

Report

The World Medical Association General Assembly in Taipei 2016 and their activities before and after that: Declaration of Taipei; Declaration of Geneva; and the 50th anniversary of the Declaration of Helsinki

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Abstract

The World Medical Association (WMA) General Assembly (GA) 2016 and the 204th/205th Council Session were held in Taipei, Taiwan, from 19 to 22 of October 2016. During this GA, the proposed revision of the “WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks” (Declaration of Taipei) was adopted. It was the first time for Taiwan to host the official meeting of the WMA and all the program was successfully convened with doctors and people of medical field coming from all over the world. During this meeting, Dr. Ketan Desai of Indian Medical Association was inaugurated as the President of the WMA from the term of 2016 to 2017; Dr. Yoshitake Yokokura of Japan Medical Association was appointed as the president-elect of the next term.

The Declaration of Taipei should be regarded as the important statement to complement the Declaration of Helsinki (DoH). The term of biobank was included for the first time in 2013 revision of DoH, however, the Declaration of Taipei covers wider issues beyond “research” activities. This means that by the Declaration of Taipei, the WMA gave deeper insights about the issues associated with activities dealing with large size of data and biological samples derived from human being. The Declaration of Taipei intends to meet the demand of rapid progress of medical science and technology such as “big data” analysis and whole genome sequencing, along with rigorous protection of human dignity and human rights.

This is an impression report of the 2016 GA in Taipei, with an unofficial summary of recent activities of the WMA concerning the revision of the Declaration of Geneva in 2017; as well as the 50th anniversary of the Declaration of Helsinki in 2014.

Key words

Declaration of Taipei, Declaration of Helsinki (DoH), World Medical Association (WMA), biological material, human right

Rinsho Hyoka (Clinical Evaluation). 2018 ; 46 : W29-W40.

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1. Recent activities of the World Medical Association

We previously reported the activities of the World Medical Association (WMA): 1) the Expert Conference on the Revision of the Declaration of Helsinki¹⁾ in Tokyo, 2013 (Vol. 41, No. 2)²⁾; 2) the WMA Council Session in Tokyo, 2014 (Vol. 42, No. 2)³⁾. In the 2013 revision of the Declaration of Helsinki, a term of biobank was included for the first time. Then in October 2016, the revised declaration on ethical considerations regarding health databases and biobanks (Declaration of Taipei)⁴⁾ was adopted at the General Assembly in Taipei, which we attended as observers. This Declaration seems to complement the Declaration of Helsinki. Kurihara also observed the Expert Conference in Seoul on this topic of health databases and biobanks, held in Seoul, January 2016. At the Taipei General Assembly, we were privileged to see just the moment when Dr. Yoshitake Yokokura, President of the Japan Medical Association was appointed as the president-elect for the next term.

After that in this year (2018), the WMA agreed with the World Health Organization (WHO) on the Memorandum of Understanding (MoU) on cooperation⁵⁾. Interview with Dr. Yokokura is included in this issue⁶⁾, where he talks about the MoU with WHO. This MoU is for a) the realization of Universal Health Coverage; b) human resources for health; c) promoting health-related human rights and the respect for medical ethics eliminating Discrimination in Health Care Settings by taking action on the Social Determinants of Health; and d) strengthening and developing systems of emergency and disaster preparedness. Dr. Yokokura also spoke about several other topics, e.g., “One Health” and end-of-life care.

Here, we describe recent activities of the WMA

concerning ethics of medicine and medical research not only some background information concerning the Declaration of Taipei; but also revision of another important policy of the WMA: the Declaration of Geneva revised in 2017; and the 50th anniversary of the Declaration of Helsinki in 2014.

2. World Medical Association General Assembly Taipei

2.1 Adoption of the revised policy, named Declaration of Taipei

The WMA's General Assembly was held from 19 to 22, October, 2016 at Grand Hyatt Taipei. It was first time for Taiwan to host the WMA's General Assembly. During a half-century, the Declaration of Helsinki has promoted the principles of informed consent of research participants, however, research has been evolving and large-size collections of data and biological materials have been generating substantial scientific knowledge. Therefore, the Declaration of Taipei provides principles not restricted to research context but also covering larger contexts of use of data and human samples, protecting rights of individuals⁷⁾.

2.2 Comments of Dr. Jon Snaedal, Chair of Workgroup of the Declaration

We interviewed with Dr. Jon Snaedal, Chair of the Workgroup of the Declaration of Taipei, who is a delegate of the Icelandic Medical Association⁸⁾. The debate started in March 1998 when the Icelandic Parliament introduced a bill allowing for collection of health information of every individual in the country into a single centralized database. The doctors in Iceland resisted the bill, because it was contrary to their commitment to the patients.

A company named deCODE Genetics, collabo-

rating with pharmaceutical company Hoffman-La-Roche, was starting research and development using population-based human samples and related information in Iceland, aiming at genetic testing business and drug development. After tremendous discussion, a Biobank Act was established and the company generated some research results but it filed for bankruptcy in 2009 in the United States (U.S.). The company continued being invested by some U.S. company and later merged by a pharmaceutical company Amgen. This story about deCODE is sometimes mentioned in Japan as success story, however, Dr. Snaedal talks that the company did not realize their plans on the centralized database.

The eventually adopted Declaration of Taipei established protection of dignity, autonomy and privacy of a person from which biological material and data are derived, allowing various procedures of informed consent or opt-out, on condition that these procedures are regulated by “a national law adopted through a democratic process in respect of human rights”. Comments by Dr. Snaedal suggests that some delegates of national medical association regard the Declaration too lax and others regard it too strict; and that there have been various thoughts about “recontact” to a donor of samples and/or data. However, through difficult arrangements, related people reached to international consensus about core ethical values to deal with human right protection in the context of health databases and biobank activities.

2.3 Comments of Prof. Elmar Doppelfeld in view of the Council of Europe

During the same period, the Council of Europe finalized in 2016 a revision of Recommendation (2006)4 to CM/Rec(2016)6⁹⁾ on research on biological materials of human origin. This deals with almost the same topic as the Declaration of Taipei,

but status of the document is different. To clarify the difference of the two documents mentioned above, we interviewed with Professor Elmar Doppelfeld¹⁰⁾, as a member of the German delegation to the Committee of Bioethics (DH-BIO) of the Council of Europe with the working party to elaborate the revised version of that Recommendation. Japanese translation of the Recommendation is also included in this journal issue. Professor Doppelfeld was asked for his opinion by the WMA, personally. The DH-BIO of the Council of Europe agreed to Professor Doppelfeld’s comment. He found shortages in the WMA’s draft concerning the protection of human rights and fundamental freedoms.

This can be explained as the difference of the statuses of both documents; and the range of members. Especially, legal framework in Japan is not enough in view of the Recommendation of the Council of Europe. Considering implementation of European Union’s General Data Protection Regulation, Japanese research community managing health databases and biobanks should learn from the principles of the Declaration of Taipei; Recommendation of the Council of Europe; and from the comments of our interviewees.

2.4 Biobank and protection of vulnerable populations

It is meaningful that the Declaration of Taipei was adopted at General Assembly in Taiwan. Taiwan Medical Association greatly contributed to it and they were so much delighted about the official announcement that this declaration is to be called “Declaration of Taipei”. Dr. Tai-Yuan Chiu, the President of the Taiwan Medical Association talked in our interview: “One of the most important issues is to pass the Declaration of Taipei. This is important in order to protect patients’ rights and autonomy, because this Declaration complements



The second from the right is Dr. Tai-Yuan Chiu, President of the Taiwan Medical Association. His right side is Dr. Daniel Fu-Chang Tsai, who gave a lecture at the 2013 WMA Expert Conference on the Revision of the Declaration of Helsinki in Tokyo²⁾. Both are professors of the National Taiwan University. The two on the left are authors. 2016 Oct 22, at the WMA General Assembly venue.

the Declaration of Helsinki.”

In a previous issue of this journal, Dr. Ian Chen, National Taiwan University, contributed an explanatory article about their Human Biobank Management Act (2010) and Human Subjects Research Act (2011)¹¹⁾. These laws require further protection of indigenous people in Taiwan. Before beginning of research or biobank project focusing indigenous group, authorization of a representative of these population is required.

Dr. Snaedal also mentions that importance of Material Transfer Agreement (MTA) was argued by the South African delegate. It was suggested by the presentation by Professor Ames Dhai¹²⁾ at the Expert Meeting in Seoul in January, 2016, which Kurihara observed. We can find also in the 2016 revision of the CIOMS guidelines of Health-related Research Involving Humans¹³⁾, that human right protection of donor of the samples and data have been strongly argued by developing countries especially in the context of MTA.

3. Inauguration of WMA's President for 2016-2017 and President-elect for 2017-2018

At the Taipei General Assembly, Dr. Ketan Desai, President of Indian Medical Association was inaugurated as the President of the WMA on October 21, 2016 for the term until October 2017. We previously heard from Dr. Ajay Kumar during the 2014 Council Session in Tokyo about Dr. Desai's prominent leadership in Indian physician's society, overcoming some conflicts³⁾. His inaugural speech was published in the *World Medical Journal*¹⁴⁾. We interviewed with Dr. Desai and Dr. Kumar¹⁵⁾ and heard about Dr. Desai's important contribution to propose that, firstly, the WMA should rise their status so that governments of each country takes inputs from the WMA; secondly, similarly to international peacekeeping force, it should work as world health force, wherever some



Dr. Yokokura's speech running for candidacy of WMA President before voting; Dr. Otmar Kloiber, WMA Secretary General with a ballot box.

natural or unnatural calamity occurs. He also introduced such system in India that Medical Council of India set up medical universities and physician certification; and single entrance examination in the whole country for undergraduate and post-graduate admissions, which eliminated irregularities, overcoming much of difficulties. This shows his outstanding leadership.

On October 22, there was voting for President-elect and Dr. Yoshitake Yokokura, President of the Japan Medical Association was appointed (photos)¹⁶⁾. There were also candidates from the Chinese Medical Association, the Croatian Medical Association, and the Nigerian Medical Association. Then Dr. Yokokura was inaugurated as the President at the General Assembly in Chicago in October 2017 for the term until October 2018. Interview with Dr. Yokokura is also included in this journal issue⁶⁾. He is the third Japanese physician to be inaugurated as the President of the WMA, following Dr. Taro Takemi, Dr. Eitaka Tsuboi. Dr.

Yokokura also takes long term leadership in Japanese physician's community. He already achieved in the WMA for facilitation of disaster medicine; Memorandum of Understanding with the World Health Organization (WHO), which should strengthen the WMA's influence on national governments. There are also other difficult tasks such as "One Health" approach (e.g., control of zoonoses, diseases that can spread between animals and humans)¹⁷⁾; as well as end-of-life care for which he is taking leadership.

4. Various discussions at the General Assembly in Taipei

At the General Assembly in Taipei, various policy documents (including revisions of existing documents) were adopted. In the "WMA Resolution on the protection of health care facilities and personnel in Syria" they notes great concern about the situation in Syria, where since the beginning of



Dr. Yokokura, elected as the President of WMA 2016-2017, and led to the stage.

war in 2011, estimated 270 health care facilities have been attacked and 760 health care workers have been killed¹⁸⁾.

At the Ceremonial Session of the General Assembly on October 21, the President of Republic of China (Taiwan), Ing-Wen Tsai addressed that Taiwan Medical Association's great contribution for their nation's health, also her gratitude for the WMA's support for Taiwan's attendance to the World Health Assembly of the WHO, as an official observer, which enables them to contribute to global health. At the official dinner on October 22,

Vice President of Republic of China, Chien-Jen Chen, provided a professional speech about their healthcare policy. Dr. Chen used to be affiliated to Genomics Research Center, Academia Sinica, and he provided a lecture¹⁹⁾ at Taiwan-Japan Academic Research Organization Workshop 2015 in Tokyo organized by Translational Research Informatics Center and Academic Research Organization Council of Japan. He introduced in his lecture in Tokyo in 2015 Taiwan Biobank project to collect bio-specimens from 200,000 healthy people as well as 100,000 patients from 14 medi-

cal centers for different kinds of diseases.

5. Revision of the Declaration of Geneva

At the General Assembly in October 2017, where Dr. Yokokura was inaugurated as the President, the revision of the Declaration of Geneva was adopted²⁰⁾. This Declaration was first adopted in 1948, the next year of the establishment of the WMA, being conceived of as a modernized successor of the Hippocratic Oath, the origin of medical ethics. This 6th revision follows the previous revision in 2006 and the plan of revision was decided in 2016 and then workgroup was set up²¹⁾.

The addition of subtitle “The Physician’s Pledge” was for improvement of discoverability in online²¹⁾. The previous beginning statement used to be the pledge for “the time of being admitted as a member of the medical profession” but it changed to the pledge “as a member of the medical profession” at any time of physician’s life.

In the previous version, this first sentence was followed by statements about respect and gratitude to teachers; practice of profession with conscience and dignity; then “The health of my patient will be my first consideration” (which is quoted in the Declaration of Helsinki). This order was changed and the statement “The health and well-being of my patient will be my first consideration” comes upper, to the second statement, adding the term “well-being”. Also this statement comes to be followed a new statement: “I will respect the autonomy and dignity of my patient.” Respect for patient’s autonomy comes to be referred for the first time in this document²²⁾. Additionally, the previous version called for students to respect their teachers, but new version deviated from the Hippocratic Oath, calls for mutual respect between

teachers and students²³⁾. The most noted change is the new statement of obligation of the physicians to care their own health and well-being so that they can provide care of the highest standard.

6. The 50th anniversary of the Declaration of Helsinki²⁴⁾

Although time series of the description goes back and forth, the 50th anniversary of the Declaration of Helsinki was held in Helsinki, Finland, on November 11, 2014. 2013 revision of the Declaration seemed to show a certain convergence on the controversies concerning placebo-controlled clinical trial; post-trial access to effective interventions proven by the trial. People engaged in this revision process said they did not intend 2013 revision specifically for the preparation for the 50th anniversary. Also we should notice that 2016 revision of the CIOMS guidelines¹³⁾ takes different wording about the ethical acceptability of placebo-controlled trial. In the ceremony, delegates of national medical associations and other experts have given lectures reflecting the historical process since the adoption of the first version. Finish President and Minister of Social Affairs and Health also given their lectures. There were almost 200 participants in this academic event.

We could not participate in this event, but it seems to provide important opportunity to learn the trend of various discussions about this Declaration as “living document”, its impact on national regulations as well as on medical research practice, and future direction of continuing discussion. Here, we outline the session from the article in *World Medical Journal*²⁴⁾.

Dr. Tuula Rajaniemi, President of the Finnish Medical Association opened the morning session entitled “The Declaration of Helsinki in a real world—The implementation of the Declaration”.



**Guests at the ceremony commemorating 50 Years Declaration of Helsinki.
Picture courtesy of the Finnish Medical Association.**

Dr. Ramin Parsa-Parsi, Chair of the workgroup of 2013 revision, German Medical Association, talked about the significant meaning of this ceremony held at Helsinki, revisiting its adoption in 50 years ago. Also he mentioned that the recent revision reflected various opinions from stakeholders. The Paragraph 37 was referred in the WMA's consideration for ethics in the use of unproven intervention at the time of outbreak of Ebola hemorrhagic fever.

Dr. Jeff Blackmer, Canadian Medical Association, talked about controversy on placebo-control trial in North and South America. In April 2006 U.S. Food and Drug Administration (FDA) ended their requirement of clinical trial outside the U.S. to comply with the Declaration of Helsinki. FDA has continuously argued that if the trial is for mild symptomatic condition placebo control design is not unethical even though there is a standard therapy and it may be needed to prove efficacy of the

intervention. Meanwhile, in Uruguay national legislation had incorporated the 2000 version, where placebo control was acceptable only when there is no standard therapy. In Brazil, 2008 version of the Declaration concerning the use of placebo (almost the same context as the current version) was immediately contested. Its governmental position is to stay with the principle in 2000 version. He also mentioned that the Congress of the Latin-American and Caribbean Bioethics Network of UNESCO had approved the "Declaration of Cordoba on Ethics in Research with Human Being" which proposed to Latin American governments and organization to refuse 2008 version of the Declaration of Helsinki and to recommend to take the Universal Declaration on Bioethics and Human Rights, by UNESCO (2005)²⁵⁾.

Professor Dominique Sprumont, a health lawyer of Switzerland, said that the Declaration of Helsinki did not reinforce the Nuremberg Code, but adopted



From left to right, Dr. Tuula Rajaniemi, President of the Finnish Medical Association; Dr. Heikki Pälve, Secretary General of the Finnish Medical Association; The President of Finland, His Excellency Sauli Niinistö. Picture courtesy of the Finnish Medical Association.

with an attempt to accelerate research. There was earlier draft in 1962 but in 1964 with financial difficulties of the WMA welcoming support from industries, another draft of different level of protection of research participants was adopted.

Professor Lasse Lehtonen of University of Helsinki spoke about the impact of the Declaration on European human rights development. He talked about postwar development of human rights framework led by the Council of Europe with its Convention on Human Rights. In 1992 the Council set up a Steering Committee on Bioethics and the Convention on Human Rights in Biomedicine was adopted. Along with European Union's regulations on clinical trials, the Declaration of Helsinki have had long time impact on research framework in Europe.

Professor Ames Dhai, previous President of the South African Medical Association, and Director of Steve Biko Center for bioethics at the University of the Witwatersrand, illustrated the situation in developing world where basic healthcare resource as well as research literacy of people are limited. She stressed the importance of protection of these vulnerable people in research context. Especially the issue of compensation for research-related injury is an important issue. In South Africa there are many clinical trials sponsored by companies or U.S. National Institutes of Health (NIH) as well as Centers for Disease Control and Prevention (CDC), and in their typical informed consent document they state that cost of the treatment for trial-related injury will be provided by means of public healthcare system of the host country or insurance com-

pany of participant's affiliation. This seems to be fair at first glance but their research ethics committees do not agree with such arrangement.

The afternoon session entitled "Ethics as a foundation of research" was opened by Dr. Xavier Deau, president of the WMA at this term. He acknowledged the contribution of Dr. Eugène Marquis, French physician, founding President of the WMA. Dr. Deau also mentioned about the Declaration which have led codes of ethics of many countries and international organization, as it combines pragmatism and wisdom.

Professor Urban Wiesing, ethics adviser to the WMA mentioned about the 1953 first proposal of position paper submitted to the Medical Ethics Committee of the WMA, which was later published as "Resolution on Human Experimentation", and in 1961 the Medical Ethics Committee presented the first draft of the Declaration. He explained about continuing discussions and stated that a principle in the Declaration about the "treatment of an individual patient, where proven intervention do not exist" was shown to be appropriate in the case of Ebola outbreak.

The President of Finland, His Excellency Sauli Niinistö, described about the contribution of the Declaration as worldwide accepted guidance on medical research during the past 50 years, turning theory into practice. He also stressed the right of individuals to control personal information in the environment where modern methods of information analysis have been completely different level from the previous days.

Dr. Laura Rätty, Finnish Minister of Social Affairs and Health spoke about her position as a politician and physician where ethics is the bases of her decision-making. She also introduced "Health in all policies" to consider that the different sectors of society must evaluate the impact of their decisions on people's wellbeing and health. This agenda was

adopted as a resolution of WHO initiated by Finland for about these ten years.

7. Conclusions

We have provided an impression report of the WMA's General Assembly in 2016 with an unofficial summary of recent activities of the WMA. We have found emerging agendas of research ethics, such as protection of human rights in the context of research dealing with large size of data and samples; health care in the situations of natural and human-made disasters including military conflicts; and in One Health approach to control zoonoses to achieve global health. In the 1990s research ethics controversy in developing world have been focused placebo-control trials and post-trial access. Now through these discussions, some of developing countries have come to appear as communities with strong sense of entitlement, equipped with rigorous legal protection of well-being of their vulnerable populations from exploitation. Additionally, Main interests of bioethics and medical ethics come to be directed to serious situations in disasters including military conflicts. We wish to watch the leadership of professional autonomy of the WMA to challenge various difficult agendas for the worldwide healthcare.

After the General Assembly in Taipei, in May 2017, Taiwan was blocked to participate in WHO's World Health Assembly as an official observer. It was reported that Taiwan's Vice President Chen Chien-jen talked about this situation as the global health risk ²⁶⁾. Additionally in April 2018 South-North Korea summit meeting was realized and now it is time to see the necessity of medical assistance to North Korea which is extremely distressed ²⁷⁾. We should tackle with big issues of bioethics in global scale.

Acknowledgement

We greatly appreciate the World Medical Association and Japanese Medical Association to provide precious cooperation for this publication. Especially we appreciate Dr. Otmar Kloiber, Secretary General of the WMA to review this report and to provide continuous support to our publications about valuable activities of the WMA.

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