- COVID-19 and bioethics -

Part1 Ethical Challenges and COVID-19: The Recommendation No. 01/2020 of the Brazilian Society of Bioethics (SBB)^{*1}

Invited lecturer Dirceu Greco¹, Professor Emeritus, Federal University of Minas Gerais, Brazil

Organizers & Discussants Chieko Kurihara^{2, 6}, Takeo Saio³, Eisuke Nakazawa⁴ COVID-19 Task Force, Japan Association for Bioethics

Discussants

Rihito Kimura (Professor Emeritus, Waseda University, Japan⁵)

Lynette Reid (Associate Professor, Department of Bioethics, Faculty of Medicine,

Dalhousie University, Canada)

Domenico Criscuolo (Faculty, IFAPP Academy, Italy)

Sandor Kerpel-Fronius (Professor of Clinical Pharmacology, Semmelweis University, Hungary ⁶) Kyoko Imamura (Project Professor, Social Cooperation Program of IT Healthcare, The Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan ⁷)

Co-organized by the COVID-19 Task Force, Japan Association for Bioethics & Brazilian Society of Bioethics Cooperation: Clinical Evaluation; Bioethics Policy Study Group; Pharmaceutical Study Group Supported by Clinical Research Risk Management Study Group

(Thursday, 2020 Oct 22, 9:00-11:00a.m. in Brazil/9:00-11:00p.m. in Japan Web-based International Workshop using Zoom system)

*1 This is a record of the web-based meeting, of which related information and video-recorded version is available at: http://cont.o.oo7.jp/sympo/covidandbioethics.html Japanese translation is published in this journal issue:

http://cont.o.oo7.jp/48_3/48_3contents.html

¹ Chair of the Brazilian Society for Bioethics (2019-2021); Member and Vice-chair of International Bioethics Committee of United Nations Educational, Scientific and Cultural Organization (UNESCO) (2018-2021)

² Specially appointed Professor, Kanagawa Dental University

³ Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital

⁴ Department of Biomedical Ethics, Graduate School of Medicine, The University of Tokyo

⁵ Faculty Affiliate, Kennedy Institute of Ethics, Georgetown University; President, Japan Association for Bioethics (2009-2012); President, Keisen University (2006-2012)

⁶ Working Group on Ethics of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

President (2018-2020), International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

Abstract

The global pandemic of the new coronavirus disease (COVID-19) has raised several bioethical challenges. To confront them the Brazilian Society of Bioethics developed a set of recommendations (Recommendation 01/2020). Professor Dirceu Greco, currently Chair of the Society, has been invited to participate in a webbased debate to introduce this recommendation to Japan and provide an opportunity for discussion with clear objectives:

- To enhance respect for and protection of human dignity and human rights aiming at assuring equalitarian access to healthcare in public health emergencies.
- To discuss on the implementation of adequate guidelines and algorithms to achieve equitable access to healthcare even in pandemic situations.

Professor Greco has been also involved with the establishment of Brazil's infectious disease control and bioethics since the beginning of the HIV/AIDS crisis in the 1980s, and has also participated in the development and/or revision of international documents of ethics concerning HIV/AIDS, tuberculosis, such as the 2016 revision of the CIOMS ethical guidelines for health-related research, WMA's Declaration of Helsinki and statements by the UNESCO International Bioethics Committee, including ethical consideration for COVID-19.

The debate will include a brief overview of the situation of THE COVID-19 PANDEMIC in Brazil and also UNESCO's bioethical positions.

It will be an opportunity to discuss the COVID-19 response from a global perspective of with the basis in the unequivocal respect for human dignity and human rights.

Key words

COVID-19, bioethics, universal healthcare access, distributive justice

Rinsho Hyoka (Clinical Evaluation). 2020; 48(3): 661-84.

Lecture by Professor Dirceu Greco: Ethical Challenges and COVID-19 Brazilian Society of Bioethics (SBB) Recommendation 01/2020

- On respect for and protection of human dignity and human rights aiming at assuring equalitarian access to healthcare in public health emergencies;
- Also to the challenges to develop and implement adequate guidelines and algorithms with these objectives.

1. Introductory remarks

Chieko Kurihara Thank you everyone for your participation. The COVID-19 and Bioethics webinar is co-organized by the COVID-19 Task Force, Japan Association for Bioethics and the Brazilian Society of Bioethics (SBB). I am one of the members of this Task Force.

Dirceu Greco, Professor Emeritus Infectious Diseases and Bioethics, Federal University of Minas Gerais in Brazil, was invited to discuss the recommendation by SBB, responding to COVID-19 crisis*², and the UNESCO statement, as well as actual pandemic situation in Brazil. Professor Greco is current Chair of SBB. He has been involved in the establishment of Brazil's infectious disease control and bioethics since the HIV crisis in 1980s. Currently, he is the Co-Vice Chair of UNESCO International Bioethics Committee and engaged in the development of its statement on Ethical Consideration for COVID-19.

The lecture would be of 1 hour, followed by 1-hour of free discussion. Participants are invited to take part in the discussion by asking questions, making comments or opinions or raise a difficult debate which Professor Greco welcomes. The lecture and the discussion will be recorded for publication, after each commentator's permission.

This is a great opportunity to discuss COVID-19 response from a global perspective based on the respect and protection of human dignity and human rights in the serious, difficult situations prevalent in today's world, which is shared among us.

I invite two organizers, Professor Eisuke Nakazawa, the leader of the COVID-19 Task Force and Dr. Takeo Saio, Member of the Task Force, to briefly introduce the webinar.

Eisuke Nakazawa Nice to meet you, Professor Greco. I wish to briefly introduce the Japan Association for Bioethics. It was launched 30 years ago in 1988. Its aim is to promote research on bioethical issues,

* 2	Recommendation in three languages by the Brazilian Society of Bioethics:
	RECOMENDAÇÃO SBB No 01/2020
	https://drive.google.com/file/d/1-Iy-xGRe-3g8HfdJUG2cMj7Pc_AIpRkL/view
	Brazilian Society of Bioethics (SBB) RECOMMENDATION No. 01/2020
	$https://drive.google.com/file/d/1GM-eSRPFOfmCwekX9epykRQGw-pcr_PY/view$
	Sociedad Brasileña de Bioética (SBB) RECOMENDACION No 01/2020
	https://drive.google.com/file/d/1u0ilzE7FOqjowao77XNGDtF34RUW3TLA/view
	Japanese translation is published in this journal issue:
	http://cont.o.oo7.jp/48_3/48_3contents_e.html

臨床評価 48巻3号 2020



Professor Dirceu Greco, M.D., Ph.D.

Dirceu Greco is Professor Emeritus of Infectious Diseases and Bioethics at the School of Medicine, Federal University of Minas Gerais (UFMG), Belo Horizonte, Brazil. He received his MD degree and this PhD from UFMG, with further specialization in Clinical Immunology at the State University of New York (Buffalo) and at the University of London, England. Dean for Post-graduation, UFMG (1994-1998), Chief, Infectious and Parasitic Diseases Service, University Hospital-UFMG (2009-2011), Chair of UFMG University Hospital Centre for Clinical Research (2005-2010), founding member of the UFMG Research Ethics Committee and member from 2007 to 2010 of the

Brazilian Research Ethics Commission (CONEP); member, Brazilian AIDS Commission (Ministry of Health-MoH).

Currently he is responsible for the discipline Seminars in Bioethics at the Graduate Course in Tropical Medicine and Infectious Diseases (UFMG). Main topics of interest include Infectious and Parasitic Illnesses, bioethics, public health and clinical immunology. He has participated in several working groups that gave rise to national/international guidelines related to ethics, prevention, care and treatment of HIV/AIDS and TB. He has frequently acted as temporary advisor to many national/international institutions, such as the Brazilian AIDS Programme, WHO, UNITAID, UNAIDS, UNICEF, UNESCO, CIOMS, the United States Presidential Commission for the Study of Bioethical Issues and The World Medical Association.

He is currently member and one of the Co-Chairs of UNESCO's (Paris) International Bioethics Commission (IBC) and Chair of the Brazilian Society of Bioethics (2017-2019; 2019-2021)

From 2010 to 2013 he directed the Department of STD, AIDS and Viral Hepatitis (Secretary of Health Surveillance, MoH, Brazil).

including research ethics, clinical ethics and related social issues. There are about 1,200 members from all over Japan, including medical professionals, philosophers, ethicists, sociologists and jurists. It is an interdisciplinary space.

This year (2020), the Steering Committee of Japan Association for Bioethics authorized the COVID-19 Taskforce. Its main purpose is to support members who want to conduct research on ethics of COVID-19, providing web resources on ethical issue of COVID-19, collecting specialized comments and holding a symposium and/or a workshop. The taskforce also promotes members' spontaneous researches.

The Annual Meeting of Japan Association for Bioethics is to be held online coming December. There are six symposiums or workshops regarding the Ethics of COVID-19.

It is a pleasurable and a precious opportunity for me and for the Japan Association for Bioethics to attend the workshop and hear Professor Greco's lecture.

Takeo Saio I am happy to see Professor Greco again. I am Dr. Takeo Saio, practicing internal medicine and psychiatry. Your lecture of last December in Tokyo^{*3} was extremely valuable. At that time I learned so

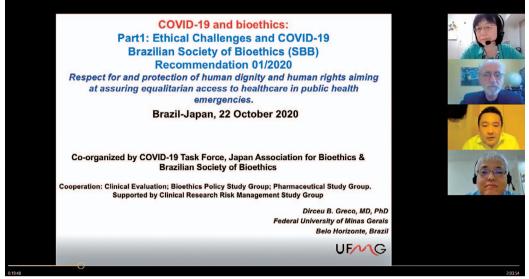
^{*&}lt;sup>3</sup> Greco D. Shimoda K, Watanabe H, Organizers and chairs. Kurihara C, Organizer. The Past, Present, and Future of Ethics of International Health Research: Research as a stepping-stone to Universal Public Health Care Access. *Clin Eval.* 2020; 48(1): W29-W53.

http://cont.o.oo7.jp/48_1/w29-w53.pdf

Other related articles are in the same issue:

http://cont.o.oo7.jp/48_1/48_1contents_e.html

Clin Eval 48 (3) 2020



Screen shot of lecturer and organizers in Webinar by Zoom system

much that in Brazil you achieved equitable access to HIV drug for everyone who needed it in Brazil. This must have been a difficult task for the society as it came just after the country's democratization. I urge everyone to read his previous lectures, the English version of which are available on the journal website, with URL on today's webinar's leaflet.

Today's lecture provides a chance to learn about Professor Greco's struggle during the difficult situation of COVID-19.

Thank you very much, so please start your lecture.

Dirceu B. Greco Hello, everyone. It is an honor to be invited for the Part One of the "COVID-19 and Bioethics". It is a pleasure to see you again, Chieko, Takeo, Prof. Kimura, Prof. Imamura, and for the first time, Dr. Nakazawa, Prof. Reid, Dr. Cricuolo, Prof. Kerpel-Fronius and other participants, even though it is virtually.

The topic of today's talk is entitled *Ethical Challenges and COVID-19*. Tackling COVID is a difficult task for everyone. It may not so much, relatively, for the Japanese, but in Brazil we are having a hard time.

The lecture reflects on what is being done, present a picture of how things are being discussed, what may happen at the end of the pandemic and more specifically, discuss the recommendations prepared by the Brazilian Society of Bioethics (SBB) and exchange views during the discussion.

Interestingly, SBB was established in 1995, and has a little bit more members than its Japanese counterpart.

Today's talk would include: SBB's Recommendation 01/2020, situation of COVID-19 pandemic in Brazil and Japan, and the overview of COVID candidate vaccines.

Belo Horizonte, in the Southeast of Brazil, is a city of 3 million people. It may be the fourth largest city in Brazil. Brazil has 210 million inhabitants, a lot of whom live in an exceedingly difficult situation and approximately 11 million earned less than US\$2 a day before the pandemic. Brazil is located at a distance of 19,000 kilometers away from Japan. Social and demographic conditions in Japan are very much different from Brazil.

2. Happenings in the recent pandemic

In December 2019, the COVID-19 pandemic started in Wuhan, China. Coincidentally, I spent around 13 days in China, after leaving Japan, at which time the virus was probably already circulating. I returned to Brazil with a terrible cold but was unaware of what it was. Retrospectively, I feel that I could have been infected at that time, although subsequent serological tests revealed that it was not COVID but something else.

Interestingly, in 1947, Albert Camus authored a book on plague (*The Plague*). He stated, "Plagues and wars have always happened in human history, but both always take the population by surprise." This is true. If we reflect over the last century, there have been many epidemics that have taken the world by surprise. Actually, the world should not be surprised as there will be many more epidemics that will come. Coincidentally, the book had a fictitious city, Oran. Interestingly, in China, it was in Wuhan.

Brazil is a big country, concentrated in the south, the southeast and the northeast where most people live. There have been cases throughout the country, and the spread of much faster than with the AIDS epidemic, as the coronavirus spreads easily through the air.

3. Comparison by dates

As of August 3rd, the total cases in the world reached 17 million, with 680,000 deaths. There is not much difference in the number of deaths per day from a few months ago, although it seems to be stabilizing a bit as the numbers are a little smaller than it was in August.

The United States (US) had 4 million cases in August and 8 million, almost double. The number of death rose from 153,000 to 218,000. Brazil has 2.7 million cases. In a short time, the number of deaths almost doubled, to over 150,000. People are a bit more optimistic now as the number of daily deaths has dropped to less than 400 over the last 2 weeks as compared to about 1,000 cases per day at that time.

Notably, Japan has half the population of Brazil. In terms of the number of cases, Japan seems to be doing a good job. With 1,600 deaths, the difference is amazing. At the last count, there were three deaths in a day.

In Canada, the number of cases is much less. As of yesterday, there were 118 cases. Canada is doing much better than its neighbor, the United States of America.

Against some expectations, COVID-19 numbers are still growing, especially in Europe, in the US and also in Brazil. There is no clarity on what will happen number-wise and how this epidemic will maintain its spread throughout the world. Many people hope that a vaccine will change the situation but there are many obstacles for the development and deployment of safe and efficacious vaccines and this needs to be thoroughly.

4. Selected facts and proposals

Even though the death rate of SAR-CoV 2 infection is apparently low, the sheer number of cases is extremely high. As of October 20, Brazil had more than 150,000 cases. COVID affects the elderly disproportionately, but it affects the socially-vulnerable much more intensely. It is important to seriously discuss

access to care to counteract the social determinants of health.

More importantly, currently there is no effective pharmacological treatment. The only exception is dexamethasone but it is specifically used for severe situations. Thus, we must stress on the need for physical isolation and not for social isolation. This is evident in today's meeting, socially, we are much closer now than before thanks to digital connectivity. Now, people can be in many places at the same time.

For a long time now, Brazil, Canada as well, has been reinforcing a comprehensive, inclusive, free-for-all universal health system. The fundamental role of an universal health system is one of the most important things that COVID-19 has shown to the world. It is very unlikely that there will be a magic bullet that will control the pandemic. Many people think that there will be a vaccine in the near future but there are many obstacles to that. And thus, there is an urgent need to establish clear, ethical and transparent rules for coping with various aspects of the pandemic. This includes respect for the human rights and dignity of the population at risk and affected by the new coronavirus infection. This mantra needs to be repeated all the time.

Increased financing is needed everywhere, even in Japan, for health and education, to tackle the social determinants of health, especially in a situation that affects the whole world. For the whole population, the essential role of a true universal health system should be reinforced with emphasis on the importance of primary care for confrontation. As it happened with HIV-AIDS, the civil society must be involved as they need to emancipate to fight for their rights. With COVID-19 this is not yet true in Brazil. With all the fake news and Infodemia, there is a need to accentuate the role of science by adequately financing it for the control of this pandemic.

5. COVID-19 and selected guidelines from UNESCO Universal Declaration on Bioethics and Human Rights, 2005

There are many ethical guidelines. The UNESCO's UDBHR states that people, without distinction, should benefit from the same high standards in medicine and life science research. The aim of the declaration is to promote respect for human dignity and protect human rights. It is hard to think that some people can be against all things that are mentioned in the declaration. The main problem is enforcing it in a good way so that everyone can use it as a part of their emancipation to fight for their rights.

Article 3 talks about human dignity and human rights. Human dignity, human rights and fundamental freedoms must be fully respected.

Article 14 on social responsibility states that progress in science and technology should advance, with access to quality healthcare and essential medicine.

All this has existed much before COVID-19 but needs to be really enforced.

Article 15 on sharing of benefits states that people should share all benefits from the scientific research.

Article 18 addresses promoting decision-making and addressing bioethical issues with professionalism, honesty, integrity and transparency.

In terms of vocabulary, the English word 'must' was used instead of 'should.' In Portuguese, there is not much distinction between the two, but in English, there is. 'Should' is where we expect to and 'must' is where it has to be done. Seemingly, during the discussion on declaration, a consensus could not be reached on a word other than that.

6. Brazilian Society of Bioethics Recommendation 01/2020

It should be stressed that the Brazilian Society of Bioethics Recommendation 01/2020 was released just 3 months after the pandemic reached Brazil. SBB, a co-sister of the Japanese Bioethics Society was established 25 year ago, in 1995.

The recommendation talks about respect for and protection of human dignity and human rights, aiming at assuring equalitarian access to healthcare and public health emergencies. Although other international recommendations already existed, it was felt that it would be good to have something that is applicable to the Brazilian specificities and even the judiciary system sometimes uses these recommendations to decide on issues related to COVID. It is important to have a document to help professionals get guidance on this complex subject and to apply to their local situations. The recommendation addresses the fundamentals and ethical aspects of the pandemic in Brazil, although most of its scope can be applicable to many other countries. The recommendations advocate for the protection of the most vulnerable, for indispensability of an universal health system - here specifically the Brazilian Unified Health System (Sistema Único de Saúde: SUS)- and the right to access to all safe and efficacious products of research related to the new coronavirus and to equal access to all ICU beds.

In Brazil, although the whole population has the right to access to SUS, there is also a complementary private sector. The number of public ICU beds is the same as that of the private. However, private beds are accessible to only 25% of the population (those who acquire a private health plan), and public beds to 75% or to all the Brazilian population. The Document defines that everyone in Brazil must have equalitarian access to all ICU beds, private and public. It also deals with the ethical and scientific dilemmas arising in an eventual situation of insufficiency of available beds.

7. Recommended considerations of the Brazilian Society of Bioethics

In the decision-making for allocation of health resources and technologies at the current stage of the COVID pandemic, the constitutional principles of human dignity and human solidarity, attaching to bioethics principles, must be respected, and include the following:

Decision on resource allocation must ensure equal rights to all. This includes not only patients who are infected by the new coronavirus but also those are at the risk of being infected.

If adequate financing is assured, there will be less chances to have sufficient ICU beds. And it must be emphasized that the previous government, which took over after President elected Dilma Roussef was wrongly impeached in 2016, approved a law forbidding any expansion of expenses for health and education for 20 years! It cannot be acceptable that funding for health cannot be expanded in a country where more people are getting older, subject to more chronic conditions and with all the urgent needs related to this pandemic.

There is still no legal instrument clearly defining specific price policies for developed products to confront the pandemic. Although not included in the current recommendation, SBB concurs with those who understand that every product for COVID should not be patented and must be accessible to all and distributed through the public health system (SUS). Preventive measures are still needed and are important to avoid a recrudescence of cases as is happening especially in Europe, where they probably expanded economic and leisure activities too soon. We must be very prudent as not to have the same situation in our countries.

The Recommendation also stresses the need to ensure patients' rights, including equal access, guaranteed to all levels of care. Primary and intermediate care is just or maybe more important than intensive care because if there is good access to primary and intermediate care, the need for intensive care may be lowered. Public health should regulate all intensive care beds, public and private, aiming at equalitarian access.

It also points out that all mechanisms to ensure secrecy and confidentiality must be in place. On the other hand, there is an immediate need for timely, clear and science-based information to all people. This is very important, especially with background of all the fake news that is circulating. Thus, scientists, bioethicists must ensure that the information provided to the media and to the population is true, but unfortunately sometimes the opposite is happening. With the spread of fake news on not scientific proved medications, on "magic" treatments, and on the negation of the gravity of the pandemic, people, especially in Brazil, believe that there is no need to worry, and that we are facing "just another flu". This misinformation is bad for everyone and those who spread this kind of news should be legally sued.

In terms of the appropriate number of health professionals and ancillary services, in Brazil, the recommendation clear defines that new, repurposing or off-label use of drugs is only be permitted in the course of clinical trial or under exceptional compassionate access, duly approved by an independent Research Ethics Committee. It is not the case where a few patients are treated, seem to get better and then the drugs can be used for everyone. It must be emphasized that this is not true and we have to work against this perception.

Even though all private and public ICU beds have been relocated to public health system, situations may arise where they are insufficient. To tackle such cases, the Recommendation provide a of flowchart based on scientific knowledge and ethical directives regarding how to decide in cases where the number of ICU beds are not sufficient.

8. Hospital Bioethics Commissions

In 2015, the Brazilian Medical Council recommended all hospitals to have a Bioethics Commission. Unfortunately, there are not that many up until now.

In October 2021, SBB's 14th Brazilian Ethics Congress, will for the first time include a first Congress on Hospital Bioethics Commissions, where we expect to convene all individuals involved with the theme to help establish commissions throughout the country.

In decision-making allocation of needed health resources and technology with the objective of establishing criteria for prioritization of access, the bioethical, dignity and human rights principles must be respected. To this end, bioethics commissions should apply SBB's recommendations, which are based on principles of the Universal Declaration on Bioethics and Human Rights, with due consideration to professionalism, honesty, integrity and transparency.

Individuals and professionals involved should be regularly included in a common process of dialogue. Opportunities should be promoted for pluralistic public debates, seeking to express all relevant opinions.

Importantly, even in the absence of Bioethics Commission, this is being done in each hospital and SBB

recommends to gather individuals from their own hospitals that have experience both in clinical and bioethical issues, with the involvement of civil society.

When the pandemic is eventually controlled, investment needs to be made in public health system, research and training aiming at increasing the number of multiprofessional researchers in Brazil.

9. Flowchart

This already mentioned flowchart establishes ethical criteria for the people in need*². It is based on validated scientific knowledge, ensuring absolute respect to ethical principles, fundamental rights and human dignity, without discrimination of any nature or factor unrelated to the health condition. This goes against the thought that the young should be saved and the old should be left to their own fate. This is a wrong notion and needs to be discussed.

When the recommendations are implemented, intense pressure may arise on allocation of ICU beds, which is related to tertiary care of COVI 19 patients. It must be noted again, that as importantly, the decisions and need to adequate access start with a symptomatic individual who thinks he might be infected. Here there is a need for timely and egalitarian access to care aiming at mitigating risk for severe disease and eventually to intensive care. This may also lower the risk for insufficient ICU beds. Recommendations are made in a way that all access and all decisions are strictly based on ethical principles, fundamental rights, and human dignity.

10. Fundamentals of Humans Rights

What Norberto Bobbio, said in the Fundamentals of Human Rights of 1964, is still applicable today. He stated, that the gravest problem of our times, in relation to human rights, is not any more to set its foundations, but to protect and implement them. We can go back to 1947 start with the International Declaration of Human Rights and get all the other documents/covenants already established for individual human rights protection – most of what is needed are already there but we have to find ways to really implement them.

11. Equity and WHO ACT

Next, we will discuss equitable access to vaccine. The importance of the development and deployment of vaccine(s) is being been discussed in various fora. About a month ago, in the WHO ACT Accelerator for Bioethics Symposium, with the participation of individuals from various parts of the world, one of the discussion topics was what should be done to ensure access to COVID vaccines on development. Many defend that access may be similar to what is accepted, for instance, to access to seasonal influenza vaccines: initially include front-line professionals, the elderly and those most at risk for severe infection. This sounds ethically acceptable and after there are enough production of safe and efficacious vaccines, access to all be warranted.

12. Vaccines on clinical trial

Many vaccine trials are ongoing in many countries. This are in the three needed phases to ascertain safety and efficacy. Two of them have been emergencially approved for specific situations in China and Russia, but as of today none have yet been approved for general use. And also, there are many challenges to be overcome after a phase 3 vaccine is registered and this include but not limited to production, costs, availability, deployment, storage, health professionals.

For many reasons, vaccines are on phase 3 trial in Brazil, and this happen for more than one reason: 1. The country has a well-established research environment, with two large public laboratories which have been producing several vaccines for many years, including the largest world manufacturer of yellow fever vaccine. 2. The pandemic is not controlled, with lots of people exposed to the virus. Four vaccines are on phase 3 trials: ①Oxford/Astra-Zeneca in partnership with Brazilian FIOCRUZ; ②Chinese Sinovac in partnership with Brazilian Butantã; ③BioNTech/Pfizer Wyeth and ④Johnson & Johnson/Janssen-Cilag.

13. WHO SAGE (Strategic Advisory Group of Experts on Immunizations): vaccine allocation

The WHO has established a set of goals and principles for the access to COVID vaccines. Importantly, its overarching goal is that the vaccine(s) eventually developed must be a global public good and contribute significantly to the equitable protection and promotion of human well-being around the world.

In the preparation for this distribution, it was pragmatically decided that its strategy should involve the largest number of countries in a way that the initial access could be ensured to rich and poor countries alike. The framework of envisioned access includes:

human well-being; equal respect; equity; national equity; reciprocity and legitimacy.

14. COVAX

The global COVAX Facility was established in April 2020 by WHO, GAVI & CEPI (Coalition for Epidemic Preparedness Innovations) in response to this pandemic aiming at achieving access to developed vaccines. It is expected that "all participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers." It must be noted that as of August AMC has raised less than US 700 million of the initial target of US 2 billion by the end of 2020.

This first and pragmatic step to egalitarian access to developed vaccines has drawbacks – access here is based upon the availability of donated funds to ensure equal participation of LMIC (Lower Middle Income Countries), which may hamper equalitarian access. Moreover, many low-income countries may have difficulties in acquiring vaccines even at subsidized prices.

To mitigate this risk of shortage of funds to support access of the lower-income countries, a separate fund-

ing mechanism, the COVAX Advancement Market Commitment (AMC) was set, with COVAX funding, plus contributions from the private sector and philanthropy. They expect that this arrangement should make possible the participation of all the 92 LMIC countries already associated and should also ensure equal access at the same time as 75 higher-income, self-financing countries already on board. Another protective decision was that even though self-financing participants can request for enough doses to vaccinate between 10-50% of their population," no country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this same amount."

15. Equity and right to health

Many countries, such as Brazil, Canada and England, have real to an universal health system. UN proposal for Universal Health Coverage (UHC) is not quite the same as free of charge access to all people that need it. In some situations, universal coverage means the presence of coverage which may not reach those unable to need out of pocket money to access health care.

As an example of a real universal health system is the response to HIV in Brazil which started officially in 1985. For people that are unaware, Brazil faced a terrible military dictatorship from 1964 to 1985. A new constitution was approved 3 years after Brazil democratized again. Interestingly, Article 196 of this new constitution states that health is a right of all and a duty of the State and to this end it was necessary to establish an universal health system. And in 1988 the Unified Health System (SUS) was founded. And in article 198 defined that would be maintained with public funds only, from the social welfare budget of the Union, the states and municipalities.

16. Unified Health System (Sistema Único de Saúde: SUS)

Brazil is in many ways an amazingly diverse country and even with all the unacceptable disparities SUS has achieved important goals. Its dimension is quite amazing. It comprises more than 30,000 Family Health teams for primary care.

It has 8,500 hospitals, with 500,000 beds, that provide emergency care, secondary and tertiary facilities. It has the world largest network of human milk bank and performs the majority of organ transplantation in the country. It funds 90% of preventive vaccines, 80% of all oncology treatments and 90% of total hemodialysis procedures.

And since the beginning of AIDS the epidemic, all anti-retroviral drugs, with eleven of them produced by public laboratories, and lab exams are also funded by SUS. On the same token all antiviral drugs for hepatitis B and C are provided by SUS.

Interestingly, the R&D expenditure of Brazil is small. The graph reflects R&D expenditure of Japan; Europe; India where it is a lot; and North America. It is important to have R&D expenditure to make things happen. It is exactly the same with regards to access to funds for health and education.

Unfortunately, the system has been chronically underfinanced, and this has worsened since the right-wing government took office in 2018.

17. Role of bioethics in emergency situations

This slide, although not didactic, specifies the role of bioethics in emergency situations, especially in the COVID pandemic. Access to adequate healthcare at all levels is part of several international documents and conventions. Most countries participated in their development and approval. Examples are the Universal Declaration of Human Rights 1947 and the 2005 UNESCO's UDBHR.

Many disparities have been denuded by the impacts of the COVID-19 pandemic but they existed prepandemic. Disparity is one of the most important problems in Brazil but poverty also affects many countries, developed and underdeveloped.

In this respect it is important to discuss the social determinants of health, which include but are not limited to situations that affect physical and mental health, affect access to adequate education, sanitation, quality water and food. These circumstances, that reach a significant portion of the world population, are accentuated by the unequal distribution of income, power and resources, both locally and globally. These circumstances are the framework for situations of increased vulnerability in marginalized populations. And this is very clear in Brazil, which has a large proportion of population who are poor, unemployed, underemployed and with disparity affecting more intensely blacks, women, people living on the street and people deprived of liberty.

In Brazil, there are 750,000 people deprived of liberty, a substantial portion of the population are live in slums and/or in the outskirts of large cities, and minority communities such as LGBTQI+, and all suffer with inadequate access to everything, including public health services. Unacceptably regarding people deprived of liberty, Brazil comes second or third in the world, with USA in first.

Merrill Singer described in an article on HIV/AIDS this situation as a Syndemia which is important to use in the current pandemic situation. According to her the relationship between drug abuse, violence and the AIDS epidemic, form a unique union that puts together the social determinants of health and specific and deleterious happenings in the health of many people.

All pre-existing conditions of injustice and inequality interact synergistically and negatively on individual and population health specifically but are not exclusive to COVID-19. What is worth emphasizing is the need to control chronic non-communicable diseases. More than that, tackling the social background of vulnerability are prerequisites for effective control of the current epidemic.

In Brazil, the social and health situation of the majority of the population was already intolerable before the epidemic. In 2019, extreme poverty already reached 13.5 million people surviving on up to \$1.9 per day. And with the pandemic extreme poverty is growing throughout the world.

During President Lula's presidency (2002-2010) these numbers were going down, but in the last 4 years it has been increasing, and since 2014, 4.5 million have fallen to the level of extreme poverty. And according to the World Bank, in 2020 the COVID-19 pandemic is estimated to push an additional 88 million to 115 million people into extreme poverty, with the total rising to as many as 150 million by 2021, depending on the severity and duration of the economic contraction.

18. Role of bioethics in research and public health

The roles for the Bioethics in research and public health includes the discussion on access to care and treatment. This may be considered outdated in relation to research and the debate today should not be any more about how people will have access during the time they are on a research trial but how to objectively provide access to all efficacious products of research and public health to everyone who needs them.

Universal access to current established and future research products must be internationally sanctioned and enforced through international covenants and resolutions issued by the UN. The status quo of inequality must not be an immutable fact and the fight must be to have universal health system everywhere.

Contradictorily, this may sound like asking for more resolutions but what I mean, concurring with Bobbio, is that what is needed now is enforcement of what already exists.

Last but not least, we must be prepared for the upcoming ethical challenges. COVID pandemic is just one example. It is not the first and it will not be the last one. When a vaccine or a treatment comes, many people will think that they can get back to their "normal" lives. The SBB states that it was not normal what we had before the pandemic, which was already very bad for most people. The hope is not to get back to normal, but to work together to make things different, to make people decide what they need and how they live and provide all with the means for this.

19. Conclusion: quotation and a tribute

In the Peloponnesian Wars, Thucydides stated, "Justice will come only when those who are not subjected to justice are as indignant as those who are."

It may be expected that although not everyone is subjected to injustice, we may hope that we are all indignant with the prevailing disparities. But this may not be enough.

My objective is not to go against Thucydides but make some changes stating that "Justice will prevail, when those affected and indignant by injustice are able to fight for their rights." Many people call the former "empowerment". In Portuguese, it has been translated directly and it is many times not as, "I am empowered" but as "I am going to empower you." My point is that in this meaning it never happens, as power is not given, it is always taken.

The latter I consider as "emancipation" in the same sense as Paulo Freire has stated, "People have to emancipate to fight for their rights and not expect to someone to empower them".

And as a tribute I bring to your attention the Opening Ceremony of the 2012 Winter Games when the British National Health System was used as its main motto. And those who took part in the inaugural ceremony were NHS nurses. This was really a good example to be followed and on the same token very recently an UK airline company painted one of their planes thanking the work done by the NHS during the current pandemic.

Finally, I thank everyone for the attention and conclude this presentation.

Discussion

Kurihara Thank you, Professor Greco for your valuable lecture. Last December, you gave an amazing lecture on achieving equitable, universal access to healthcare for the people who need it, as Brazil is a relatively resource limited country. Your struggle for this same aim, in this COVID-19 pandemic situation must be respected. Health is a right for people who need it.

Greco Interestingly, in 1996, when Brazil decided to provide antiretroviral treatment to everyone, the country was facing many difficult situations. Although the decision was political, the economic situation at the time was bad. Everything was done, from involving the government, universities and the civil society, financing a lot of research from the NGOs and having the NHS work properly. Although this example should have been used to tackle COVID, the exact opposite is being done. The government got in late and negated and still negates the severity of COVID. They did not finance the national health system (SUS) properly. Historically, we have the exemplary way that the AIDS epidemic was dealt with, since the beginning in the 80s and especially from 1996, with the provision of antiretrovirals to all in need. All that was used at that time are still in place, but unfortunately Brazilian health authorities are not using it for this pandemic.

Kurihara Now we will invite participants to actively participate in the discussion session by making comments or asking questions on the issue of equitable access to limited healthcare resource; vaccine development or ethics for clinical trial.

Rihito Kimura Thank you, Professor Greco for your fascinating talk. Your final comment quoting Thucydides, the famous Greek historian, was very impressive. Your analysis based on such a long-time span was also very inspiring. This is the third presentation of yours that I have attended following your two lectures in December in the last year (2019) in Tokyo and I am very much appreciated your consistent emphasis on human dignity and human rights.

I wanted to ask you one specific question. Yesterday, there was an article in the newspaper in Tokyo about the sudden death of a young physician in Brazil who was in the vaccine clinical trial of AstraZeneca.

I read that this man was actually in the control group, and therefore, his death was not a result from the new vaccine. Do you know if this is true?

Greco There was a sudden death of a participant from the control group. This is what the newspapers said. This should be true as they had to open to the DSMB (Data Safety Monitoring Board) and they have confirmed what the participant was getting.

In terms of vaccines, the future is not known. Another trial was stopped due to a side effect related to the vaccine. Although it is very soon to say if a vaccine will be ready in the next few months, the hope is that something positive happens.

Kimura Is Brazil eager to have a vaccine as it is actively conducting clinical trials?

Greco Everyone is but there is no magic bullet. There is a hope that everything will get back to "normal" which is not true. There are many hurdles even if an efficacious and safe vaccine is developed. Add to that it is certain that the effects of the pandemic will linger on for a long time. The long impact of the quarantine has affected and is still affecting, most people that are more in need. People need to work, and as they get back to work, they are getting exposed to the virus. There are going to be hard times, especially for Brazil.

臨床評価 48巻3号 2020

Although Japan has been more capable in facing the pandemic, it has been affected as well.

Kurihara Thank you so much Professor Kimura. I hope that every one of you to have a look of discussion among Professors Greco and Kimura last December. You can access from the leaflet of this webinar, which was published in Clin Eval Vol. 48 No. 1^{*4}, inclusion important discussion on Paulo Freire, a great Brazilian philosopher, whom Professor Kimura met many times, as well as Brazil's great achievement of access to health in their difficult time just after dictatorship.

Next, I wish to invite Professor Lynette Reid to make comments or questions. Lynette has authored an excellent paper on justice issue of resource allocation^{*5}. The paper is valuable and presents a precious opportunity for discussion.

Greco It would be interesting to hear Lynette's views as her paper clearly reflects what we have been discussing.

Lynette Reid Please accept my appreciation for your talk, Professor Greco, which was a wonderful demonstration of the strength of approaching health issues from a human rights perspective.

With regards to my paper in the *Journal of Medical Ethics*, early in the pandemic, while working on it, I noted that North American bioethicists in particular, but also some Anglo-American bioethicists, British bioethicists and critical care society triage authors, were publishing statements or prefacing their recommendations for critical care triage in a pandemic. They claimed that it was universally agreed that the utility that maximized the outcomes had to be the principle and take precedence in governing these kinds of triage decisions with a reference to warfare and wartime triage. This claim seemed unusual as bioethicists like to not only make consensus but also argue and disagree about fundamental points. Bioethicists hope that societal values come into play and that these issues are not settled simply.

My article drew comparison to health technology assessment and resource allocation, where multiple values are brought into play and the goal of maximizing utility and its shortcomings are well known. This is also true in organ allocation where it is understood that criteria that maximize outcomes in terms of life or life years saved could disproportionately affect a vulnerable group, given the social determinants of health or the processes of racialization and racism in a given nation.

Looking at the big picture, in other areas of allocation of resources that are directly lifesaving (e.g. in organ allocation, although lives are still at stake in other kinds of resource allocation), there is agreement that maximizing the outcomes leads to problems. This will end up distributing resources disproportionately to people who are most likely to benefit from them and have experienced the best social determinants of health. These social determinants of health will make them robust to be able to benefit from medical intervention.

In a pandemic like this, this would be especially problematic as people who enjoy good social determinants of health are able to work from home and isolate themselves from virus exposure. But people who are

*4 Greco D, Invited lecturer. Kimura R, Special guest. Victoria Perottino M, Guest Discussant. Saio T, Kurihara C, Organizers & Discussants. Ethics of international collaborative research: Perspectives from Brazil: Part 1 Selected notes on Paulo Freire: Part 2 Access, Compulsory license, Case Study. *Clin Eval*. 2020; 48(1): W95-W123. http://cont.o.oo7.jp/48_1/w95-w123.pdf Other related articles are in the same issue: http://cont.o.oo7.jp/48_1/48_1contents_e.html

*5 Reid L. Triage of critical care resources in COVID-19: a stronger role for justice. *J Med Ethics*. 2020 Aug;46(8):526-530. doi: 10.1136/medethics-2020-106320. Epub 2020 Jun 16. PMID: 32546657; PMCID: PMC7316108.

involved in running the infrastructure and providing provisions are in a more precarious situation as they are not able to isolate themselves at home. They are both vulnerable to infection and less robust to survive infection, if they are potentially infected. In this environment, it becomes important to articulate fundamental equality and social justice concerns which are visible in the Brazilian process more specifically.

Obviously, Brazil has adopted survival to discharge and not overall life years as a valid measuring criterion in the triage. Whereas in North America, the UK and in English-speaking Europe, after agreeing to maximize the outcomes, the emphasis is on how to push maximizing outcomes.

The next discussion on life years or life stages or other kinds of things will privilege the young and the healthy. The disproportionate burden and the social determinants of health remain concerns.

Although less efficient, there are existing commitments in society to distribute resources that might save fewer lives. It is important to fulfil obligations such as respecting human rights, enabling participation for the disabled and for the elderly who as a stigmatized group might be disadvantaged. This is visible in many European countries.

In a jurisdiction where 90% cases were in long-term care facilities, there was a severe problem in an attempt to protect the critical care resources of hospitals. Many people were discharged to or kept in long-term care facilities. When people in long-term care had COVID, they were not taken back to the hospital. As a result, long-term care facilities became overcrowded. In one province, 90% COVID deaths were in long-term care which leads the world—or rather comes at the bottom in the world—in that measure.

When it comes to medical criteria versus ethical criteria or human rights criteria, "medical criteria" mean that we can measure medically, with some reference, the potential to survive without the intervention or some reference to degree of need, or acuity, or suffering: many different kinds of claim can be measured medically.

With regards to Brazil, what are the observations about the different ethical criteria that can be implicit in medical criteria used in the triage? What were the conversations around that? Ethicists who think about this come to the idea that actually randomization and waitlists are not ethically bad, as they do not discriminate the worth of people. This kind of randomization of access to scarce resources is a way of saying that everybody's claim is recognized and is equal.

There is no criterion that can decide life and death. A random process, like the time of presentation, might be used though it is not perfectly random, or a lottery system might be used. Though when reasoned, it sounds plausible, the public or professionals do not like the idea of gambling with life by having a random process that actually decides life and death. Were there discussions or thoughts around either of those two points that are related?

Greco I have read your paper which was interesting in the way it puts things into perspective as compared to another written by Ezekiel J. Emanuel et al.*⁶, on which Chieko asked me for opinion. Your paper also mentions about how most Anglo-Saxons pragmatically deal with these difficulties brought about by the pandemic, although Canada is an exception. But the pragmatism is about the other, usually not about themselves. People who are protected can be pragmatic.

^{*6} Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, Zhang C, Boyle C, Smith M, Phillips JP. Fair Allocation of Scarce Medical Resources in the Time of Covid-19. *N Engl J Med.* 2020 May 21; 382(21): 2049-2055. doi: 10.1056/ NEJMsb2005114. Epub 2020 Mar 23. PMID: 32202722.

臨床評価 48巻3号 2020

Thinking about suffering, Brazil has a good experience in seeing how things are not working medically and bioethically. When SBB document was being prepared, it was initially due to the expectation that there would be a lot of deaths in the hospitals as there were not enough ICU beds. We then decided to expand the scope of the document to the whole cascade of needed care for the affected individual.

The important point related to the pandemic and must be thoroughly discussed is the need to focus care since the beginning of the illness – it means that the sooner diagnostic is made and proper orientation is given, risks for severe disease may be mitigated as access to tertiary care can be timely provided. Of course, this last point in the treatment cascade (access to ICU beds) is also very important and was dealt with much detail.

In many of the decision-making venues related to ethics, there may be struggle due to a difference of opinion. Most of the times, especially in research ethics, in subjects such as access post trial, limits to placebo use, you may see some literature saying that a universal agreement has been reached. It is not an universal agreement neither a consensus. Many times, these publications have their origin in the USA, and of course this is not universal. Different opinions, which are expected, arise frequently for instance at the UNESCO International Bioethics Committee (IBC), reflecting the background of the international participants in this committee.

Many times, documents that are written by international committees quote only European or USA documents. Of course, there are important documents from many other parts of the world. This is the point that the world needs to get together and truly have an equal collaboration to overcome this disparity.

Going back to comparing SBB document and other, we have not included randomization, which some referred to as a lottery, in the decision related to insufficient ICU beds.

With regards to the suggested flowchart, we have endorsed the position of the Brazilian Society of Intensive Medicine, which was based both in science and ethics. And they also have not included the possibility of randomization in their specific guidelines. This is a difficult theme and many places in the world may face the need to decide to whom an ICU bed be provided.

Luckily, at least for now, ICU beds have been enough in most hard-hit places. And people may get relaxed thinking that everything has resolved. As a matter of fact, it has not resolved because it may happen again with the recrudescence of the pandemic.

In terms of emancipation, it is hard to do as people have many day-to-day difficulties (food, employment, lack money) which make it complicate to really fight for emancipation. But it must be done. In Brazil, people can have a discordant voice. Even in a barbarian situation with the government as the Brazilian President is worse in dealing with the pandemic than the North American President, we have seen resistance movements slowing spreading throughout the country. I finished medical school when the military dictatorship was in their worst, so many difficulties have happened before, and bad situations may and are repeated over and over again. It is not known how long it will take to change and social vulnerabilities have to be the main point to be used to fight for egalitarian access to health care. It is probably not us and the participants in this seminar that will make all the needed changes, but we must multiply our voices and be together with the most vulnerable. We need to keep this discussion going.

Now I pass the floor to Lynette. Hi, where are you located currently?

Reid I am in Halifax, Nova Scotia, on the east coast of Canada, where no community transmission had

been reported for weeks. It is the safest place to be in the world, if there was an excuse to move.

Kurihara Thank you, Lynette, to give an important insight based on your paper.

So, now Domenico is coming from Italy. Italy faced a severe situation.

Prior to opening this webinar I paused a question to Professor Greco. In a paper by Emanuel et al, there are arguments:

"...removing a patient from a ventilator or an ICU bed to provide it to others in need is also justifiable."

"...many guidelines agree that the decision to withdraw a scarce resource to save others is not an act of killing and does not require the patient's consent."

Whether or not this is agreeable in Brazil.

But people well know about Italy was in very serious situation and in March "Triage guidelines" were issued from SIAARTI. This was very much publicized in Japan. I would like to hear from Domenico how is the situation in Italy.

Domenico Criscuolo Please accept my appreciation for a discussion on an interesting topic. I wanted to know about Brazil's situation as indeed there is not much news about Brazil. Sometimes medical journalists are concentrating more on the local news because the general public is more interested in the local situation rather than the global picture. The belief is that since the task is global from the beginning, presumably every-one is curious about other countries. There are some interventions or ideas that are being considered are being discussed.

Greco Thank you, Domenico for your participation. It is very nice to meet you.

It is evident in the paper from Emmanuel et al that they are very pragmatic about things and about other people. Maybe it would happen in the US, but it has not happened in Brazil. Maybe Italy had to deal with it. At one time of the epidemic, Italy had so many patients in the hospitals that people had to make decisions. Hopefully, it did not reach the point where people took someone out of a bed to give it to someone else as it is not known which patient will survive a bit longer.

One thing that people are doing and talking about, and that has happened in Italy and in Brazil, is that with the development of the pandemic, professionals, especially intensivists, are much better qualified now to face the disease at the beginning.

Italy may be used as an example as a lot of knowledge emerged from the experience there. In the first months mortality in hospital was very high and with the cumulative knowledge it is going down.

With the second wave, the need is to make diagnosis much earlier, treat people much before they need to get to the hospital hoping to avoid the need for the ICU. The discussion should head in this direction instead of trying to make a decision only when there is a high risk of death.

With other conditions, such as HIV/AIDS this holistic approach happened in Brazil, as there was no need to decide who will be accepted or medicated, as everyone was equally treated. Brazil has an experience in deciding the priorities for the seasonal influenza vaccine. The elderly is first chosen together with health professionals, as theoretically these are the people who are more prone to get infected or to have more severe disease.

The answer is that this proposal would not be approved by the Brazilian National Research Ethics commission.

Criscuolo With regards to the situation in Italy, it is a fact that after China, Italy was the first western

country to be hit by the infection. The infection probably arrived in Italy in December 2019, in and around the area of Milan, where several companies do business with China.

A lot of people were travelling to and from China. Presumably, one manager of a company doing business with China, was in one of the areas where the virus had started to spread in December and brought the infection back to Italy. Italy was terribly hit by the infection, also because it was not prepared. There were a high number of infected people. The critical issue is that most of these people arrived at the hospital quite late. There were a significant number of deaths, as people did not possibly get an early diagnosis or an early treatment.

Additionally, there was a lot of confusion about the best therapy. Even at the beginning, a lot of discussions were centred around some clinicians asking to avoid steroid use, as it was felt that steroids will diffuse the infection more.

It is now known that dexamethasone is one of the therapies that can be used. Luckily, after 2 months of crisis, that was mainly in March and April, Italy entered the summer season. As Italy moves into springtime and summertime, since this is a respiratory virus, the viral load will decrease, and Italy will benefit from the seasonal change.

Indeed, Italy had a low number of cases in summertime. Unfortunately, people, especially young, assumed that the infection was over, so they headed to beaches and discos. This created an environment where the virus was still disseminating. With the first cold days of September, the infection is spreading again.

Italy is now (Oct 2020) moving at a critical number of about between 10,000 to 15,000 new cases per day, which is more than the number of around 1,000 we had 2 months ago. However, there are some differences between October and March. In March, people went to the hospital quite late, and most of them had to go to the emergency unit care to get intubated and so on. Now, people go to the hospital early. Some of them are even recommended to stay at home as they do not have the need to be in the hospital. They stay at home, as there is less disease severity. The situation is still critical, with the onset of winter season, especially in the area of Milan, where it is raining and is cold. This will last the whole months of November and December.

It is not a lockdown situation, like it was in March and April. Authorities recommend, especially to elderly people, to stay at home as long as possible and to avoid useless wandering. There is a lockdown at night as well between 11 p.m. and 5 a.m. in the morning. People are required to stay at home unless there is a clear medical justification. This is a measure that was enforced already for a couple of days to see if it produced some benefit or not.

The schools were kept open as this is a must. The situation was critical with children at school from February and March until June. For school children another year cannot be lost because in many cases, both parents are working. If schools close down, the situation will become critical.

Most companies are now getting back to work onsite rather than work from home.

In conclusion, the situation is still critical and needs attention. The virus still exists. The situation is different, as the world now has almost 1 year experience in dealing with the virus. The world needs to be patient at least for the next few months.

It is difficult that vaccines will be available initially with millions of doses. It is not only to get vaccines but to get millions of doses and to inject the vaccines to millions of people, which cannot be done over a weekend. It is a matter of months. People that work in the pharmaceutical industry know the difficulty in producing millions of vials, as these are not tablets that can be produced quickly. These are vials and the machines producing vials have a limited speed. They cannot produce thousands or millions of doses in a few days.

In short, the need is to be careful, in trying to maintain key activities open and trying to avoid all possible occasions that will facilitate contacts and dissemination of the virus.

Greco Interestingly, Brazil is facing the same situation. There are still a lot of cases, and it is not possible to ascertain when it will be controlled.

Firstly, the thing that happened in Italy, and that Brazil followed, is that people were being put on respirators quite early on. They found out that this was not good. Many people died because of this. Now, health professionals are much more capable to take care of the severe cases of the disease.

Secondly, diagnosis should be made early on. By making a diagnosis, we will be able to identify a cluster. Everyone that was in contact can be tested and isolated. This may help in controlling the spread.

With regards to Italy and similarly to Brazil, many people did not have a source of income while they were staying at home. They did not have jobs, salaries or food. One more reason to implement the Universal Basic Income (UBI). This needs to be achieved, even if the world moves away from the current situation. A vaccine is not going to be a magic bullet. It will take some time before they are shown to be safe and effective and to have them available in large numbers. And the production includes the need for vials, syringes, cold-chains, and people to inject them. We still do not the price, the duration of immunity, the number of doses needed. Many obstacles to be overcome.

Kyoko Imamura Thank you, Professor Greco for your nice presentation. It is nice to meet you again. Your lecture in last December and round-table discussion was really impressive.

Since the situation in Brazil is quite different from Japan, I wish to learn about actual situation for implementation of your recommendation. Recommendations and a number of good things have been described and are well tabulated, but it is not a legally-binding document. There are many difficulties to implement this amongst the chaotic situation. What would be the strategy to make everyone follow the recommendations?

Greco Quoting Bobbio, from Italy, this is what the Anglo-Saxons called as the \$500 million question. The point is that there is no way to make it binding. The only way that it can be done, and what was decided, was to spread the word. There is now a document that states the way it should be done, so people can use it. Hopefully, this may be a counterpoint to the Barbarian situation. It may happen in many countries, even in parts of Canada and Japan where there are more people, and something is needed that says that there is a document.

This happened with research ethics. People are using informed consent to ask if what they are entitled to is not binding, but people can do it. It is a hard way. It is a slope that is difficult to go through the end of it, but that is the beginning. In a way, everyone has to be a part of the discordant voice but not many people are voicing their disagreement. It would be nice to have it enforced. Although it is difficult, we need to keep fighting for it.

In terms of Brazil, a group of institutions, entities and the SBB, made a document that is 70 pages long. There is a plan to tackle the epidemic, although it is not binding. The document was shown to the court, the politicians, and is being spread all over to say that there are things that are documented and that need to be done. Entities that are visible to the population should be used to propagate the document.

臨床評価 48巻3号 2020

Sandor Kerpel-Fronius To consider about the implementation, it is interesting to look at the second wave. The second wave in Europe has hit extremely hard. It is partly because Europe changed its approach towards the disease. In the first part, it tried to control the disease. Now, the effort is to control the national economics so that companies do not close down. Cultural places are not closed. Most of the restrictions are made only voluntarily. There is an effort to save the elderly population. However, the elderly population becomes totally isolated from the society.

Secondly, an enormous number of young people become infected, who have to work to maintain the economy. When a large number of young infected people are seen, everybody knows that the elderly population will get infected later and many people will die.

It is a difficult ethical decision that young people have to go to work during the second wave in order to keep the economy functioning. This is a major ethical problem for the entire society.

Greco This is a particularly good point. It is happening in Brazil too. Many places have been opened up. Where I live, Belo Horizonte, a big city of 3 million people, people go to places mostly by car or by insufficient public transport. People are now visible everywhere. They are going about as if nothing is happening. Many of them are young and think that it is not a problem for them as there is a lot of fake news circulating, including by the current President, who still negates the seriousness of this pandemic. It is known that maybe 35% of severe disease occur before the age of 50. Problems are there but it is being difficult to tackle them.

Kerpel-Fronius A large number of people are getting infected now much more than before. A given percentage of the younger generation who has some kind of weakness, possibly immunological weakness, gets seriously sick, and either die or have a very long disease, with post-infection problems and symptoms.

Finally, there will be a large decrease in the working force. Although people are getting out into the society to keep the economy running, it might be that at the end there will be a decrease in the working force from not only the elderly but also from the younger generation. Overemphasizing to keep up the normal function of the society and the economic life is a serious problem. This is one of the ethical problems which is seen as a major problem coming up in the society.

Greco This can act as an opportunity as well. There is a need to establish an Universal Basic Income (UBI). Most people are not going to be able to work for a long time. This is happening in Brazil. The richest people in the country got richer, as there was opportunity for these individuals to buy from those in need at a cheaper price. And the banks also have had a boost in their profit. Maybe this is the time where everyone needs to get together and fight for UBI and against disparity.

Even before the current pandemic, Europe has been discussed the possibility of establishing an UBI for everyone. Maybe if it is implemented in other continents it can lower the impact of the social determinants as the economy can be kept running in parallel to the pandemic. But when the pandemic goes away, all the other diseases, like hypertension, diabetes, other infectious diseases such as HIV and other ISTs, will still be there and it will be a problem to deal with them. Unfortunately, a pandemic does not make the other diseases disappear, it just adds to them.

Kurihara I think another point for implementation of the Recommendation is the role of Hospital Ethics Committee. You said that the first-time meeting would be held next October. The algorithm written in the recommendation is excellent but it is difficult to implement, but the "Hospital Bioethics Commission" may have an important role in implementing this kind of resource allocation or a difficult decision-making. How does the Hospital Bioethics Commission work in Brazil?

Greco When SBB's Recommendations were being prepared, we understood how difficult to really implement all the much-needed protection. We listen to the Brazilian Society of Intensive Medicine and agreed with their argument of the need of its application even if there was no well-established Bioethics Commission in the hospital. In the same aspect, SBB has been trying to help expand the possibility of having more hospitals with bioethics commissions. Currently, most of these are concentrated in Southeast of Brazil, especially in Sao Paulo, which is Brazil's largest city where most hospitals are located.

One of the vice presidents of the SBB proposed that we could have the first national meeting related to Hospital Bioethics Committees and we decided to have it together with our next Brazilian Society of Bioethics Congress, October 2021. It should be a good start for a problem that everyone is going to face. Brazil is facing these challenges without the presence of a dedicated commission. And people are doing their best but will be important to establish these commissions widely. Maybe this push will help to have more committees throughout the country.

How is it in Japan?

Kurihara Some of the hospitals have Hospital Ethics Committee, but there are no guidelines from the government or from the Bioethics Association. It is important to have some kind of organizational activity to discuss about these things for the whole nation. If there is some kind of governmental instrument, it will be effective.

Now we have much precious talk with participants not only from Japan and Brazil, but also from Canada, Italy, Hungary. Now it is time when we have to close the session. I wish to I invite Professor Nakazawa to make comments and closing remarks.

Nakazawa Thank you, Professor Greco for your nice talk. I thank everyone who participated in the fantastic workshop.

I have some concerns about the aftereffects of COVID-19, which is an infectious disease, but at the same time, it is a disease of imparity, distrust and isolation. In Japan, some news broadcasts said that solitary death in elder generation and suicides in younger generation had increased in Japan. Such problem would become severer as the aftereffect of COVID-19 in Japan. Severe aftereffects will be confronted in the near future. International collaboration is needed to tackle this. From this viewpoint, the discussion for world happiness and international collaboration in the near future should be continued.

Greco Thank you, Professor Nakazawa. I hope to have continued collaboration between the two societies and more committees to discuss this. Even with the distance, me, Chieko, Takeo, Professor Kimura, Professor Nakazawa and Lynette, and members from IFAPP, can keep talking. There was a good comment from the audience as well that said that public health is a prerequisite for a strong economy. We can have a strong economy only by saving people. It is not the other way around.

This has been happening for a long time. People say a big cake needs to be made before it can be shared. It is the other way around. Maybe when the pandemic ends, it will provide a window of opportunity to change the status quo of disparity.

Professor Nakazawa mentioned about the need for international participation which is extremely important but difficult to occur.

Domenico mentioned that many Italians do not know what happens in Brazil. Although Brazil has one of

the largest Italian community in the world outside of Italy, communication is lacking. We have to be certain to use opportunities such as today's where everyone can come together and spread the word. If people do not save their surroundings, they cannot save themselves. This could be the way to proceed from now on.

I am happy to be a part of this first long-distance debate as well as to see my old friends and get to know new people.

Kurihara Thank you everyone for your participation. The next discussion will be session to discuss Clinical Trial Ethics, following which there will be more collaboration on this kind of ethics and COVID-19.

*

(Published Dec 25, 2020)

*

*