

Aug. 5. 2024

Patient and public opinions to the revision of the Declaration of Helsinki: Our proposals to the WMA

Yoshiko Saito, Master of School Design, Breast cancer survivor; Fellow Member of the JAB

1)

Good evening, everyone.

Thank you for the introduction.

My name is Yoshiko Saito, and I am a breast cancer survivor.

I am very grateful for the opportunity to speak today.

Today I will cover the opinions of patient and public on the revision of the Declaration of Helsinki.

I've prepared this presentation with Ms. Chieko Kurihara, based on discussions in the patient and public working group of Japanese Institution for Patient Engagement, Ji4Pe.

2)

Now, let's move on to the main topic. I'd like to speak about three points today.

3)

Let's start with the background of our group.

4)

The Declaration of Helsinki is a set of ethical principles for medical research involving humans that are directed at physicians.

It was developed by the World Medical Association WMA.

It is assumed that research participants often first see its title in an informed consent document when asked to participate in medical research.

But it is not widely known in society.

This is why our working group has been holding monthly online meetings since November 2020 to discuss its contents.

Aug. 5. 2024

5)

During the process, some members initiated to re-write and explain the Declaration of Helsinki in our own words using plain language addressed to patient and public.

This process led to the project to develop a three -part document titled “Our WMA Declaration of Helsinki”.

First part of each paragraph is a Reproduction of the Declaration of Helsinki under the permissions of WMA and Japanese Medical Association JMA.

Second part is re-written and explained in our plain language.

And third part is about our opinion on the Declaration of Helsinki from our perspectives.

6)

Because the Declaration of Helsinki is a set of basic principles that are internationally recognized, we thought the issues and proposals that we had noticed would be worth sharing internationally, and we were given the opportunity to have them published as a part of a book.

Its title is "Ethical Innovations for Global Health", and it was published by Springer in November 2023.

7)

In addition, "Our WMA Declaration of Helsinki" was published in its entirety in the July 2024 issue of the Japanese journal "Clinical Evaluation."

8)

Responding to the WMA Public Consultation, we submitted opinions based on our past discussions and publications in February and June this year.

9)

In order to understand the Declaration of Helsinki, it is necessary to have a

Aug. 5. 2024

common understanding of various international treaties, domestic norms, and various WMA declarations.

10)

Furthermore, from the South African Constitution, we learned that the Japanese Clinical Research Act does not establish fair protection for research participants.

In addition, we strongly believe that research ethics principles must ensure the protection of privacy rights.

11)

We also learned that the WMA has issued many declarations and statements not only on research ethics but also on medical practice and patient care.

Recently, large amounts of patient data have been used to develop various medicines, including artificial intelligence.

Therefore, the "Taipei Declaration" on health databases and biobanks is particularly important.

12)

In the second part, we present our opinions on the WMA's draft document for revising the Declaration of Helsinki.

13) 14)

We have three key points:

15)

First, simplifying the language.

The Declaration of Helsinki is written in very difficult language, and hard to understand for patients.

Patients also encounter it in informed consent documents when they are asked to participate in a clinical research.

Aug. 5. 2024

Secondly, we support the change from “subjects” to “participants”, as the word ‘participant’ accurately describes a person who voluntarily takes part in research.

However, the Declaration of Helsinki as a whole is paternalistic, and there is no indication in the proposed revision.

We are concerned that people in weaker and more vulnerable positions will be left without a sense of participation despite being described as “participants.”

We believe the term “participants” will only have its true meaning when the importance of advocates is also emphasized.

16)

Next, I would like to talk about the two public consultations in detail.

17)

All nine members of the Working Group prepared the Public Consultation comments last February and June.

Ms. Chieko Kurihara supported us, but she led another group’s comment, so we have included her in the acknowledgement.

18)

Now, I will show you our comments.

#1 The term “social value” was once added in the first draft, but it was omitted in the second draft.

Omitting social value might cause us to lose sight of the trajectory towards achieving the SDGs.

#2 For research participants who cannot consent themselves, we must find advocates who best protect their rights and interests.

Aug. 5. 2024

#3 We proposed the concept of shared decision-making based on informed consent.

#4 We hope the fairness of research ethics committees and the participation of general committee members will be clearly stated in the Declaration of Helsinki.

#5 It's nearly impossible for patients to understand the conditions for using a placebo when an intervention has been already proven.

#6 We believe that post-trial access should be guaranteed, and also it should be included in the informed consent document.

Without documentation at the time of participation in a clinical research, the patient cannot request the continuation of the study drug even though it is necessary at the time of completion.

19)

#7 The proposed Declaration of Helsinki revision lacks provisions for accumulating data and monitoring safety and effectiveness regarding the use of unproven clinical interventions.

However, these are already included in the WHO document.

I have additional comments, but due to limited time, I will only show the keywords about on the right side of this slide.

20)

Finally, we look towards the future.

21)

As we continue to learn, we have restarted a bioethics group made up of patient and public as one of Ji4Pe's working groups last month.

I took over the leadership role from my predecessor, Ms. Keiko Inoue.

Our group came up with three goals.

Aug. 5. 2024

We plan to develop a patient and public research ethics statement.

This comes from Professor Ames Die's advice in a webinar last December at the time of the Springer book publication.

And, with permission from the WMA and JMA, we will publish the second edition of Our WMA Declaration of Helsinki after the 2024 version of the Declaration of Helsinki is released.

We hope it will be a guide from the perspective of patient and public.

Third goal is to conduct a survey on patient and public participation in medical care based on the report from CIOMS.

22)

By the way, our presentation slides, video-recordings of webinars and open access papers are available on the website in both Japanese and English. You can also see the Graphic Recordings by Ms. Kanna Yoshikawa.

She joined our several discussions and provided these illustrations to describe our questions and opinions.

23)

Well, this brings me to the end of my presentation.

Lastly, let me introduce the members of the Bioethics Working Group of Ji4Pe.

I have posted photos of everyone on the slide.

Also, I would like to express my heartfelt gratitude to the President of Ji4Pe, Dr. Kyoko Imamura and I would like to thank our mentor, Prof. Chieko Kurihara for her guidance and support.

Thank you very much for your attention.

Aug. 5. 2024