Participation in WMA meeting in Washington DC:
Taking forward bioethics and human rights, maximizing the impact of the NEW DoH

Chieko Kurihara, BA

Specially-appointed Professor, Kanagawa Dental University; Vice-chair of Certified Review Board, National Institute for Quantum Science and Technology; Member of the Japan Association for Bioethics; Member of Ethics Working Group of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

(My personal view, not from WMA side; Not representing any organisation)

Slide 1: Cover

I will briefly report my participation in WMA meeting in Washington DC. My talk is for taking forward bioethics and human rights, objective of this webinar. And for Maximizing the impact of the NEW DoH, which is the objective of my session at WMA's meeting.

Slide 2: Contents: Meeting with Peter Lurie in Washington DC

Slide 3: Meeting with Dr. Peter Lurie

Today we invited Peter as a guest commentator. We met at the venue of WMA meeting in Washington DC, although he did not attend the WMA meeting. I wish to introduce his achievement as background of placebo debate.

Slide 4: Brazil

Just a bit about historical issue. During the HIV/AIDS pandemic, Prof. Greco took a role of principal investigator of vaccine trial and there is a good example of community engagement to improve study protocol while negative image of mass media against "human experimentation". He has been also engaged in governmental HIV program as well as clinical practice.

Slide 5: Establishment of Best-Proven Intervention to prevent HIV perinatal transmission

One big event was establishment of the best-proven intervention to prevent perinatal transmission.

Slide 6: NEJM, Lancet

After the establishment of the best proven intervention, in 1997, Peter opened the international debates on injustice of placebo controlled trials, sponsored by developed countries and performed in developing countries, which could not be performed in rich countries. In 2005, his paper with Greco criticized the FDA to abandon the requirement for

adhering the DoH for clinical trials outside US, replacing it with the ICH-GCP.

Slide 7: Crisis of the Declaration of Helsinki

This is my rapid response to a BMJ paper, expressing objection to the DoH 2002 Note of Clarification to permit high risk placebo-controlled trials, which is as if a Guidance for Industry. Such text in DoH is still now continuing.

Slide 8: Webinar to discuss placebo, access during COVID-19 pandemic, June 2021

We also discussed injustice of placebo studies and importance of post-trial access during the COVID-19 pandemic. This led to the proceedings and Springer book publication.

Slide 9: Discrepancy between DoH and CIOMS

What is the acceptable risk of placebo-controlled trial when there is a proven intervention??

There is **Discrepancy** between **DoH** and **CIOMS**

DoH: No increase of risk of serious or irreversible harm

CIOMS: Minor increase above minimal risk

Between these two, there are risks of continuing pain, burden, but not “serious” (regulatory definition: hospital admission), and not irreversible. These are acceptable for the DoH, but not acceptable for COMS.

Slide 10: Contents: WMA meeting in Washington DC

Slide 11, 12: North American Regional Meeting on the Declaration of Helsinki, held by AMA and WMA

These are topics to be discussed.

Just about some impressive discussions. There was unanimous voices supporting inclusiveness of vulnerable people. Social value was once included but deleted in the second draft. Still now it does not come back. It was surprising that all the US government representatives, FDA, OHRP, NIH, CDC, argued to deregulate the DoH, core principle to prioritize patient interest to goal of research; disregard Taipei Declaration and post-trial access. Korean bioethicist and I expressed objections to defend these core principles in the DoH. The last session was for maximizing impact of the New DoH, where I argued the importance of these principles.

Slide 13: Contents: Discussion at my session*: Maximizing the impact of the DoH; Taking forward bioethics and human rights

Slide 14: Maximizing impact

The moderator was the current president of the WMA, Speakers are Secretary General of the WMA, immediate past president of CIOMS, who are WG chair of the research guidelines, and representative from patient organizations, and I represented IFAPP, but talked a personal opinion.

Slide 15: Continuing discussions on the revision of the DoH with various stakeholders

I introduced discussions on the DoH and Springer book in which patient and public expressed their opinions on the DoH.

Slide 16: Next collaboration of Springer book authors

The book got a lot of readers worldwide and we are planning NEXT book to discuss on the New DoH. I argued that this book could maximize the impact of the NEW DoH, including debates during the revision process, which will improve the actual practice of clinical research.

Slide 17: What is the value of the NEW DoH?

The question is whether the DoH is highest ethical standard or minimum requirements.

Slide 18: Table 1 Key concepts missing in the new DoH (1)

This Table shows how key concepts are missing in the proposed draft. Most of these items are in CIOMS, Opinions form patient groups, IFAPP; Japanese guidelines already incorporated many of these items, but missing in the New DoH. It is surprising because Japanese people believe that the DoH is No. 1.

Slide 19: My proposal

This is my proposal at the end of my talk. First, missing items in Table 1 should be filled, according to CIOMS. Second, placebo-controlled trial, risk should be minimized according to CIOMS. “serious or irreversible harm” such terminology as guidance for industry should be deleted. It is not for Declaration of Helsinki, Ethical Principles. Third, Post-trial access should be assured for all who need it. The proposed draft states “Exceptional case must be approved by ethics committee” such kind of excuse is not necessary, should be deleted. Post-trial access should be assured for study participant; trial host community, and finally those most in need worldwide.

Slide 20: Contents: Actions for future, meet at Helsinki

Slide 21: Actions for the future

- Continuing expression of objections and clarifying missing items in respectful matter would be important for the improvement of the impact of the New DoH.
- Continuing collaboration with the WMA to fill the missing items and caring for contested opinions would contribute to **better protections of research participants**. It would be achieved by:
    - Publications of books, papers;
    - Webinars; In-person meetings;
    - Actual research practice, ethics committee reviews, etc.
- Let’s start preparation for the **next 10 years**!

Slide 22: Meet at Helsinki!

The new DoH will be adopted at the General Assembly of the WMA in October.
Some of us will have a web/in-person meeting, so we wish you to join.

Slide 23: ***Thank you for your attention***

Thank you for your attention! We hope that you visit these websites to upload continuous discussions.