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The Global Newsletter on Pharmaceutical Medicine

Webinar COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access

Feedback from the Participants

“This was a truly outstanding meeting with open and frank discussions on central issues at a critical time. The type of speaker and the quality of the debate was excellent.” (Ulf Schmidt, one of the speakers)

“An extraordinary meeting with extraordinary speakers, discussants and interaction. It was a meeting that will drive major developments in the ethics field.“ (Varvara Baroutsou, President Elect, IFAPP)

“The speakers addressed topics of high importance in today's world and I agreed very much with the statements.” (Brigitte Franke-Bray, IFAPP)

“I was so excited to witness a historic moment. I'm sure it will receive much acclaim.” (Keiko Inoue, lay person with expertise in public engagement)

“With the analysis, insights and energy of all speakers, we must find a new way forward for bioethics, adhering to the principles established in the Nuremberg Code in 1947, just after World War II, all the way through to the experience of this pandemic, and consider the more critical emergent issues of our time.” (Rihito Kimura, Japanese professor, one of the founders of global bioethics at the Kennedy Institute of Ethics at Georgetown University)

The webinar entitled “COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access”, held on June 4 and 11, 2021 was highly acclaimed as a memorable, historical turning point in research ethics. The event was co-organised by the COVID-19 Task Force, the Japan Association for Bioethics and the Brazilian Society of Bioethics, supported by the Japanese Association of Pharmaceutical Medicine (JAPhMed) and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). The video-recorded version is available at the following websites:

June 4, Day 1
https://www.youtube.com/watch?v=eD8mF9mKTIQ

June 11, Day 2
https://www.youtube.com/watch?v=jpgd3jzVCD4

All invited speakers (table), including Dirceu Greco, Chair of the Brazilian Society of Bioethics, played historically critical roles in the entitled topics. The ethics of “placebo-controlled trial” and “post-trial access” to the intervention proven to be effective in the trial have provoked international debate since the 1990s, during the world pandemic of HIV/AIDS, and led to revisions of the World Medical Association’s (WMA) Declaration of Helsinki (DoH). Our objective is to revisit these topics considering the experience of the COVID-19 pandemic. Two guests from the WMA participated in discussion: Ramin Parsa-Parsi, Working Group Chair of 2013 revision of the DoH and Otmar Kloiber, Secretary General of the WMA. Moderator Takeo Saio congratulated the WMA for having received the Golden Arrow Award from the Vienna Congress, representing doctors combatting COVID-19 (1).

[i] Duncan N. WMA Wins Prestigious Award; Otmar Kloiber Acceptance Speech; David Barbe Acceptance Speech. World Medical Journal. 2021; 67(1): 11-14.

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Table: Webinar speakers and moderators:

June 4
Chieko Kurihara, BSocSc., Specially appointed Professor, Kanagawa Dental University.: Opening remarks and situation in Japan and the world: Proposal on "Ethics of Placebo-Controlled Trials and Post-Trial Access in the Declaration of Helsinki"
Ruth Macklin, Ph.D., Distinguished University Professor Emerita at Albert Einstein College of Medicine in New York City: "Ethics in Vaccine Research: The COVID-19 Pandemic"
Peter Lurie, M.D., MPH., Center for Science in the Public Interest, Washington, DC: "Revisiting the Debate over Placebo Use in Developing Countries in the Age of COVID-19"
Ulf Schmidt, Ph.D., Professor of Modern History, University of Hamburg: "From Nuremberg to Helsinki: Historicising Research Ethics during Health Crisis"

June 11
Ames Dhai, M.D., Ph.D., Specialist Ethicist at South African Medical Research Council, Johannesburg: "Ethics in Vaccine Allocation in Developing Countries"
Tammam Aloudat M.D., Ph.D.,"Médecins Sans Frontières (MSF) Access Campaign for Equitable Access in the World"
Dirceu Greco, M.D., Ph.D., Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais: "Post Trial Access for all Perspective of Achieving Universal Access to Adequate Public Health"
Francis P. Crawley, BPhil., Executive Director of the Good Clinical Practice Alliance – Europe: "Special Comments"
Moderators: **Takeo Saio**, M.D., COVID-19 Task Force, Japan Association for Bioethics and **Kyoko Imamura**, M.D., Ph.D., Past President of IFAPP and JAPhMed.
*Co-authored by Takeo Saio, Kotone Matsuyama, Kyoko Imamura

In the Day 1 session, Kurihara and Macklin provided criticism of an article authored by a group of experts appointed by the World Health Organization and published in the New England Journal of Medicine. The article stated that, following emergency use authorisation of effective vaccines, placebo-controlled trials were permissible in regions where access to these vaccines did not exist or was severely limited (2). This resulted in a double-standard, in which it was acceptable to conduct placebo-controlled trials in low- and middle-income countries but impermissible in wealthier countries. That double standard has been criticised for at least the past two decades. Lurie (3, 4), Greco (4, 5) and Macklin (6, 7) are global leaders of this argument. The discussion based on the COVID-19 experience clarified that placebo-controlled studies after the establishment of effective and safe interventions must be limited to the situations in which this intervention has not been shown to be effective and safe (e.g., populations excluded from the clinical trials). It was also clarified that post-trial access to proven interventions must be ensured for those who need it in the world. Thus, DoH only to suggest to "make provisions" for post-trial access in study protocols and informed consent forms is not enough.

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Schmidt described the history of the Nuremberg Trial 1946/47 to punish the War Crime of Nazi Doctors' human experimentation and the establishment of the DoH. He mentioned the importance of the DoH to ensure protection of vulnerable research subjects, presenting one example of unethical influenza vaccine trial by global companies involving homeless people. Kimura underlined Japanese war crime of human experimentation in China. Greco mentioned an unethical observational study of the United States on Hiroshima bombing survivors without providing care. The debate led to our determination to avoid exploitation of vulnerable study participants.

In the Day 2 session, Dhai and Aloudat strongly argued for unequal allocation of COVID-19 vaccines and need of humanitarian, alternative framework of medicines development and health systems to ensure fair, equal access to effective interventions for all who need it. It was timely that discussions on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) waiver for COVID-19 related products have made a big progress at the beginning of June this year. Dhai is a founder of the Steve Biko Centre for Bioethics overcoming apartheid and now engaged in vaccine allocation programmes in African countries. Aloudat is a Syrian physician who has been engaged in Access Campaigns of Médecins Sans Frontières (MSF). Greco articulated the statements of international documents regarding post-trial access, in most of which he had participated during the development process. Showing the successful experience of Brazil, he argued the need for changes in these important documents to make sure it is a right of the participants of post-trial access to products that have shown to be effective and safe. He added that this right to access at the post clinical trial should help establishment of a more difficult but needed fight for equal access in public health to needed products to all.

Kloiber stressed that inequity in this world was not happening since the COVID-19 pandemic, but it has been existing and revealed by this pandemic. Both Kloiber and Parsa-Parsi expressed the importance of a continuous discussion and suggested the possibility of future DoH revisions. Crawley stressed the importance of research ethics by more focusing om public health responding to actual problems. All the discussants agreed in the continuing discussion. Johanna Schenk, member of the IFAPP Communication Working Group, extended "Congratulations on this thought-provoking meeting, looking forward to future collaborative efforts of IFAPP".

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Screenshot at the end of the second day, just a little bit edited, and including photos of some speakers and active participants who could not stay until the end of the second day, under their permission of using images. There were 110 registrants and about 60 participants were confirmed, and most of them participated at both dates. The proceeding of this webinar is to be published in the Journal Clinical Evaluation.

http://cont.o.oo7.jp/specialissue_e.html

References:

1. Duncan N. WMA Wins Prestigious Award; Otmar Kloiber Acceptance Speech; David Barbe Acceptance Speech. World Medical Journal. 2021; 67(1): 11-14.
2. Krause PR, et al. WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation doi: 10.1056/NEJMp2033538.
3. Lurie P, Wolfe SM. Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries. N Engl J Med. 1997; 337: 853-6.
4. Lurie P, Greco DB. US exceptionalism comes to research ethics. Lancet. 2005 Mar 26-Apr 1;365(9465):1117-9.
5. Greco DB. Ethical limits to placebo use and access to Covid-19 vaccines as a human right. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-14. doi: 10.20529/IJME.2021.027. PMID: 33908350.
6. Macklin R. Double standards redux. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-7. doi: 10.20529/IJME.2021.021. PMID: 33908355.
7. Macklin R. Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine. Oxford University Press (1999)

Chieko Kurihara, BSocSc. Specially appointed Professor, Kanagawa Dental University, and member of the IFAPP Ethics Working Group.