structured overview enhances understanding and facilitates essential features of the current worldwide immunization schemes.

However, significant skepticism persists around COVID-19 vaccines regarding their safety, long-term adverse effects, insufficient testing and clinical trials, and the violent pro-inflammatory response from T-cells. Various factors including insufficient neutralizing antibodies, weak memory T-cells responses, and new SARS-CoV-2 variants, may contribute to low efficacy and impact long-term protection from infection (33).

2.5 Tackling the threatening SARS-CoV-2 variants: an era of scientific challenges

The global emergence of several SARS-CoV-2 variant strains has resulted in an international population that is susceptible to infection, increased disease severity, seasonality of dissemination, transmissibility, and different modes of transmission, all of which are undoubtedly a significant threat to the control of the COVID-19 pandemic, as well as causing a vital public health burden. Together, these factors contribute to substantial morbidity, mortality, and concomitant economic losses worldwide, dramatically increasing over time (5, 34). The SARS-CoV-2 variants are classified by WHO into three categories: (i) a variant of concern (VOC), (ii) a variant of interest (VOI), and (iii) a variant of high consequence (VOHC). As of December 11, 2022, WHO has designated five VOCs: alpha, beta, gamma, delta and omicron (Figure 2) (35–39).

The increasing spread of COVID-19 variants has resulted in a substantial increase in the number of individuals experiencing prolonged symptoms resulting in long COVID, posing challenges for patients, their families, and the economy. In addition, this situation could put a strain on healthcare systems and have an impact on global workforce efficiency. The key to overcoming these epidemiological barriers requires providing sufficient resources, intended research, and comprehensive support services along with technological innovation. By achieving the diverse needs of long COVID patients and reducing the burden on individuals and healthcare systems, we can effectively address these challenges (40).

2.6 Unified approach for air travel recommendations

According to a narrative review by Bielecki et al. (41), the temperature screening method to detect COVID-19 infection is highly ineffective, particularly regarding the lack of benefit of this approach to identify infected young people. Future strategies at airports could include the following: a telemedicine approach, performing systematic rapid tests, performing a combination of saliva and antigen tests, and ensuring that travelers complete self-assessment forms before flights. Henceforth, saliva testing on arrival could be used to isolate and quarantine the traveler, which would ultimately help reduce the number of quarantines. Another approach is that, from the moment that travelers enter the airport and until they leave the airport, they must practice proper hand hygiene and physical distancing. Always covering the face is one of the key elements for preventing SARS-CoV-2 transmission. The passengers within two rows of an index case are at higher risk, despite the high-efficiency filtering used in aircraft. Even with one positive case aboard, however, the findings of a retrospective study must be considered, which showed that the transmission of SARS-CoV-2 is one case for every 27 million travelers, with stringent in-flight hygiene measures. Most flight crews disinfect the aircraft and enforce wearing face masks/shields and following social distancing to a certain degree; however, their guidelines are indeed challenging to research, and other precautions must be more transparent and less confusing to interpret. Non-pharmaceutical interventions such as masks and the use of hand sanitizers are mostly recommended from door-to-door and during travel. The IATA guidelines are straightforward. However, there is no common platform for contact tracing and telemedicine approaches using preflight questionnaires and COVID-19 test results. It is now necessary for all stakeholders to take a unified approach, to validate existing rapid tests, and to form an expert committee to make prevention strategies more systematic so that evidence-based air travel recommendations are followed (41, 42).

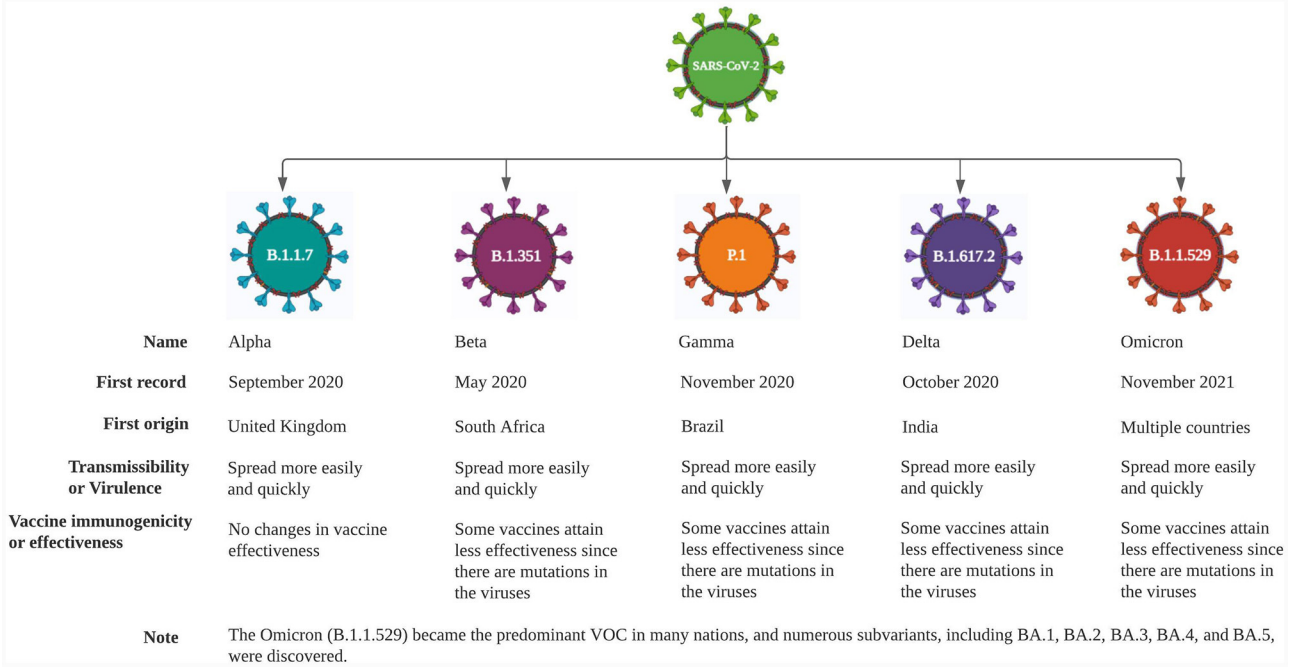
The introduction of vaccination passports does not withdraw any recommendations for wearing masks and social distancing on flights. Whether digital or paper-based, the evolution of vaccination passports is certain; however, this outcome requires careful navigation (43). Indeed, the contemporary echo chamber effect may instigate vaccine hesitancy and unethical practices; one of the most likely weaknesses is that people could falsify vaccination records. Regardless, one principle is certain: It is important for each person to actively contribute to the ethical protection of public health, the economy, and society as a whole.

3 Epidemiological obstacles renders impact on the verification of variables in the health passport—elaborated review and possible resolutions

Organizations worldwide collaborating to develop plans for further opening up the economy and restoring the perception of normalcy around the world have achieved significant results. The economy has made substantial progress in its path to recovery, with air travel almost reaching pre-pandemic levels. It is important to acknowledge these positive advancements. Vaccine passports, travel passes, and global health certificates are all different names for the same purpose. During the pandemic and pre-pandemic periods, a significant reduction in air travel was apparent, with a decrease in the number of passengers departing. Global travel trends are essential to understand in this context, and they indicate that the fastest and most resilient travel flows for recovery are domestic flights and travel to neighboring countries, last-minute travel, visits to friends and family, and quintessential travel.

3.1 Potential epidemiological barriers and stumbling blocks for verification and validation of the health passport

The following are the five essential elements for recovery and policy changes for the introduction of vaccination passports: (i) competition, (ii) epidemiology, (iii) technology, (iv) ethics, and (v) politics—neglecting to take these factors into account could



Name	Alpha	Beta	Gamma	Delta	Omicron
First record	September 2020	May 2020	November 2020	October 2020	November 2021
First origin	United Kingdom	South Africa	Brazil	India	Multiple countries
Transmissibility or Virulence	Spread more easily and quickly	Spread more easily and quickly	Spread more easily and quickly	Spread more easily and quickly	Spread more easily and quickly
Vaccine immunogenicity or effectiveness	No changes in vaccine effectiveness	Some vaccines attain less effectiveness since there are mutations in the viruses	Some vaccines attain less effectiveness since there are mutations in the viruses	Some vaccines attain less effectiveness since there are mutations in the viruses	Some vaccines attain less effectiveness since there are mutations in the viruses
Note	The Omicron (B.1.1.529) became the predominant VOC in many nations, and numerous subvariants, including BA.1, BA.2, BA.3, BA.4, and BA.5, were discovered.				

FIGURE 2
Variants of concern as of December 11, 2022.

result in unforeseen distress in the future. Health passports have the potential to protect the air travelers, and residents at the destination and transit stops. Both the IATA and WHO, various countries, and continental agglomerations jointly handle the implementation of health passports. The essential data to be included in a health passport are the following: (i) date of passport issue, (ii) place of passport issue, (iii) type of vaccine, (iv) information on the passport verification process, and v) validity of the passport.

The health passport program can be successfully realized only when the minimum scale is exceeded, considering the views of epidemiologists on a global scale. On the contrary, without sufficient scale, the health passport program can have the opposite effect of the original intention, leading to "bubbles" instead of re-connecting the world. These "bubbles" will essentially align with the current political, ideological, and economic considerations (44). Moreover, several challenges are related to epidemiological research, similar to the challenges posed by the pandemic and variants, in terms of implementing health passports. We categorize these epidemiological barriers into four domains (i) testing, (ii) immunity, (iii) vaccination, and (iv) variants, all of which play an essential role in implementing health passports.

3.2 Uncertainties of current COVID-19 testing and diagnostic strategies

At the moment, two types of viral tests can be used: nucleic acid amplification tests (NAATs) and antigen tests. Antibody testing, also known as serology testing, may tell if the individual has had a prior infection. Antibody testing must not be used to diagnose a present infection (45). Ribeiro da Silva et al. (46) pointed out that laboratory diagnosis is "crucial for the clinical management of patients and the implementation of disease control strategies to contain SARS-CoV-2 at the clinical and population level." Despite the fact that the current testing strategies have proven to be the golden standard, many uncertainties around the testing process might impact freedom from the pandemic and the health passport.

3.2.1. Falsification of a negative polymerase chain reaction test

A person who produces significantly higher amounts of infectious aerosols may be more likely to spread the infection and be accountable for the "super spreader effect," in which that person is responsible for the infection of an unusually large number of susceptible persons (47). Likewise, the WHO scientific summaries indicated that persons with a negative test and none of the symptoms are less likely to cough and sneeze, making them probably in charge of most transmissions (48). Therefore, the current negative PCR test in the individual and transmission from people without COVID-19 symptoms are the major problems.

The decision-analytic model assessed by Johansson et al. (49) reported various levels of transmission of SARS-CoV-2 from pre-symptomatic, defined as infectious before symptom onset, never symptomatic, and symptomatic individuals across a range of scenarios in which the proportion of transmission from people who never develop symptoms (i.e., those who remain asymptomatic) and the infectious period varied according to published best estimates. This degree of variation means that the outcomes may not be valid for an extended period of time.

3.2.2 Contingencies around a positive antibody test

A positive antibody test suggests that individuals may have antibodies from a previous infection or vaccine for the virus that

causes COVID-19 (50). The accuracy of the test result depends on the test being used and the prevalence of SARS-CoV-2 immunity in the population (51). If the test is performed between 15 and 35 days after symptoms appear, or more than 1 week after infection, a positive result may be caused by the existing infection and can thus imply a current risk of transmission (52). The production of antibodies after the infection seems to be variable in terms of amount and duration. The duration of protection is unclear, and protection may decrease over time (53). Still, the evidence for the efficacy of immune antibodies is insufficient to effectively ensure the accuracy of health passports.

3.2.3 A chaotic state against the negative rapid antigen test

Rapid antigen tests are helpful to determine if an individual has COVID-19 before exposure to the crowd or event or if symptom onset has occurred. The rapid antigen SARS- CoV-2 tests and some rapid NAATs are considerably less sensitive than most real-time-polymerase chain reaction (RT-PCR)-based NAATs. The variation in the performance among different tests is substantial (54). Special attention is required regarding the accuracy of different tests regarding false-negative results, most notably when non-professionals rather than laboratory scientists administer the tests (55, 56). Dauntingly, a high rate of false-negative results makes it harder to control hospital infections and make clinical decisions (57). Apart from these concerns, the passengers who carry false COVID-19 test results and false health passports to travel might jeopardize the sector's efforts to limit the spread of the disease and especially as air travel has reopened completely to pre-pandemic level.

3.2.4 Dilemmas in testing: positive RT-PCR test results in patients recovered from COVID-19

According to a review by Lan et al. (58) a proportion of cured patients may continue to carry the virus. Notwithstanding, a follow-up study by Wu et al. (59) suggested that recovered patients with repeat positive PCR tests were not infectious when the test was performed. The duration of immunity from disease is unclear and appears to be variable (60). A symptomatic infection is typical, and it is rarely missed by various tests (61). Most likely, these conflicting results could affect the usefulness of a health passport.

3.2.5 Noteworthy resolutions for uncertainties in COVID-19 testing and diagnostics

Health passports built based on antibody testing or tests for infection confront significant technical, legal, and ethical challenges (62). Today, the existing scientific reviews provide possible solutions. However, well-designed experiments are always necessary for finding a solution to diagnostic and testing uncertainties.

3.2.5.1 Test sensitivity and specificity

Grassly et al. (62) suggest that molecular tests must have high specificity to avoid false negative results because a lower specificity would reduce the usefulness of a molecular-based health passport. To maximize financial grant approval for the fight against COVID-19 and the implementation of health passports, it is now time to invest in testing capacity, policies, and planning (63).

3.2.5.2 Sample pooling

Pool testing strategies combine samples from specimens (e.g., throat swabs) from numerous people and test them as a group in a single test. To elucidate these strategies, Bish et al. (64) implemented a robust pooling strategy within a sequential framework, which shared pool sizes weekly for each risk group based on test data from the previous week. As demonstrated by this study, a robust approach for pooled testing can be a helpful strategy for significantly increasing the COVID-19 screening and testing capacity. Due to the dynamic and uncertain prevalence of the disease, this customization is beneficial for testing various populations.

3.2.5.3 Quality control of COVID-19 testing

Infection control measures, outbreak monitoring, and management are mostly based on test results. Hence, quality control at all levels, from design up until end use, as well as high internal standards, is Health Kit identifiers needed to obtain an acceptable report in diagnostic testing and the implementation of new tests.

Significantly, obtaining official, formal FDA approval, optimization of additional tests, and better extended clinical and epidemiological validation are also required. Moreover, biobanks and actual patient monitoring continue to be lacking, and artificial intelligence and machine learning tools must be developed and implemented in data interpretation (63). We expect that these testing-related interventions will be restorative and help retain accurate information in the health passport.

3.3 The unpredictability of immunity against COVID-19

The immune system of more than 95% of individuals recovering from COVID-19 showed long-term memories of the virus up to 8 months after infection. In the same way, clinical research suggests that people who are vaccinated against SARS-CoV-2 will develop similar long-term immune memories (65).

3.3.1 Skepticism about lasting immunity to COVID-19

Many questions remain about natural immunity and SARS-CoV-2 vaccine induced immunity. According to Baraniuk's (66) reviews, in some cases it is unclear how long the developed immunity will persist when the body's immune system responds to COVID-19 infection. Notably, COVID-19 is an entirely new disease, and scientists are still working specifically on how the body repels it. Although it is difficult to state definitively, one could predict that the immunity could last for several months or up to 2 years based on what is known about other viruses and what has been seen to date in terms of antibodies in COVID-19 patients and individuals who have been vaccinated. Moreover, concerning immunological studies on COVID-19, outcomes are

inconsistent, so it is not easy to develop a "ballpark figure" estimate of lasting immunity.

3.3.2 Suspicion of perceived personal immunity

The use of vaccination passports may suffer severe problems if the underlying degree of immunity is not understood and with limited knowledge of the actual risks for seen. The dynamics of humoral immune responses after SARS-CoV-2 infection and the certainty of the potential for reinfection would require decades to understand, so these passports will be deployed with little understanding of the real risks (67).

3.3.3 Imprecision about antibodies and immunity in COVID- 19 infected persons

According to Wang et al. (68), research demonstrates that after a SARS-CoV-2 infection, most people, even those with mild infections, seem to have some protection from the virus for at least 1 year. In addition, other research confirms that vaccinating these individuals considerably improves their immune response and gives them strong resistance against the variants of concern, including the delta variant (B.1.617.2) (69).

A serological-based study conducted by Ripperger et al. (70) demonstrated that individuals who recovered from COVID-19 had observed antibodies still remaining in their blood 5–7 months after the illness. Evidence suggests that neutralizing antibodies last several months for individuals already infected with COVID-19 but then gradually decrease over time. Additional investigation is required to determine precisely how the body fights SARS-CoV-2 and how long multifunctional antibodies could play a defensive role after infection or vaccination. This knowledge is essential to grant access to health passports.

3.3.4 Noteworthy resolutions for unpredictability in immunity against COVID-19

Being able to represent "active immunity" is essential in developing protocols to protect the population globally and to cure resistant diseases in the future. Accordingly, the available studies to date suggest that determining the exact duration of immunity is unattainable by the scientific goals of the researchers (71). Marovich et al. (72) reported that neutralizing monoclonal antibodies to SARS-CoV-2 is beneficial for therapeutic and prophylactic applications. According to their suggestion, monoclonal antibodies are an additional method for preventing COVID-19. A passive infusion of monoclonal antibodies as pre-exposure or post-exposure prophylaxis could immediately protect against infection, which could last for weeks or months. More recent technologies modify the fragment crystallizable region of the antibody to extend the half-life of the monoclonal antibodies and may supply potentially protective levels for months, based on the requirements for monoclonal antibody concentration. In the event of an outbreak, it may be beneficial to administer monoclonal antibodies to nursing home residents to mitigate disease progression during the early stages of rapid infection that may go undetected.

According to Rafi Ahmed, a viral immunologist at Emory University in Atlanta, Georgia, SARS-CoV-2, like all pathogens, uses several mechanisms to disable and escape the host immune response. This mechanism allows the virus to survive better by causing the host's innate immune response to be inefficient. It is challenging to dissect how much collateral damage is caused by the virus itself and what percentage is the immune response. Because of these uncertainties, scientists will develop a new method, nearing a combination therapy (73).

The Kirkcaldy et al. (74) viewpoint study conveyed that amid this uncertain public health crisis, thoughtful and robust scientific data are essential to provide guidance on public health policy, planning, and practice. According to existing reviews, to improve the outcomes of COVID-19 studies, several governmental interventions, including direct financial investments, loans, and policymakers, must be pursued to allow scientific innovation teams to equip the necessary facilities and test their new ideas. It is our hope that these movements will support creating the health passport more efficiently.

3.4 Perplexities about COVID-19 vaccination

Vaccinations save millions of lives annually. Although not without its repercussions, numerous safe and effective vaccines prevent people from becoming critically ill or dying from COVID-19.

3.4.1 The right vaccination strategy

As WHO has stated on numerous occasions, the pandemic cannot end until the entire world is vaccinated. The choice of the right vaccination strategy is an epidemiological challenge, with so many different approaches taken worldwide (44). The government must provide insights to the rural, frontier, and tribal organizations about the COVID-19 vaccine roll-out. It is considered vital to discuss challenges in rural communities, including access barriers and vaccine hesitancy, and to propose innovative strategies to address these challenges. This approach will help determine unmet needs and potential strategies as the vaccination process moves forward.

3.4.2 Protection against infection and transmission after vaccination

While it will be essential to have COVID-19 vaccines that prevent infection and transmission, proof is still needed that protection is happening. Protection against transmission can be hard to prove because several factors can cause a decline in infections (75). Although it would be unusual for vaccines not to prevent infection, the level of protection is unknown, impacting the success of implementing the health passport.

3.4.3 Correlates of protection against symptomatic and asymptomatic infections after vaccination

The messenger RNA (mRNA) vaccines produced by Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) are highly

effective in stopping SARS-CoV-2 infection in real-world conditions. Based on previous clinical trials, these vaccines were known to be effective in preventing symptomatic diseases (76). What was not known, however, was whether these vaccines were stopping asymptomatic infection. The Centers for Disease Prevention and Control and Prevention (CDC) conducted a prospective cohort study in eight locations across the United States during the period December 14, 2020, to March 13, 2021. The organization confirmed that prospective cohorts of 3,950 healthcare personnel, first responders, and other essential and front-line workers completed weekly SARS-CoV-2 testing for 13 consecutive weeks. The CDC reported that receiving two doses of an mRNA vaccine provides 90% protection from infection. Even one dose is considerably effective, lowering infection rates by approximately 80%. These findings indicate that authorized mRNA vaccines confer more long- lasting protection against severe outcomes of hospitalization and death than against asymptomatic and symptomatic SARS-CoV-2 infections (77). However, supplementary data are needed to specify a percentage of protection to analyze the risk factors and support the most effective health passport.

3.4.4 Individuals receiving just one dose, mix and match vaccines

The clinical trials of the Pfizer and Moderna vaccines were conducted with two vaccinations separated by either 21 or 28 days. In people who have already had COVID-19, a single dose of the vaccine produces a robust antibody response similar to a second dose (78). However, at present, there is no single-dose recommendation for those who have already been infected, and the recommendation to complete the vaccine series is primarily due to the concern about the emergence of variants. Until further data are available, all individuals receiving available mRNA vaccines should be given two doses. As of October 20, 2021, the CDC and FDA authorize the use of heterologous booster doses (or "mix and match") for currently available COVID-19 vaccines in the United States (79). It is important to consider the risks and outcomes of mixing coronavirus vaccines to develop a holistic health passport.

3.4.5 Timing of COVID-19 vaccine booster doses: the necessity for boosters and the use of monovalent and bivalent boosters

A growing number of infections are caused by the highly contagious variants of SARS-CoV-2 and indicate that COVID-19 vaccine-induced immunity could diminish over time. Some countries are looking at the possibility of giving other doses to those who have been completely vaccinated. However, scientists do not know if most people need these booster doses (80, 81).

The antigenic evolution of the SARS-CoV-2 virus yet to be researched will answer most of the questions about booster vaccination. For example, repeated vaccination for influenza is required, whereas other vaccinations for infections, such as measles, are provided during childhood and protected for life. As a result, many questions arise regarding the lasting immune protection, the nature of that protection, protection against the likelihood of reinfection, and the healthcare disease burden that the system can tolerate (82).

Following the FDA regulatory action on August 31, 2022, the EUA for the bivalent formulations of the Moderna COVID-19 vaccine and the Pfizer-BioNTech vaccine were amended for use as booster doses after 2 months of either primary or booster vaccination. Subsequently, CDC updated its recommendations following the FDA amendments for COVID-19 boosters for people aged 12 years and older from Pfizer-BioNTech and for those aged 18 years and older to provide better protection against the recently circulating COVID-19 variants (83).

Vaccine-induced protection likely depends on variables such as the vaccine product, primary vaccination schedule, vaccine recipient's age and medical conditions, exposure risk, and the specific variants in circulation. Thus, the decision to recommend a booster vaccine depends on a complex set of variables beyond consideration of clinical and epidemiological data alone.

The following are some of the markers to be considered: (i) epidemiology and burden of disease; (ii) assessing the performance of booster doses; (iii) optimal timing of the booster dose; (iv) consideration of homologous vs. heterologous boosters; (v) possibility of dose-sparing for booster doses; and (vi) booster needs of individuals already infected (84).

3.4.6 Vaccine efficacy for pregnant and lactating women

Craig et al. (85), addressed the considerations required for COVID-19 vaccination during pregnancy. Key findings included: (i) COVID-19 infection among pregnant women has been linked to an increased risk of morbidity and mortality; (ii) a significant proportion of healthcare workers are pregnant and will potentially be eligible to be vaccinated before studies can be conducted during pregnancy; and (iii) FDA-approved vaccines must not be withheld from women solely based on their pregnancy or lactation status when they otherwise meet the vaccination criteria. In a systematic review and meta-analysis study on the effects of COVID-19 immunization in pregnancy, Prasad et al. (86) found that COVID-19 mRNA immunization during pregnancy appears to be safe and is linked to a decrease in stillbirth. According to CDC reports on breastfeeding mothers, those who had received mRNA COVID-19 vaccines protected their infants through the antibodies in their breastmilk, with no evidence showing any harmful effects on either the infant or the mother (87). When providing epidemiologically validated health passports, additional data are required to decide what level of protection these antibodies provide to pregnant women and infants of lactating mothers.

3.4.7 Jabs for infants and children under EUA

Children are more susceptible to having asymptomatic cases of COVID-19 and could act as unknown carriers of SARS-CoV-2 (88). According to Ludvigsson et al. (89) a systematic literature review revealed that children linked to exposure and host factors are the largest age group of asymptomatic carriers of SARS-CoV-2, followed by adults and older adults. It is well-known that a child's immune system is not well- developed, and the maturity and binding capacity of ACE2 in children may be lower than that of

young adults. On October 29, 2021, the FDA authorized and the CDC recommended that children age 5–11 years could receive an age appropriate dose of the Pfizer-BioNTech COVID-19 vaccine for emergency use to help protect against infection (90). According to the FDA, the bivalent approval for the Pfizer-BioNTech COVID-19 Vaccine in children aged 5–11 years stands as valid in addition to the earlier approval for a monovalent vaccine (91). However, it would be hard to justify a decision to require children to receive a vaccine because the role of children in the spread of infection to adults and to those at risk remains questionable (92).

3.4.8 Safety for people after they are completely vaccinated

Unestablished facts about the duration of vaccine-induced immunity and the risk of new variants with complete vaccine-escape capabilities raise challenges about the validity period of health passports and ensuring that holders of health passports are still immune to circulating viral strains (93).

3.4.9 Noteworthy resolutions for perplexities in COVID-19 vaccination

New biomarkers are essential to manage patients by facilitating early diagnosis of severe COVID- 19 and play a vital role in developing a COVID-19 vaccine. Use of these biomarkers can speed clinical trials, reduce costs, guide participant selection, reduce patient safety, and enable easier verification of the mechanism of action (63). Thus, biomarkers are a relevant factor in developing a COVID-19 vaccine. Efficient vaccine effectiveness studies are needed to nourish greater immunogenicity and to guide periodic revaccination of the general population. The opinion article by Baay and Neels (94) represents that the controlled human infection (CHI) model could help speed vaccine development. To support vaccine research, CHI can provide fundamental security, tolerability, immunogenicity, and efficacy.

Compatible collaboration is necessary to develop medicines and vaccines. Optimally, information should be shared among the currently available digital technologies, regional and international health surveillance institutes, industrial partners, and innovation drivers such as bioinformatics data management (termed big data), biobanks, and innovation science teams (63).

Therefore, each vaccine category must be evaluated separately to provide essential scientific information for the COVID-19 health passport. In this state of affairs, crucial scientific information such as the duration of immunity and efficiency in reducing infection and virus transmission must be examined (95). Correspondingly, WHO recommends a preference for standardized study reporting based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance. The STROBE statement aims to assist authors in enhancing the reporting of observational studies and facilitating critical evaluation and understanding of the results (96). In accordance with the viewpoint study of Gostin et al. (10) ideally the digital health passports would include the completion dates of the vaccine series to determine the expiration date once the duration of the protection is more clearly illustrated. Modern evaluation studies and global scientific partnerships could be helpful in obtaining better defined details regarding vaccine protection, encouraging health passport use, and making the use of a health passport worthwhile.

3.5 Emergence of COVID-19 variants may hamper the freedom from infection

Scientists are steadily monitoring the new genetic changes that COVID-19 is undergoing. Some emerging variants are alarming, whereas many variants are inconsequential. The most challenging task is recognizing, tracing, and controlling those variants that may be significant.

3.5.1 COVID-19 variants as game changers

Currently, the future of COVID-19 is decided by its mutations. As a natural process, often mutation does not affect the virus and may even cause disease in some cases. Variants of concern pose distress and represent a significant number of infections worldwide with high transmission rates. The foundations for a thorough understanding of why vaccination against COVID-19 is required include the level of immunity to the virus, efficacy of current vaccines against emerging variations, and international air travel that may spread the variants globally. These intense challenges can lead to a completely chaotic system of competing variants, competing vaccines, and competing passports prevails (43, 44). Protection from emerging variants of SARS-CoV-2 continues to be unclear. The Delta and Omicron variants create new uncertainty and thus lead to new revisions of the health passport.

3.5.2 Vaccine effectiveness against new variants

New variants will continue to emerge, and it is important to understand the phenotypes of emerging variants in terms of infectious disease, transmissibility, virulence, and antigenicity. It is also essential to quantify the phenotypic effect of specific mutations present in the variants, both individually and in combination with other mutations (97). When the Omicron variant evolved in early 2022, persons with healthy immune systems who were eligible to receive the third and fourth doses of the COVID-19 vaccination were provided significant protection, according to a recent Morbidity and Mortality Weekly Report.

According to the CDC, experts reviewed VISION Network data for more than 214,000 emergency department/urgent care visits and more than 58,000 hospitalizations with a diagnosis of COVID-19-like illness in 10 States from mid-December 2021 to mid-June 2022 to assess the efficacy of 2, 3, and 4 doses of mRNA COVID-19 vaccines (Pfizer-BioNTech or Moderna) among adults with healthy immune systems (Table 2) (98, 99). Indeed, it is unclear to what extent the results of an infection might be attributed to prejudice because of test-seeking performance being affected by vaccination status.

3.5.3 Noteworthy facts: learning from the management of similar deadly viruses in the past

The influenza A (H1N1) virus caused the 1918 flu pandemic; the 1957 flu pandemic was caused by an influenza A/H2N2 virus;

TABLE 2 Effectiveness of booster vaccines against new variants.

Occasions/incidents	Vaccine effectiveness (VE) before COVID-19 booster	Vaccine effectiveness (VE) after COVID-19 booster
When BA.1 became predominant variant	VE was 61% for two doses against COVID-19 associated hospitalizations	VE increased to between 85–92% after the third/booster dose
When BA.2/BA.2.12.1 became the predominant variant	VE was 24% for two doses against COVID-19-associated hospitalizations	VE increased to between 52–69% after a third/booster dose
Emergency department and urgent care encounter attained	Attained lower VE during BA.2/BA.2.12.1 predominance	Attained higher VE with 3 or 4 doses compared to VE with 2 doses
Adults ages 50 years and older during BA.2/BA.2.12.1	VE against COVID-19–associated hospitalization was 55% higher than 4 months after a booster/third dose	VE against COVID-19–associated hospitalization was increased to 80% more than a week after the fourth dose

and the 1968 flu pandemic was caused by influenza A/H3N2 virus; moreover, the 2009 swine flu pandemic was caused by the H1N1 virus. The pattern shows declining fatalities year over time due to vaccination and exposure to pathogens for natural immunity (82, 100). Based on this pattern, booster doses for the SARS-CoV-2 virus are likely to be required at specified intervals until proper drugs and therapeutics are developed.

3.6 Concerns regarding potential vectors and animal reservoirs for disease eradication, as well as future prospects

The future reality of SARS-CoV-2 will also depend on its ability to become established in a wild animal population. A few diseases that have been brought under control, such as yellow fever, Ebola virus, and Chikungunya virus, persist because of animal reservoirs. It is likely that SARS-CoV-2 originated from bats and can easily infect some animals, including cats, rabbits, and hamsters, and it is particularly contagious in minks (101).

According to the hypothetical synopsis provided by Kahn et al. (102) primary vaccinations are likely to have unpredictable efficacy for subgroups of the population and it may take time to achieve herd immunity with primary vaccinations. The homogenized digital solutions must be regionally and internationally standardized in the electronic platform to document and validate COVID-19 e-vaccination certificates. Future outbreaks of a pandemic are imminent. Therefore, it is the need of the hour to develop the framework and policies guiding the integration and synchronization of digital vaccination solutions in an emergency. However, these technological interventions must follow strict ethical guidelines (103). Expectedly, until longer-term follow-up results are available, the duration of protection seems to be uncertain and thus immunity might take time to become endemic.

3.7 Possibility of COVID-19 becoming endemic: potential future standpoints

For both the outbreaks of SARS in 2003 and Ebola in 2014, public health measures brought them to an end. Although SARS-CoV-2 virus differs from both in comparison, possibly the current improved public health systems and successful surveillance systems can help in achieving endemic status. In contrast, however, the current pattern of human contacts, number of susceptible individuals, and transmissibility add further to the woes of putting an end to the SARS-CoV-2 virus (82, 104).

In January 2021, the journal Nature asked more than 100 immunologists, infectious disease researchers, and virologists working on the coronavirus whether it was possible to eradicate it. The prognostications from this survey revealed that many scientists expect the virus that causes COVID-19 to become endemic but that it could pose less of a danger over time. More than one-third of survey respondents believed that SARS-CoV-2 could be eliminated from some regions while it still circulates in others. In the region with zero COVID-19, a continued risk of disease outbreaks would exist, but these outbreaks could be quickly curtailed by herd immunity if most people had been vaccinated (105).

One scenario foreseen by scientists for SARS-CoV-2 is that the virus might behave similarly to the past four endemic coronaviruses OC43, 229E, NL63, and HKU1. Of these viruses, three have been circulating for more than 100 years, and two caused 15% of respiratory infections. Although the childhood immunity developed at age 6 years might wane, reinfection as an adult does not lead to any complications. Similar behaviors can be expected in SARS-CoV-2, but the results are unclear. Scientific studies have shown that immunity declines after 6–8 months and reinfection does occur. However, the body manufactures antibodies using B-cell memory and eliminates the virus using T-cell memory. This waning immunity might be the primary driver for SARS-CoV-2 to become endemic. In this endemic phase, the number of infections will be constant throughout the years, with occasional flare-ups. Achieving this state might take several years or decades, depending on how quickly herd immunity is achieved through natural infections or vaccinations (105). However, it is hard to predict when this change will occur.

4 Substantial resolutions for robust international health passport development: general outlook

To re-open borders without quarantine and reawaken the aviation sector, governments must be confident that they can effectively mitigate the risk of introducing COVID-19. This

necessity supports the need for reliable information on the COVID-19 health status of the passengers. Notifying passengers about any necessary tests, vaccinations, and other measures they need prior to travel, providing details of where they can get tested, and providing them the opportunity to share their test and vaccination results in a verifiable, safe, and privacy protecting manner is the key to giving governments the confidence to open borders. To make it easier for passengers, key steps are to: (i) create a digital passport; (ii) ensure that the passenger tests/vaccinations meet the regulations; and (iii) share the passenger test or vaccination certificates with authorities to make travel easier (106).

The term digital health passport is a newly emerging technology, and its configuration is exclusively centered on uncertain and evolving scientific information. Some factors to consider regarding "how to use digital health passports" include whether the strategy and information can be relevant to all countries and states in all conditions. Accurate data and robust information systems are vital to refining health passports in the context of COVID-19. A multi-factor authenticated (MFA) and validated health passport could be the solution.

4.1 Confirmation for safe travel and integration

The effectiveness of COVID-19 vaccines is a concern with many scientific mysteries, including the inefficacy in preventing disease, use for asymptomatic infection, timing of booster doses, vaccine recipient age, population groups to be prioritized, specific contraindications, and limiting transmission, including SARS-CoV2 variants and the vaccination administration time to be determined before travel. The new COVID-19 vaccine recommendations are compiled based on the WHO Strategic Advisory Group of Experts on Immunization (SAGE) advice (107).

Clifford et al. (108) performed a study of health screening for international travel. They reported that when the number of cases are low in the exporting country, the screening may delay the onset of the epidemic by up to 1 week in the importing country. Likewise, Mandal et al. (109) conducted a mathematical modeling study. They found that if proper screening could detect 90% of asymptomatic persons, it could delay the average epidemic times by 20 days in select countries.

Because the clinical and epidemiological features of the virus are still inconsistent, assessing the potential effectiveness of the travel measures is challenging. Moreover, because of the limited transparency of the Public Health Emergencies of International Concern declaration process, the risk assessment conducted by the IHR Emergency Committee is unknown (110).

The introduction of health passports could help ensure safe travel for those carrying proof of immunization, facilitate the opening of air travel, and contribute to reviving national economies. In another regard, the reasons for ECDC or the WHO not recommending the "immunity passports" are the undefined duration and parameters of immunity, costly antibody testing, proliferating exposure to infection and reinfection issues, and new strain susceptibility.

Currently, WHO does not recommend proof of vaccination or immunity for international travel as a condition of entry. Nevertheless, WHO is working on technical specifications and standards for a smart vaccination certificate to support collaborative processes for adding the COVID-19 vaccine into the IHR updated version (43, 111). Correspondingly, the validity, the expiration date-–6 months is the current period—and the renewal of the health passport for the administered vaccination are still unanswered. Modern digital and scientific technologies, collaborations with government and private interventions, and innovation science teams can likely overcome these challenges. Thus accessing a presumably MFA and validated health passport can be within reach.

4.1.1 Digital platforms as outbreak response tools

Digital solutions can be a boon in integrating care and support for people on a large scale during the COVID-19 pandemic. At any time, the vision for healthcare can be realized by focusing on flexibility and interoperability to achieve sustainability. Digital solutions can turn the idea into reality, with responsibility to ensure the best healthcare systems for people's benefit.

An effective digital platform collaborates several inter-related factors in one place, such as the following: (i) a comprehensive national epidemiologic strategy for the public health systems, (ii) interoperability of data sharing and data re-use needs to be promoted by technology and architecture models, (iii) widespread connectivity of mobile devices, and (iv) an integrated digital solution for safeguarding all stakeholders' safety and privacy following the appropriate regulatory and legislative laws (112, 113).

4.1.2 Concise conceptual points for how and why to implement MFA in health passports

Traditional user identification and password logins can be easily compromised and costly to the organization. Brute-force attackers can use automated password-cracking tools until they find the right combination of usernames and passwords. Hackers have various methods to gain system access, even if a login can be locked after unsuccessful login attempts. For this reason, the MFA is used to reduce security risks.

The use of MFA can be based on the three most common categories, which usually combine the following concepts. First is something you know, or the knowledge factor. The knowledge factor requires the user to answer personal security questions. Something known is typically information such as a family member's name, birth city, phrase, and other points. Second is something you have, or the possession factor. The possession factors include a badge, security tokens, SMS (short message service, or a text message), a SIM (subscriber identity module card), and a smartphone app with an OTP (one-time password). Something you have can be a mobile phone, app, and generated code. Third is something you are, or the inherence factor. The inherence factor primarily uses biological traits, such as a retina scan, fingerprint scan, voice/face recognition, hand geometry, and digital signature. Something you are includes facial recognition, finger printing, and other biometric values. The least common factor can be the user location obtained with a global positioning

system, usually provided as a built-in feature of the smartphone. For example, a bank ATM (automated teller machine) card cannot be used in the United States and then used again in Russia within a few minutes, because this incident can be identified and logically locked to prevent fraud.

Businesses today promote the 'Bring Your Own Device' approach, wherein employees are encouraged to work using their personal devices such as mobile phones and laptops, which presents a serious security risk for business. The security policy can be specified from person to person and group to group with the MFA solution.

Identity and Access Management has advanced from simple usernames and passwords to MFA, as it is now called, for which users must prove their legitimacy to authenticate and gain access to the system. The simplified MFA technique is one of the goals instead of remembering multiple passwords providing both security and fraud prevention (114, 115).

4.2 Data/scientific accuracy in implementing the health passport

Health passports have the potential to become a proper tool to manage COVID-19 in safer domestic, national, and international travel, although uncertainties exist on the pathway of the pandemic. Despite a unique understanding of the virus that leads to efficient disease control and vaccine development, scientific knowledge is still in progress on the effectiveness of protection offered through tests, vaccines, or antibodies, on which a vaccine passport relies.

Point-of-care testing (also called bedside testing) that shows negative evidence offers no future protection against COVID-19. With many low-accuracy tests, the reliance on test results is a challenge when implementing a passport system. The principle of a health passport is that it requires an accurate, more consistent, and reliable test system. Health modeling should support digital passports for people who work in person with vulnerable groups. Health passports normalizing individualized health risk assessment may pave the way for more widespread sharing of health data and intrusive data collection after pandemics.

The IATA develops health passports for international travel and tourism. The EU has envisaged a Digital Green Certificate, whereas WHO has developed a digital version of the International Certificate of Vaccination and Prophylaxis. A digital health passport consists of four components with different functions and purposes: (i) health information consisting of the recording and communication of vaccine status or test results through a certificate/digital certificate; (ii) identity information which may include a biometric, a passport, or a health identity number; (iii) verification to connect a user's identity to health information for checking validity; and (iv) authorization or permission, either allowing or blocking actions based on the health and identifying information.

Health passports must consider a wider breadth of the socio-technical system—one that goes beyond the scope of just data and software and includes: (i) data, (ii) software, (iii) hardware and infrastructure, (iv) people, skills, and capabilities, (v) organizations, and (vi) formal and informal institutions. Health passports form part of extensive societal systems. The public health system includes: (i) tests, (ii) trace and isolate services, (iii) mask-wearing and social distancing, or (iv) wider biometrics and digital identity ecosystem (116).

The dynamism of the health passport system should consider the differing efficacy of various vaccines, the known contrasts in efficacy with circulating variants, and changes in effectiveness over time. A health passport should be considered to work in tandem with other public health measures and cannot be regarded as a "safe haven" pass or certificate of immunity. Instead, the health passport must be considered as one of the risk mitigation tools, including NPIs. Another benefit of a health passport could be scheduling and monitoring the booster vaccines (116, 117).

Within the framework of the Razzaq (118) prospective study, a comprehensive solution for the creation of a health passport is presented, while our primary aim revolves around and goes beyond the identification of epidemiological barriers. We not only pinpoint these barriers but also offer insightful perspectives on potential solutions. This provides significant value for the design of the digital health passport for current situation, while also offering a proactive strategy for addressing future pandemics. This article demonstrates how digital health app designers in critical sectors like travel, transport, tourism, immigration, and governmental bodies can develop valuable applications from our comprehensive insights. Our goal is to establish a resilient health passport system, by providing a comprehensive analysis of the obstacles and possible remedies.

5 Conclusion

Waves of SARS-CoV-2 infections suggest that coronavirus poses a sustainable threat to human life, even in contemporary times. Uncertainty will surround the epidemiological approach of relying solely on health certificates once peer-reviewed and validated data support claims that vaccination reduces SARS-CoV-2 transmission, which a health passport app can address. This pandemic might become endemic in due time because of weak viral mutations. The design of a health passport app for the pandemic will differ substantially from an app for an endemic because the restrictions during the endemic are relaxed, whereas they are stringent in the pandemic. We assume that the opinions discussed herein will be helpful to app developers in updating their versions. Similarly, health passports encourage many people to choose to be vaccinated instead of hesitating to be vaccinated, thereby contributing to herd immunity. Also, security should be the foundation of health passport development to give people confidence that their data is protected from misuse, falsification, and breaches of personal and health information privacy. This review article states current epidemiological obstacles in creating a pragmatic COVID-19 health passport and suggests possible solutions to address several of them. Researchers will need to conduct future research in several domains, depending on the evolution of COVID-19.

Author contributions

RA: Data curation, Resources, Writing—original draft, Writing—review & editing. RS: Conceptualization, Formal analysis, Supervision, Writing—review & editing. JM: Conceptualization, Data curation, Formal analysis, Resources, Supervision, Writing—original draft, Writing—review & editing. AM: Data curation, Resources, Writing—original draft.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Acknowledgments

We wish to thank research participant Gideon Towett for his continuing support for the review of this article. We owe a debt of gratitude to Dr. Isaac Prada y Nogueira for his insightful guidance.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. Carbone M, Lednicky J, Xiao S-Y, Venditti M, Bucci E. Coronavirus 2019 infectious disease epidemic: where we are, what can be done and hope for. *J Thorac Oncol Off Publ Int Assoc Study Lung Cancer.* (2021) 16:546–71. doi: 10.1016/j.jtho.2020.12.014

2. Wang X, Zhou Y, Liu L, Ma J, Wu H, Zhao L, et al. Coronavirus disease 2019 (COVID-19): diagnosis and prognosis. *Blood Genomics.* (2020) 4:96–107. doi: 10.46701/BG.2020022020120

3. WHO. *Coronavirus (COVID-19) Dashboard [Map]*. Geneva: World Health Organization (2020).

4. Sharma A, Ahmad Farouk I, Lal SK. COVID-19: a review on the novel coronavirus disease evolution, transmission, detection, control and prevention. *Viruses.* (2021) 13:202. doi: 10.3390/v13020202

5. Gebru AA, Birhanu T, Wendimu E, Ayalew AF, Mulat S, Abasimel HZ, et al. Global burden of COVID-19: situational analyis and review. *Hum Antibodies.* (2021) 29:139–48. doi: 10.3233/HAB-200420

6. Ledford H. Six months of COVID vaccines: what 1.7 billion doses have taught scientists. *Nature.* (2021) 594:164–7. doi: 10.1038/d41586-021-01505-x

7. WHO. *WHO Reveals Leading Causes of Death and Disability Worldwide: 2000-2019.* Geneva: World Health Organization (2020).

8. Savulescu J, Pugh J, Wilkinson D. Balancing incentives and disincentives for vaccination in a pandemic. *Nat Med.* (2021) 27:1500–3. doi: 10.1038/s41591-021-01466-8

9. Karopoulos G, Hernandez-Ramos JL, Kouliaridis V, Kambourakis G. A Survey on digital certificates approaches for the COVID-19 pandemic. *IEEE Access.* (2021) 9:138003–25. doi: 10.1109/ACCESS.2021.3117781

10. Gostin LO, Cohen IG, Shaw J. Digital health passes in the age of COVID-19: are "Vaccine Passports" lawful and ethical? *JAMA.* (2021) 325:1933–4. doi: 10.1001/jama.2021.5283

11. Rimmer A. Covid-19: Certifying status for "vaccine passports" must not increase GPs' workload, says Royal College. *BMJ.* (2021) 373:n919. doi: 10.1136/bmj.n919

12. Wilson K, Flood CM. Implementing digital passports for SARS-CoV-2 immunization in Canada. *CMAJ Can Med Assoc J J Assoc Medicale Can.* (2021) 193:E486–8. doi: 10.1503/cmaj.210244

13. Pavli A, Maltezou HC. COVID-19 vaccine passport for safe resumption of travel. *J Travel Med.* (2021) 28:taab079. doi: 10.1093/jtm/taab079

14. Ortiz-Prado E, Simbaña-Rivera K, Barreno LG, Diaz AM, Barreto A, Moyano C, et al. Epidemiological, socio-demographic and clinical features of the early phase of the COVID-19 epidemic in Ecuador. *PLoS Negl Trop Dis.* (2021) 15:e0008958. doi: 10.1371/journal.pntd.0008958

15. Chen PZ, Bobrovitz N, Premji Z, Koopmans M, Fisman DN, Gu FX. Heterogeneity in transmissibility and shedding SARS-CoV-2 via droplets and aerosols. *Elife.* (2021) 10:e65774. doi: 10.7554/eLife.65774

16. Karia R, Gupta I, Khandait H, Yadav A, Yadav A. COVID-19 and its modes of transmission. *Sn Compr Clin Med.* (2020) 2:1798–801. doi: 10.1007/s42399-020-00498-4

17. Salian VS, Wright JA, Vedell PT, Nair S, Li C, Kandimalla M, et al. COVID-19 transmission, current treatment, and future therapeutic strategies. *Mol Pharm.* (2021) 18:754–71. doi: 10.1021/acs.molpharmaceut.0c00608

18. CDC. Community NPIs: *Flu Prevention in Community Settings.* Cent Dis Control Prev US (2019). Available online at: https://www.cdc.gov/nonpharmaceutical-interventions/community/index.html (accessed January 21, 2022).

19. CDC. Environmental NPIs: Surface Cleaning. *Cent Dis Control Prev US* (2019). Available online at: https://www.cdc.gov/nonpharmaceutical-interventions/environmental/index.html (accessed January 24, 2022).

20. CDC. *Personal NPIs: Everyday Preventive Actions*. Cent Dis Control Prev US (2019). Available online at: https://www.cdc.gov/nonpharmaceutical-interventions/personal/index.html (accessed January 27, 2022).

21. Dhar Chowdhury S, Oommen AM. Epidemiology of COVID-19. *J Dig Endosc.* (2020) 11:3–7. doi: 10.1055/s-0040-1712187

22. Zhou L, Ayeh SK, Chidambaram V, Karakousis PC. Modes of transmission of SARS-CoV-2 and evidence for preventive behavioral interventions. *BMC Infect Dis.* (2021) 21:496. doi: 10.1186/s12879-021-06222-4

23. El-Elimat T, AbuAlSamen MM, Almomani BA, Al-Sawalha NA, Alali FQ. Acceptance and attitudes toward COVID-19 vaccines: a cross-sectional study from Jordan. *PLoS ONE.* (2021) 16:e0250555. doi: 10.1371/journal.pone.0250555

24. Aschwanden C. Five reasons why COVID herd immunity is probably impossible. *Nature.* (2021) 591:520–2. doi: 10.1038/d41586-021-00728-2

25. Barker P, Hartley D, Beck AF, Oliver G, Sampath B, Roderick T, et al. Rethinking herd immunity: managing the covid-19 pandemic in a dynamic biological and behavioral environment. *Catal Non-Issue Content.* (2021) 2. doi: 10.1056/CAT.21.0288

26. Lauer SA, Grantz KH Bi Q, Jones FK, Zheng Q, Meredith HR, Azman AS, et al. The incubation period of coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application. *Ann Intern Med.* (2020) 172:577–82. doi: 10.7326/M20-0504

27. Rogers K. *Why is it Important to Know the Incubation Period of a Disease?* Chicago, IL: *Encycl Br.* (2020).

28. Zaki N, Mohamed EA. The estimations of the COVID-19 incubation period: a scoping reviews of the literature. *J Infect Public Health.* (2021) 14:638–46. doi: 10.1016/j.jiph.2021.01.019

29. Varga Z, Flammer AJ, Steiger P, Haberecker M, Andermatt R, Zinkernagel AS, et al. Endothelial cell infection and endotheliitis in COVID-19. *Lancet Lond Engl.* (2020) 395:1417–8. doi: 10.1016/S0140-6736(20)30937-5

30. Zeyaullah M, AlShahrani AM, Muzammil K, Ahmad I, Alam S, Khan WH, et al. COVID-19 and SARS-CoV-2 variants: current challenges and health concern. *Front Genet.* (2021) 12:693916. doi: 10.3389/fgene.2021.693916

31. Zimet GD, Silverman RD, Fortenberry JD. Coronavirus disease 2019 and vaccination of children and adolescents: prospects and challenges. *J Pediatr.* (2021) 231:254–8. doi: 10.1016/j.jpeds.2020.11.002

32. Zhang W, Wu X, Zhou H, Xu F. Clinical characteristics and infectivity of asymptomatic carriers of SARS-CoV-2 (Review). *Exp Ther Med.* (2021) 21:115. doi: 10.3892/etm.2020.9547

33. Sharma A, Kontodimas K, Bosmann M. Nanomedicine: a diagnostic and therapeutic approach to COVID-19. *Front Med.* (2021) 8:648005. doi: 10.3389/fmed.2021.648005

34. Mallah SI, Ghorab OK, Al-Salmi S, Abdellatif OS, Tharmaratnam T, Iskandar MA, et al. COVID-19: breaking down a global health crisis. *Ann Clin Microbiol Antimicrob.* (2021) 20:35. doi: 10.1186/s12941-021-00438-7

35. Forchette L, Sebastian W, Liu T. A comprehensive review of COVID-19 virology, vaccines, variants, and therapeutics. *Curr Med Sci.* (2021) 41:1037–51. doi: 10.1007/s11596-021-2395-1

36. *WHO. Tracking SARS-CoV-2 Variants. World Health Organization* (2021). Available online at: https://www.who.int/activities/tracking-SARS-CoV-2-variants (accessed December 11, 2022).

37. Bhattacharya M, Chatterjee S, Sharma AR, Lee S-S, Chakraborty C. Delta variant (B16172) of SARS-CoV-2: current understanding of infection, transmission, immune escape, and mutational landscape. *Folia Microbiol.* (2023) 68:17–28. doi: 10.1007/s12223-022-01001-3

38. Lee C, Mangalaganesh S, Wilson LOW, Kuiper MJ, Drew TW, Vasan SS. Tracking co-occurrence of N501Y, P681R, and other key mutations in SARS-CoV-2 spike for surveillance. *Zoonotic Dis.* (2022) 2:147–62. doi: 10.3390/zoonoticdis2030014

39. Subissi L, von Gottberg A, Thukral L, Worp N, Oude Munnink BB, Rathore S, et al. An early warning system for emerging SARS-CoV-2 variants. *Nat Med.* (2022) 28:1110–5. doi: 10.1038/s41591-022-01836-w

40. Ambalavanan R, Snead RS, Marczika J, Kozinsky K, Aman E. Advancing the management of long COVID by integrating into health informatics domain: current and future perspectives. *Int J Environ Res Public Health.* (2023) 20:6836. doi: 10.3390/ijerph20196836

41. Bielecki M, Patel D, Hinkelbein J, Komorowski M, Kester J, Ebrahim S, et al. Air travel and COVID-19 prevention in the pandemic and peri-pandemic period: A narrative review. *Travel Med Infect Dis.* (2021) 39:101915. doi: 10.1016/j.tmaid.2020.101915

42. Yang N, Shen Y, Shi C, Ma AHY, Zhang X, Jian X, et al. In-flight transmission cluster of COVID-19: a retrospective case series. *Infect Dis Lond Engl.* (2020) 52:891–901. doi: 10.1080/23744235.2020.1800814

43. Schlagenhauf P, Patel D, Rodriguez-Morales AJ, Gautret P, Grobusch MP, Leder K. Variants, vaccines and vaccination passports: challenges and chances for travel medicine in 2021. *Travel Med Infect Dis.* (2021) 40:101996. doi: 10.1016/j.tmaid.2021.101996

44. Sun X, Wandelt S, Zhang A. Vaccination passports: challenges for a future of air transportation. *Transp Policy.* (2021) 110:394–401. doi: 10.1016/j.tranpol.2021.06.018

45. CDC. *Benefits of Getting a COVID-19 Vaccine*. Cent Dis Control Prev (2023). Available online at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html (accessed November 16, 2023).

46. da Silva SJR, Silva CTA da, Guarines KM, Mendes RPG, Pardee K, Kohl A, et al. Clinical and laboratory diagnosis of SARS-CoV-2, the virus causing COVID-19. *ACS Infect Dis.* (2020) 6:2319–36. doi: 10.1021/acsinfecdis.0c00274

47. Dhand R, Li J. Coughs and sneezes: their role in transmission of respiratory viral infections, including SARS-CoV-2. *Am J Respir Crit Care Med.* (2020) 202:651–9. doi: 10.1164/rccm.202004-1263PP

48. WHO. *Transmission of SARS-CoV-2: Implications for Infection Prevention Precautions*. World Health Organization (2020). Available online at: https://www.who.int/news-room/commentaries/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions (accessed April 4, 2022).

49. Johansson MA, Quandelacy TM, Kada S, Prasad PV, Steele M, Brooks JT, et al. SARS-CoV-2 transmission from people without COVID-19 symptoms. *JAMA Netw Open.* (2021) 4:e2035057. doi: 10.1001/jamanetworkopen.2020.35057

50. CDC. Overview of Testing for SARS-CoV-2, the virus that causes COVID-19. Cent Dis Control Prev US (2020). Available online at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html (accessed February 20, 2023).

51. Vogl T, Leviatan S, Segal E. SARS-CoV-2 antibody testing for estimating COVID-19 prevalence in the population. *Cell Rep Med.* (2021) 2:100191. doi: 10.1016/j.xcrm.2021.100191

52. Deeks JJ, Dinnes J, Takwoingi Y, Davenport C, Spijker R, Taylor-Phillips S, et al. Antibody tests for identification of current and past infection with SARS-COV-2. *Cochrane Database Syst Rev.* (2020) 6:CD013652. doi: 10.1002/14651858.CD013652

53. Harvey RA, Rassen JA, Kabelac CA, Turenne W, Leonard S, Klesh R, et al. Association of SARS-CoV-2 seropositive antibody test with risk of future infection. *JAMA Intern Med.* (2021) 181:672–9. doi: 10.1001/jamainternmed.2021.0366

54. CDC. *Nucleic Acid Amplification Tests (NAATs)*. Cent Dis Control Prev US (2020). Available online at: https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html (accessed April 18, 2022).

55. CDC. *Considerations for SARS-CoV-2 Antigen Testing for Healthcare Providers Testing Individuals in the Community*. Cent Dis Control Prev (2020). Available online at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html (accessed November 18, 2023).

56. Loeffelholz MJ, Tang Y-W. Detection of SARS-CoV-2 at the point of care. *Bioanalysis.* (2021) 13:1213–23. doi: 10.4155/bio-2021-0078

57. Gupta-Wright A, Macleod CK, Barrett J, Filson SA, Corrah T, Parris V, et al. False-negative RT-PCR for COVID-19 and a diagnostic risk score: a retrospective cohort study among patients admitted to hospital. *BMJ Open.* (2021) 11:e047110. doi: 10.1136/bmjopen-2020-047110

58. Lan L, Xu D, Ye G, Xia C, Wang S, Li Y, et al. Positive RT-PCR test results in patients recovered from COVID-19. *JAMA.* (2020) 323:1502–3. doi: 10.1001/jama.2020.2783

59. Wu X, Wang Z, He Z, Li Y, Wu Y, Wang H, et al. A follow-up study shows that recovered patients with re-positive PCR test in Wuhan may not be infectious. *BMC Med.* (2021) 19:77. doi: 10.1186/s12916-021-01954-1

60. Rodda LB, Netland J, Shehata L, Pruner KB, Morawski PA, Thouvenel CD, et al. Functional SARS-CoV-2-specific immune memory persists after mild COVID-19. *Cell* (2021) 184:169–83.e17. doi: 10.1016/j.cell.2020.11.029

61. Sah P, Fitzpatrick MC, Zimmer CF, Abdollahi E, Juden-Kelly L, Moghadas SM, et al. Asymptomatic SARS-CoV-2 infection: a systematic review and meta-analysis. *Proc Natl Acad Sci U S A.* (2021) 118:e2109229118. doi: 10.1073/pnas.2109229118

62. Grassly NC, Pons-Salort M, Parker EPK, White PJ, Ferguson NM. Imperial college COVID-19 response team. Comparison of molecular testing strategies for COVID-19 control: a mathematical modelling study. *Lancet Infect Dis.* (2020) 20:1381–9. doi: 10.1016/S1473-3099(20)30630-7

63. Vandenberg O, Martiny D, Rochas O, van Belkum A, Kozlakidis Z. Considerations for diagnostic COVID-19 tests. *Nat Rev Microbiol.* (2021) 19:171–83. doi: 10.1038/s41579-020-00461-z

64. Bish DR, Bish EK, El-Hajj H, Aprahamian H. A robust pooled testing approach to expand COVID-19 screening capacity. *PLoS ONE.* (2021) 16:e0246285. doi: 10.1371/journal.pone.0246285

65. NIH. *Lasting Immunity Found After Recovery From COVID-19*. Natl Inst Health NIH (2021). Available online at: https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19 (accessed February 16, 2023).

66. Baraniuk C. How long does covid-19 immunity last? *BMJ.* (2021) 373:n1605. doi: 10.1136/bmj.n1605

67. Kellam P, Barclay W. The dynamics of humoral immune responses following SARS-CoV-2 infection and the potential for reinfection. *J Gen Virol.* (2020) 101:791–7. doi: 10.1099/jgv.0.001439

68. Wang Z, Muecksch F, Schaefer-Babajew D, Finkin S, Viant C, Gaebler C, et al. Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection. *Nature.* (2021) 595:426–31. doi: 10.1038/s41586-021-03696-9

69. Abbasi J. Study suggests lasting immunity after COVID-19, with a big boost from vaccination. *JAMA.* (2021) 326:376–7. doi: 10.1001/jama.2021.11717

70. Ripperger TJ, Uhrlaub JL, Watanabe M, Wong R, Castaneda Y, Pizzato HA, et al. Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humoral immunity. *Immunity.* (2020) 53:925–33.e4. doi: 10.1016/j.immuni.2020.10.004

71. Chvatal-Medina M, Mendez-Cortina Y, Patiño PJ, Velilla PA, Rugeles MT. Antibody responses in COVID-19: a review. *Front Immunol.* (2021) 12:633184. doi: 10.3389/fimmu.2021.633184

72. Marovich M, Mascola JR, Cohen MS. Monoclonal antibodies for prevention and treatment of COVID-19. *JAMA.* (2020) 324:131–2. doi: 10.1001/jama.2020.10245

73. Ledford H. How does COVID-19 kill? *Uncertainty is hampering doctors' ability to choose treatments. Nature.* (2020) 580:311–2. doi: 10.1038/d41586-020-01056-7

74. Kirkcaldy RD, King BA, Brooks JT. COVID-19 and postinfection immunity: limited evidence, many remaining questions. *JAMA.* (2020) 323:2245–6. doi: 10.1001/jama.2020.7869

75. Dagan N, Barda N, Kepten E, Miron O, Perchik S, Katz MA, et al. BNT162b2 mRNA Covid-19 vaccine in a nationwide mass vaccination setting. *N Engl J Med.* (2021) 384:1412–23. doi: 10.1056/NEJMoa2101765

76. Feng S, Phillips DJ, White T, Sayal H, Aley PK, Bibi S, et al. Correlates of protection against symptomatic and asymptomatic SARS-CoV-2 infection. *Nat Med.* (2021) 27:2032–40. doi: 10.1101/2021.06.21.21258528

77. Hall V, Foulkes S, Insalata F, Kirwan P, Saei A, Atti A, et al. Protection against SARS-CoV-2 after Covid-19 vaccination and previous infection. *N Engl J Med.* (2022) 386:1207–20. doi: 10.1056/NEJMoa2118691

78. Krammer F, Srivastava K, Team the P, Simon V. Robust spike antibody responses and increased reactogenicity in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine. *medRxiv.* (2021) 2021.01.29.21250653. doi: 10.1101/2021.01.29.21250653

79. FDA. *Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines*. U.S. Food and Drug Administration (2021). Available online at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines (accessed June 12, 2022).

80. Callaway E. COVID vaccine boosters: the most important questions. *Nature.* (2021) 596:178–80. doi: 10.1038/d41586-021-02158-6

81. Lawton G. Are booster shots coming? *New Sci.* (2021) 250:8–9. doi: 10.1016/S0262-4079(21)00808-3

82. Feldscher K. *What Will It Be Like When COVID-19 Becomes Endemic?* Boston, MA: The Harvard TH Chan School of Public Health–News. (2021).

83. CDC. ACIP. *Evidence to Recommendations (EtR) for Use of Bivalent COVID-19 Vaccine Booster Doses under an Emergency Use Authorization*. Atlanta, GA: Cent Dis Control Prev US (2021).

84. WHO. *Interim Statement on Booster Doses for COVID-19 Vaccination*. Geneva: World Health Organization (2021). Available online at: https://www.who.int/news/item/04-10-2021-interim-statement-on-booster-doses-for-covid-19-vaccination (accessed July 4, 2022).

85. Craig AM, Hughes BL, Swamy GK. Coronavirus disease 2019 vaccines in pregnancy. *Am J Obstet Gynecol MFM.* (2021) 3:100295. doi: 10.1016/j.ajogmf.2020.100295

86. Prasad S, Kalafat E, Blakeway H, Townsend R, O'Brien P, Morris E, et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. *Nat Commun.* (2022) 13:2414. doi: 10.1038/s41467-022-30052-w

87. CDC. *Vaccination Considerations for People Pregnant or Breastfeeding*. Cent Dis Control Prev (2023). Available online at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html (accessed November 16, 2023).

88. Syangtan G, Bista S, Dawadi P, Rayamajhee B, Shrestha LB, Tuladhar R, et al. Asymptomatic SARS-CoV-2 carriers: a systematic review and meta-analysis. *Front Public Health.* (2020) 8:587374. doi: 10.3389/fpubh.2020.587374

89. Ludvigsson JF. Systematic review of COVID-19 in children shows milder cases and a better prognosis than adults. *Acta Paediatr Oslo Nor.* (2020) 109:1088–095. doi: 10.1111/apa.15270

90. FDA. *Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 Through 11 Years of Age*. Silver Spring, MA: US Food and Drug Administration (2021).

91. FDA. *Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups*. U.S. Food and Drug Administration (2022). Available online at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines (accessed November 16, 2023).

92. Caselli D, Aricò M. SARS-CoV-2 vaccination for children-an open issue. *Pediatr Rep.* (2021) 13:95–7. doi: 10.3390/pediatric13010013

93. The Lancet Microbe. Vaccine certificates: does the end justify the means? *Lancet Microbe.* (2021) 2:e130. doi: 10.1016/S2666-5247(21)00067-7

94. Baay M, Neels P. Controlled human infection to speed up SARS-CoV-2 vaccine development. *Front Immunol.* (2021) 12:658783. doi: 10.3389/fimmu.2021.658783

95. Government of Canada. *Scientific Considerations for Using COVID-19 Vaccination Certificates*. (2021). Available online at: https://science.gc.ca/site/science/en/office-chief-science-advisor/scientific-considerations-using-covid-19-vaccination-certificates (accessed July 4, 2021).

96. WHO. *Evaluation of COVID-19 Vaccine Effectiveness*. World Health Organization (2021). Available online at: https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-vaccine_effectiveness-measurement-2021.1 (accessed August 14, 2022).

97. Harvey WT, Carabelli AM, Jackson B, Gupta RK, Thomson EC, Harrison EM, et al. COVID-19 Genomics UK (COG-UK) Consortium, et al. SARS-CoV-2 variants, spike mutations and immune escape. *Nat Rev Microbiol.* (2021) 19:409–24. doi: 10.1038/s41579-021-00573-0

98. CDC. *COVID Vaccine Effectiveness Data Show Protection Gained by Boosters*. Atlanta, GA: Cent Dis Control Prev (2022).

99. Link-Gelles R, Levy ME, Gaglani M, Irving SA, Stockwell M, Dascomb K, et al. Effectiveness of 2, 3, and 4 COVID-19 mRNA vaccine doses among immunocompetent adults during periods when SARS-CoV-2 Omicron BA.1 and BA.2/BA.2.12.1 Sublineages Predominated - VISION Network, 10 States, December 2021-June 2022. *MMWR Morb Mortal Wkly Rep.* (2022) 71:931–9. doi: 10.15585/mmwr.mm7129e1

100. Kilbourne ED. Influenza pandemics of the 20th century. *Emerg Infect Dis.* (2006) 12:9–14. doi: 10.3201/eid1201.051254

101. Torjesen I. Covid-19 will become endemic but with decreased potency over time, scientists believe. *BMJ.* (2021) 372:n494. doi: 10.1136/bmj.n494

102. Kahn R, Rid A, Smith PG, Eyal N, Lipsitch M. Choices in vaccine trial design in epidemics of emerging infections. *PLoS Med.* (2018) 15:e1002632. doi: 10.1371/journal.pmed.1002632

103. Mbunge E, Dzinamarira T, Fashoto SG, Batani J. Emerging technologies and COVID-19 digital vaccination certificates and passports. *Public Health Pract Oxf Engl.* (2021) 2:100136. doi: 10.1016/j.puhip.2021.100136

104. Lavine JS, Bjornstad ON, Antia R. Immunological characteristics govern the transition of COVID-19 to endemicity. *Science.* (2021) 371:741–5. doi: 10.1126/science.abe6522

105. Phillips N. The coronavirus is here to stay - here's what that means. *Nature.* (2021) 590:382–4. doi: 10.1038/d41586-021-00396-2

106. IATA. *Travel Pass Key to Reopening Borders Safely*. IATA (2021). Available online at: https://www.iata.org/en/pressroom/pressroom-archive/2020-press-releases/2020-11-23-01/

107. WHO. *Interim Position Paper: Considerations Regarding Proof of COVID-19 Vaccination for International Travellers. World Health Organization* (2021). Available online at: https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers (accessed November 29, 2021).

108. Clifford S, Pearson CAB, Klepac P, Van Zandvoort K, Quilty BJ, CMMID COVID-19 working group, et al. Effectiveness of interventions targeting air travellers for delaying local outbreaks of SARS-CoV-2. *J Travel Med.* (2020) 27:taaa068. doi: 10.1093/jtm/taaa068

109. Mandal S, Bhatnagar T, Arinaminpathy N, Agarwal A, Chowdhury A, Murhekar M, et al. Prudent public health intervention strategies to control the coronavirus disease 2019 transmission in India: a mathematical model-based approach. *Indian J Med Res.* (2020) 151:190–9. doi: 10.4103/ijmr.IJMR_504_20

110. Grépin KA, Ho T-L, Liu Z, Marion S, Piper J, Worsnop CZ, et al. Evidence of the effectiveness of travel-related measures during the early phase of the COVID-19 pandemic: a rapid systematic review. *BMJ Glob Health.* (2021) 6:e004537. doi: 10.1136/bmjgh-2020-004537

111. WHO. *Digital Documentation of COVID-19 Certificates: Vaccination Status: Technical Specifications and Implementation Guidance, 27 August 2021. World Health Organization* (2021). Available online at: https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Digital_certificates-vaccination-2021.1 (accessed November 26, 2021).

112. Kouroubali A, Kondylakis H, Katehakis DG. Integrated care in the era of COVID-19: turning vision into reality with digital health. *Front Digit Health.* (2021) 3:647938. doi: 10.3389/fdgth.2021.647938

113. OECD. *Data Portability, Interoperability and Competition*. Organ Econ Co-Oper Dev (2021). Available online at: https://www.oecd.org/daf/competition/data-portability-interoperability-and-competition.htm (accessed December 16, 2023).

114. Shacklett ME. What is multifactor authentication? *TechTarget Security.* (2021). doi: 10.1016/S1353-4858(21)00004-0

115. Tran H. The *Importance Of Multi-Factor Authentication*. Houston, TX: IT Matters Inc. (2021).

116. Jones E, Freeguard G, Parker I. *Checkpoints for Vaccine Passports*. London: Ada Lovelace Institute; Nuffield Foundation (2021).

117. European Commission. *Coronavirus: Commission proposes a Digital Green Certificate*. Eur Comm (2021). Available online at: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1181 (accessed January 28, 2022).

118. Razzaq A, Mohsan SAH, Ghayyur SAK, Al-Kahtani N, Alkahtani HK, Mostafa SM. Blockchain in healthcare: a decentralized platform for digital health passport of COVID-19 based on vaccination and immunity certificates. *Healthcare.* (2022) 10:2453. doi: 10.3390/healthcare10122453

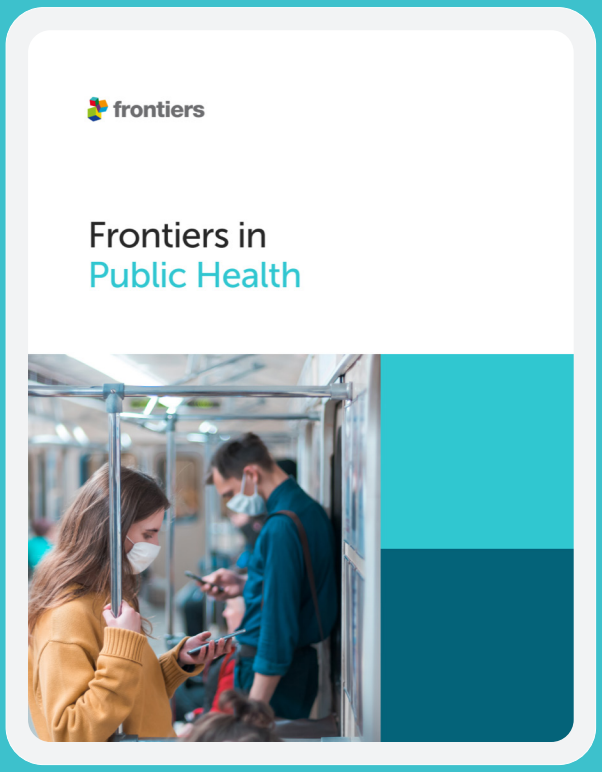
Frontiers in Public Health

Explores and addresses today's fast-moving healthcare challenges

One of the most cited journals in its field, which promotes discussion around inter-sectoral public health challenges spanning health promotion to climate change, transportation, environmental change and even species diversity.

Discover the latest Research Topics

See more →



Frontiers

Avenue du Tribunal-Fédéral 34
1005 Lausanne, Switzerland
frontiersin.org

Contact us

+41 (0)21 510 17 00
frontiersin.org/about/contact