Opinion

Opinions from patients and the public for the revision of the WMA Declaration of Taipei

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Abstract

Bioethics Working Group of the Japanese Institute for Public Engagement (Ji4pe) expresses its opinions so that the following points will be incorporated into the revision of the World Medical Association (WMA)'s Declaration of Taipei (DoT):

1. Plain Language;
2. Respect for deceased persons; consideration of human embryos and germ cells; explicit mention of artificial intelligence;
3. Patient and Public Involvement in all stages of management and ethical review of health databases and/or biobanks (HDBs/BBs);
4. Equitable Benefit Sharing and Prohibition of Exploitation;
5. Outcomes from the uses of HDBs/BBs as Public Goods;
6. Sustainable Development Goals (SDGs) and "Gifts" for Future Generations;
7. Consent in the Age of Information Technology, e.g., Broad Informed Consent and Dynamic Consent, ensuring the Right to Know and the Right Not to Know in Shared Decision-Making (SDM);
8. Participation of Persons with Limited Capacity;
9. Social Consensus Building and Health Literacy in the Digital Age;
10. Achievement of the Highest Global Ethical Standards.

Agreement on the ethical principles for HDBs/BBs must be based on equal participation of all relevant interested parties, including patients and the public.

Kew Words

Ethical principles for health databases and biobanks, patient public involvement, equitable benefit sharing, sustainable development goals (SDGs), artificial intelligence (AI)

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Introduction

Bioethics Working Group of the Japanese Institute for Public Engagement (Ji4pe) has been holding monthly online study sessions since 2020 on bioethical issues, starting with the World Medical Association (WMA)'s Declaration of Helsinki (DoH). Ahead of the 2024 revision of the DoH[1], we have expressed our opinions on the DoH, sharing ideas with global research ethics communities, including the WMA, through publications and presentations at webinars both in English and in Japanese[2,3,4,5,6].

We are pleased that some of our views have been reflected in the 2024 DoH, including:

(1) Patient and public involvement at every stage of research;

(2) Diversity and participation of public members in research ethics committees;

(3) The use of plain language; and

(4) Research under the scope of the DoH also adhering to the Declaration of Taipei (DoT)[7] on health databases and biobanks (HDBs/BBs).

Whilst some views were not incorporated, we have globally disseminated our "Patient and Public Declaration of Research Ethics"[4, 5] and the "GREEN Statement"[8], hoping that our proposals will be reflected in future revisions of global research ethics norms, as well as the implementation of ethics in the everyday practice of research and research review.

The 2024 DoH[1] referred the DoT[7] for the first time. The DoT entered its next revision process in April 2025, with the first public meeting held in Taipei, Taiwan, in December 2025[9,10,11]. The second open meeting was held in Sao Paulo, Brazil. The revised DoT is planned for adoption at the WMA General Assembly in October 2027. The DoT on HDBs/BBs handling large volumes of human-derived data and/or materials (data/materials) has to be adhered to also in the development and use of artificial intelligence (AI)[12]. For this reason, the DoT represents crucial issues for patients and the public. This is because it will involve a far larger scale of use of data/materials of patients and the public than in the case of clinical trials. Japan has contributed to the development of international norms regarding AI[13,14,15], and current AI regulations vary significantly by region.

On this premise, we express our opinions to ensure that the views of patients and the public are incorporated into the revision of the DoT. The first half of this paper outlines the issues recognised by patients and the public, while the second half details the points we wish to see incorporated into the revision of the DoT, as summarised in Table 1.

The opinions described here were compiled from texts written by ourselves in a Google Form, followed by extensive discussions during about 10 web meetings, one international webinar[16], and another conference[17].

Table 1 The critical points which should be incorporated into the revised Declaration of Taipei

1. Declaration written in Plain Language
2. Respect for the dignity of the deceased persons; more in depth consideration of human embryos and germ cells, explicit mention of artificial intelligence (AI)
3. Patient and Public Involvement in all stages of management and ethical review of health databases and/or biobanks (HDBs/BBs)
4. Equitable Benefit Sharing and Prohibition of Exploitation
5. Outcomes from the use of HDBs/BBs as Public Goods
6. Sustainable Development Goals (SDGs) and "Gifts" for Future Generations
7. Consent in the Age of Information Technology: Broad Informed Consent; Dynamic Consent; Tiered Consent, ensuring the Right to Know and the Right Not to Know in Shared Decision-Making (SDM)
8. Participation of Persons with Limited Capacity
9. Social Consensus Building and Health Literacy in the Digital Age
10. Achievement of the Highest Global Ethical Standards

＜Critical challenges recognised by patients and the public＞

Regarding the ethics of HDBs/BBs, we have recognised the following critical challenges:

- The utilisation of big data is an important measure for enhancing the precision of research outcomes and their application in practice. On this premise, our concern is that, due to the absence of direct human interaction or intervention, the perspective of prioritising human rights may be underestimated in the handling of data/materials. Furthermore, there is a risk to overlooking the necessity of the engagement of patients, public, and relevant communities from the early stages of planning and designing of HDBs/BBs and data-driven research.
- The majority of patients and the public lack sufficient opportunities to learn that their health information is being reused or how the results are being returned to society.
- Patients and the public providing data/materials often consent to the use of sensitive data for unspecified purposes without compensation. Meanwhile, industries and researchers gain profit from the utilizations of patient data/materials. Yet, industry and researchers do not sufficiently disclose their confidential information. Their transparency is insufficient. For example, procedures and systems have not been established to disclose meaningful findings from the research to the individuals who provided their data/materials. This has raised concerns that commercial benefits have not been fairly and equitably returned to society. Patients and the public are worried about how their data/materials are handled and whether research outcomes benefit patients and society, fearing that they may solely serve the interests of specific companies or governments, widening disparities in benefit sharing.
- For patients and the public, it remains unclear how ethical frameworks and consent mechanisms are established for the use of data/materials for unspecified purposes, while ensuring that the dignity, rights, and interests of patients and the public are protected.

- The concept of "consent to governance" has been discussed[10]. However, governance mechanisms often fail to function effectively even if they are explicitly stated as a policy. Cases of information leaks and data tampering have been steadily increasing. Furthermore, even where governance is established, intentional violations continue to occur, such as malicious actors leaking large volumes of personal data for individual profit, and ransomware attacks where perpetrators cannot be identified. Japan's Ministry of Internal Affairs and Communications, citing survey results from Statista, IBM, Sophos (global), FBI (United States), National Police Agency, and TrendMicro (Japan), indicates that the scale of cybersecurity incidents increased tenfold over the six years from 2018 to 2024. The annual total cost to deal with such incidents reached $9 trillion in 2024 and is estimated to reach $15 trillion in 2029[18]. Stringent legal regulations are needed to cover the handling of vast amounts of data, and ethics should represent the highest standard guiding such legislation. For the realisation of patient-centered healthcare, shifting the focus from healthcare providers to healthcare users, governance with a legal foundation is a prerequisite. Such a stringent governance framework will protect both patients and healthcare providers.
- Concerns regarding discrimination and exploitation against indigenous peoples and ethnic minorities remain unresolved in debates regarding health databases and biobanks[19]. In Japan, three academic societies and the University of Tokyo officially apologized between 2024 and 2025 for their practices involving the collection of remains from ethnic minorities and conducting discriminatory research[20,21,22]. These actions are a response to the United Nations Declaration on the Rights of Indigenous Peoples in 2007[23]. Meanwhile, despite the requirement that benefits from research using data/materials should be shared with the regions of origin of those resources[24,25,26,27], benefit sharing for the indigenous people has not been sufficient[28].
- Furthermore, the rapid advancement of genomic testing raises concerns that individuals with specific genomic information may face discrimination in employment, insurance and other areas, while the development of treatments remains slow. Our group has expressed objections to such potential future scenarios[29].
- Regulations on personal data protection and on the use of human-derived materials vary by country. For this reason, to foster consensus on HDBs/BBs within global society towards a universally shared legal framework that respects human dignity and human rights, a forum for dialogue involving all interested parties, especially patients and the public, with equal decision-making rights and responsibilities, is indispensable.

＜Our Opinions on the Revision of the Declaration of Taipei＞

We wish to discuss and see the following points reflected in the revision of the DoT. Discussions should not be confined to forums accessible only to experts. We urge the WMA and other influential organisations to facilitate dialogue platforms enabling patients and vulnerable people globally to participate online and voice their opinions. Furthermore, we hope that experts, including members of the WMA, will participate in forums for dialogue we plan and organise.

- **【Declaration in Plain Language】** The wording of the DoT must be written in plain

language to ensure it is accessible and easily understood by patients and the public[2-5].

- 【Scope of the Declaration】 The DoT covers the handling of data/materials from diceased persons. The dignity of the deceased must be respected. Also, more in-depth consideration is required regarding the handling of human embryos and germ cells. Meanwhile, it should state that additional technical requirements concerning safety and ethics are needed when human-derived materials are used for clinical application, e.g., cell and/or tissue transplantation. It should also explicitly state that AI systems containing health information are within the scope of the DoT, as mentioned in the WMA Statement on AI[12].
- 【Patients and the Public Involvement in the Establishment and Implementation of HDBs/BBs】 Patients and the public providing their data/materials are not mere "research resources"; our data/materials embody "lived experience" with individual diseases and personal values. We are not passive subjects of observation, but active, autonomous partners with dignity in co-creation, engaging with HDB/BB activities and data-driven research. We must be termed "participants". To achieve this, as in the 2024 DoH[1], patients, the public, participants, and communities must engage meaningfully in planning, operating HDBs/BBs, and the dissemination and implementation of results gained from the use of HDBs/BBs.
- 【Participation in Governance as Committee Members】 The membership of the committees reviewing the establishment, operation, and use of data/materials from HDBs/BBs must incorporate the same requirements as the DoH[1], ensuring community values are reflected and assuring diversity, including public representatives. Reviews concerning vulnerable individuals, including those incapable of decision-making, should involve representatives who advocate on their behalf. When there is no direct benefit to the individuals concerned, it must be rigorously assessed whether measures to bring future benefits to them are in place.
- 【Equitable Benefit Sharing and Prohibition of Exploitation】 Patients and the public provide their data/materials without receiving compensation, but for the sake of society. For this reason, even if intellectual property rights arise from the use of data/materials, the implementation of such rights must be limited and structured to enable broad societal access. Should commercial use generate profits, the purpose of such use must ensure that benefits are returned to society. In addition, not only the prohibition of discrimination already stipulated in the current DoT, but also the prohibition of exploitation must be explicitly stated.
- 【Outcomes as Public Goods】 The results derived from the use of HDBs/BBs must be made publicly available for anyone to utilize, recognizing the research outcomes as "Public Goods". A clear mechanism should be established to disclose and explain the purpose and nature of the products being developed based on the use of HDBs/BBs.
- 【SDGs and Gifts for Future Generations】 The activities using HDBs/BBs should be directed towards the Sustainable Development Goals (SDGs)[30] defined by the United Nations, as "Gifts" for future generations[31]. Diversity and inclusivity must be promoted, and consideration should be given to the negative impact on individuals, and their communities who provided their data/material, as well as the impact on society, mental wellbeing, ecosystems, and future generations[2~5, 31].

- 【Consent in the Age of Information Technology】 Even when utilising vast amounts of information, transparency and accountability are required to maximise respect for individual dignity and rights, including privacy rights, in the style and content of information disclosure, alongside quality improvements in the process of informed consent. To this end, guidelines should be clarified for:
  - "Broad Informed Consent" [32] (based on sufficient understanding of expected future uses, according to CIOMS 2016);
  - "Dynamic Consent" [33] (involving ongoing interactions with participants, according to CIOMS Report XI 2022); and
  - "Tiered Consent" [34] (to limited, categorized uses),

  covering the scope and limitations of use for each, along with necessary procedures. While the concept of "consent to governance" is discussed, the governance framework must have strict legal bases. The abuse of easy application of "opt-out" procedures must be avoided, and it is essential to make every effort to obtain the aforementioned types of explicit consent from the very first point of interaction with the relevant individuals.
- 【Participation of Persons with Limited Capacity】 When facilitating the participation of persons with limited decision-making capacity or those with difficulty expressing their wishes, we shall devise communication methods tailored to each individual's capacity of understanding and expressing their will. We must listen carefully to their wishes, and obtain support from advocates to protect their rights, thereby enabling autonomous expression of their own will and autonomous decisions. We respect the principle "Nothing about us without us", which underpins the United Nations Convention on the Rights of Persons with Disabilities[35].
- 【The Right to Know and the Right Not to Know in Shared Decision-Making (SDM)】 From the perspective of respecting both the "right to know" and the "right not to know"[36], more thorough explanations are required, including the validity, accuracy, and clinical value as well as the limitations of the information to be provided. We are now in an era where AI is utilised throughout the entire lifecycle of pharmaceuticals as well as in clinical practice, with the possibility of expanding the use of validated and unvalidated information. Patients and the public are requested to make decisions based on information that, while not entirely meaningless, lacks sufficient scientific validity or clinical significance. Such decision making should not be left solely to the individual. Instead, continuous shared decision-making (SDM)[37] must be promoted, centred on the individual concerned, and involving their family members, diverse professionals from multiple relevant disciplines, peer supporters[38], patient organisations, and other interested parties. SDM will contribute to the governance framework of HDBs/BBs.
- 【Social Consensus Building】 Given the limitations in the functioning of informed consent procedures for individual projects, the commitment of professionals engaged in HDBs/BBs to ongoing dialogue with participants is crucial. Beyond merely participating in the operation of individual HDBs/BBs, the involvement of patients and the public as committee members in various academic societies or working groups fosters social dynamism. This facilitates the formation of social consensus regarding the collection, storage, and utilisation of large volumes of data, thereby contributing to better outcomes

and the societal implementation of HDBs/BBs.

- **【Patients and the Public Learning in the Digital Age】** Patients and the public must deepen their understanding of healthcare and medicine in the digital age. This includes education on genomic medicine as well as the development and use of AI, within school curricula, ensuring the public gains accurate foundational knowledge. Health literacy is paramount.
- **【Achievement of with the Highest Global Standards】** Recent AI-related legislation and international standards (such as those from UNESCO[39] and United Nations (UN)[40,41] demonstrate the highest ethical standards, as pursued by the "Patient Public Declaration of Research Ethics"[4,5] and the "GREEN Statement"[8]. Simultaneously, these international norms of AI-related ethics incorporate such ethical principles into digital education. The ethical principles for HDBs/BBs including AI should be aligned with such high-level global norms of AI presented by UNESCO and the UN, contributing to the social values of all people around the world, directed towards solving the global societal challenges outlined in the SDGs.

In conclusion

We shall continue our efforts to ensure that ethical principles concerning HDBs/BBs achieve:

- The highest ethical standards, including equitable benefit sharing;
- Accessibility and comprehensibility to patients and the public;
- Agreement through the equal participations of all relevant interested parties, including patients and the public; and
- Coverage of research conducted under the stewardship of our civil society, including the research initiated by patients and the public.

HDBs/BBs must be managed with people, for the benefit of everyone. By prioritising transparency, inclusion, and equity today, we are not just managing data; we are building a foundation of trust that will serve as a lasting gift for future generations.

Conflict of interest

There is no conflict of interest declared related to this manuscript.

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