Overview of the revision process of the 2024 Declaration of Helsinki: Part 1- focusing on placebo study

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Slide 1: Cover

Thank you for your kind introduction. I am Takeo Saio, Japanese physician practicing internal medicine, psychiatry, and occupational health. I am one of the early advocates of evidence-based medicine in Japan.

Slide 2: Conflict of interest disclosure

I have no conflict of interest on this presentation. I present you my opinion from the stand point of a clinician who has some knowledge on bioethics as a whole.

Slide 3: WMA Regional Meetings

There have been seven WMA's Regional meetings until now. The main themes of each meeting are shown on this slide. The WMA put public consultations two times.

Kindly, some of the regional meetings accepted online observation by the public, but the numbers of online participants were strictly limited because their opening announcements are always just a few days before the event which made a sort of barrier for physicians, patients and general public to view the meetings. However generous enough, the video-recordings of some of them are available from these websites.

Slide 4: Public consultations

As of the public consultations, In the Phase 1 public consultation, I submitted a comment co-authoring with Prof. Greco; and for Phase 2 co-authoring with Prof. Greco and Prof. Bussinguer, the past and the current Presidents of the Brazilian Society of Bioethics, representing the society. This is a great honor of me.

Slide 5: Paragraph 33 Conditions of placebo study

Most important topic I wish to focus is the condition of placebo-controlled study when there is a proven intervention. The 2000 version the DoH permits placebo study only when there is no proven intervention. However, in 2002 a small working group changed this condition to current idea "no additional risk of serious or irreversible harm", according to ICH-GCP E10 guidelines. It was discussed by small group to reverse the 2000 General Assembly decision. We argued during this time that this process is unfair. Then current proposed revision keeps this condition that placebo study when there is a proven intervention is permitted if there is no additional risk of serious or irreversible harm. However this condition

is inconsistent with CIOMS 2016 guidelines that states that placebo study when there is a proven intervention can be permitted when there is only minor increase above minimal risk. Our opinion is that the DoH should follow the CIOMS.

Slide 6: WMA's explanation in public consultation document

What I would like to point out now is that WMA's explanation in public consultation document about the paragraph 33 seems to be Deceptive or Unfair for me.

They omitted in the revision draft on the two the most important debates. One is the "Standard of care" which means local standard or global standard, and another is the Risk Threshold. With the risk threshold, it is obvious that the DoH's high risk standard is inconsistent with the CIOMS standard which allows only minor increase above minimal risk. However, the WMA's explanation in the draft is confusable treating Latin American countries and CONFEMEL agree with proposed version to keep 2013 version at the regional meeting in Sao Paulo. The draft only changed "proven intervention" to "an intervention proven to be safe and effective". And there is some minor change. Adding "safe" is important but not the focus of international debate.

Slide 7: Questions

So I would like to ask Latin American colleagues whether Declarations of Cordoba, Buenos Aires, and Pachuca are still now effective or not.

I learned that Latin American organizations rejected the DoH because of weakened protection in placebo and access paragraphs.

Slide 8: JMA's view at the time of 2000 (not necessarily same views are kept)

I would like to introduce what Dr. Eitaka Tsuboi stated, when he was the President of Japanese Medical Association and also the President of the WMA at the time of 2000 revision.

He stated that the JMA did not accept the 2002 note of clarification to permit placebo study when there is a proven intervention if there is no additional risk of serious or irreversible harm. For this reason, JMA did not publish a Japanese translation of this note on the JMA website.

Tsuboi explained that Japan expressed objection to proposal from American Medical Association because developing countries were not in a position to express objection because they benefited from the US. For this reason, we expressed non-Western spirit that ethical reason takes precedence over scientific needs and pragmatism.

Tsuboi stated that the placebo clause in the 2000 version is a perfect, prima facie norm.

Slide 9: Thank you for your attention!

More in depth analysis on placebo study was discussed in our paper and will be discussed by other speakers today. Thank you so much for your attention!