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# World Medical Association Officers, Chairpersons and Officials

**Dr. Heidi STENSMYREN**  
WMA President  
Swedish Medical Association  
(Villagatan 5) P.O. Box 5610  
SE-114 86 Stockholm  
Sweden

**Dr. Osahon ENABULELE**  
WMA President-Elect  
Nigerian Medical Association  
8 Bengehzi Street, Off Addis Ababa  
Crescent Wuse Zone 4, FCT,  
P.O. Box 8829 Wuse Abuja, Nigeria

**Dr. David BARBE**  
WMA Immediate Past-President  
American Medical Association  
AMA Plaza, 330 N. Wabash, Suite  
39300 60611-5885 Chicago, Illinois  
United States

**Prof. Dr. Frank Ulrich  
MONTGOMERY**  
Chairperson of Council  
Bundesärztekammer  
Herbert-Lewin-Platz 1 (Wegelystrasse)  
10623 Berlin  
Germany

**Dr. Otmar KLOIBER**  
Secretary General  
World Medical Association  
13 chemin du Levant  
01212 Ferney-Voltaire  
France

**Dr. Kenji MATSUBARA**  
WMA Vice-Chairperson of Council  
Japan Medical Association  
113-8621 Bunkyo-ku, Tokyo  
Japan

**Dr. Ravindra Sitaram  
WANKHEDKAR**  
WMA Treasurer  
Indian Medical Association  
Indraprastha Marg 110 002  
New Delhi  
India

**Dr. Marit HERMANSEN**  
WMA Chair of the Medical Ethics  
Committee  
Norwegian Medical Association  
P.O. Box 1152 sentrum  
107 Oslo  
Norway

**Dr. Jung Yul PARK**  
WMA Chairperson of the Finance  
and Planning Committee  
Korean Medical Association  
Samgu B/D 7F 8F 40 Cheongpa-ro,  
Yongsan-gu  
04373 Seoul  
Korea, Rep.

**Dr. Joseph HEYMAN**  
WMA Chairperson of the Associate  
Members  
163 Middle Street  
West Newbury, Massachusetts 01985  
United States

[www.wma.net](http://www.wma.net)

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### Editor in Chief

Dr. med. h. c. Pēteris Apinis, Latvian Medical Association, Skolas iela 3, Riga, Latvia  
[editorin-chief@wma.net](mailto:editorin-chief@wma.net)

### Co-Editor

Prof. Dr. med. Elmar Doppelfeld, Deutscher Ärzte-Verlag, Dieselstr. 2, D-50859 Köln, Germany

### Advisor

Helena Chapman, MD, MPH, PhD

### Assistant Editor

Mg. Health. sc. Maira Sudraba, Velta Pozņaka; [lma@arstubiembra.lv](mailto:lma@arstubiembra.lv)

### Journal design by

Pēteris Gricenko

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## Editorial

Severe morbidity and mortality from Covid-19 have reached huge numbers worldwide, and each country is fighting the pandemic differently. In autumn 2021, researchers and doctors had already a lot of information both on the coronavirus SARS-CoV-2 and on the pathogenesis, the course of disease as well as changes in the body caused by the virus.

Critical and important are lessons learned that the coronavirus SARS-CoV-2 causes more severe disease and higher mortality in people who have a sedentary lifestyle, overweight, hyperlipidaemia, high arterial blood pressure, carbohydrate disorder and high sugar level as well as other chronic diseases. The currently available information also shows a higher incidence of severe disease and higher mortality from Covid-19 not only among somatic patients, but also among mental patients.

We have information that mortality is lower among those patients with hypertension, dyslipidaemia and diabetes who are meticulous and compliant in the treatment of their chronic diseases during the pandemic compared to patients who are noncompliant with medication, who have medication non-adherence. Several studies have shown that in patients who have regularly used cholesterol-lowering drugs during the pandemic, including statins, severe disease and death rates are lower than in patients who stopped taking statins before or during the illness.

The difference between the rates of the severity of disease and mortality in different age groups depending on the treatment/non-treatment of chronic diseases is high, up to 3–5 times. This makes

us reasonably concerned about the need to treat chronic diseases during the pandemic.

Now, when politicians in all countries of the world place emphasis on vaccination and various restrictive measures, it is the time for doctors to stress the extreme importance of prevention and treatment of chronic diseases. The reduction of low-density cholesterol, adjustment of blood pressure and control of sugar level are very important areas in decreasing the Covid-19 severity and reduction of mortality rate. Governments that limit the volume of medical services to treating Covid-19 patients make a very big mistake, since it might increase severe morbidity and mortality.

Increasing the volume of physical activities, particularly in the elderly with chronic diseases and risk factors for cardiovascular diseases, is very important in circumstances where, very likely, we are to live with SARS-CoV-2 for a long time. It is the doctor's responsibility to promote healthy lifestyles, at least half an hour of physical activity daily, optimally aspiring to each person taking 10,000 steps a day.

So, let us encourage vaccination, take care of restrictions on disease transfer, and at the same time actively promote sports and physical activities as well the treatment of chronic somatic and mental diseases. No one else will explain this to governments and the media if it is not done by the leaders of the World Medical Association and national medical associations.

*Dr. med. h. c. Peteris Apinis,  
Editor-in-Chief of the World Medical Journal*

## Valedictory Speech by the WMA President, David O. Barbe, MD MHA. WMA General Assembly London, UK (virtual), October 15, 2021



*David O. Barbe*

Thank you, Dr. Montgomery. Dr. Kloiber, officers, Council and Assembly members and our JDN and Associate members. Let me start by thanking you again for the great privilege of serving as your president for this past year. It has been one of the most unusual and challenging years the WMA and our profession has ever faced. Due to the pandemic, this is now the second General Assembly we have found necessary to hold virtually and the fourth Committee and Council sessions.

Although conducting our WMA business virtually is bad enough, the pandemic has kept us apart for many more NMA meetings, scientific conferences, and from many opportunities to be together to share a time of friendship and productive discussions outside of the formal business sessions. I know we all hope we will be able to start meeting together again soon – both to conduct our business and to keep our relationships with one another strong. In my inaugural remarks a year ago, I stated that “It is in times like these that our fellow physicians and our patients need our leadership more

than ever.” I went on to say that “We need strong physician organizations at every level: the WMA, our NMAs and state and local medical societies.” This year, I have been proud to see that strong leadership in action in the work that you have done. I’ve seen the Indian Medical Association raise funds for their colleagues impacted by COVID, speak out against violence directed at health care workers, and resist expansion medical practice by persons without medical training. I have seen the Turkish Medical Association advocate for members wrongfully imprisoned and fight to retain recognition of their Association. I have seen the Korean Medical Association speak out against intrusion of the government into the operating theater. I’ve seen physician leaders in Nicaragua and Egypt speak out against oppression and threats against physicians in their countries.

These are but a few of the many examples of NMAs advocating for their members and for their patients. In all of these situations, the WMA was right there with these NMAs and physicians supporting them in their struggle to protect physicians and deliver high quality care to their patients. That is leadership ... and that shows the importance of our professional organizations and the WMA.

In spite of the pandemic, many association meetings, scientific meetings and advocacy meetings were held virtually, and the WMA participated in many of them. In addition to NMA meetings, the WMA participated in multiple meetings related to various aspects of the pandemic including the recently completed meeting sponsored by the Pontifical Academy for Life at the Vatican in Rome at which we were invited to give the physician’s perspective on the impact of the pandemic. We participated in several conferences on equitable distribution of vaccines and on the need to improve our

ongoing response to this pandemic and our planning for the next.

WMA leadership participated in other conferences including ones on the contemporary relevance of bioethics, medical ethics and professionalism, person centered medicine, violence against physicians and health care, and on the role of health professionals in encouraging adherence to the Treaty on the Prohibition of Nuclear Weapons. So, in spite of the limitations of the pandemic, the WMA has continued to be a strong and recognized voice for physicians around the world.

The Scientific Sessions associated with our General Assembly meetings continue to be important forums for international discussion of key issues facing medicine. The session in September on the ethical challenges of organ donation and transplantation processes coordinated by the General Council of Official Medical Colleges of Spain and last week’s session on antimicrobial resistance coordinated by the British Medical Association were both excellent sessions and brought together experts from around the world to present and discuss these critical and timely topics.

We have a responsibility as a profession to engage in scientific sessions like these and the many others in which you and the WMA are involved to address the challenges we face in many areas of science, medicine, and ethics. I commend those who organize such scientific session for helping us fulfill that responsibility to our physician colleagues, to our patients, and to society.

Because the WMA is recognized as having broad involvement in activities such as those I have just mentioned and very specifically in recognition of physicians’ work and sacrifice around the world during the COVID-19 pandemic, the WMA received the “Golden Arrow 2021” award last Janu-

ary at the 18<sup>th</sup> Vienna Congress co-hosted by the Medical Doctor's Association of Austria. The WMA was the first organization to receive that prestigious award previously awarded only to individuals.

In my remarks to that group, I told them "there are many physicians around the world who do not feel appreciated or supported for the risk they have taken or the sacrifices they have made in caring for patients with COVID. Many are demoralized. Many feel their governments, and, in some cases, their hospitals have let them down. Some feel taken for granted or even taken advantage of.

This Golden Arrow award proclaims to the physicians of the world – You are appreciated. We recognize all you have done and thank you for the sacrifices you have made."

I think physicians need to hear that. I think you need to hear that. It is our job as leaders to make sure our physicians know we are proud of them and that their efforts and their sacrifice are appreciated.

I am also proud of the important work you continue to do on the issues on our agenda at this meeting... continued work on revising the international code of medical ethics... addressing racism in medicine... emphasizing women's right to healthcare... advocating for access to medications and vaccines... improving our principles on end-of-life care... and multiple statements related to improving patient safety and specific areas of medical care. Thank you for the time and energy you devote to this work.

Before my closing comment, I want to sincerely thank Dr. Kloiber, Sunny, Clarisse, Magda and all our staff at the WMA for the tremendous work they do on our behalf and the support they give WMA leadership as we represent the organization. Thank you. I also thank the American Medical Association again for their confidence and support in nominating me for this position 2 years ago. And finally, a loving thank-you to my wife, Debbie, who has been a constant source of support and encouragement dur-

ing the many years I have served in our professional organizations. Thank you, Debbie. In my inaugural speech a year ago, I included a quote by American baseball legend Babe Ruth. He said, "It's hard to beat a person who never gives up." We must never give up in our efforts to advance our policies and our work to achieve our common goals. We must never fail to advocate on behalf of patients and physicians. I know that Drs. Stensmyren and Enabulele will do that as your elected leaders. I know that Drs. Montgomery and Kloiber will do that in their respective roles. I am confident that you will also leave our meeting this week encouraged and inspired by the actions we have taken, and that each of you will use the WMA resolutions, statements, and declarations in your countries to support your physicians and accomplish our common goal and the WMA's purpose of achieving "the highest international standards in medicine...and health care for all people in the world." Thank you very much.

## Presidential Inaugural address by Dr. Heidi Stensmyren. WMA General Assembly London, UK (virtual), October 15, 2021

Honored colleagues, dear friends,  
Humbled by the distinguished work of my predecessors let me first express my gratitude to Dr. Barbe, for your excellent work as president during the past year. It has been a challenging year of office, but you have managed to be present despite the lack of in person meetings. I want to thank the Swedish Medical Association, for putting your trust in me and supporting my candidacy. This is the effort of many, but I especially thank the board and President Sofia Rydgren Stale and CEO Hans Dahlgren – keeping the organization on top to the benefit of all of us engaging in organized medicine. A special thank to our international secretary Tomas Hedmark; always on track and on time. Thank you all for good teamwork and for true friendship. Thank

also to Björn Zoega for including me in the leadership of Karolinska University Hospital where I now serve.

My deepest gratitude to my family; My two wonderful children Nora and Fröja. You have spent many hours underneath boardroom tables, on a coach in the office or in the back of a conference room waiting for me. My dear parents who have supported me in every way and who are the most wonderful grandparents. I could not have made it without you. Thank you! Colleges, friends, and family are important, especially in times like this. ....over 230 million COVID cases since the start of the pandemic...and over 4.7 million deaths. But we are fighting back.... With almost 6 billion vaccines given worldwide.

All of us have faced personal and professional challenges during the pandemic, and a virulent virus still ravages our world. Healthcare has been pushed to the limit. Physicians have toiled on the frontlines, risking self and family to provide care to countless patients that have fallen ill to Covid-19. The working conditions are beyond challenging. Many physicians have become victims of the virus, and some of us have died while caring for others.

The pandemic has shown that we share a very small world. What happens in one corner of our planet affects us all; the "Butterfly Effect" has never been demonstrated more poignantly. Physicians everywhere strive for that same effect, hoping that providing good medical care to patients in their corner





*Heidi Stensmyren*

of the world will translate into a “global defense.” Viruses know no borders, but neither do medicine or the ethics that guide us.

The pandemic has raised difficult questions and some grim ethical and moral quandaries

- How do we prioritize care?
- What are the best vaccines and vaccination programs?
- What is the fairest method to distribute resources?

Patients, populations, and governments look to us for guidance when health is at stake, and these difficult questions about the ethical practice of medicine must be addressed. The WMA must lead the way – providing a firm foundation to respond to these challenges that remain critical to every man, woman, and child on our planet.

Let us not forget that ‘ethics’ is the core of the WMA. “The health and well-being of my patient will be my first consideration” and “I will share my medical knowledge for the benefit of the patient and the advancement of healthcare.” Words we promote and the pledge by which we live.

The WMA policies are frameworks and guidelines implemented by physicians and

institutions every day all over the world. The vision of my Hospital is “We will cure and relieve tomorrow what no one can cure or relieve today”.

A vision that has come through recently is the advancement to produce a vaccine against malaria. This is fruits of years and years of hard work by vital organizations on a global level. Next to the vaccine, global cooperation is the most crucial component to fight disease and this virus in particular. No other physician organization has the inclusiveness and reach of the WMA; therefore, we need to help bridge governments and borders. As the most important international organization for physicians, we should foster even more robust cooperation between international organizations. It is important to continue to engage in, and deepen our relations and cooperation with the WHO on issues of common interest. Efficient and effective initiatives, such as CEPI, Coalition of Epidemic Preparedness Innovations, or GAVI, co-leading COVAX distributing covid-19 vaccines, has a better chance to succeed when global agreements are in place. I urge all of our national members to promote your countries to support the global institutions.

The pandemic has also highlighted the importance of medical research and development. Vaccines, their development, and distribution have been at the center of the pandemic. And the speed with which vaccines have been developed is awe-inspiring and demonstrates what can be achieved in a global emergency.

Medical research always raises ethical questions, even more so in situations where there is intense pressure to achieve results quickly. The pandemic has put us under extreme pressure; with demands for revolutionary research results leading to new therapies and vaccines to be provided to patients quicker than ever. Under such conditions ethical guidelines are crucial. The WMA Declaration of Helsinki guiding in ethical

issues related to medical research involving human subjects. I take office highly aware of the necessity that this core WMA declaration must continue to be well-known. It must remain a relevant touchstone of ethics in medical research. At the core of good research and good medical practice is a solid basis in evidence-based medicine. There has been and continues to be, fearmongering, misinformation, and false claims. Some of these claims are highly concerning and present potentially serious health risks to global health. We have a responsibility to speak out against fraudulent claims, to represent science. We are also responsible for explaining this science in ways the general public can grasp and comprehend. Moving forward, this will be an increasingly important task for the WMA. As president of the WMA I will add “vaccinate!” to the quote “test, test, test” made by Theodor, Director-General of the WHO.

Many physicians and researchers have worked tirelessly to get us back to a more normal life. Thinking about a “normal” life again, we should remind ourselves of the necessity to ensure a sustainable life for all of us on our planet. Nature continues to be an essential source for developing new patient treatments. The new vaccines are such examples, partly founded upon research in biology. If the loss of biodiversity continues, we will be less resilient. The WMA has vital policies on environmental issues. As president, I stress the importance to highlight the value of protecting our environment to achieve sustainability. Our future patients’ health depends on it.

As physicians, our colleagues worldwide stand at the center of health, and the WMA should be the global guiding light for all of us. Please help me continue to build a strong international voice for the WMA, a voice that speaks for every Physician on our small planet. Thank you for electing me as your president. The honor humbles me. I will do my best to represent you and the WMA.

## WMA 2021 Virtual General Assembly Report

October 11–15, 2021



Nigel Duncan

### Monday October 11

For the second year in succession, the WMA's annual General Assembly had to be organised as a virtual event. London was due to host a week of meetings. But instead, the Scientific Session, the Council, committee meetings and General Assembly were all held online over a period of seven days. Two days were set aside for the Scientific Session (see separate report) in the first week, with the Council meeting starting the second week.

### Council

More than a hundred National Medical Association (NMAs) delegates from more than 20 different time zones logged on to hear the Chair of Council, Dr. Frank Ulrich Montgomery, welcome them and express his hope, once again, that they would soon be meeting face to face. The Secretary General, Dr. Otmar Kloiber, welcomed two new Council members, Dr. Jack Resnik (Ameri-

can Medical Association) and Dr. Jian Wang (China).

### President's Report

Dr. David Barbe, in his written report, said that despite the Covid-19 pandemic the WMA leadership had participated in many conferences addressing various aspects of the pandemic. Their emphasis had been on protecting physicians and other healthcare workers, recognizing the personal risk they took in carrying out their task of caring for patients with Covid-19 under very difficult circumstances. They had also participated in conferences on equitable distribution of Covid-19 vaccine, overcoming vaccine hesitancy, and improving vaccination rates.

Dr. Barbe said he had been especially proud to speak out about violence against physicians and other health care providers and to provide support and advocacy for NMAs and individual physicians who had been targets of violence, governmental oppression, or punishment simply for advocating for their patients, providing medical care to political protesters, or advocating for improved management of the Covid pandemic and vaccinations in their countries.

Two specific events had highlighted his presidential year – the WMA's receipt of the Golden Arrow Award for the medical profession's service during the pandemic and the Vatican workshop on Covid-19.

### Chair of Council's Report

Dr. Montgomery said the last year had changed all their lives dramatically. Covid-19 had taken its toll. Among many other colleagues and friends they had to mourn was their esteemed colleague and friend K.K. Aggarwal from India who had passed

away from the disease in May. He listed some of the many activities the WMA had engaged in about the pandemic and vaccine equity. He said it was true that national governments had an obligation to service their own population, but "vaccine nationalism" was not the road to freedom. They had to share wisdom, knowledge and vaccines.

The Chinese Medical Association again raised a protest about the WMA's policy seeking observer status at the World Health Organisation for Taiwan. It said it was impossible for China to accept this policy, as Taiwan was an inseparable part of China. The protest was noted.

### Urgent Items

Two emergency issues were raised. The first related to Covid-19 and the fact that citizens of some countries were experiencing serious complications in travelling, as their vaccinations were not accepted as proof of full protection. Many countries accepted only a certain set of vaccines considered as suitable protection, while other vaccines were not recognized. The Council proposed an emergency resolution calling for an end to this discrimination.

Dr. Kloiber said that many of the countries had installed vaccine requirements for travel, social events and leisure. Usually this was shown by having compliance with vaccination. For travel, it was necessary to have a full vaccination defined by each country in a different way. But the vaccines being authorised were very different from country to country. Even people fully vaccinated might not be able to travel because they had been vaccinated with the assumed wrong vaccine. The emergency resolution was saying that it should be the effectiveness of the vaccine which counted, not the authorisation of the vaccine. Governments needed to reconsider their current rules to allow international meetings to be held. There had been a lot of concern from colleagues in Asia and Africa who were having big problems in travelling to Europe.

The meeting approved the Resolution.

The second urgent item related to the situation in Nicaragua. It was agreed to discuss this later in the week.

The Council meeting was adjourned until Friday.

## Finance and Planning Committee

The committee was called to order by the Chair, Dr. Jung Yul Park (South Korea).

### *Audited Financial Statement for 2020*

The committee considered the Audited Financial Statement for 2020. The Treasurer, Dr. Ravindra Sitaram Wankhedkar, stated that the WMA's finances in 2020 were very solid, with cost savings due to the effects of Covid-19 and restrictions on meeting and travel expenses.

The committee agreed that the Audited Financial Statement for 2020 be approved by the Council and forwarded to the General Assembly for adoption.

### *Membership Dues*

Delegates also heard a report on the Budget and Membership Dues Payments for 2021 and Membership Dues Arrears and Dues Categories 2022.

It agreed that the proposed Budget for 2022 be approved by the Council and forwarded to the General Assembly for adoption. It also agreed that the Dues Categories 2022 be forwarded to the General Assembly for information.

### *Strategic Plan*

Dr. Kloiber gave an oral report, saying that ambitions to enlarge the membership of the Association had been interrupted by Covid-19. They still had a lot of targets to deal

with. He also said that the Secretariat had been exploring options for hybrid meetings.

### *Statutory Meetings*

The committee considered the planning for future meetings and two invitations from the Sindicato Médico del Uruguay and the Ordem dos Médicos (Portugal) to host the Council Session in 2024 or 2025, or the General Assembly in 2025. The two organisations agreed to discuss the matter between themselves and return with co-ordinated dates.

### *Special Meetings*

Dr. Kloiber reported that the WMA continued to play an active role in a series of webinars as a member of the World Health Professionals Alliance, which were focused on Covid-19 related issues of mental health and institutional changes.

Participation in meetings to discuss the International Code of Medical Ethics at the international level were planned next year at the 14<sup>th</sup> World Conference on Bioethics in March in Porto and at the 16<sup>th</sup> World Congress of Bioethics in July in Basel.

### *Associate Membership*

The committee received a report of the Associate Membership and the report from the Chair of Associate Members Dr. Joseph Heyman. He said that the total number of associate members who were in good standing was 1,487. The regional breakdown was Japan 605 members in good standing and in all other countries 882 members. Two successful webinars had been held, the first on 'How Healers became Killers: Nazi Doctors and Modern Medical Ethics', and the second 'The Frustrating Hydra of Municipal Social Fabric Weaknesses Revealed by the Pandemic'. Task forces had been established to consider revising the Declaration on The Protection and Integrity of Healthcare Personnel in Armed Conflicts and on revising the Statement on Guiding Principles for

the Use of Telehealth for the Provision of Health Care. Work was also under way on eHealth and Medical Technology and on Advocacy and Communication.

### *Junior Doctors Network*

An oral report on the activities of the Junior Doctors Network was given by the Chair of the JDN, Dr. Yassen Tcholakov. He said a new team had now been elected. Despite the challenges and adaptations forced on them by Covid-19, they had had many new members and had managed to maintain strong member engagement during these unusual times. The Network had maintained virtual activities and had seen continued membership requests from junior doctors from diverse backgrounds globally. The leadership had worked on streamlining the membership onboarding process and were looking forward to rolling out the new system as soon as the IT changes took place.

### *Past Presidents and Chairs of Council Network*

The committee received a report on the activities of the Past Presidents and Chairs of Council Network. Dr. Yoram Blachar had been playing an active role to set the official relationship with the International Chair of Bioethics as a WMA Cooperating Center and continued to be liaised to the 14<sup>th</sup> World conference on Bioethics, Medical Ethics and Health Law for the conference. This was originally planned in Porto, Portugal, May 2020, and was now postponed till March 7–10 2022.

Drs Ardis Hoven, Cecil Wilson, Kati Myllymaki, Jón Snaedal and Dana Hanson had continued to join the Steering Committee of the Associate Members and had been actively participating in the discussion on ideas of how to improve the membership activities and engagement. They had also contributed to the proposed new rules for Associate Membership.





## *Bylaws Amendments*

The committee considered a report and recommendation from the workgroup on Bylaws Amendments proposing additional committee members and the issue of voting rights.

The committee agreed the proposed revisions should be sent to the Council and forwarded to the General Assembly for adoption.

## *Legal Seat of the WMA*

The Secretary General reported that he had been working on how to proceed with the transition of moving the legal seat of the WMA from the USA to France, as approved by the Council in April 2021. He informed the committee about the timeline and next steps, which would be presented for the consideration of the Council and General Assembly, with the aim of completing the transition by 2022.

## *Rules Applicable to WMA Associate Membership*

The committee considered a proposed revision of the rules applying to WMA Associate Membership. Members were told that the changes would not alter the relationship between the Associate Members and the WMA Council or Assembly, but were designed to make the rules more democratic. The Japan Medical Association proposed setting up a workgroup to consider the ideas and it was agreed that the proposals needed more discussion.

The committee agreed to recommend that a workgroup be set up.

## *Procedures of conducting virtual meetings*

A proposal from the Chinese Medical Association for developing procedures for conducting virtual meetings was presented to the committee. It was argued that it was reasonable to expect that virtual meetings would

still be widely used in the post-pandemic era. It was therefore imperative for the WMA to develop written procedures regarding the adoption and conducting of virtual meetings, including the quorum, communication, and voting rules. Developing such procedures would help to clarify responsibilities of different entities of the WMA, streamline the meeting procedures, and most importantly, improve the efficiency, as well as transparency among constituent member associations.

The committee recommended that a workgroup should be set up to prepare a draft proposal on procedures.

## *LGBTQ Equity in Venues Hosting WMA Meetings and Functions*

A proposed Resolution on LGBTQ Equity in Venues Hosting WMA Meetings and Functions was considered. It set out proposals for host nations' policies to be considered when venues were proposed for WMA meetings. After several speakers raised points of concern, it was agreed that the matter required further discussion in a workgroup.

The committee agreed to postpone the issue until the next meeting.

## *Green Guidelines for WMA Meetings*

The committee considered a set of proposals to ensure that WMA meetings were eco-neutral events. It was argued that this was a process that required a change in event culture. The proposals included guidelines for greening transport, food and beverage and event material and merchandise. The suggestion was that the proposals should be phased in by either creating a green policy or guidelines for event organizers and participants and then incorporating them progressively at a small scale.

The committee recommended that the proposed guidelines should be circulated among members for comment.

## *World Medical Journal*

A written and oral report were received from the Editor of the World Medical Journal, Dr. Peteris Apinis. He said this had been one of the strangest years of our lives. The pandemic had caused fear, not only in governments, health ministries, medical leaders, doctors, nurses, but even more in their patients – and the media had given them only one message, fear. Governments had succumbed to this mass psychosis and did unthinkable things, far from related to epidemiology and infection prevention. Medical journals were full of contentious views as different nations chose different methods to reduce the spread of the infection and vaccinate the population.

In 2020, four WMJ magazines were issued, both paper and digital. This year, three issues had come out. Dr. Apinis ended by saying that it was time for him to stand down as editor in chief to allow someone younger to take over.

The committee thanked Dr. Apinis for all his hard work.

## **Tuesday October 12**

### **Socio-Medical Affairs Committee**

The committee was called to order by the Chair, Dr. Osahon Enabulele (Nigeria).

### *Health and Environment*

The committee received an oral report from Dr. Peter Orris (Associate Member), Co-Chair of the Environment Caucus. The Caucus had discussed an update of My Green Doctor, about greening physician's offices and Guidelines on healthcare practice towards clinic sustainable environmental choices, by Todd L Sack, Executive Director of My Green Doctor Foundation. It had discussed a suggestion for a new oath for medical and

health professionals, incorporating planetary health, and these discussions were continuing. And it had discussed the WMA's involvement in the UN Climate Change Conference (COP26) in Glasgow in November.

## *Protection and Integrity of Medical Personnel in Armed Conflicts and Other Situations of Violence*

A revised Statement on the Protection and Integrity of Medical Personnel in Armed Conflicts was presented to the committee, updating the existing Declaration and merging it with other Declarations and statements. The revised Statement made it clear that healthcare personnel must be protected, and this was confirmed by a number of international agreements. It noted with concern that attacks on health personnel were on the rise, but even in armed conflict health care personnel had to stick to medical ethics. The Statement made several recommendations to governments and all other parties involved in armed conflicts. It stressed the importance of bringing to justice culprits of violence against health personnel and the need for data to do this. And finally, it called on governments and NMAs to raise awareness about this problem.

Speakers welcomed the document, but it was suggested that it could be improved, and might benefit from being circulated for further comments. There was insufficient emphasis on medical neutrality as a guiding principle. There was also no mention that serious violence was likely to amount to war crimes, and there was lack of reference to the International Criminal Court.

The committee agreed to recommend that the document be circulated again among members for comment.

## *Medical Technology*

The committee received an oral report from the workgroup on Medical Technology. It was told that the workgroup had discussed

the definition of medical technology and had worked on an inventory of WMA policies related to medical technology to identify missing and/or overlapping policies. It would return in April 2022 with new ideas.

## *Trade Agreements and Public Health*

A proposed revision of the Council Resolution on Trade Agreements and Public Health was presented to the committee. This emphasised that negotiations should take into account that the right to health and to a healthy natural and social environment were well-prioritized. Trade agreements should be directed at contributing to global health and equity.

The committee heard that conflicting views had been expressed by NMAs and a compromise was now being proposed. After a brief debate the following sentence was approved without a vote: 'The WMA considers that patenting on medicines on medicines/vaccines must be regulated in accordance with the ethical principles and values of the medical profession in order to ensure effective and global action for public health and therefore recognizes that it may be necessary to temporarily waive patents in times of public health emergencies'.

Following further debate, the committee recommended that the document be sent to the Council for forwarding to the General Assembly for adoption.

## *Use of Telehealth for the Provision of Health Care*

A proposed major 10-year revision of the Statement on Guiding Principles for the Use of Telehealth for the Provision of Health Care was presented to the committee. It was explained that three WMA policies had been merged into one single E-Health statement.

In a brief discussion, there was opposition to the phrase in the document that 'At pres-

ent, face-to-face consultation should remain the gold standard of clinical care'. This was described as simplistic, and an amendment was proposed that 'The gold standard of the delivery of clinical care is whichever provides the patient with the optimal care in the specific circumstances'. The amendment was supported.

Other speakers questioned whether the document captured the differences between digital health and mhealth, and it was suggested that further consideration should be given to the issue.

A proposal to recirculate the document was approved.

## *Supporting the Rights of Patients and Physicians in the Islamic Republic of Iran*

An oral report was given to the committee that physicians in the Islamic Republic of Iran had reported a deliberate denial of medical care in detention, withholding of essential and readily available medications by physicians and other health professionals. There was widespread use of torture and ill-treatments in detention and concern about the veracity of documentation related to the death of patients, as well as physicians being forced to produce clinically distorted documentation.

The document was approved by the committee to be sent to the Council for forwarding to the General Assembly for adoption.

## *Health Hazards of Tobacco Products and Tobacco-Derived Products*

A proposed major revision of the Statement on Health Hazards of Tobacco Products and Tobacco-Derived Products was presented and it was explained that it had been updated to include the many novel forms of tobacco use.

The committee agreed that the document should be circulated for comment.

## *Global Burden of Chronic Disease*

An oral report was given to the committee on revising the Statement on the Global Burden of Chronic Disease. This declared that the world should pay more attention to chronic non-communicable diseases. These were the leading cause of mortality and disability in both the developed and developing world, the four main NCDs being cancers, cardiovascular diseases, chronic respiratory diseases, and diabetes. Together they accounted for seven of every ten deaths worldwide.

The committee recommended that the revised Statement should be circulated to members for comment.

Minor revisions were agreed to three policies:

- WMA Declaration on Leprosy Control around the World and Elimination of Discrimination against persons affected by Leprosy
- North Korean Nuclear Testing
- Protection of Health Care Facilities and Personnel in Syria

## *Implementation of the WHO Framework Convention on Tobacco Control*

The committee was presented with a minor revision to the WMA Convention on Tobacco Control.

Several amendments were proposed. The Danish Medical Association proposed a new paragraph which read: 'In line with its Statement on Electronic Cigarettes, calls on Member States to include e-cigarettes and other electronic nicotine delivery systems in the scope of application of the WHO Framework Convention and to ensure that that these products be subjected to local regulatory approval and be entrenched in smoke free laws'. The amendment was approved.

The American Medical Association proposed two new sentences which were also approved. The first referred to governments

combatting 'the tobacco industry's predatory marketing tactics by adopting comprehensive bans on advertising, promotion and sponsorship' and the second urged governments 'to introduce initiatives that break brand recognition, including plain packaging of cigarettes and other smoking products'.

The amendments were agreed and the committee agreed that the Resolution, as amended, should be sent to the Council for forwarding to the Assembly for adoption.

## *Child Safety in Air Travel*

A minor amendment was submitted to the Resolution on Child Safety in Air Travel, which expressed concern that adequate air safety systems for infants and children had not been generally implemented. It called for a ban on the use of inappropriate "loop belts" frequently used to secure infants and children in passenger aircraft and urged all airline companies to take immediate steps to introduce safe, thoroughly tested and standardized child restraint systems.

The American Medical Association proposed an amendment to strengthen the wording on loop belts to read 'However, the practice of holding an infant or child in a lap or using a "loop belt" continues and is not a sufficient safety measure'. It was argued that the WMA should clearly state that the practice of using a "loop" or "lap" belt was no longer recommended because it was unsafe. The amendment was approved.

The committee agreed that the Resolution, as amended, should be sent to the Council for forwarding to the Assembly for adoption.

## *Occupational and Environmental Health and Safety*

A major revision to the 2016 Resolution on Occupational and Environmental Health and Safety was submitted by the Kuwait Medical Association.

The committee was told that during the Covid-19 pandemic, an increased number of workers worked outside the employer's premises using digital information and communication technologies either full-time or part-time. Such digital working environment could offer a flexible work schedule, and reduce commuting time. But it also had its own risks, as it isolated employees, particularly individuals living alone, and resulted in increased level of stress and anxiety. A healthy digital working environment needed to be in place to ensure employee health and safety. This had been taken into account in the new revised document.

The committee recommended that the revised Resolution be circulated to members for comment.

## *Racism in Medicine*

The German Medical Association submitted a proposed new Declaration on Racism in Medicine.

The committee agreed to circulate this document for comment.

## *Patient Safety and Professional Regulation*

The committee considered the proposed Statement on improving patient safety.

The British Medical Association said this was a really important issue. Patient safety was directly related to resources, infrastructure and workforce restraints. They needed to be clear that if governments wanted to ensure patient safety, they must address resources, otherwise physicians became targets. They had to recognise that systemic factors were the largest contributor to safety issues. Workforce culture affected every nation. They knew that negative cultures affected patient safety. Targeting doctors meant they would not be open and would not learn. When it came to physician wellbeing, they knew that when doctors were under stress, feeling harassed, the risks of errors went up.

On medical regulation, the biggest omission in WMA policies was that they were always reinforcing the idea of regulating individuals rather than regulating systems. But if they were to regulate medical professionals, the regulator should at all times consider the wider context of resource constraints, infrastructure, culture, and well-being. The entire system should be considered. The BMA said the proposed Statement had clear recommendations.

The committee agreed to recommend that the proposed Statement be circulated for comment.

### *Discrimination against Elderly Individuals within Healthcare Settings*

The Spanish Medical Council proposed a Declaration on Discrimination against Elderly Individuals within Healthcare Settings, which declared that elderly individuals experienced all kinds of discrimination and were often perceived as a burden on healthcare systems and their financial sustainability. The Spanish said the aim of the proposed Declaration was to strengthen the health of elderly people. The Covid-19 pandemic had affected elderly people very seriously.

The committee agreed to recommend that the proposed Declaration be circulated for comment.

### *Providing Covid-19 Vaccines for All*

The Turkish Medical Association submitted a proposed Resolution for Providing Covid-19 Vaccines for All, which proposed measures for the access and equity of vaccines.

The committee recommended that the proposed Resolution be circulated for comment.

### *WFME Standards for Distributed and Distance Learning in Medical Education<sup>1</sup>*

The Secretary General gave an oral report on a document from the World Federation for Medical Education 'Standards for Distance Learning for Medical Education'. During the pandemic, this had become an extremely important issue with the need for online learning. These standards had now been published.

The document was endorsed by the committee.

### *The Repression of Nicaraguan Doctors*

An emergency Resolution on the situation in Nicaragua was presented to the committee. Members were told that this was a very urgent issue because doctors in the country were facing threats of imprisonment for speaking out about the state of the country's health care system.

The committee agreed that the Resolution should be forwarded to the Council for adoption by the General Assembly.

## Wednesday October 13

### Medical Ethics Committee

The committee was called to order by the Chair, Dr. Marit Hermanson (Norway)

### *International Code of Medical Ethics*

The committee heard an oral report on the progress being made in revising the International Code of Medical Ethics. Members were told that a revised draft version had been sent out for public consultation in May, attracting a tremendous response from physicians and ethics experts throughout the world. Three productive virtual meetings had been held to review these comments in detail and the result of these discussions was the revised draft now presented to the committee.

The committee was told that the paragraph on conscientious objection would be han-

dled separately, as the workgroup was still reviewing the vast feedback this paragraph had received from the public consultation. Further conferences would be held early next year and it was hoped to have two more regional conferences in Asia and Africa. A small expert meeting was planned for some time in August next year.

The Spanish Medical Council said it was disappointed that points raised at a Latin American Spanish regional meeting had not been included in the draft. But it was told that the workgroup wanted to keep the document to a certain length and did not want it to go into too much detail.

The committee agreed that the proposed draft could be used for further conferences next year.

After a brief debate on conscientious objection, the committee agreed to recommend to Council that the proposed draft paragraph be used as a basis for discussion at a dedicated conference later next year.

### *Assisted Reproductive Technologies*

As part of the annual 10-year policy review process, a major revision of the Statement on Assisted Reproductive Technologies was submitted to the committee. A workgroup under the South African Medical Association had been set up to coordinate with the workgroup on Genetics and Medicine, given the number of cross-cutting issues, and the document had undergone much discussion. The document's opening words stated 'Assisted reproductive technologies may raise profound issues. Views and beliefs on assisted reproductive technologies, which vary both within and among countries. Assisted conception is also regulated differently in various countries'.

The committee was given an outline of the document's recommendations. It was proposed that the document should be circulated for comment.

<sup>1</sup> This document is available in English only



The committee agreed to recommend this approach to the Council.

## *Physicians Treating Relatives*

A proposed Statement on Physicians Treating Relatives was presented to the committee. This declared that physicians should generally avoid treating relatives, except in an emergency, or for minor short-term health problems or where there was no other qualified physician available.

The committee heard that this document had already been circulated for comments and changes had been made, including omitting 'friends' from the title of the document. It was proposed that the document should now be approved.

However, the Japan Medical Association objected to such a Statement being issued by the WMA. It argued that physicians had an obligation to treat anyone in an emergency, and therefore this Statement was not necessary. Other speakers also expressed their doubts about the document, some arguing that it was too long, others that it contained inconsistencies.

The committee eventually agreed by 10 votes to six to recommend that the document, as amended, be sent to Council for forwarding to the Assembly for adoption.

## *Organ Donation in China*

The committee received an oral report on talks that had been held between the German Medical Association and the Chinese Medical Association about the Resolution on Organ Donation in China, which the Chinese asked to be rescinded. The Chinese said it would like to see the whole issue being discussed more comprehensively within the WMA. It had suggested setting up a workgroup to review existing WMA policy relating to coerced organ transplants, including the use of death penalty prisoners' organs. The Chinese said it had

no problem in condemning the practice of coerced transplants, but pointed out that there were other countries still carrying out the practice. But there had been no criticism from WMA about these countries and it urged the WMA to correct this.

The committee agreed to recommend that a workgroup be installed with the mandate to discuss and review existing WMA policies related to the fight against coerced organ procurement, including the use of death penalty prisoners' organs.

## *Declaration of Venice and End of Life Care*

A proposed 10-year revision of the Declaration of Venice on Terminal Illness was presented to the committee. The American Medical Association, which was tasked with merging the Declaration of Venice with the Declaration on End-of-Life Medical Care, explained that this was a major update. The workgroup had decided that the Declaration of Venice should remain the base document. The draft contained new content on palliative care and sedation and it was suggested that when the proposed revision was adopted, the Declaration on End-of-Life Medical Care should be rescinded and archived. The AMA proposed circulating the document for comment.

The British Medical Association informed the committee that the BMA had moved from a position of opposition to all forms of physician assisted dying and euthanasia to neutrality on the issue. This meant they were neither opposed nor in favour of assisted dying, but that if there were legislative proposals brought forward in Parliament, they would comment on those proposals in order to address doctors' interests and concerns and in particular to provide for conscientious objection.

The committee heard some criticism that merging the two Declarations was confusing, since the two policies had much in common but also several differences. A

motion was proposed to split the two documents again, but on a vote the proposal was defeated by nine votes to five.

The committee recommended that the draft Declaration of Venice on Terminal Illness should be circulated to constituent members for comment and the Declaration on End of Life Medical Care be rescinded and archived.

## *Medical Ethics in the Event of Disasters*

A proposed Statement on Medical Ethics during Public Health Emergencies was presented to the committee, setting out revised guidance to physicians on the ethical standards and principles required to confront public health emergencies.

The committee was told that the Statement took into account two existing policy statements and the recommendation was to set up a workgroup.

The committee agreed to recommend that a workgroup be established.

## *Professional and Ethical Use of Social Media*

The Junior Doctors Network submitted a proposed major revision of the Statement on the Professional and Ethical Use of Social Media. It was explained that the policy had been updated to address the importance of evidence-based information on social media, the role of doctors standing against misinformation and to examine the professional and ethical challenges facing physicians and patients.

The committee agreed to recommend that the document be circulated for comment.

## *Monitoring of the Declaration of Tokyo*

The committee considered a proposed minor revision to the Recommendation on the Development of a Monitoring and Reporting Mechanism to Permit Audit of Adher-



ence of States to the Declaration of Tokyo. The Declaration establishes guidelines for physicians concerning torture and other cruel, inhuman or degrading treatment or punishment in relation to detention and imprisonment.

A new paragraph was proposed to provide support to WMA constituent members and their individual physicians members to resist such violations, and as far as realistically possible, stand firm in their ethical convictions. After further amendments were proposed, the committee agreed wording, stating that the medical profession and governments should also protect physicians endangered because they adhered to their professional and ethical obligations.

The revision was agreed and the committee recommended that the document, as amended, be sent to Council for forwarding to the General Assembly for adoption.

### *Human Rights*

The committee received an activity report on human rights.

## **Thursday October 14**

### **Resumed Council Session**

The reconvened Council meeting was opened by the Chair, Dr. Frank Ulrich Montgomery. It considered reports from its three committees.

### **Medical Ethics Committee**

#### *Physicians Treating Relatives*

The Japan Medical Association reopened the debate on the proposed Statement on Physicians Treating Relatives by saying that the policy as currently worded contained several inconsistencies. It was not against the policy, but believed that further discus-

sion should be had about the possible problems of treating relatives. The Statement did not take into account patients' wishes. It proposed that the document should be circulated to members once again.

Other speakers also raised issues of concern, and it was decided by 16 votes to eight to recirculate the document.

The remainder of the Medical Ethics Committee's report was approved without debate.

### **Finance and Planning Committee**

#### *Statutory Meetings*

It was reported that the medical associations of Portugal and Uruguay had agreed dates on future meetings and it had been agreed that the Council meeting in the Spring of 2025 should be held in Montevideo and the Assembly that year should be held in Porto.

The Council agreed to recommend the dates to the General Assembly.

#### *Legal Seat*

The Secretary General updated the Council on plans to change the legal seat of the WMA from the USA to France. He explained the constraints of the current situation because of being legally domiciled in the US. He said the change was purely technical and would have no bearing on the purpose of the Association.

The Council approved the report.

#### *Public Relations*

The Council received an oral report on public relations. Members were told that the WMA had maintained a very high profile over the past 18 months with its views about how the Covid-19 pandemic was being dealt with. The President, the Chair of Council and the Secretary General had all

conducted many media interviews to put across the WMA's various messages about the pandemic, vaccine equity and vaccine hesitancy.

Press releases from the Assembly would highlight new policy documents on the availability of medicines, women's access to health care and the situation in Nicaragua. NMAs were asked to ensure that their media outlets received these.

The remainder of the Finance and Planning Committee's report was approved without debate.

### **Socio-Medical Affairs Committee**

Finally, the Council considered the report of the Socio-Medical Affairs Committee and approved it without debate.

#### *Advocacy and Communication*

An oral report was given by the workgroup, including activity on social media, Wikipedia and assistance to smaller NMAs on accessing WMA communications. The report was received by the Council.

#### *World Health Organisation*

The Secretary General reported on discussions that were going on within the WHO on developing a pandemic treaty. He urged NMAs to assist with information about these talks, as it was important for NGOs and civil society to be involved.

## **Friday October 15**

### **GENERAL ASSEMBLY**

#### *Ceremonial Session*

WMA President Dr. David Barbe called the session to order and welcomed everyone to the second online General Assembly.

Dr. Chaand Nagpaul, Chair of the host British Medical Association, welcomed delegates and reminded them that it was in BMA House that the idea of creating the WMA was first born in 1945 in a meeting between leaders of medical associations from different nations.

He went on: 'Throughout the pandemic doctors from around the world have worked day in day out in the most challenging of circumstances with selflessness and dedication. Many risked their own health and lives as they exposed themselves to this deadly virus. We accepted wholesale change overnight to our lives. Many doctors moved from their usual specialty to learn new skills to care for Covid patients. Working above and beyond, we showed determination and courage. We have done our duty. While fighting the virus, it is a tragedy that too many doctors around the world have lost their lives in the course of their duties. They will be remembered and never be forgotten.'

'However, within the past year we have also witnessed a breakthrough in medical science in the development of Covid vaccines anew within 10 months in what normally takes up to 10 years. It just shows what can be achieved with the collective efforts of medical researchers and scientists working across the globe and which has brought hope to the world that there is a way through this pandemic. The pandemic also reminded us we are one global community and that no one is safe until everyone is safe.'

He spoke about the need to prioritise support and aid to those nations worst affected by the pandemic. It was also a time to recognise the central importance of a universal doctrine. The Declaration of Geneva committed them to recognise the dignity of every human being, irrespective of nation or border. These principles reminded them that the pandemic would not end until they tackled Covid in every nation, ensuring equitable access to vaccines in all parts of the

world. The unique strength of the WMA was more important now than ever before, bringing together medical leaders from across the world to connect and collaborate and to share information about best practice, to speak out to protect human rights and the independence of doctors, including those threatened by their own governments. It was a crucial moment that required cooperation, solidarity and support.

He concluded by saying: 'It is a time for all of us to hold our countries to account and inspire them to act together as one in service to the benefit of all nations, to finally pull through the pandemic together. All nations must recognise the efforts of doctors and the toll it has taken on their lives. This has been an emergency that most governments were unprepared for, so it was left to health care workers to tend to a crisis that many of us never could have imagined. This has led to a new wave of physical exhaustion and mental health issues for doctors, whose wellbeing must now be properly supported if health services are to deal with the continuing scale of challenges ahead.'

The honoured guest, Professor Chris Whitty, Chief Medical Officer for England and Chief Medical Adviser to the UK Government, expressed his deep respect and personal gratitude to the millions of physicians represented by WMA leaders. The professionalism and compassion they had, and continued to demonstrate, was remarkable. He also praised the communication and collaboration within the medical community in responding to the global emergency. He had valued the support and advice he had received from public health colleagues all over the world. The international knowledge and data sharing had played an essential role in their understanding of Covid-19. In addition, they had also seen countries provide essential resources to others in need and this international network would continue to be important as they recovered from this pandemic and faced other global health issues in the future. He said he was

hopeful that together as a medical community they could respond effectively to these challenges.

Physician delegates logged onto the meeting were then invited to recite the Declaration of Geneva, also known as the Physician's Pledge.

Dr. Barbe paid tribute to physicians who had died in service during the pandemic, including Dr. K.K. Aggarwal from India and Dr. Mykola Tyshchuk from the Ukraine.

The Chair of Council, Dr. Montgomery, paid tribute to Dr. Barbe's Presidency, saying he had tirelessly promoted the messages for Covid-19 testing and vaccination.

Dr. David Barbe delivered his valedictory address and was presented with a Past President's medal by Dr. Montgomery.

Dr. Montgomery then installed President Elect, Dr. Heidi Stensmyren as President for 2021/22. Dr. Stensmyren took the oath of the office of President and was presented with the Presidential Medal. She then delivered her inaugural address.

### *Plenary Session*

Dr. Montgomery opened the plenary session of the General Assembly.

### *Minutes of the last Meeting*

The Chinese Medical Association expressed its opposition to paragraph in the minutes reporting the Resolution adopted at last year's General Assembly on Human Rights Violations against Uighur people in China. It said this contained serious procedural flaws and ignored facts and evidence. Its allegations about the health of the Uighur people were completely groundless.

In a vote on whether to accept the Uighur paragraph in the minutes, 98 votes were in favour and 15 against.

In a further vote on whether to accept the minutes as a whole, 101 votes were cast in favour and 13 against.

## *Election of President for 2022/23*

The Secretary General reported the results of the election for President-elect. There were two candidates, Dr. Osahon Enabulele (Nigeria) and Dr. Muhammad Ashraf Nizami (Pakistan). A total of 49 member associations participated in the vote with a total of 144 votes. The result was that Dr. Enabulele was elected with a majority of votes to become President in 2022–23.

In his acceptance speech, Dr. Enabulele said this was the first time since the establishment of the WMA in 1947 that a physician from Nigeria, the most populous country in Africa with a population of well over 200 million people, had been elected to lead the WMA.

‘Coming from an underserved, under-represented, and poorly understood region of the world, deprived of quality healthcare – the African region with 54 countries – I had in the run up to the Presidential election, emphasized the need to give fair consideration and opportunities to physicians from the African region, to lead the organization, in a way that highlights the fact that everyone counts in the WMA, and that we can all learn and benefit from each other’s experiences’.

He added: ‘I consider it an important affirmation of the fact that every member and every region counts in the WMA, and that at different moments, the various members and regions of the organization will have the opportunity to lead at different levels of the WMA. On behalf of the Nigerian Medical Association, my country Nigeria, the African region, and indeed my family, I wish to express profound gratitude to all National Medical Associations from all regions of the world, and to physicians across the globe, for reposing huge confidence in me and the African region, and for finding me worthy to be elected to serve the WMA

in the high office of President for the 2022–2023.’

Dr. Enabulele concluded by saying: ‘The issues of health disparities and inequities, made worse by the Covid-19 pandemic, the issue of quality patient care, physician wellbeing, rights and autonomy, remain critical issues for engagement. We must therefore continue to make our contributions to the management of the Covid-19 pandemic that has devastated the health system, lives and livelihoods, including the lives of physicians and other health professionals. I cannot end these remarks without paying special tribute to our colleagues who lost their lives in the course of duty, in this Covid-19 pandemic era’.

## *Report of the Council*

The reports of the three committees were presented to the Assembly from Council.

The Assembly adopted the following policies:

- Resolution on Covid-19 Vaccines and International Travel Requirements
- Resolution in support of Myanmar Health Personnel and Citizens
- Resolution in support of the Countries worst affected by the Covid-19 Crisis
- Revised Declaration on Principles of Health Care for Sports
- Revised Statement on Access of Women and Children to Health Care
- Revised Statement on Women’s Right to Health Care and How that Relates to the Prevention of Mother-to-Child HIV Infection
- Statement on Photoprotection
- Statement in Support of Ensuring the Availability, Quality and Safety of All Medicines
- Revised Statement on Medical Liability
- Statement on Access to Surgery and Anaesthesia Care
- Revised Resolution on Trade Agreements and Public Health
- Revised Resolution Supporting the Rights of Patients and Physicians in the Islamic Republic of Iran

- Resolution on the Repression of Nicaraguan Doctors

Minor revisions were agreed to the following policies:

- Declaration on Leprosy Control around the World and Elimination of Discrimination against persons affected by Leprosy
- North Korean Nuclear Testing
- Protection of Health Care Facilities and Personnel in Syria
- Resolution on Child Safety in Air Travel
- Implementation of the WHO Framework Convention on Tobacco Control
- Revised Recommendation on the Development of a Monitoring and Reporting Mechanism to Permit Audit of Adherence of States to the Declaration of Tokyo
- Revised Resolution on Plain Packaging of Cigarettes

## *Taiwan*

The Chinese Medical Association proposed rescinding the proposed Resolution calling for observer status for Taiwan at the World Health Organisation. It argued that the Resolution was factually and legally wrong. There was only one China and Taiwan was an inalienable part of China. This principle was universally recognised in the international community and the WMA had always claimed it did not hold any political position on the issue of national sovereignty. It was also inconsistent with the principles and practices upheld by the United Nations and the World Health Organisation. The proposed Resolution violated both the UN Charter and the WMA’s statement not to take any political stance. There was no barrier whatsoever for the Taiwan medical community to communicate with the WHO.

However, the delegate from Taiwan., Dr. Tai-Yuan Chiu said that Taiwan had not been invited to the World Health Assembly as an observer since 2017. From 2009 to the end of 2020 Taiwan had applied to attend 199 technical meetings held by the WHO.

It was allowed to attend only 64, a 70 per cent rejection rate. The WHO had failed to fulfil the principles of universality, equality and its ethical aspirations.

On a vote, the motion to rescind the Resolution was lost by 99 votes to 19.

On a second vote, the proposed Resolution was adopted by 91 votes to 16.

*Proposed revision of Statement on Medical Care for Refugees, including Asylum Seekers, Refused Asylum Seekers and Undocumented Migrants, and Internally Displaced Persons*

The Assembly was asked to adopt the proposed revision of the Statement on Medical Care for Refugees, which sets out physicians' duty to provide migrants with appropriate medical care, based solely on clinical need, regardless of the civil or political status of the patient.

The delegate from Bangladesh referred to the paragraph urging governments to ensure access to safe and adequate living conditions and essential services for all. He proposed adding to the end of the sentence the words 'migrants even with the support from the donor agencies and/or philanthropists if needed'. He argued that if countries, where the displaced people migrated, could not afford to bear by itself the economic burden created due to influx of migrants, external support from the donors and philanthropists was needed to support the healthcare services effectively.

His amendment received support from Pakistan and the Assembly agreed to include the new words in the Statement.

The whole document, as amended, was then adopted without a vote.

## *Family Violence*

A proposed revision of the Statement on Family Violence was submitted for adoption.

Dr. René Héman (Royal Dutch Medical Association) proposed several amendments. The first was to delete the word 'often' from the sentence 'Victims often become perpetrators of family violence and violent acts against non-intimates' and replace it with the word 'can'. He argued that to say that victims of family violence *often* become perpetrators themselves was too strong. Inter-generational transmission of violence was a known phenomenon, but did not necessarily happen to victims of this violence.

After a brief debate, the deletion of the word 'often' was agreed without a vote.

Dr. Héman also said he was not in favour of making the reporting of family violence compulsory. Reporting should be considered on a case-to-case base and should be seen as a final step in a series of possible interventions, such as providing. He proposed several amendments to make this clear. On a vote, these were agreed.

The Assembly then adopted the Statement, as amended.

## *Treasurer*

The Treasurer, Dr. Ravindra Sitaram Wankhedkar, gave a brief report on the Association's financial situation. He referred to the Association's net income, the membership dues which had been paid, the financial earnings which continued to be low and the substantial cost savings because of Covid-19. He reported on the budget for 2022 and said the Association's finances were very solid.

His reports were approved by the Assembly.

## *Future Meetings*

The Assembly was informed that the 2025 Council session would be held in Montevideo, Uruguay from April 24–26 and the General Assembly that year would be held in Porto, Portugal from October 8–11.

A request had been received from the Royal Dutch Medical for the 2026 General Assembly to be held in the Netherlands

The Assembly approved the reports.

It was reported that the theme at the scientific session in Berlin on October 6 2022 would be 'Medical Ethics in a Globalised World'. The General Assembly from October 5–8 would coincide with the 75<sup>th</sup> anniversary of the German Medical Association.

This was approved by the Assembly.

## *Bylaws Amendments*

The Assembly approved amendments to the bylaws proposing additional committee members and the issue of voting rights.

## *Associate Members*

Dr. Ankush Bansal presented a report from the Associate Members. He said Dr. Joseph Heyman had been re-elected to the chair and proposals to amend the group's rules had been discussed and would now be circulated to members for comment.

The report was accepted.

## *International Day of the Medical Profession*

Dr. Huerta (Spain) reminded the Assembly of the Resolution, adopted at last year's General Assembly, for October 30<sup>th</sup> to be the International Day of the Medical Profession. He asked the WMA and its members to promote activities to celebrate this day, the first time that it had been celebrated. The Spanish Medical Council was going to send out letters and posters in Madrid and meet with the chairs of societies all over Spain to ask them to promote this day and the profile of the medical profession.

The Assembly ended with the showing of a film on Berlin, the venue for the next General Assembly in October 2022.



## WMA Declaration on Principles of Health Care in Sports Medicine

*Adopted by the 34<sup>th</sup> World Medical Association General Assembly, Lisbon, Portugal, September/October 1981, amended by the 39<sup>th</sup> World Medical Association General Assembly, Madrid, Spain, October 1987, by the 45<sup>th</sup> World Medical Association General Assembly, Budapest, Hungary, October 1993, by the 51<sup>st</sup> World Medical Association General Assembly, Tel Aviv, Israel, October 1999, reaffirmed by the 185<sup>th</sup> WMA Council Session, Evian-les-Bains, France, May 2010, and amended by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

Sports medicine physicians are physicians concerned with the prevention and treatment of injuries and disorders that are related to participation in sports. In some countries, sports medicine physicians are recognized as medical specialists. They are trained to address issues associated with nutrition, sports psychology and substance misuse, and may also counsel athletes on injury prevention.

Considering the involvement of physicians in sports medicine, the World Medical Association (WMA) recommends ethical guidelines for sports medicine physicians, recognizing the special circumstances in which their medical care and health guidance is given.

### Anabolic Agents and Performance Enhancing Drugs and Methods

The use of anabolic agents, performance enhancing drugs, pain killers and performance enhancing methods by athletes is contrary to the rules and ethical principles of athletic competition as set forth by most sports governing bodies. Performance enhancing drugs and methods have been associated with adverse health effects.

The sports medicine physician should be aware that methods, drugs or interventions which artificially modify blood constituents, biochemistry, genome sequence, gene expression or hormone levels and do not benefit patients, violate the basic principles of the [WMA's Declaration of Geneva](#), which states: "the health and wellbeing of my patient will be my first consideration."

The WMA believes that the use of anabolic agents and performance enhancing drugs and methods is a threat to the health of athletes and is in conflict with the principles of medical ethics. The physician must oppose and refuse to administer or condone any means or method which is not in accordance with medical ethics, or which might be harmful to the athlete using it. The physician must also inform athletes of potential health risks.

Examples of these drugs and methods include, but are not limited to:

- The use of drugs or other substances whatever their nature and route of administration, including central-nervous-system stimulants or depressants and procedures which artificially modify reflexes, alter a sense of well-being and/or general mental outlook.
- Procedures or therapeutics to mask pain or other protective symptoms if used to enable the athlete to take part in events or training activities when clinical signs make his or her participation inadvisable. This includes allowing participation in athletic activity when doing so would be dangerous to the athlete.
- Procedures or therapeutics used to mask the presence of other performance enhancing drugs or to induce rapid water or weight loss.
- Measures aimed at an unnatural improvement in or maintenance of endurance or oxygen carrying capacity during competition. This includes the manipulation of blood and/or blood components defined as the administration or reintroduction of blood or red blood cell products of any origin into the circulatory system, artificially enhancing the uptake, transport, or delivery of oxygen using chemicals such as erythropoietin, or other forms of intravascular manipulation to artificially increase red blood cell mass, unless medically indicated for the treatment of a documented disease or medical condition. Blood doping also exposes the athlete to unwarranted and potentially serious health risks.
- Use of anabolic agents including "designer steroids", which are substances that are undetectable through the use of standard testing methods.
- Use of anabolic steroid precursors, including dietary supplements, that claim to provide "safe" steroid equivalents, but that metabolize in the body into anabolic steroids.
- Use of non-approved substances which have no current approval by any governmental regulatory health authority for human therapeutic use, for example, drugs under pre-clinical or clinical development, discontinued drugs, designer drugs or substances approved only for veterinary use.
- Use of peptide hormones, growth factors and related substances to increase red blood cell count, blood oxygenation or oxygen-carrying capacity.
- Use of hormone and metabolic modulators, which are substances to modify hormone activity by blocking the action or increasing the activity of a hormone.



Of special concern is the use of anabolic agents and steroid precursors in adolescents. Young users are considered particularly susceptible to potentially serious health problems during this physically and emotionally vulnerable period when their own hormonal cycles are changing. In females, anabolic agents have been associated with a number of adverse effects, some of which appear to be permanent even when drug use is stopped. Physicians should strongly discourage using these products.

## World Athletics Gender Rules for Classifying Female Athletes

World Athletics 2018 Eligibility Regulations for Female Classification [1] imposes an upper hormonal limit for athletes wishing to compete in the female category in certain disciplines of international athletics competitions.

The WMA opposes World Athletics' rules [2] requiring female athletes with differences in sex development to take drugs to reduce and maintain their natural level of blood testosterone in order to compete. The mere existence of a condition caused by a difference in sex development, in a person who has not expressed a desire to change that condition, does not constitute a medical indication for treatment. Medical treatment solely to alter athletic performance is unethical.

## Recommendations

1. Sports medicine physicians have an obligation and duty to respect and comply with the ethical standards of the medical profession.
2. The sports medicine physician who cares for athletes has an ethical responsibility to recognize the special physical and mental demands placed upon athletes by their participation in athletic activities. The physician's duty is to preserve the athlete's mental and physical health and not solely to increase athletic performance.
3. When the sports participant is a professional athlete and derives livelihood from that activity, the physician should understand the occupational health aspects involved.
4. The sports physician should give his or her objective opinion about the athlete's state of fitness clearly and precisely, leaving no doubt as to his or her conclusions.
5. In all sporting events, it is the physician's duty to decide whether the athlete is medically fit to compete in an event. This decision cannot be delegated to other non-physician professionals.
6. In order to carry out his or her ethical obligations, the sports medicine physician's authority must be fully recognized and up-

held, particularly when it concerns the health and safety of the athlete. Concern for the athlete's health and safety must override the interests of any third party.

7. The sports medicine physician is obligated to uphold the ethical principles of the medical profession. This includes the right to privacy and respect for the confidential nature of the patient-physician relationship. These principles and obligations should be supported by an agreement between the sports medicine physician and the athletic organization involved.
8. The sports medicine physician must oppose and refuse to administer any substance or condone any means or treatment method which is not in accordance with medical ethics and/or which might be harmful to the athlete using it. The physician must also inform athletes of potential health risks.
9. The sports medicine physician should be invited to participate in the design and modification of a sport's rules and regulations in order to protect the health and safety of athletes.
10. The sports medicine physician, with patient consent, should work cooperatively with the patient's personal physician, and keep him or her fully informed of the patient's current condition.
11. All physicians should recognize that the desire to enhance performance, appearance, and/or well-being is not limited to elite athletes. Amateur and recreational athletes, as well as adolescents, are also at risk of and subject to sociocultural pressures to misuse anabolic agents and performance enhancing drugs and methods. A harm-reduction approach with discussions focused on risks, harm minimization, prevention strategies, and health promotion is recommended.

## WMA Resolution in Support of Medical Personnel and Citizens of Myanmar

*Adopted by the 217<sup>th</sup> WMA Council Session, Seoul (online), April 2021 and by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

The World Medical Association notes with increasing alarm, the continuing actions of the current police and Myanmar security forces including arbitrary arrests and detention of health personnel and other citizens, attacks against physicians and other health personnel and facilities, and continuing harassment and intimidation

of protesters, human rights defenders and journalists. The WMA and its members are seriously disturbed by their terrorizing, arresting, kidnapping and murdering health care workers for treating protesters.

With a collapsed health system, the Covid pandemic is devastating Myanmar with lack of medical equipment and personnel and increasing deaths. Recent reports of forcing hundreds of physicians to secretly treat Covid patients and ambushing and arresting physicians after luring them to a non-existent Covid patient's home, are cause for further dismay.

These activities are in total opposition to the international recommendations in the [WMA Declaration on the Protection of Health Care Workers in situation of Violence](#), the [WMA Statement on the Protection and Integrity of Medical Personnel in Armed Conflicts and Other Situations of Violence](#) as well as the [United Nations Declaration on Human Rights Defenders](#).

Thus, the WMA and its members demand that the Myanmar security forces take immediate action to:

- Guarantee, in all circumstances, the physical and psychological integrity of protesters, including health personnel who are arrested;
- Release protesters and personnel immediately and unconditionally, and drop all charges against them since their detention is arbitrary as it only aims at preventing freedom of expression and their human rights activities;
- Put an urgent end to attacks against health personnel and facilities and ensure their protection to provide adequate health care provisions to all.
- Stop all acts of harassment, intimidation, and killing, against protesters, human rights defenders and journalists and comply with all the provisions of the [United Nations Declaration on Human Rights Defenders](#);
- Ensure in all circumstances respect for human rights and fundamental freedoms in accordance with international human rights standards and international instruments, including the International Covenant on Economic, Social and Cultural Rights.
- Cooperate with international fact-finding commissions.

## WMA Resolution in Support of Taiwan's Participation in all WHO Health Programs and Inclusion in the International Health Regulations (IHR) Mechanism

*Adopted by the 170<sup>th</sup> WMA Council Session, Divonne-les-Bains, France, May 2005 and revised and adopted as a Resolution by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

In line with the Charter of the United Nations, Member States of the WHO recognize the “*enjoyment of the highest attainable standard of health*” as a fundamental right of every human being “*without distinction of race, religion, political belief, economic or social condition*”, uphold that “*the health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States*” (Preamble of WHO's Constitution).

Taiwan, located at a key position in the Asia-Pacific region, has long enjoyed close relationship with countries and areas of the region, with over 20 million regional and international travelers per year. Thus, the devastating outbreak of the 2019 Novel Coronavirus further highlights the urgency and importance of inclusiveness and leaving no one behind in the global health network. By continuing to refuse to grant Taiwan observer status to the WHA and full access to its meetings, mechanisms and activities, the WHO fails to fulfill the principles of universality and equality established in WHO's constitution as well as the ethical standards of the organization.

From 2009 to 2016, Taiwan was invited to participate in the World Health Assembly (WHA) as an Observer, with very limited access to WHO technical briefings, mechanisms and activities. Since 2017, the WHO has not granted the Observer status to Taiwan anymore.

Although Taiwan has been officially included in the implementation framework of the International Health Regulations (IHR) since 2009, its contact point information is not included on the IHR Portal established by WHO, impeding timely exchange of information and communication to the detriment of Taiwan. Delayed and/or incomplete medical information can impact adversely on the Taiwanese population, causing a gap in Taiwan's domestic disease control network, with unavoidable implications for global health.

Allowing the participation of Taiwan to the World Health Assembly and fostering its inclusion in all WHO's health programmes and in the International Health Regulations would benefit the people in Taiwan, but also the WHO and its member states as well as all related parties.

## Recommendations

1. Considering the Sustainable Development Goal 3 aiming to ensure healthy lives and promoting well-being for all at all ages and WHO's primary objective to "attain by all peoples the highest possible level of health" (article 1 of WHO's Constitution), both aims requiring a true inclusive strategy comprising all populations worldwide,
2. Reminding the ethical core value of the medical profession to serve humanity regardless of any other considerations than people's health and well-being, and firmly committed to the safeguard and promotion of health-related human rights, the WMA and its constituent members call on:
  - WHO to grant Taiwan observer status to the World Health Assembly and to ensure Taiwan's participation in all its health programs based on a substantive, timely and professional basis,
  - WHO and its Member States to include Taiwan as a full participating party to the International Health Regulations, allowing its critical contribution to the global health protection network.

## WMA Resolution in Support of the Countries Worst Affected by the Covid-19 Crisis

*Adopted by the 217<sup>th</sup> WMA Council Session, Seoul (online), April 2021 and adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

The World Medical Association is deeply concerned to see the alarming and worsening Covid crisis in many countries worldwide. We recognise the huge challenges doctors and other healthcare professionals are facing in maintaining healthcare systems in such harrowing conditions. The WMA calls on the international community and governments to urgently prioritise support and aid to these the worst affected nations, including oxygen, drugs, vaccines, Personal Protective Equipment (PPE) and other equipment as needed, and to strengthen healthcare system resilience in the face of future pandemics. The pandemic will not end until we tackle Covid in every nation and this is a time for global cooperation, solidarity and support for one another.

## WMA Resolution on Covid-19 Vaccines and International Travel Requirements

*Adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

While international travel has begun to normalize for many of those who have been vaccinated against SARS-CoV 2, fully vaccinated citizens of some countries are still subject to significant travel restrictions, as the vaccines they have received are not accepted as proof of full protection in all countries. Many countries only consider those who have received certain vaccines from specific countries to be fully vaccinated, while other vaccines are not recognized or available.

These practices effectively lead to discriminatory border restrictions against travelers who have been fully vaccinated using vaccine regimens approved in their home countries. This may restrict international cooperation and business, mainly disadvantaging poorer countries and regions. In some cases, it has even led fully vaccinated individuals to request third and fourth vaccine doses in order to provide proof of the required level of protection.

The WMA understands the reluctance of pharmaceutical authorities to allow the market introduction of vaccines for which an authorization has not been applied in their jurisdiction, or which are still in the process of authorization, or which may have been rejected because their ethical or technical standards of testing or production do not meet the required standards.

However, the WMA considers it necessary to evaluate Covid-19 vaccines based solely on their effectiveness against infection and severe illness when determining the reliability of their protection for travel purposes. Presently, there are enough data available to assess the protection offered by vaccines, independent of their marketing authorization status. Should vaccines be deemed to be ineffective, and therefore not acceptable as proof of protection, the reasons for such decisions should be made public.

We call on national governments and the European Union to immediately adopt fair, harmonized, and non-discriminatory rules to enable safe and fair travel opportunities, and to inform the public about any serious concerns that may hinder the acceptance of specific vaccines.

## WMA Resolution on the Repression of Nicaraguan Doctors

*Adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

Nicaragua is currently in a phase of accelerated expansion and community transmission of COVID-19. It is urgent for health authorities to promote necessary and proportionate measures to contain the progress of the pandemic.

The exponential increase in COVID-19 cases has caused a collapse of Nicaragua's public and private healthcare system. The lack of basic medical devices has contributed to dozens of doctors and healthcare professionals becoming infected and a large number who have died.

The Nicaraguan medical profession, through more than 30 medical societies and the COVID-19 citizen observatory, has been denouncing this situation for a long time. Nonetheless, the Special Cybercrime Act approved by the Government of Nicaragua, in force since 30 December 2020, establishes sentences of 1 to 10 years in prison for all those who spread news that produces fear or anxiety in the population.

This situation of persecution is compounded by the approach to the COVID-19 pandemic, as doctors in the public sector who demanded protective measures like masks, gloves or vaccines, were dismissed under the accusation that they disrupted the public peace. Private-sector physicians who cared for patients or guided the population on self-protection measures against the pandemic were called to stop those statements, under penalty of withdrawing their licence to practice medicine or the imposition of criminal penalties, among other terrorism-related charges.

The General Assembly of the World Medical Association (WMA) hereby ratifies the [letter from its president, Dr Barbe](#), sent on 31 August to the president of the Republic of Nicaragua, Mr Daniel Ortega, which outlines the dramatic situation suffered by Nicaraguan medical professionals and offers its support to the Declarations of 25 June 2018 and 23 August 2021 from CONFEMEL (Latin American and Caribbean Medical Confederation).

The World Medical Association (WMA) opposes and observes with extreme concern any governmental interference that threat-

ens the freedom of professional practice and freedom of expression of any doctor. It also urges the government of Nicaragua and the members of its National Assembly:

- to protect all health professionals;
- to avoid or modify any legal regulation that may harm the professional autonomy of physicians.

The World Medical Association (WMA) also wishes to highlight the extraordinary role of Nicaraguan doctors, which is inherent to our ancient profession. It actively supports and promotes the right of everyone to receive information and medical care based solely on their clinical needs.

## WMA Resolution Supporting the Rights of Patients and Physicians in the Islamic Republic of Iran

*Adopted by the 60<sup>th</sup> WMA General Assembly, New Delhi, India, October 2009, and amended by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### WHEREAS

Physicians in the Islamic Republic of Iran have reported:

- Deliberate denial of medical care in detention, withholding of essential and readily available medications by physicians and other health professionals;
- Widespread use of torture and ill-treatments in detention;
- Concern about the veracity of documentation related to the death of patients and physicians being forced to produce clinically incorrect documentation;
- Lack of essential functioning medical equipment and supplies
- Denial of the rights of hunger strikers; and
- Physicians' complicity in facilitating the death penalty for juveniles in violation of children's rights.

### THEREFORE, the World Medical Association

1. Reaffirms its [Declaration of Lisbon on the Rights of the Patient](#), which states that whenever legislation, government action or any other administration or institution denies patients the right to medical care, physicians should pursue appropriate means to assure or to restore it.

2. Reaffirms its [Declaration of Hamburg Concerning Support for Medical Doctors Refusing to Participate in, or to Condone, the Use of Torture or Other Forms of Cruel, Inhuman or Degrading Treatment](#), which encourages doctors to honor their commitment as physicians to serve humanity and to resist any pressure to act contrary to the ethical principles governing their dedication to this task.
3. Reaffirms its [Declaration of Tokyo – Guidelines for Physicians Concerning Torture and other Cruel, Inhuman or Degrading Treatment or Punishment in Relation to Detention and Imprisonment](#), which:
  - Prohibits physicians from participating in, or even being present during the practice of torture or other forms of cruel or inhuman or degrading procedures;
  - requires that physicians maintain utmost respect for human life even under threat and prohibits them from using any medical knowledge contrary to the laws of humanity.
4. Reaffirms its [Resolution on the Responsibility of Physicians in the Documentation and Denunciation of Acts of Torture or Cruel or Inhuman or Degrading Treatment](#), which states that physicians should attempt to:
  - ensure that detainees or victims of torture or cruelty or mistreatment have access to immediate and independent health care;
  - ensure that physicians include assessment and documentation of symptoms of torture or ill-treatment in the medical records using the necessary procedural safeguards to prevent endangering detainees.
5. Refers to the [WMA International Code of Medical Ethics](#), which states that physicians shall be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity.
6. Reaffirms its [Declaration of Malta on hunger strikers](#) which prohibits force-feeding of hunger strikers as “degrading and inhuman,” even when this is the only way to save their lives.
7. Refers to the [United Nations Nelson Mandela Rules](#), which emphasizes that the provision of health care for prisoners is a State responsibility, and that the relationship between health-care professionals and prisoners is governed by the same ethical and professional standards as those applicable to patients in the community.
8. Refers to the [WMA Statement on Access of Women and Children to Health Care](#), which categorically condemns violations of the basic human right of women and children, including violations stemming from social, political, religious, economic and cultural practices.
9. Refers to the [WMA Statement on Natural Variations of Human Sexuality](#), which condemns all forms of stigmatization, criminalization and discrimination of people based on their sexual orientation.
10. Urges the government of the Islamic Republic of Iran to respect the International Code of Medical Ethics and the standards in-

cluded in the aforementioned declarations to which physicians are committed.

11. Stresses that physicians who adhere to the professional and ethical obligations outlined in the entire WMA policy apparatus, including the aforementioned declarations, must be protected

## WMA Statement in Support of Ensuring the Availability, the Quality and the Safety of Medicines Worldwide

*Adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Introduction

Over the past decade, pressure on supply has led to shortages of certain medical products, including vaccines. In many situations, these shortages result from putting economic objectives before public health. These shortages are detrimental to patient care, to maintaining public health and to the organisation of healthcare systems.

The world is going through rapid change; technological progress, radical progress in matters of communication and access to information as well as the increasing power of multi-nationals are transforming the global landscape, including the pharmaceutical industry. Unfortunately, some of these developments have encouraged the production and sale of medical products which do not meet the required safety standards, whether due to the manufacturing process or inappropriate storage, or due to the criminal manufacture and fraudulent distribution of sub-standard or falsified medicines.

According to the WHO's Global Surveillance and Monitoring System (GSMS) for sub-standard and falsified medical products, around one out of ten medicines is either of a sub-standard quality or falsified in countries with low or medium income. This observation is not limited to the most expensive medicines or the most well-known brands, but also concerns patented and generic products. The medicines most often flagged are the antimicrobials and antimalarials.

The WMA reiterates its position on biosimilar medicines, its resolution on prescribing medicines, its position on the substitution of medicines and resistance to antimicrobials.



The rational use of medicines implies ensuring that research, regulation, production, distribution, prescription, financing, delivery and proper administration of these medicines comply with coherent and rational scientific, professional, economic and social criteria.

From a healthcare point of view, a shortage of medicines is unacceptable, as it has a negative impact on confidence for patients, doctors, pharmacists and the healthcare system, it leads to insecurity and uncertainty and compromises treatment continuity; with all the risks that this implies.

With the objective of combatting the intolerable missed opportunities that such shortages represent for patients, undermining public trust in the healthcare system, the WMA is calling for the implementation of the following recommendations:

## Recommendations

### Availability of medicines

1. As a public health issue and out of concerns for safety, the WMA urges national governments to improve the availability of medicines.
2. National governments and regulatory authorities should:
  - Create a national entity responsible for gathering and communicating information relative to demand and offer for medicines under their jurisdiction. Establish standards and mechanisms guaranteeing the continuity and the supply of medicines and thus avoid shortages.
  - Improve the monitoring of medical product supply chains, as the weakness of regulatory structures make the application of good medical product distribution particularly difficult.
  - Design contingency strategies to counter the dependence of States on foreign medicine production due to the delocalisation and centralisation of the majority of structures which produce the main pharmaceutical components used in the composition of major medicines.
  - Encourage national healthcare authorities to maintain stocks of essential medicines in order to minimise the risk of shortages. Indeed, the Covid-19 health crisis has demonstrated the limits of stocks held by States and has constrained them to reorganise and restrict access to certain medicines.
  - In the case of global epidemic, to pool scientific research and clinical trials with the objective of accelerating the development of vaccines and/or treatments to eradicate the pandemic.
  - Support legislative and regulatory initiatives which guarantee an appropriate national capacity to produce pharmaceutical products, in the interests of the well-being of the populace and national security.

- Identify and create sustainable mechanisms which will guarantee sufficient stocks and sufficient access to necessary medicines.
- Promote co-operation between governments in the prevention and the management of medicine and vaccine shortages.
- Encourage governments to be more directive in their dealings with the pharmaceutical industry, notably in terms of adjusting quotas, of accelerating approvals and of importing substitute medicines when pharmaceutical companies are not able to ensure a continuous and adequate supply of medicines.
- Consider demanding that medicine producers establish a continuity plan for the supply of vital and necessary medicines and vaccines in order to avoid production shortages wherever possible.
- Ensure the transparency, sharing and availability of quality information coming from reliable sources in order to establish a trustworthy flow of communications between all stake-holders and healthcare professionals and to the patients. In the case of shortages, governments should divulge and detail the causes to all stake-holders.
- Enable WMA member states to acquire, via common supply contracts, healthcare and vaccine products in sufficient quantities during a pandemic and thus to have greater influence in negotiations with laboratories.
- Avoid the 'first come, first served' approach, notably during a pandemic, leading to counter productive competition acting against the safeguarding of public health.
- Allow an industrial level of security of supply in line with the deployment of Interpol's programme combatting pharmaceutical criminality.

### Safety of medicines

3. The objective is to set up active supply processes to ensure the continuity of quality medical supplies while guaranteeing their safety.
4. Elements of a high-quality, active supply process comprise:
  - Improvements in quantification, including forecasting.
  - Direct communication between supply agents and the manufacturers on the question of sustainable capacity.
  - Deliberate and well-considered approaches to a specific situation for each product (long term, short term, split contracts, etc.)
  - Responsible pricing with the emphasis on quality
  - Rational and necessary contracts.
  - Establish frameworks which limit the excessive accumulation of medicines and the useless scrapping of unused medicines with the objective of preserving the quality of their pharmaceutical properties.
  - Encourage governments to promote the sharing of public information on the real price of medicines. The authorities must

regulate and limit the possibility of reaching agreements on price and discounting confidentiality in the medicine evaluation process. The system must be made more transparent in all areas, including the evaluation of new medicines.

5. The WMA is clear on the fact that the quality of medicines is a public health priority and is recommending national medical associations and doctor members to:

- Increase awareness among the public and medical practitioners of sub-standard and fake products.
- Create a list of 'essential' medicines meeting a country's health-care needs.
- Create an early alert system, based around vital medicines and those intended to treat a debilitating pathology, in particular those for which no alternative therapeutic options are available. The activation of such a system would trigger a sequence of measures for all the stake-holders (licensed manufacturers, wholesalers, hospital pharmacists) alongside reporting obligations and a close monitoring of corrective actions.
- Create a scenario and emergency programmes, including a stress test for manufacture and inspection systems at regular intervals, with appropriate communication strategies adapted to the different stake-holders.
- Pursue efforts to harmonise regulatory standards between the countries and beyond regions.
- Set up proactive and productive collaboration between all the essential stake-holders in order to prevent medicine shortages and mitigate the harmful effects these have on patient care.
- Work with healthcare user associations to fight against the growing culture of ill-advised self-diagnosis, self-prescription and self-medication, which could make the supply chain vulnerable to the introduction of non-approved or counterfeit products.
- Restrict the prevalence of low quality medicines by implementing and applying current good practices in manufacturing, storage and distribution which respect the environment (cGMP) and by preventing the deterioration of medicines.
- Encourage the pharmaceutical sector to undertake to guarantee the continuity of supply of medicines, in order to avoid any interruptions in treatment.

6. The WMA is insisting that national governments, in tandem with healthcare user associations and other stake-holders, do everything possible to ensure awareness of medicine safety for all patients.

- At an international level and working together, Health Ministers and Medical Regulators should recommend that national medical associations actively oppose the illegal misappropriation of medicines, the illegal sales of medicines on the internet, the illegal importing of medicines and the counterfeiting of medicines.

- Improve regulation and monitoring of the online pharmaceutical market through national regulation of e-commerce activities.
- Regulations and mechanisms should be adopted to immediately close all websites illegally offering medical products not controlled by state authorities.
- Improve the identification and the revelation of counterfeit medical products all over the world.
- Launch international campaigns warning of the health risks linked to the use of counterfeit medical products, informing people about the dangers of buying medicines, or products offered as such, on the internet (counterfeit or fake medicines, etc.).
- Improvement in detecting falsified and sub-standard medicines, including vaccines and other medical products, and their reporting worldwide. Falsified and sub-standard medicines, including vaccines and other other medical products, should be reported to the appropriate authorities whenever they are discovered. Pharmacies, hospital pharmacies and patients must be prevented by whatever means from being supplied with falsified or sub-standard medicines. All adverse side-effects of a falsified or sub-standard medicine must be immediately highlighted via an efficient and adapted reporting system.
- Strengthen and align international rules against counterfeit medical products, allowing an efficient fight against the growing challenges of the systems of governance caused by the globalisation of manufacturing processes and supply chains.

## Covid-19 health crisis

7. The Covid-19 health crisis has highlighted the fundamental problems of availability, quality and safety of medicines.
8. The already significant problems of availability, quality and safety of medicines have been starkly brought to light by the Covid-19 health crisis. The importance of these questions is even bigger, on a global scale, and the Covid-19 pandemic has created unprecedented challenges for the authorities of every State. A pandemic leads to a sharp increase in demand for certain medicines and major expectations of specific medicines and vaccines, creating the conditions for multiple tensions.
9. The problem of **medicine availability** is particularly apparent for anesthetics and curares in life support, which are subject to closely monitored delivery in order to avoid any break in supply. The prescription and delivery of certain other medicines have been closely supervised in order to maintain supply for chronic illnesses.
10. As a response to the unequal access to vaccinations, the implementation of the COVAX mechanism must be developed in the future so as to promote access to and distribution of vaccines, with the objective of protecting the people of all countries.
11. The WHO warns and cautions consumers, healthcare professionals and health authorities about **medicine safety**: the

growing offer of falsified medical products in the context of the Covid-19 pandemic is aided by the possibility of shortages.

12. Concerning the **quality of medicine**, the health crisis has highlighted the risks of self-medication and the need for the States to set up information systems aimed at the general population. False hopes of possible cures for or prevention of Covid-19 by scientifically unproven methods have been known to have serious consequences for the health of the individual.
13. Economic and/or political interests must not be in competition with the health of the public. Pooling of public health interests must be developed in order that economic and/or political interests are not the cause of failure to manage the situation, of stock shortages or of anti-competitive behaviour.
14. The evolution of the current health crisis and notably the arrival of new variants show that States must be able to respond scientifically to this evolution without being hampered by overly-restrictive international regulations.

## WMA Statement on Access of Women and Children to Health Care

*Adopted by the 49<sup>th</sup> WMA General Assembly, Hamburg, Germany, November 1997 and amended by the 59<sup>th</sup> WMA General Assembly, Seoul, Korea, October 2008, by the 70<sup>th</sup> WMA General Assembly, Tbilisi, Georgia, October 2019 and by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

For centuries, women and girls worldwide have suffered from gender inequality and an uneven balance of power between men and women. Historically based gender bias has led to women and girls being restricted in their access to, inter alia, employment, education and health care.

Gender inequality creates dangers in medical treatment. When both genders are not offered equal quality treatment and care for the same medical complaints or when different manifestations of disease are not considered based on sex, patient outcomes will suffer.

In addition, in some countries, female healthcare providers have been prevented from, or face barriers to practicing their profession

or being promoted to leadership positions due to religious and/or cultural convictions, or discrimination based on the intersecting grounds of sex and religion/ethnicity. A lack of gender representation and diversity within the medical profession may lead to female patients and their children not having equitable access to health care.

Discrimination against girls and women damages their health expectation. It serves as a barrier to accessing health services, affects the quality of health services provided, and reinforces exclusion from society for women and girls. For example, the education of girls positively affects their health and well-being as adults. Education also improves the chances of their children surviving infancy and contributes to the overall well-being of their families. Conversely, secondary discrimination due to social, religious and cultural practices – which diminishes women's freedom to make decisions for themselves and to access employment and healthcare opportunities – has a negative impact on health expectation.

National laws, policies and practices can also foster and perpetuate discrimination in health care settings, prohibiting or discouraging women and girls from seeking the broad range of health care services they may need. Evidence demonstrates the harmful health and human rights impacts of such laws. For example, in some countries and due to national laws, legislations or social norms, women and girls lack decision-making power about their own medical treatment, surgery, childbearing or contraception.

Addressing discrimination in health care settings will contribute to the achievement of many of the United Nations Sustainable Development Goals (SDGs), ensuring that no woman or girl is left behind. It is fundamental to securing progress towards SDG 3, Good health and wellbeing, including achieving universal health coverage and ending the AIDS and tuberculosis epidemics; SDG 4, Quality education; SDG 5, Gender equality and women's empowerment; SDG 8, Decent work and inclusive economic growth; SDG 10, Reduced inequalities; and SDG 16, Peace, justice and strong institutions.

Gender is a social determinant of health and health problems may manifest themselves differently in men and women. There is a need to address the differences in health and unequal health care between men and women, including both the biological and socio-cultural dimensions.

Access to healthcare, including both therapeutic and preventative strategies, is a fundamental human right. This imposes an obligation on government to ensure that these human rights are fully respected and protected. Gender inequalities must be addressed and eradicated in all aspects of healthcare.

Machine learning, predictive algorithms and artificial intelligence (AI) in healthcare are expected to drastically change the way healthcare is practiced and managed. For example, AI could change the way in which diseases such as cancer are diagnosed and treated. However, even with the introduction of AI in healthcare, resource limitations may prevent most women globally from accessing such healthcare. In order not to amplify any gender inequalities, information being programmed into artificial intelligence algorithms being created to inform medical diagnoses and management must take into account the specific health considerations of women, for example women may present with different symptoms to men.

The WMA Declaration of Geneva establishes the physician's respect for human dignity and that it should not allow considerations of gender to come between "*my duties and my patients.*"

## Recommendations

Therefore, the World Medical Association urges its constituent members to:

1. Promote the equal human right of health for women and children;
2. Categorically condemn violations of the basic human rights of women and children, including violations stemming from social, political, religious, economic and cultural practices;
3. Insist on the rights of all women and children to full and adequate medical care, especially where religious, social, and cultural restrictions or discrimination may hinder access to such medical care, and promote women's and children's health and access to health as human rights;
4. Advocate for parity of health insurance premiums and coverage to ensure that women's access to care is not impeded by prohibitively high expenses;
5. Governments have an obligation to ensure that the information being programmed into artificial intelligence algorithms being created to inform medical diagnoses and management must include a representative sample of data from women to ensure the gender inequality gap is not amplified further.
6. Ensure universal access to sexual and reproductive healthcare;
7. Promote the provision of pre-conception, prenatal and maternal care, and post-natal care including immunization, nutrition for proper growth and healthcare development for children.
8. Advocate for educational, employment and economic opportunities for women and for their access to information about healthcare and health services.
9. Work towards the achievement of the human right to gender equality of opportunity and gender equality of treatment.

## WMA Statement on Essential Surgical Care as a Part of Access to Healthcare

*Adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

Surgery and anesthesia care encompass all clinical fields and all health care providers dealing with surgical disease and pathologies. This includes, but is not limited to anesthesia, obstetrics and gynaecology and surgery including all of its subspecialties. They have historically been a neglected part of global health with very little investments made in developing surgical health systems, while an estimated quarter of the burden of disease worldwide can be attributed to surgical diseases. Moreover, the majority of the world's population lacks access to safe, timely and affordable surgical care.

A workforce of 20 surgical, anesthesia and obstetric physician providers for every 100.000 members of the population is necessary to provide 80% of the world population essential and emergency surgical care within 2 hours. This includes emergency surgical and obstetric care such as caesarian sections and surgical care to prevent death and disability due to illnesses likely to benefit from surgical treatment such as injuries, cataracts and cancer. The majority of low- and middle-income countries (LMICs) fall far below this target, with the need being especially great in the poorest regions of the world.

Surgeon shortages may be exacerbated by a lack of gender equity in the surgical workforce which remains a challenge. Despite the fact that in a number of countries, there are more female than male medical students, men still outnumber women by far in the surgical workforce.

Surgery and anesthesia care have been proven to be cost-effective, especially in LMICs. Surgical interventions are as cost-effective as common public health interventions like malaria bed nets, HIV drugs or childhood vaccinations.

Sixty percent of cancer patients and eighty percent of trauma patients will need some form of surgical intervention throughout their treatment. Considering both non-communicable diseases (NCDs) and injuries are on the rise globally, the demand for surgical care is expected to continue to increase.

In 2015 the World Health Assembly recognized surgery and anesthesia care as a vital component of Universal Health Coverage (UHC) through their Resolution 68.15 “Strengthening emergency and essential surgical care and anesthesia as a component of universal health coverage”.

## Recommendations

WMA recommends that the relevant national authorities:

1. Integrate quality surgical and anesthesia care in all levels of health care, including comprehensive primary health care in order to realize UHC and Sustainable Development Goals by 2030.
2. Develop specific surgery and anesthesia guidelines and policies for their respective countries or jurisdictions adapted to local needs and capacities.
3. Implement policies regulating the process of task shifting in surgery and anesthesia care in line with the “WMA Resolution on Task Shifting from the Medical Profession”.
4. Invest in health system strengthening and advocate for increased financing and budgetary allocation for surgery and anesthesia care without depriving other areas of necessary funds.
5. Provide the necessary infrastructure and procurement lines for hospitals to deliver safe, high-quality surgical care.
6. Ensure policies, including narcotic and regulated drugs policies, do not hamper access to necessary surgical medications including analgesia and anesthetic agents.
7. Create clinical protocols or guidelines at the national or regional level to assure antibiotics use in the peri-operative period are prescribed in a sustainable manner and in line with applicable antimicrobial resistance guidelines.
8. Include surgical care and diseases in relevant courses to fight the dogma that surgical care is too expensive and complex to provide in low-resource settings.
9. Offer equitable residency training opportunities to locally trained medical students of both genders in the field of surgery and anesthesia based on scientifically projected needs of the country or region in line with the “WMA Statement on Gender Equality” and contributing to the Global strategy on human resources for health: Workforce 2030.
10. Allow adaptive training and work schedules to accommodate the potential need for maternity or paternity leave, and a healthy work-life balance, in order to make training programs more accessible irrespective of the trainee’s family responsibilities.
11. Seek regional, national and international collaboration in clinical and academic domains where local capacity and resources may be lacking and where exposure could be beneficial to those from areas without high capacity or resources, such as through bilateral exchange programs.

12. Support national initiatives on surgical data collection, capacity building, advocacy, policy planning and systems strengthening through collaboration with NGOs, universities, research initiatives, local communities, development banks, governmental organizations, and other stakeholders;

### WMA commits to:

13. Advocate at local, regional and national, and international fora in favor of person-centered care creating a more holistic health care system, offering medical, surgical, mental health and preventive health services in a national UHC approach, supporting WHA Resolution 68.15 “Strengthening emergency and essential surgical care and anesthesia as a component of universal health coverage”.

## WMA Statement on Family Violence

*Adopted by the 48<sup>th</sup> WMA General Assembly, Somerset West, South Africa, October 1996, editorially revised by the 174<sup>th</sup> WMA Council Session, Pilanesberg, South Africa, October 2006, amended by the 61<sup>st</sup> WMA General Assembly, Vancouver, Canada, October 2010 and by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

Family violence is a grave universal public health and human rights problem that affects individuals, regardless of age, gender, sexual orientation, racial/ethnic background, culture, religion, socio-economic status or any other factor.

Though definitions vary, the term family violence is generally applied to the physical, sexual, verbal, economic, spiritual, psychological or emotional abuse, or neglect of a person by someone with whom the victim is physically, financially, emotionally or socially related and/or dependent.

Although the causes of family violence are complex, a number of contributing factors are known, such as lack of basic education, lack of economic independence/poverty, underlying and/or undiagnosed mental health issues, substance abuse (particularly alcohol), stress, rigid gender roles, poor parenting skills, interpersonal conflicts within the family, the perpetrator’s experience of maltreatment and family violence as a child, or familial social isolation.



Family violence has adverse physical, mental, emotional and psycho-social consequences on the individual and negatively impacts the health and wellbeing of the affected individual. There may also be socio-economic impacts as well as impacts on a witness of family violence, the family and community. These adverse effects could be short-term/immediate or long-term/chronic. They include physical harm/injuries, death, impact on reproductive health/mis-carriage, dysfunctional families, educational disruptions and poor academic performance, sexually transmitted diseases, juvenile delinquency, professional disruptions and loss of employment, social exclusions and homelessness, insomnia, anxiety, depression, resort to substance abuse and crime, post-traumatic stress disorder, and suicide. Victims can become perpetrators of family violence and violent acts against non-intimates (intergenerational transmission of violence).

The World Medical Association (WMA) firmly condemns all forms of violence and reaffirms its policies on Violence against Women and Girls, Child Abuse and Neglect, the Abuse of the Elderly, and Violence and Health.

## Recommendations

### Governments and National Health Authorities

WMA urges governments to:

1. Strengthen the sense of social responsibility, develop and enforce policies, legal frameworks, and national plans with allocated budget for the prevention and elimination of family violence, as well as for protection of victims and witnesses of family violence.
2. Address the root causes of violence in relation to social determinants of health and to promote health equity. This should include addressing gender inequality and other harmful societal practices.
3. Recognise that times of intense individual and/or national stress increase the risk of family violence and ensure that appropriate resources are publicized and made available during such times.
4. Provide tools to recognize, act upon and if necessary report cases of family violence.
5. Develop data collection systems on family violence, that holistically include vital aspects of family violence such as mortality, morbidity, injuries, family or community environment, risk factors, costs of interventions, loss in productivity, legal costs among others.
6. Provide secure private reporting mechanisms and safe havens to protect the individual from feelings of guilt and shame to avoid stigma and retaliation.
7. Require a guideline that indicates how to act on suspicion of family violence and what interventions are available. Reporting

should only be done when, in the opinion of the physician, doing so will not endanger the individual experiencing the violence. If possible, this should be done in consultation with the individual experiencing the violence.

8. Institute and promote high-quality research programs to provide a strong evidence base on the multiple facets of family violence such as the magnitude, risk profiles, underlying factors, and the complex interplay of factors, as well as cross comparisons among settings, countries and regions.
9. Develop and offer family violence services to those experiencing family violence, including policy and legal accompaniments, case management, advocacy, counselling, safe housing and safety planning.
10. Encourage multi-stakeholder constructive collaboration between sectors, disciplines, as well as governmental and nongovernmental bodies, including traditional and religious institutions, to eliminate and prevent family violence.

### WMA constituent members and the medical profession

WMA constituent members should:

1. Encourage coordination of action against family violence between and among components of the health care system, criminal justice systems and law enforcement authorities, including family and juvenile courts, and victims' services organizations.
2. Encourage and facilitate research to understand the prevalence, risk factors, outcomes and optimal care for victims of family violence.
3. Promote advocacy, public and professional awareness creation, and community education programs on family violence.
4. Encourage managers of public and private health facilities to provide educational materials in reception/patient waiting rooms and emergency departments, to offer patients and clients general information about family violence, as well as to inform them about available integrated and professionally good local services that can be accessed.
5. Advocate for inclusion of courses on violence, including family violence, in the academic curricula for undergraduate and post-graduate medical education.
6. Promote capacity building and Continuous Medical Education programs for physicians, on prevention of family violence.
7. Advocate for rehabilitation, counseling, and therapy to those who either cause, experience or are exposed to the violent acts, especially traumatized children.
8. Encourage adequate undergraduate family medicine education and training in family dynamics, including the medical, sociological, psychological and preventive aspects of all types of family violence.

## Physicians

In the light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to recognize and offer assistance to patients harmed by family violence and abuse.

Physicians should:

1. Routinely consider and be sensitive to signs indicating the need for further evaluations about current or past abuse as part of their general health screening or in response to suggestive clinical findings, as physicians are often the first to suspect family violence.
2. Be acquainted on ways to take an appropriate and culturally sensitive history of current and past abuse and be acutely aware of the need to maintain confidentiality and a trusting patient-physician relationship in cases of family violence.
3. Be aware of social, community and other services useful for victims, and in some cases, perpetrators of violence and refer to and use these routinely to support victims, witnesses and/or perpetrators of family violence.
4. Report suspected violence against children and other family members to appropriate protection and security services in keeping with applicable requirements, and take necessary measures to ensure that victims and witnesses of violence are not at risk.
5. Be encouraged to participate in coordinated community activities that seek to reduce the burden and impact of family violence.
6. Be encouraged to embrace patient-centred, community specific care, and to develop impartial attitudes toward those involved in family violence.

## WMA Statement on Medical Care for Migrants

*Adopted by the 50<sup>th</sup> World Medical Assembly, Ottawa, Canada, October 1998, reaffirmed by the 59<sup>th</sup> WMA General Assembly, Seoul, Korea, October 2008, amended by the 61<sup>st</sup> WMA General Assembly, Vancouver, Canada, October 2010, and by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

For the purpose of this Statement, in line with the [International Organisation for Migration index](#), “migrant” is an umbrella term reflecting the common lay understanding of a person who moves away

from his or her place of usual residence, whether within a country or across an international border, temporarily or permanently, and for a variety of reasons.

The WMA considers health to be a basic need, a human right, and one of the essential drivers of economic and social development.

According to the World Health Organisation, universal access to health implies that all people and communities have access to comprehensive health services, without barriers or discrimination, according to their needs, within the framework of equitable and supportive health systems.

Recalling the [WMA Declaration of Geneva](#), the WMA underlines every physician's duty to not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to interfere with the physician's duty to his or her patient.

The WMA underlines that physicians should offer help in medical emergencies in accordance with the WMA International Code of Medical Ethics.

Taking into account the [WMA Declaration of Ottawa on Child Health](#) and the [WMA Statement on Medical Age Assessment of Unaccompanied Minor Asylum Seekers](#), the WMA reiterates that children should enjoy special protection, including the right to adequate health care without discrimination.

These fundamental WMA principles also echo the principles laid down in the [Universal Declaration of Human Rights](#), the [United Nations Convention on the Rights of the Child](#) and the [International Covenant on Economic, Social and Cultural Rights](#).

The [WMA Declaration of Lisbon on the Rights of the Patient](#) declares that every person is entitled without discrimination to appropriate medical care. However, national legislation varies and is often not in accordance with this fundamental principle.

At any time, large numbers of migrants are seeking protection, fleeing from natural disasters, desperate poverty, violence and other injustices and abuses with potentially very harmful effects to mental and physical health.

Recalling the WMA statement on Armed Conflicts and the WMA declaration on Health and Climate Change, the WMA recognizes that climate change, natural disasters, warfare, armed conflicts and other emergencies, including continuous civil strife, unrest and violence, will inevitably lead to the displacement of people from their homes.

The WMA is concerned by the precarious situation of certain categories of migrants, such as refugees, asylum seekers, refused asylum seekers, undocumented migrants and displaced persons, whose access to health care is often undermined, and where physicians are required in some countries to intervene outside the scope of their medical duty, in contradiction with medical ethics.

Bearing in mind the above-mentioned principles, international conventions and WMA policies, the WMA advocates a strong and continued engagement of physicians in the defence of human rights and dignity of all people including migrants worldwide, while making the following recommendations for its constituent members and individual physicians:

## Recommendations

WMA constituent members should:

- Prioritize the medical care of human beings above any other personal, material, economic, or political interest.
- Actively support and promote the right of all people to receive medical care on the basis of clinical need alone and speak out against legislation and practices that contradict this fundamental right.
- Call for governments to reach political agreements that facilitate the availability of sufficient resources for the delivery of adequate and coordinated health services to migrant populations, including in refugee camps where the conditions of living make them more susceptible to the spread of disease and viruses.
- Urge governments to ensure access to safe and adequate living conditions and essential services to all migrants, even with support from the donor agencies and/or philanthropists if needed.
- Promote equality, solidarity and social justice, guaranteeing access of migrants and refugees to health and social services.
- Implement policies, actions and commitments that promote the health of all, without discrimination, addressing the social determinants of health related to migrants and refugees.

Physicians:

- Have a duty to provide appropriate medical care, based solely on clinical need, regardless of the civil or political status of the patient.
- Should speak out against legislation and practices that prevent the fulfilment of this duty.
- Cannot be compelled to participate in any punitive or judicial action against migrants, including refugees, asylum seekers, refused asylum seekers, undocumented migrants and or displaced persons, or to withhold medically necessary treatment, or to administer any non-medically justified diagnostic measure or treatment, such as sedatives to facilitate easy deportation from the country or relocation.

- Must be allowed adequate time and be provided with sufficient resources, including interpretation services, to assess the physical and psychological condition of migrants, including refugees, asylum seekers, refused asylum seekers, undocumented migrants and displaced persons.

## WMA Statement on Medical Liability

*Adopted by the 56<sup>th</sup> WMA General Assembly, Santiago, Chile, October 2005, reaffirmed by the 200<sup>th</sup> WMA Council Session, Oslo, Norway, April 2015 and amended by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

In this statement the World Medical Association (WMA) addresses issues related to medical liability claims and the implications of defensive medicine. The laws and legal systems in each country, as well as the social traditions, social welfare and economic conditions of the country, will affect the relevance of some portions of this statement for some countries, but do not detract from its fundamental importance.

A culture of medical liability litigation is growing in some countries, increasing health care costs, restraining access to health care services, and hindering efforts to improve patient safety and health care quality. In other countries, medical liability claims are less prevalent, but National Medical Associations (NMAs) in those countries should be aware of the issues and circumstances that could result in an increase in the frequency and severity of medical liability claims brought against physicians.

Many medical liability systems divert scarce health care resources away from direct patient care, research, and physician training. The lawsuit culture has also blurred the distinction between negligence and unavoidable adverse outcomes. This has led to undue reliance on litigation and other dispute resolution systems to distinguish between the two, and a culture that enables the pursuit of cases without genuine merit in the interest of financial gain. Such a culture breeds cynicism and distrust in both the medical and legal systems with damaging consequences to the patient-physician relationship.

An increase in the frequency and severity of medical liability claims may result, in part, from one or more of the following circumstances:

- Advances in medical knowledge and medical technology that have enabled physicians to achieve treatment results that were not possible in the past, but that may involve considerable risks.
- Pressures on physicians by private managed care, other health-care organizations or government-managed health care systems to limit the costs of medical care.
- Confusing the right of access to health care, which is attainable, with the right to achieve and maintain health, which cannot be guaranteed.
- The role of the media, advocacy groups and even regulatory bodies in fostering mistrust of physicians by questioning their ability, knowledge, behaviour, and management of patients, and by encouraging patients to submit complaints against physicians.

A growing culture of litigation and an increase in medical liability claims may result, among other things, in a rise in defensive medicine, defined as “the practice of ordering medical tests, procedures, or consultations of doubtful clinical value in order to protect the prescribing physician from malpractice suits.”[1] Depending on the situation, defensive medicine may entail active behaviour, such as performing tests and procedures that are not clinically indicated or prescribing unnecessary hospitalization, or passive behaviour, such as avoiding high-risk patients or avoiding potentially beneficial but risky procedures.

A distinction must be made between harm caused by medical negligence, defined as failure to conform to the standard of care in treating the patient, and harm caused by adverse outcomes occurring in the course of medical care provided in accordance with appropriate standards of care.

Compensation for patients suffering a medical injury should be determined differently for injuries caused by negligence than for adverse outcomes that may occur during medical care, unless there is an alternative system in place such as a no-fault system.

The laws of each jurisdiction should provide the procedures for establishing liability and for determining the amount of compensation to be awarded to the patient in those cases where negligence is proven.

Criminalizing medical judgment interferes with appropriate medical decision making and is a disservice to patients.

The mounting evidence of preventable deaths as a result of medical error has led for experts to call for improved safety measurements in hospitals. With this in mind, investigations should take into account the wider context, identifying systemic failings, with recommendations for change, in order to improve patient safety.

## Recommendations

The WMA:

1. Makes an urgent call to all national governments to ensure the existence of a reliable system of medical justice in their respective countries. Legal systems should ensure that patients are protected against harmful practices, and physicians are protected against unmeritorious lawsuits.
2. Demands that investigations consider the complete context, in order to identify systemic failings.
3. Encourages health care providers to develop systems which improve the quality of patient-safety practices.

NMAs should consider the following activities to encourage fair and equitable treatment for both physicians and patients:

4. Educate and instruct physicians to have clear and detailed documentation of patient records.
5. Develop appropriate remedial training for physicians found to be deficient in knowledge or skills.
6. Encourage NMAs and Specialist Interest Groups to produce updated protocols and guidelines to guide medical professionals and staff.
7. Inform the public, physicians, and government of the dangers that various manifestations of defensive medicine may pose. These include:
  - an increase in health care costs;
  - an undermining of the doctor-patient relationship;
  - the commission of unnecessary test or treatments;
  - the avoidance of high-risk treatments;
  - the over-prescription of medications;
  - the disaffection of young physicians for certain higher risk specialties and
  - the reluctance by or avoidance of physicians or hospitals to treat higher-risk patients.
8. Educate the public as to the possible occurrence of adverse medical outcomes, and increased fees, and establish simple procedures to allow patients to receive explanations in such cases and to be informed of the steps that must be taken to seek resolution, if appropriate.
9. Encourage medical workplaces to break the culture of blame in the wake of medical errors or adverse outcomes and advocate for confidentiality of quality assurance processes in order to enable physicians to practice medicine to the best of their ability free from the threat of medical liability litigation and discipline.
10. Advocate for legal protection for physicians when patients are injured by adverse results not caused by any negligence.
11. Develop emotional and practical support for physicians involved in adverse events.
12. Participate in the development of the laws and procedures applicable to medical liability claims, with special emphasis on highlighting the difference between errors and adverse outcomes.

13. Actively oppose meritless or frivolous claims.
14. Explore innovative alternative dispute resolution procedures for efficiently resolving medical liability claims, such as mediation and arbitration.
15. Require physicians to have adequate medical liability insurance coverage or other resources against medical liability claims, paid by the practitioners themselves or by their employer.
16. Encourage the development of voluntary, confidential, and legally protected internal systems for reporting adverse outcomes or medical errors for the purpose of analysis and for making recommendations on reducing errors and improving patient safety and health care quality.
17. Advocate against the increasing criminalization or penal liability of medical judgment in consideration of adverse events. Aside from truly negligent behaviour or intentional misconduct, most adverse events are the result of unintentional human error, system failures, or uncontrollable circumstances and should not brand the physician with criminal motive or behaviour.
18. Support the principles set forth in the WMA's Declaration of Madrid on Professional Autonomy and Self-Regulation.

## WMA Statement on Solar Radiation and Photoprotection

*Adopted by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

The sun is a great source of health benefits, but it is important to know its harmful consequences as well. The prevention of the harmful effects of the sun on our skin is advisable at all ages, especially in children and adolescents. Solar radiation generates a series of biological and physiological effects in the body that depend on the proportion and intensity of the radiation and that have beneficial effects, such as stimulating the synthesis of vitamin D, favoring the formation of hemoglobin and improving the mood, while other effects are harmful and aggressive to the skin, such as erythema, phototaging of the skin and precancerous or cancerous lesions. Dermatoses produced or aggravated by sun exposure are a health problem that healthcare professionals face most frequently.

Solar light is composed of a continuous spectrum of electromagnetic radiation divided into three major groups: ultraviolet (UV), visible and infrared. UV radiation is classified as UV-A, UV-B and UV-C.

The intensity of UV radiation can be measured by international standardized instruments such as the UV index which measures the strength of sunburn-producing solar UV radiation at a particular place and time.

Solar UV radiation, especially through UV-B, is an extremely important, yet neglected causative factor for skin cancers, both melanoma and non-melanoma, for ocular pathologies (e.g., cataracts, and age-related macular degeneration), and harmful effects on the immune system [3]. Recurrent and severe sunburns are a risk factor for non-melanoma skin cancer.

Solar radiation can also induce the onset and exacerbation of chronic actinic dermatitis (CAD) and melasma. Blue light plays an important role as well in the pathogenesis of melasma, therefore broad-spectrum photoprotection should be advocated and the intake of photosensitive foods and drugs should be reduced.

Risk of skin cancer differs according to skin type as well as the duration and intensity of solar light exposure. Chronic, long-term, cumulative UV exposure is associated with actinic keratosis and squamous cell carcinomas, while high-intensity, intermittent UV exposure, especially at a young age, is associated with basal cell carcinomas and melanomas. Therefore, photoprotection is important in young ages.

The World Health Organization (WHO), through the International Agency for Research on Cancer has raised the issue of solar UV radiation being a carcinogen since 1992 and since 2012 has classified solar UV radiation as a group 1 carcinogen (carcinogen to humans). Other well-known group 1 carcinogens are plutonium, asbestos and ionizing radiation.

Furthermore, current climate changes and the depletion of the ozone layer by approximately 4% per decade since the 1970s has led to a diminished filtration of UV-A and UV-B radiation and to increased UV radiation that reaches sea-level.

As a consequence, the incidence of melanoma and non-melanoma skin cancer is increasing worldwide.

WHO evidence indicates that four out of five cases of skin cancer can be prevented and simple preventive measures, such as limiting UV exposure in the midday sun, wearing UV protective clothing and hats or using mineral-based sunscreens, are recommended.

Photoprotection also includes make-up products, sunglasses, and windshields.

The WHO recognizes that while protection against UV exposure is recommended globally, there is concern that lack of UV exposure



may reduce beneficial effects of vitamin D, including its potential to reduce the risk of some types of cancer.

## Recommendations

1. Photoprotection is a key preventative health strategy as most skin cancers are a result of UV solar exposure.

### National Governments should:

2. Inform health professionals and the public about the characteristics that sunscreen should meet (one that provides balanced, safe and easy-to-use protection) in order to avoid variability between the products supplied by laboratories, as well as improve safety and the labelling of the sunscreen.
3. Recognize solar UV exposure as an important risk factor for developing skin cancer. UV exposure also is a prime cause of some ocular diseases and immune system dysfunctions.
4. Work together to develop a Global Action Plan for the Prevention of Skin Cancer based on Photoprotective measures. This should include action against climate change to help reduce damage from ultra-violet radiation.
5. Support skin cancer screening campaigns.
6. Recognize prevention of skin cancer as a national health priority.
7. Improve skin cancer's screening, diagnosis and management.
8. Include all forms of skin cancer in all National Cancer Registries and improve the reporting of UV induced skin cancers and legislative frameworks to protect outdoor workers (recognition as occupational disease).
9. Work with relevant stakeholders to liaise, engage and organize online and offline skin cancer prevention campaigns and educational programs on sun protection, with a primary focus on ages 0–18, in order to raise awareness of this health hazard and to encourage sun safety (use of protective clothing and hats, adequate sunscreen use, avoidance of excessive exposure) and healthy lifestyle choices among the young.
10. Promote policies to fight climate change and air pollution.
11. Consider the environmental impact of sunscreen.

### WMA and its members should:

12. Interact with healthcare providers and medical practitioners who have a significant role in empowering and educating their patients in the promotion of skin cancer awareness, sun-protective measures and encouraging patient access to screening, diagnosis and treatment.
13. Educate primary care physicians and occupational physicians to recognise and refer patients with suspect lesions to dermatologists.
14. Support the development of national guidelines on photoprotective measures and continued scientific research in this field to derive the risk-benefit balance of UV exposure.

15. Support continued research and development of adequate protective clothing.
16. Promote campaigns to encourage the measurement of UV exposure within each nation.
17. Support media campaigns and educational programs that explain the harmful effects of UV exposure and optimal photoprotective measures targeting the most vulnerable, such as children and teenagers, fair skinned people, outdoor workers (e.g. agriculture, fishery, construction, forestry, athletes, swimming pool attendants).
18. Promote health education and information on sunscreens and the most recommended and healthy habits for the skin, establishing correct sun protection habits that make it possible to enjoy the beneficial effects of the sun and avoid sun damage.

### Individual physicians should:

19. Counsel patients about the major health risks associated with excessive solar UV radiation exposure, inform patients about appropriate sun protective measures (e.g. skin coverage, sunscreen, and sunglasses) and encourage patients to undergo regular medical check-ups and to participate in skin cancer screening campaigns, where available.
20. Counsel patients to self-examine their skin.
21. Counsel those patients at risk (for example, patients on certain anti-cancer drugs) to understand the extra importance of protective measures.
22. Counsel employers on UV light as a work-related health risk.

## WMA Statement on Trade Agreements and Public Health

*Adopted by the 200<sup>th</sup> WMA Council Session, Oslo, April 2015, and adopted, with amendments by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

Trade agreements are treaties between two or more countries which include provisions addressing trade in goods and/or services. Trade agreements are tools of globalization and typically seek to promote global wealth through trade liberalization. They can have significant implications for the social, commercial, political and ecological determinants of health as well as the delivery of health care.

International trade contributes significantly to increases in national wealth which is a key factor in building strong health care systems.

While trade agreements are designed to produce economic benefits and global wealth, it is fundamental to identify public health implications that may arise from these agreements.

Negotiations should take into account broad impact to ensure that the right to health and to a healthy natural and social environment are well-prioritized. Trade agreements should be directed at contributing to global health and equity.

Trade agreements may have the ability to promote the health and wellbeing of all people when they are well-designed to protect health and preserve the ability of governments to legislate, regulate and plan for health promotion, health care delivery and health equity.

Recent trade agreement negotiations have sought to establish a new global governance framework for trade and have been unprecedented in their size, scope and secrecy. A lack of transparency and the selective sharing of information with a limited set of stakeholders are anti-democratic.

There must be recognition of the importance of innovation sharing in public health. This is particularly important during health emergencies. Access to medicines and medical supplies is essential to address the major public health problems such as pandemics and trade agreements must not act as a barrier to that access.

Investor-state dispute settlement (ISDS) provides a mechanism for investors to bring claims against governments and seek compensation, operating outside existing systems of accountability and transparency. ISDS in existing trade agreements has been used to challenge evidence-based public health measures including tobacco plain packaging. Inclusion of a broad ISDS mechanism could threaten public health actions designed to support evidence-based tobacco control, alcohol control, healthy and safe food consumption including regulation of obesogenic foods and beverages, access to medicines, health care services, environmental protection/climate change and occupational / environmental health protections. Efforts by industry to challenge domestic public health laws and regulation have targeted nations with limited access to legal resources and some of the world's most vulnerable populations.

Access to affordable medicines is critical to controlling the global burdens of communicable and non-communicable diseases. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established a set of common international rules governing the protection of intellectual property including the patenting of pharmaceuticals. TRIPS safeguards and flexibilities including compulsory licensing seek to ensure that patent protection does not supersede public health.

The WMA Statement on Patenting Medical Procedures states that patenting of diagnostic, therapeutic and surgical techniques is unethical and "poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients."

Trade agreements should not pose a new difficulty in accessing medicines, especially for developing countries and for the most vulnerable populations.

There must be a fair balance established between the prices of medicines and the protection of intellectual property through patents.

The WMA considers that patenting on medicines/vaccines must be regulated in accordance with the ethical principles and values of the medical profession in order to ensure effective and global action for public health and therefore recognizes that it may be necessary to temporarily waive patents in times of public health emergencies. Moreover, to produce fast and comprehensive results, sustainable solutions for patent issues must be supplemented by the transfer of technology, knowledge, and manufacturing expertise, global investment in manufacturing sites, training of personnel, and quality control.

The [\*WMA Resolution on Medical Workforce\*](#) states that the WMA has recognized the need for investment in medical education and has called on governments to "...allocate sufficient financial resources for the education, training, development, recruitment and retention of physicians to meet the medical needs of the entire population..."

The [\*WMA Declaration of Delhi on Health and Climate Change\*](#) states that global climate change has had and will continue to have serious consequences for health and demands comprehensive action.

The [\*WMA Declaration on Fair Trade in Medical Products and Devices\*](#) states that purchasing policies for medical goods should be fair and ethical, working conditions should be safe and modern slavery should be eradicated throughout supply chains. Health product manufacturers should establish a plan for continuity of supply of vital and life-sustaining products to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies.

## Recommendations

Therefore, the WMA calls on national governments and constituent member associations to:

1. Call for transparency and openness in all trade agreement negotiations including public access to negotiating texts and meaningful opportunities for stakeholder engagement.

2. Call for a proactive assessment of anticipated effects on health, human rights, and the environment for all trade agreements.
3. Advocate for trade agreements that protect, promote and prioritize public health over commercial or political interests, and secure services in the public interest, especially those affecting individual and public health. This should include new modalities of health care provision including eHealth.
4. Ensure that trade agreements do not have negative impacts on health systems, human resources for health and universal health coverage (UHC). Ensure trade agreements do not interfere with governments' ability to protect and regulate health and health care, or to guarantee a right to health for all. Government action to protect and promote health should not be subject to challenge through an investor-state dispute settlement (ISDS) or similar mechanism.
5. Work to ensure that patents on medicines and vaccines are regulated in accordance with the principles of medical ethics, in order to protect public health in global emergency situations.
6. Therefore, urge NMAs to promote the possibility of temporarily waiving patents on medicines and vaccines to protect public health in global emergency situations while ensuring fair compensation for the intellectual property of the patent holders, global investment in manufacturing sites, and knowledge transfer. Promote public health, equity, solidarity and social justice and protect countries and people who are weaker economically and health-wise, and therefore most vulnerable.
7. Oppose any trade agreement provisions which would compromise access to health care services or medicines including but not limited to:
  - Patenting (or patent enforcement) of diagnostic, therapeutic and surgical techniques;
  - "Evergreening", or patent protection for minor modifications of existing drugs;
  - Patent linkage or other patent term adjustments that serve as a barrier to generic entry into the market;
  - Data exclusivity for biologics;
  - Any effort to undermine TRIPS safeguards or restrict TRIPS flexibilities including compulsory licensing;
  - Limits on clinical trial data transparency.
8. Oppose any trade agreement provision which would reduce public support for or facilitate commercialization of medical education.
9. Oppose any trade agreement which would facilitate the inappropriate privatization of public services in areas such as conservation of natural environment, education, healthcare, and daily necessities such as energy and water.
10. Ensure that trade agreements promote environmental protection and support efforts to reduce activities that cause climate change.

11. Ensure that trade agreements promote equity and human rights and include mechanisms for accountability following implementation.

## WMA Statement on Women's Rights to Health Care and How that Relates to the Prevention of Mother-to-Child HIV Infection

*Adopted by the 53<sup>rd</sup> WMA General Assembly, Washington, DC, USA, October 2002, amended by the 64<sup>th</sup> WMA General Assembly, Fortaleza, Brazil, October 2013 and by the 72<sup>nd</sup> WMA General Assembly (online), London, United Kingdom, October 2021*

### Preamble

Since the start of the global HIV epidemic, women and girls in many regions have been disproportionately affected by HIV. Young women (aged 15–24), and adolescent girls (aged 10–19) in particular, account for a disproportionate number of new HIV infections.

Gender inequality contributes to the spread of HIV. It can increase infection rates and reduce the ability of women and girls to cope with the illness. Often, they have less information about HIV and fewer resources to take preventive measures. Sexual violence, a widespread violation of women's rights, exacerbates the risk of HIV transmission.

Many women and girls living with HIV struggle with stigma and exclusion, aggravated by their lack of rights. Women widowed by AIDS or living with HIV may face property disputes with in-laws, complicated by limited access to justice to uphold their rights. Regardless of whether they themselves are living with HIV, women generally assume a disproportionate burden of care for others who are sick from or dying of AIDS, along with the orphans left behind. This, in turn, can reduce prospects for education and employment. It can also significantly reduce prevention of mother-to-child transmission (PMTCT) efforts and strategies.

Access to healthcare, including both preventative and therapeutic strategies, is a fundamental human right. This imposes an obligation on government to ensure that these human rights are fully respected

and protected. Gender inequalities must be addressed and eradicated. This should impact every aspect of healthcare.

The promotion and protection of the reproductive rights of women are critical to the ultimate success of confronting and resolving the HIV/AIDS pandemic.

## Recommendations

The WMA requests all national member associations to encourage their governments to undertake and promote the following actions:

1. Develop empowerment programs for women of all ages to ensure that women are better supported and free from discrimination. Such programs should include universal and free access to reproductive health education and life skills training,
2. Develop programme to provide HIV testing and post-exposure prophylaxis in the form of antiretrovirals to all survivors of assault.
3. Governments must provide universal access to antiviral therapy and treatment to all HIV infected women, protecting their health, and in the case of pregnant women, preventing mother to child transmission.
4. Provide universal HIV testing of all pregnant women, with patient notification of the right of refusal, as a routine component of perinatal care, and such testing should be accompanied by privacy protection, basic counseling and awareness of appropriate treatment, if necessary.
5. Patient notification should be consistent with the principles of informed consent. Universal and free access to antiretroviral therapy must also be provided to all HIV-positive pregnant women in order to prevent mother to child transmission of HIV.

## London Scientific Session

October 7–8

A Scientific Session on anti-microbial resistance was held as part of the WMA's annual General Assembly hosted by the British Medical Association. The two-day event, in advance of the Assembly, was organised online because of the Covid-19 pandemic.

The theme of the event was 'Global response to antimicrobial resistance in the context of Covid-19'.

### 7 October 2021 Scientific Session Day 1

Both days were chaired by Professor Dame Parveen Kumar, Chairperson of the BMA's Board of Science. Welcoming those who had logged in online, she said that the threat of a post-microbial age, where current antimicrobials would be rendered ineffectual due to increasing levels of resistance, was not limited to a single country. It was an international situation. The challenges posed by AMR had not been resolved. There had been no dramatic improvements in recent years and now they were facing a global

pandemic. It was these challenges they would be discussing over the next two days.

The first session was entitled 'Harnessing international cooperation to tackle antimicrobial resistance globally' and it began with two opening speakers. The first was WMA President Dr. David Barbe, who said that the WMA first developed a statement on AMR 25 years ago. The Association described it as 'a growing threat to global public health' and as a 'multi-faceted problem of crisis proportions with significant economic, health and human implications'. He said that AMR was as much a threat now if not more so than when that statement was first adopted in 1996. The statement was revised in 2008 and again in 2019. It had a long list of recommendations, spanning global and national and local domains. It encouraged collaboration among countries. It recognised the importance of surveillance and the use of new technology, prevention and the role of vaccination. It emphasised the need for educating both physicians and their patients in the more responsible use of antibiotics. Hopefully, they had learned from the

current pandemic. They had seen again how a virus usually responsible for no more than a common cold could develop a novel form that was dramatically more virulent and capable of triggering a global pandemic. The resources devoted to understanding the behaviour of this virus had been unprecedented. But there was more work to be done. He concluded by saying that out of challenges came opportunities and if that was true, then the Covid-19 pandemic had presented them with some great opportunities.

The second opening speaker was Dr. Chaand Nagpaul, Chair of the British Medical Association Council. He said the impact of AMR would be very far reaching if they did not act. It knew no borders and impacted every single nation. It could not be dealt with piecemeal, but had to be dealt with globally. He said they could see a post-antimicrobial age. That was the threat. It would mean that patients would not be able to get the treatment to treat them or save their lives. This was not a small issue. It would impact on doctors' abilities to be able to care for their patients. The United Kingdom Government had a five-year plan to reduce AMR by 15 per cent by 2024, as well as a longer 20-year plan. This was an issue that was a problem for every single nation, but the solution could

only occur if all of them pulled together putting pressure on their governments.

The first keynote address was given by Dr. Kitty van Weezenbeek, Director of the World Health Organisation AMR Department of Surveillance, Prevention and Control. She talked about the global situation, the AMR patient pathway and programmatic AMR response and WHO initiatives. She said that antimicrobials were crucial for human and animal health. But they needed collaboration to address AMR. The threat was enormous. If nothing was done, there would be 10 million AMR related deaths by 2050, nine million of which would be in low- and middle-income countries. Every third minute a child died from sepsis due to antibiotic resistant infections.

She referred to the five objectives approved in 2015 by member states at the World Health Assembly – to improve awareness and understanding of AMR, to strengthen the knowledge and evidence base, to reduce the incidence of infection, to optimize the use of antimicrobial medicines in human and animal health and to develop the economic case for sustainable investment.

Low- and middle-income countries need urgent support on AMR with further analysis of underlying causes. Routine diagnosis and surveillance required strengthening. The AMR Patient Pathway was a new concept and put the patient at the centre of the AMR response. The six interdependent building blocks of programmatic AMR response required strong national health systems with political commitment, early diagnosis in the laboratory network, access to appropriate treatment, prevention of infection, an uninterrupted quality supply chain and surveillance and evidence generation. What they now needed was to develop a second generation of national action plans. Many countries had plans, but the problem was that they were not costed. The WHO had now developed a costing and budgeting tool for national action plans.

Dr. van Weezenbeek spoke briefly about the National AMR Stewardship programme and the antimicrobial pipeline. She said many pharmaceutical companies were exiting the scene. She spoke about the WHO's global activities in AMR research and development. She referred to SECURE, a new collaboration between the WHO, Unicef and others to provide countries with sustainable access to new antibiotics and existing antibiotics. SECURE would establish a quality assured portfolio driven by public health and clinical needs.

She spoke about infection, prevention and control and the development of a curricula for health facility cleaning staff.

Finally, she spoke about AMR and Covid-19, the shared issues and the differences. Both need strong governance and leadership co-ordination. The newer lessons learned from Covid-19 relevant to AMR included the weak pandemic response everywhere, societal mistrust, the role of social media, the potential of digital health and preaching equity.

The second keynote speaker was Professor Dame Sally Davies, UK Government Special Envoy on Antimicrobial Resistance and former Chief Medical Officer for England. She said AMR was costing the National Health Service at least £90 million a year in England. She said she knew how difficult it was for front line staff to deal with antimicrobials when they had patients in front of them. Surveillance underpinned their understanding of an issue that was a priority. She outlined the various activities that were going on around the world and the global partnerships that had been formed and she said national action plans could drive change. Turning to advocacy, she said this was very difficult, but they had to continue spreading the word. It was vital that AMR was included in post Covid-19 strategies, as well as in any new pandemic treaty.

In a question and answer session, Dr. van Weezenbeek and Dame Sally Davies were joined by Dr. Chantal Morel, a health economist from the University of Geneva, Dr. Henry Skinner, CEO of Arm Action Fund and Dr. Otmar Kloiber, Secretary General of the WMA.

Dr. Morel said her work involved looking at how to incentivise the production of novel drugs and what drove physicians to wait for a laboratory result rather than prescribing too quickly. She also worked on how to encourage hospital managers to report cases of AMR and how to incentivise pharmacists and veterinarians.

Dr. Henry Skinner said the Arm Action Fund came about from a WHO initiative and was a new fund financing innovation in new antibiotic drug development. Their goal was to buy time to look to pay for new antibiotics.

Dr. Kloiber said that antimicrobials had been an extremely important tool for the past half century, but there were problems in the quality of prescribing and in the availability of the drugs. He wanted to broaden the discussion by saying that it was not just a clinical problem or a problem of the supply chain. It was a matter of the social determinants of health, how they lived and worked. Hygiene, prevention, availability of vaccinations were all crucial to reducing AMR. New drugs were not the sole solution. He said that when the WMA began looking at this issue in 1994, they considered where antimicrobials were being used. The vast majority were not being used in health care. They were being used in veterinary health, and they were not tackling this husbandry. There was some belated EU legislation to reduce antimicrobials as growth promoters. But a more recent piece of EU legislation allowed the use of reserve antibiotics for mass farming and mass breeding of animals. He said this was outrageous and something which should be avoided. These drugs should be used extremely carefully.



and restricted and should not be allowed for mass breeding of animals, which was ethically doubtful. He said that economic interests in the agricultural sector were clearly weighed much higher by politicians than public health, and that was something that had to be changed.

During the question and answer session, Professor Davies said that what they had learnt from Covid-19 was that they could improve infection prevention and control. They owed it to the world to deliver sanitation, hygiene and clean water across the world as a basic right. Dr. Kloiber said there some countries were doing better than others. The Scandinavian countries, for instance, had been very successful in drastically reducing antibiotics in farming. And their example could be copied elsewhere.

He said the proposed pandemic treaty was a good place to start with regulation. In most countries, the use of antibiotics was not sufficiently regulated. They could still be bought over the counter and in many countries there was no control over the quality of antibiotics. A lot of them were substandard or even fake. And if there was a sub-standard drug, there would be resistance.

At the conclusion, each panellist was asked to choose the most important point from the day's discussions. Dr. Kloiber wanted a broader approach to the debate, as this was not a single item issue. There were more ramifications than they had been discussing and the proposed pandemic treaty was a good place to start. Dr. van Weezenbeek wanted a less fragmented, rational, prioritised, evidence-based approach at country level. Dr. Skinner chose global collaborative solutions as the way forward. Dame Sally Davies said she wanted everyone to take personal responsibility to make AMR go away and Dr. Morel said that they should not take too many lessons from Covid-19. They should not assume they could do the same thing if a multi drug resistant bacterial infection broke out.

## 8 October 2021 Scientific Session Day 2

The second day's session was entitled 'Lessons learned from Covid-19', and once again it was chaired by Professor Dame Parveen Kumar, Chairperson of the BMA's Board of Science.

The first speaker was Prof. John-Arne Røttingen, Ambassador for Global Health at the Ministry of Foreign Affairs in Norway. He began by saying that the Covid-19 pandemic had had a devastating impact on the world with more than 230 million reported cases, 4.7 million deaths and a cost of at least nine trillion dollars. They were now increasing the delivery of vaccines worldwide, but a very small number were being delivered in low income countries. The inequities in distribution were particularly evident in Africa and parts of Asia, where there was very low vaccination coverage. However, vaccines were now making Covid less lethal. Antimicrobial resistance was a global collective problem and they needed to solve it collectively. The more antibiotics they used, the faster they stopped working. However, it was also a fact that more people were dying because they were not taking antibiotics.

He then spoke about the functions necessary to deal with the global problem. The global health system had an overarching function to provide stewardship and leadership. It had three different functions – the provision of global public goods, managing externalities such as cross border health checks like epidemics and AMR, and it had to provide solidarity. This should start with universal access to effective antimicrobials to prevent infection. Then they needed responsible use to reduce demand for antimicrobials, as well as measures to reduce their need. And they needed proper surveillance and monitoring as well as research and development and innovation. And he said it was not only a human health issue, it was also an animal health issue.

Surveillance policies required stronger international collaboration. They needed collective action, collaborative decisions, co-ordination, communication and common norms, principles and goals. On innovation policies, they needed to finance and perform the necessary research and development. They now needed to hope that the Covid-19 pandemic would not be forgotten, because they had seen an increasing frequency of epidemics caused by zoonosis, as well as an increase in influenza.

He said that in future there would be an increasing number of epidemics and pandemics, and he asked how they could collaborate better. There were several propositions on the table. One was to establish a global health threats board or council. Another was a global health threats fund proposal. They had the pandemic preparedness partnership proposal. There were also proposals to strengthen the international health regulations. And finally, there was a proposal for having a pandemic treaty, or framework convention. So, many proposals were being discussed.

He said that global health security was a global public good. There were five types of global public goods. These included efforts to reduce unnecessary use of antimicrobials in human and animal health sectors, surveillance and alert systems to detect emerging pathogens. There was the issue of coordination with common norms and standards, and joint regulations to prohibit activities that posed risks.

He talked about the commonalities between the Pandemic Preparedness Partnership and AMR. There was the zoonosis aspect and need for a One Health approach. There was the need for a health-needs driven research and development model. There was the need for increasing transparency and the strengthening of global pharmaceutical supply chains and finally there was the need to ensure equitable, affordable and timely access to health products and prevention

efforts. He concluded by emphasising the need for an overarching One Health approach.

The second keynote speaker was Prof. Ramanan Laxminarayan, Director of the Center for Disease Dynamics, Economics and Policy, in Washington. He compared infections in the 1918 influenza outbreak and in the Covid-19 pandemic. Pneumococcal infections were a major cause of influenza-associated pneumonia and death among both military personnel and civilians in the 1918-19 flu epidemic. They had no drugs then and now they had no drugs that worked every single time reliably. So they had gone through a golden era of antibiotics and landed back closely to where they started.

There had been a lot of covid co-infections and superinfections in hospitalized patients. He also discussed secondary infections in hospitalised covid-19 patients in India.

He spoke about the challenges where they had not made progress. Market failure continued to discourage the development of new antibiotics and infection control remained weak despite Covid. He said they now faced climate change, which was both a challenge to AMR and would also expand the range of drug-resistant fungal pathogens.

He referred to global antibiotic use and resistance by income class and drug resistance across countries. For most countries there had been a high level of drug resistance and there had been an increase in total antibiotic use between 2000 and 2015. There had also been an increase in resistance in animals. The antibiotic development pipeline had improved, but there were still examples of companies not making enough money from innovation to justify continued investment.

Turning to climate change and the risk of bacterial infections, he said this would make antimicrobial resistance more common not

less common. Statistics showed an increase in resistance in low-and middle-income countries and this was a cause for concern.

The good news was that there were some opportunities and positive signs coming out of Covid-19. There was a better understanding of zoonoses and one health. There was also a recognition of the value of science responding to pandemics, and this recognition would translate into money for AMR. There was greater acceptability of adult vaccines, which was a key tool against AMR. They had always wondered what was going to be the main tool that they used against AMR. Reducing the need for antibiotics, particularly by using vaccines, had always been a significant part of that puzzle, but had never been really quantified. A number of papers had been published about the effectiveness of vaccines on AMR. And the evidence was very positive. Put simply, vaccination led to fewer infections which lowered the disease burden with less transmission, as well as less antibiotic use, with lives saved. He believed that vaccines were going to be a major approach to dealing with AMR.

He finished by saying that although there was bad news ahead from climate change, there were also some positives to learn from Covid-19 and hopefully they could build on these.

During the question and answer session that followed, the speakers discussed a comment that antibiotic prescribing and infections had fallen during Covid-19. Prof. Laxminarayan said there had been conflicting evidence. Some parts of the world had seen more antibiotic prescribing, while in more developed countries there had been a drop in infections. He said that at the moment it was hard to disentangle what had actually happened.

A question was also asked about national egoism and vaccine nationalism. Prof. Røttingen said countries' first responsibilities

were towards vaccinating their own population. It was almost impossible to challenge the fact that governments should look after their own populations first.

During the final part of the session, the two keynote speakers were joined by three other panellists. Prof. Sahiba Essack, Professor at the University of KwaZulu-Natal, reported briefly about what was going on with AMR in South Africa, Dr. Mirfin Mpundu, Director of ReAct Africa, talked about his work to support African countries develop their action plans and raise the voice of the global south, while Dr. Heidi Stensmyren, WMA President-Elect, spoke about the history of WMA policy on AMR since the early 1990s.

In the question and answer session, Prof. Laxminarayan spoke about innovations and said new antibiotics were only one part of the solution. The big innovations would come with vaccines, infection control, diagnostics and behavioural issues.

Prof. Røttingen said they needed new ways for treating infections and incentives for the private sector. Dr. Mpundu said that basic things in Africa were not available. There was no running water in most of the African health services. It was a chronic problem. They ended up depending on whatever was available. There was a supply chain issue. They also failed to get their political leaders to buy in to this issue. They had not effectively communicated what the consequences of AMR were. The political will was not really there. They still had a lot of work to do. They needed to understand what had not worked. Why had they lost six pharmaceutical companies in the last few years? Unless they started raising these issues, he thought that low- and middle-income countries would be left behind.

The panellists were asked what they thought was needed to fully fund national action plans? Dr. Mpundu said there had not been the political will that translated

into implementation, especially funding. Most plans might look good, but in many countries there was not one full time person dealing with the issue. Dr. Stensmyren talked about equal access to health care, strengthening basic health care, developing more diagnostic tools and the aggregate use of data to track and target infections.

Dr. Mpundu said that Covid-19 had created awareness on infectious diseases. This had been quite critical. It had shown how hand washing had paid off and how behaviour could be sustained, such as not going into shops without wearing masks.

Dr. Stensmyren was asked what more the WMA should do to get its policies implemented. She said that Covid-19 had shown that they needed to pay more attention to the health of the population. It had moved this issue up the agenda. But the window

of opportunity to make changes would only last a few months. They could not wait to advocate for the strengthening of global institutions. They had to start now. Dr. Mpundu said that in most countries, professional leaders did not discuss with politicians. They did not engage with the public. They should start having these discussions now.

At the end of the session, all the panellists were asked to identify one message from the session. Prof. Laxminarayan said he put his money on vaccines. This was where they could make the biggest dent. He hoped that an AMR set of vaccines would grow out of the Covid pandemic. Prof. Essack said the whole world now knew what a pandemic could do. They should leverage this awareness of the Covid pandemic and mobilize the whole of society around the silent AMR pandemic. They should highlight the fact that the AMR pandemic was going to be far

worse than Covid. It was a One Health issue. Dr. Mpundu said they had a great opportunity, especially in low-and middle-income countries, which were not ready for this pandemic. They thought that only the west was going to be affected. They did not prepare their health systems and they were not ready to handle anything like Covid-19. They now needed to do something. They could not keep silent. AMR was an active volcano. Let them learn from Covid and strengthen their health systems. Prof. Röttingen said that physicians and other professional organisations could not wait for governments to make the right decisions. They should liaise with other professional organisations to do a one health approach on what they could do and challenge their governments. And Dr. Stensmyren said her priority was vaccines globally, and to work for universal health coverage to improve access to health care for the whole population globally.

## International Roundtable Webinar on Vaccination

### Thursday 1 July 2021

More than two years ago, before the outbreak of the Covid-19 pandemic, the World Medical Association, the German Medical Association and the Pontifical Academy for Life began discussing the idea of a joint seminar on vaccination to be held in the Vatican. This was to be a follow up to the successful European Region Meeting on End-of-Life Questions in November 2017 in the Vatican. However, following the Covid-19 pandemic in 2020, the in-person seminar had to be postponed twice. On July 1 this year, the event finally took place in the form of a one-day roundtable webinar.

The event was opened by Dr. Ramin Parsa-Parsi, Head of the International Department at the German Medical Association. He introduced the speakers and spoke

about the importance of the three organizations – the World Medical Association, the German Medical Association and the Pontifical Academy for Life – coming together. He said that what physicians had in common all around the world was the duty to promote the health and wellbeing of their patients, and to fight for the equitable provision of care and promote strong and resilient health care systems. In this spirit, it was only natural that physicians collaborated internationally. The WMA had always been a cornerstone of these efforts. Another highly rewarding approach was cross sectoral activities. With partners from other sectors and different areas of expertise they could complement their knowledge and resources and expand their networks to contribute to the health and wellbeing of the people they served. During the pandemic, the need for such collaboration had become even more evident.

He said the seeds for their meeting today were planted more than two years ago, when the three organisations agreed to join forces to address the challenges of global vaccine equity and vaccination hesitancy. They saw the vast opportunities that extraordinary collaboration could provide in their efforts to build trust, to raise awareness and achieve a broader dissemination of accurate and understandable information on vaccines.

The Presidents of the three organisations then addressed the webinar.

Dr. David Barbe, President of the World Medical Association, said the WMA had had strong policy on vaccines for a long time. As they all knew, vaccine hesitancy was not new. They had seen it evolving and becoming a louder voice around the world. One of the critical reasons that this needed to be emphasized was that for many of the

diseases for which they had vaccines there was no direct treatment. So when there was no direct treatment, it was especially important and critical that they promoted the vaccinations to prevent the disease or reduce its severity.

This pandemic, although the worst in their lifetime, was not the first pandemic there had been and it would not be the last. But they had learned much from this pandemic. And he hoped they would be able to put into practice some of the things they had learned so that they would do a better job for public health preparedness, and be able to lay the groundwork for even greater collaboration between countries and governments.

Very early in the pandemic, questions arose about how long it would take to develop a vaccine and how it would be distributed. They had also seen a very natural human response, when those more affluent countries put in advance orders for vaccines. There was also the question about whether third world countries with fewer economic resources would have access to the vaccine. As they had seen, these fears had played out. There were many countries that for a variety of reasons had not yet had access to the vaccine and were facing vaccination rates that were in some cases negligible. He said the response to this could not be parochial or focused on just one country's ability to obtain the vaccine. So they must work together and collaborate to ensure equitable distribution.

During the roundtable discussion they would be focusing on the individual response to vaccination. That was critically important. They could have all the infrastructure and the supply, but if the individual was not prepared to take that step and be vaccinated, the rest was for naught. But all the other steps were still very important. One step was access to supply. There were countries that simply did not have access to that supply. They needed to continue

to work diligently to make sure distribution was available. Secondly, once the vaccine was available, the distribution within a country was critical. Many countries did not yet have the infrastructure in place for efficient and effective distribution.

There was also the question of prioritisation. Who should get the vaccine first and how should it be allocated and distributed?

A third factor was affordability and access. Many countries had very remote and rural populations. Lastly, they would spend time today talking about what was called vaccine hesitancy. The concept of vaccine confidence needed to be emphasized. They had seen, unfortunately, a lack of persuasion in attempts to debunk misinformation and disinformation. While this was a very important part of their approach, it would not necessarily win the day. They had to help people see the benefit of these vaccines and help them to make an intelligent risk benefit decision for themselves.

Dr. Klaus Reinhardt, President of the German Medical Association, said that at this year's German Medical Assembly, the German medical profession passed a resolution in support of global vaccine equity. Delegates called on the German Bundestag and the European Parliament to wave Covid vaccines patent temporarily, while ensuring fair compensation for the intellectual property of the patent holders. A proposal to lift patents was first introduced last year to the World Trade Organisation by South Africa and India. Although the German Government and the European Commission currently supported alternative approaches, including limiting export restrictions, they hoped that with increasing pressure, they would become more engaged and do justice to Europe's global responsibilities.

The need to take immediate action on speeding up the global production of vaccines was clear. They must achieve the highest possible vaccination rate around the

world as quickly as possible. But this should not be dependent on a country's economic influence. The response from wealthier countries must also include greater support for the COVAX initiative.

He said that a threat to progress was vaccine hesitancy. This was a very complex issue and was influenced by many factors. But one thing was certain – the medical profession had a tremendous responsibility to counter disinformation and build public trust in vaccines. One way they could meet this responsibility was by working across the disciplines and cultures to amplify their message about the safety and importance of vaccines. This was one of the reasons why the German Medical Association decided to join forces with the WMA and the PLA. Through this unique collaboration, they hoped that their message would resonate with a broader audience from medical professionals, to religious communities, vaccine producers, governments and other stakeholders worldwide.

Archbishop Msgr Vincenzo Paglia, President of the Pontifical Academy for Life, said that although plans for this conference were made before the pandemic, it now presented them with the possibility of co-operating with all parties in pursuit of common goals. This did not mean ignoring differences. But neither did they want differences to block initiatives that protected health and life, especially for those who were made weaker and more vulnerable by reason of social, national and international injustices. It was important to unite their voices and their strengths so that vaccines could be made available to all those who needed them. This was a commitment that would ensure their declarations about wanting to overcome inequalities and injustice did not remain a dead letter.

He spoke about the scientific and ethical doubts being expressed on vaccines. The effects produced by such doubts were dangerous and negative for everyone, not just for

those who declined to be vaccinated. Even Pope Francis had spoken to this point on a number of occasions, reminding them that vaccination was about not only one's own health and that of others, but also about the common good and justice.

The Pope had said: 'If there is a possibility of curing a disease with a drug, it should be available to everyone. Doing otherwise gives rise to injustice. There is no place for medical marginalisation'.

The first key speaker was Dr. Andrea Ammon, Director of the European Centre for Disease Prevention Control. She said the pandemic had taken an unbelievable toll in human life and had forced countries to take unprecedented measures to protect and save people's lives. Now, vaccines had given them hope, but they were still struggling, partly because of the availability and uptake.

She said there was quite a favourable epidemiological situation in the European Union. Only in five countries could they see a reason for concern. The variant of most concern was the Delta variant, which was increasing in the EU. They estimated that by August about 90 per cent of the new infections would be due to this variant. The question was whether the vaccines worked against these variants, and the evidence so far said yes. However, it required a full course, meaning a double vaccine dose.

Dr. Ammon said vaccine hesitancy was an important problem, although it was not new. It started with Edward Jenner and his smallpox vaccine. Healthcare workers had a key role in working towards the goal of improved vaccine coverage and confidence.

Vaccine hesitancy had many aspects. Not everybody who was not vaccinated rejected vaccination. There was the issue of confidence and trust in vaccines. Did they work? Were they safe? This was particularly the case with new vaccines. Then there was the issue of complacency. People thought they had no

risk from the disease. They thought it was just like flu. This was really a lack of knowledge. The last aspect was convenience and this ranged from people who thought they could not go to the doctor because it was too far away, to some populations that were hard to reach. Now they were seeing that some continents did not even get the vaccine.

Then there was the small group, possibly five per cent of hard core people who were rejecting the vaccine. The first three groups could be addressed, but the hard core rejections were very unpromising to address. So the effort had to go into the three previous areas.

There were a lot of questions being asked about product specific issues. How long would the protection last? Were the vaccines safe? Did people really need two doses?

In 12 countries, almost half of the EU, there was specific hesitancy about the AstraZeneca vaccine. Here there were information activities going on to support the increase in vaccination and to address these concerns. The second dose was also an issue of general concern and this was being addressed.

Turning to the issue of misinformation, Dr. Ammon said that migrant communities were more susceptible to misinformation, partly because of language difficulties and social exclusion. There were also other socially vulnerable populations that needed to be addressed. Misinformation and disinformation were being spread online, and a survey conducted in the EU showed that there was a vast difference between countries. The survey examined why people were getting vaccinated and why they were refusing. It was important to understand what was driving vaccine hesitancy so that they could tailor interventions to specific populations, involve the addressed populations and support healthcare providers in their communication with patients. This communication should include the importance of vaccination, support for family and friends, mak-

ing it clear that a full vaccination course was needed, and addressing misinformation.

Dr. Ammon spoke about some of the resources being produced for public health authorities in the EU. A project had been launched last month countering online misinformation. It was important to monitor misinformation, then correct it. Trends should be monitored and all these measures had to be evaluated.

She concluded by emphasizing that the pandemic was not over yet. The summer season was on them. The emergence of variants was of concern. Relaxation of non-pharmaceutical interventions could be instrumental, but should be done with extreme caution. There were challenges in vaccine access and uptake and that meant addressing misinformation and disinformation.

The next keynote speaker was Dr. Soumya Swaminathan, Chief Scientist at the World Health Organisation, who spoke about global vaccine equity. She said that only five countries had not started a vaccination campaign, while ten countries had dominated doses, administering almost 80 per cent of all three billion doses. The list was headed by China. Rollout had started in 215 countries, but in countries on the lower economic scale there had been less coverage. The AstraZeneca vaccine was the most widely used, followed by the Pfizer vaccine.

She said the gap in vaccine coverage was widening. The gap between the United States at one end and Nigeria at the other was huge, and this was something that the WHO was trying to address. But most countries had started vaccinating.

The WHO was leading several initiatives to tackle the issue of sustainable manufacturing capacity, by monitoring, strengthening local capabilities, and enhancing clinical research. It was releasing frequent ethical guidance updates for research, development, trials and vaccination. The WHO, as part of



the COVAX initiative, was aiming to establish new and expanded sustainable capacity in low and middle income countries. But she said that all this would take time.

The next speaker was Prof. Stefano Semplici, Professor of social ethics at the Tor Vergata University of Rome. He addressed the issues of individual freedom of choice and the common good in minimising the number of deaths and suffering.

His first observation was to say that 'my choice has a relevant impact not only on myself', in the same way as the choice made at community level had an impact not only on that community.

They were confronted between the duty to respect individual freedom and the duty to protect the common good. Early on in the pandemic there was a big debate about triage and the necessity to vaccinate as many people as possible. He said the issue was never just about science, but always about ethics and therefore about politics.

On the issue of individual freedom, he said it was about trust and public confidence, as well as solidarity. He referred to the view that individuals should welcome the vaccine not only for the sake of their own health, but also out of solidarity with others, especially the most vulnerable.

He asked what should happen if this did not succeed, and turned to the issue of mandatory vaccination. He quoted the Italian constitution that no-one should be forcefully submitted to medical treatment unless provided for by law. This meant that it was not absolutely impossible. The Italian Committee for Bioethics had said that the possibility of making vaccination mandatory should not be excluded, especially for professional groups that were at risk of infection and transmission of viruses. He said this issue of mandatory vaccination was a matter to be discussed, maybe not for this pandemic, but for preparedness in the future.

Prof. Semplici concluded that it was always a bad thing when individual freedom and the common good could not be brought together. A pandemic was a moment when they should be brought together more than ever. Solidarity should not be looked at as just a matter of top down beneficence. Mass vaccination was not always a scientific issue. It was a matter of ethics and anthropology. Solidarity required a sense of belonging, of integration of each individual within the group – their group first, then their country and then humankind as a whole.

Dr. Frank Ulrich Montgomery, Chair of the WMA Council, opening up the discussion with the panel, said he was interested to hear from Dr. Ammon about having to fight the issue of confidence, complacency and convenience. There was an obligation on the medical profession to talk to their communities to get acceptance of the vaccinations. He said they should not forget the prevention paradox, that the better people were, the more they were complacent and thought it was just flu and a small infection.

He was also interested to hear that three billion doses had been administered worldwide, but eighty per cent of them had been administered in ten countries, and the rate of vaccination in low income countries was 62 times less than that in high income countries.

Dr. Montgomery then introduced Dr. Demetre Daskalakis, Deputy Incident Manager and Senior Leader in COVID Data and Engagement, at the United States Centers for Disease and Prevention. Dr. Daskalakis emphasized again that this was a global pandemic that required a global view and a global response. He spoke about the pandemic in the US, where 180 million people had received at least one dose of the three available vaccines. Vaccine rollout had been a fascinating experience. Nothing on this scale had been done before. It was not just about public health. There had been considerable interaction with all stakehold-

ers, government departments, as well as as hospitals, pharmacists, and distributors.

To begin with they had prioritised vaccinations because there was a limited supply. Then this gave way to generating demand, particularly among those who were vulnerable.

Turning to the problem of vaccine hesitancy, he said the way to deal with this was to build confidence and trust based on clear and honest information. Trust relied on monitoring safety and providing safety data. They were constantly learning about how effective the vaccines were against the variants of the virus.

Looking ahead, Dr. Daskalakis said it was the people who were not interested in vaccines who were the challenge.

Continuing to focus on equity was also vital. Confidence in vaccination was key. People had to trust the vaccine, the vaccinator and the system that produced the vaccine. Engaging with stakeholders was critical. Community level engagement, not just national but local, was also critical in moving forward. And finally, communication and education, really sharing transparently good information and truth about vaccines were the cornerstone of successful vaccination and were necessary to boost confidence and address vaccine hesitancy.

During the panel discussion, Dr. Montgomery referred to the role of large religious communities, Catholic institutions and institutions of all other religions. How could they become involved as stakeholders in information communication? Dr. Daskalakis agreed and said it was critical to go to trusted messengers and to educate them. They had to get deep into the community.

Dr. Montgomery, referring to common good, said that physicians considered the common good to be the best of health. But

politicians lived in a rectangle. They had to consider the economy and social questions, such as closing schools and depriving children of education.

Dr. Ammon spoke about engaging communities. They had seen a development where at the beginning of the pandemic the overwhelming proportion of the population was very willing to go along with restrictive measures. But this broke down because the communication did not emphasise enough how important the contribution of the population as a whole was to the control effort, communicating the importance of knowledge and the necessity for restricting their rights. That was something they missed. They needed to mobilise anthropologists, sociologists and psychologists. Dr. Montgomery agreed that they had failed to bring the public along with them.

A question was raised about the amount of misinformation on social media. Should social media be used to respond to this misinformation? Dr. Ammon replied that this was exactly what needed to be done. The channels people were using for their information were the channels that should be used for responding to misinformation.

Dr. Montgomery concluded the day's proceedings with a brief summary. They had to reach out to communities in a combined effort of science and medicine, and multipliers, such as religious communities. They had to fight misinformation and fake news. They had to ensure solidarity. And they had to ensure, because in the long run they would have to make sure equity was guaranteed.

He thanked all the speakers and brought the proceedings of the day to an end.

The following day, a joint communique ([see box on p. 45](#)) was issued by the World Medical Association, the German Medical Association and the Pontifical Academy for Life, and a press conference was held at the Vatican about the outcome of the seminar.

The three panellists, Dr. Parsa-Parsi, Dr. Montgomery and Archbishop Paglia made opening speeches.

Archbishop Paglia said it had now become a kind of mantra that vaccines belonged to everyone. But vaccinations also affected the common good and justice. There should be no restrictions made based on low-income countries' limited capacity to buy vaccinations. He said it was important that the initiatives now undertaken in response to the Covid-19 emergency took future needs and structural concerns into account.

Dr. Parsa-Parsi said two key messages were highlighted in the statement. It called on all relevant stakeholders to exhaust all efforts to ensure equitable global access to vaccines, which was a key prerequisite for a successful global vaccination campaign. And it confronted vaccine hesitancy by sending a clear message about the safety and necessity of vaccines and counteracting vaccine myths and disinformation.

He went on: 'The current pandemic has illustrated the importance of vaccination, but it has also laid bare the great inequity of access to vaccines and the dangers posed by vaccine nationalism. Many developing countries are at a disadvantage due to financial restrictions and limitations on production capacity, while higher-income countries have the resources to access highly effective vaccines.'

'Unfortunately, there is not yet an adequate supply of vaccines available and, even if vaccine production was increased, it wouldn't be enough to meet the demands of all regions of the world in a reasonable and timely manner. Ultimately, vaccines need to be produced locally, but for this to occur several barriers need to be overcome. Solving patent issues is certainly one important element needed to support a self-sustaining system of vaccine production. But this must be bolstered by the transfer of knowledge and expertise and the training of staff,

international investment in vaccine production sites in resource poor settings and the guarantee of adequate quality control.

'Sadly, there are also countries where vaccines are readily available but subject to scepticism and mistrust. Vaccine hesitancy is a complex issue. Some reluctance in disadvantaged communities is rooted in historical inequities, breaches of trust in medical research, negative experiences with health care and suspicion about pharmaceutical companies. But a more malignant form of vaccine hesitancy is driven by unfounded and misleading claims and myths, including disinformation about side effects.'

'The best antidote for vaccine hesitancy is building trust, increasing transparency, and addressing communication failures. As trusted voices in the community, medical professionals play a crucial role in this scenario. By working together with the Pontifical Academy for Life, we hope to complement our efforts to generate vaccine confidence by fostering awareness and fighting the spread of myths and disinformation. Furthermore, economically or politically motivated active dissemination of false information regarding the safety and effectiveness of approved vaccines needs to be counteracted. Improving vaccine confidence is indeed an international challenge which requires international engagement, including interdisciplinary collaboration of the kind we are engaging in today.'

'We are very much aware that it is not vaccines that save lives, but rather vaccination. Our collaboration will hopefully help to boost vaccine confidence and to encourage solutions to the hurdles faced by parts of the world where vaccines are still scarce.'

Dr. Montgomery, Chair of Council of the World Medical Association, said: 'Vaccination is life! Since Edward Jenner introduced vaccination to Europe in 1796 – exactly 225 years ago – billions of lives have been saved worldwide through vaccinations. There is

probably no other intervention in medicine that has saved more lives and prevented more suffering than vaccination. We have eradicated smallpox, we are close to wiping polio off the surface of the earth and deadly diseases like measles have lost their frightening appearance. And science moves on – fast. New biological agents, viruses and bacteria are emerging, and new bacteria are spread out over the globe in a world of high mobility and increasing populations. Virus and bacteria strike back. They develop variants, mutations or simply develop resistance.

‘This is a challenge for medicine. We have just proven that we are willing and able to take up this fight. Vaccines against Corona have been developed in record time. Billions of people have already been vaccinated – less than 18 months since we learned about the existence of Sars-Cov2.

‘We have also learned about gross inequities. Whilst rich, affluent countries urgently started vaccination campaigns, the majority of the world’s population was left behind. Developing nations do not have the technology to develop vaccine production and they don’t have the resources to buy vaccines from the rich producing countries. It is our moral obligation to overcome this outcry as fast as possible.

‘And whilst children and their parents, elderly people and chronically ill in developing countries cry out for help and ask for vaccines, we see reluctance to get vaccinated and opposition to vaccination in general – without any scientific evidence. The prevention paradox hits us with its full impact. Because we are so successful in preventing disease, people forget the terrorizing sights of large numbers of people dying in endemic or pandemic situations.

‘This brings us into a most cynical position: whereas a child in a developing country is denied a safer life or even survival because its nation or its family cannot afford vaccinations, there is also a child in an affluent

country that is denied the life-saving prevention because of the ignorance or reluctance of their parents.

‘There is one more important point about vaccination. It is not only a prevention for the vaccinated person self – it also serves the population around that individual. People that cannot be vaccinated or that are not responsive to vaccines are preserved through the simple act of vaccinating others.

‘As physicians, as leaders in this world, we have an obligation to protect our people. We therefore have to offer as much prevention through vaccination as possible in an equitable way and we must undertake all possible attempts to convince “anti-vaxxers” of the advantages and the chances of vaccination.

Our speakers highlighted these issues from different angles. The necessity of vaccination was not challenged, but speakers and audience discussed ways to communicate and fight “fake-news”. Misinformation is one of the core reasons to vaccine-hesitancy. But we also see three vital factors for improving vaccinations: we have to improve confidence, fight complacency and deliver convenience.

‘Equity is a core issue for international co-operation. Ten countries in the world have delivered 80 per cent of the three billion given doses up to now. And finally, the philosophical aspects of individual freedom versus common good were highlighted and led to an interesting discussion on the issue of mandatory vaccination’.

The panellists then faced several questions from the media, about why vaccine sceptics were not included among the speakers in the roundtable discussion. Why were experts representing all sides not included, including experts against the vaccine, they asked.

Archbishop Paglia replied that the Pontifical Academy for Life, which has decided some time ago to discuss the issue of the

vaccines, wanted to treat it in a comprehensive way, bringing together all sides dealing with the issue. He said this was not only a technical, scientific issue, but also an ethical and social issue, which required a new anthropological perspective. So they would continue to debate the issue of vaccines.

Dr. Montgomery said the question showed a misconception about the webinar. They had heard from independent individuals from European Centre for Disease Prevention Control, the United States Centers for Disease and Prevention and the World Health Organisation. He refused to accept the undertone of the question that the other ‘experts’ were recognised scientists.

Dr. Parsa-Parsi said it had originally been planned to have a two-day conference with a lot of speakers. They hoped in future to have another seminar to cover a broader range of all aspects. But he added: ‘We are physicians. We represent physicians. And we are bound to science and to evidence-based medicine’.

Another journalist questioned the use of the term ‘anti vaxxers’, saying that the use of such derogatory name calling came across as very one sided. Were the doctors willing to accept that the whole debate over the MRNA vaccines was contested and that there was a high level of doubt about safety.

Dr. Parsa-Parsi said there was no reason why they should not be confident about these vaccines, while Dr. Montgomery

said he had looked at one peer-reviewed paper that had been sent to him and said he was appalled by the gross misconceptions and statistics. He said that for ideological reasons there were some people who would be against the science. These people differed from those who were vaccine hesitant.

In the days that followed the press conference, extensive worldwide media coverage was given to the roundtable webinar and to the joint press communiqué.

## Press statement

### **World Medical Association, German Medical Association and Pontifical Academy for Life collaborate to promote vaccine equity and confront vaccine hesitancy**

Millions around the world are still suffering the effects of the COVID-19 pandemic and vaccination is widely seen as a fast and effective way to control the spread of the virus and save human lives. Much as the current pandemic has brought home the importance of vaccination, it has also laid bare the great inequity of access to vaccines and the dangers posed by vaccine nationalism. While many higher-income countries had the resources to quickly sign bilateral agreements with pharmaceutical companies for promising COVID-19 vaccine candidates, this left many developing countries at a disadvantage due to financial restrictions and limitations on production capacity.

Vaccine accessibility still poses great challenges in many parts of the world, but there are also countries where vaccines are readily available but subject to skepticism and mistrust. Vaccine hesitancy is a complex issue. Some reluctance in disadvantaged communities is rooted in historical inequities, breaches of trust in medical research, negative experiences with health care and suspicion about pharmaceutical companies' behavior focused on profit. But a more pernicious form of vaccine hesitancy is driven by unfounded and

misleading claims and myths, including disinformation about side effects, which are amplified by social media and other means of enhanced communication. Adding to this complexity is the fact that vaccine hesitancy even exists in the medical community and some religious groups. Vaccine hesitancy and refusal can ultimately give rise to difficult ethical questions about the tension between individual freedom of choice and the common good.

Considered one of the greatest achievements of modern medicine, vaccines play a vital role in the prevention of infectious diseases. They have been proven to avoid millions of deaths and protect millions more from getting sick each year. But to unlock the full innovative potential of vaccines, action must be taken to overcome barriers to vaccine equity and to address the root causes of vaccine hesitancy.

Recognizing the urgency of these issues and the essential role international and cross-sectoral collaborations can play in advancing these causes, the World Medical Association (WMA), the Pontifical Academy for Life (PAL), and the German Medical Association (GMA) have joined forces to demand that all relevant stakeholders exhaust all efforts to:

- ensure equitable global access to vaccines, which is a key prerequisite for a successful global vaccination campaign, and
- confront vaccine hesitancy by sending a clear message about the safety and necessity of vaccines and counteracting vaccine myths and disinformation.

## Cordoba Scientific Session

A year after the Córdoba General Assembly had to be held virtually because of Covid-19, the postponed scientific session was finally held online, on September 17 this year. Entitled 'Physicians in the Organ Donation and Transplantation Process: Ethical Challenges', the event was organised by the WMA, the Spanish Medical Council and the National Transplantation Organisation of Spain (ONT).

Dr. Heidi Stensmyren, President Elect of the WMA, took the chair for the first part of the session, which was divided in two. The first theme looked at the ethics of transplantation and the second focused on illegal trafficking. The day's proceedings began with two opening speeches.

The first was from Dr. David Barbe, President of the WMA, who welcomed delegates. He said the challenges in organ donation and transplantation seemed to get more complex and difficult despite much work that had been done by many organisations. He said the first WMA Statement on Human Organ Donation and Transplantation was adopted just over 20 years ago and had been superseded by the WMA Statement on Organ and Tissue Donation in 2012. This was revised in 2017. The 40 principles in that document continued to form the basis for the global ethical practices on these issues. He asked why the development and promotion of medical ethics was so important. Couldn't they just rely on what their governments declared permissible? To

answer this, he referred to the 1930s and 1940s when there were horrific abuses of medicine in concentration camps and even in hospitals. When the doctors were held responsible, they claimed in the Nuremberg Trials to have acted on government orders. Partly because of this, it was now accepted that just because something was ordered by government or was even allowed by law, did not mean it was necessarily ethical or permissible for physicians. This should have been self-evident after the Nuremberg Trials. However, they continued to observe the participation of physicians in torture and this led to the WMA Declaration of Tokyo on torture.

Dr. Barbe said the profession had to take responsibility for the enforcement of medical ethics. This was not an option, but a necessity. It could not be replaced by govern-



ment decision or laws. It was a professional duty that went with professional autonomy.

The second opening speaker was Ms. Carolina Darias, from the Spanish Ministry of Health, Consumer Affairs and Social Welfare. She said that for more than 30 years Spain had been advocating for donation and transplantation to be an essential service in any health system. She spoke about the benefits of transplantation, improving the lives of those who received organs. But she said there were people who were profiting at the expense of the health and lives of others, through the practice of organ trafficking that was both reprehensible and dangerous. She said they had to make a common front against this scourge of organ trafficking, and Spain was leading that fight. In its latest campaign it was inviting Spanish citizens to leave their mark through their donations. Every donor left an invaluable mark on a recipient.

Dr. Stensmyren then moved the session on to the first round table discussion with its theme of 'Donations as Part of End of Life Care'. The first speaker was Dr. Beatriz Domínguez-Gil, Director General of ONT, the National Transplantation Organisation of Spain responsible for the oversight, co-ordination and organization of the donation and clinical use of organs, tissues and cells in Spain. She said that in 2019 there were nearly 154,000 transplants worldwide, but these covered only 10 per cent of needs. Covid-19 had had an impact on transplantation programmes which had diminished by 20 per cent last year. She asked why decreased donation rates varied so much between countries. One study carried out on end-of-life care and decision-making in the EU showed there was considerable variation in the type of care given to patients dying as a result of a devastating brain injury. Some professional providing end-of-life care to patients might not consider the possibility of organ donation or might not facilitate it for reasons that might include legal boundaries, lack of institutional support, workload

or lack of knowledge. In her view, organ transplants saved lives, improved quality of life, prevented organ trafficking and transplant tourism and promoted moral values in society. But the primary motivation of the professional should be the care of the patient or donor and their family.

Prof. Francis L. Delmonico, Chair of the World Health Organisation Task Force on Donation and Transplantation of Organs and Tissues, said that a decision to withdraw life-sustaining treatment was derived by a conclusion that further treatment would not enable a patient to survive or would not produce a functional outcome with acceptable quality of life that the patient and the treating team regarded as beneficial. But although many hospitalised patients died under such circumstances, controlled donation after the circulatory determination of death programmes had been developed only in a few countries. He went on to outline the International Collaborative Statement published last year, which aimed at expanding the circulatory determination of death in the world. This addressed three fundamental elements of the pathway: i) the process of determining a prognosis that justifies the withdrawal of life-sustaining therapies, a decision that should be prior and independent of any consideration of organ donation and in which transplant professional must not participate; ii) the determination of death should be based on the permanent cessation of circulation to the brain; iii) the acceptability of ex situ and in situ preservation measures as long as restoration of brain perfusion is precluded to not invalidate the determination of death.

Dr. Dale Gardiner, Associate Medical Director of Deceased Organ Donation at the United Kingdom NHS Blood and Transplant, spoke about the ethical conflicts for healthcare professionals in offering donation as part of the end of-life-care plan. He asked whether donation should be offered as part of routine end-of-life care on ICU and said that all the facts had to be outlined,

as well as the outcomes of relevance to the various agents involved, such as the patients, their family, ICU doctors and nurses, and society. There were many questions, such as whether donation provided a good death, and the ethical and legal challenges. They all needed answers. From the perspective of the principles of autonomy, beneficence, nonmaleficence (burden) and justice, organ donation should be offered as part of end-of-life care by health professionals, as long as the burden can be properly addressed by: i) ensuring that donation does not risk a good death (avoiding suffering and respecting the wishes of the dying patient); ii) understanding organ donation always as Kantian, not utilitarian, where patients (donors) are ends in themselves; iii) making evident the delayed benefits of organ donation; iv) learning to understand the needs of patients outside of our hospital or unit.

Prof. Milka Bengochea, Director at the National Institute of Donation and Transplantation in Uruguay, discussed the challenges of incorporating organ donation in end-of-life care in Latin America. She referred to the need to promote a new paradigm that included organ donation as a patient's right and the critical pathways for organ donation. And she talked about the situation in Argentina, Brazil and Uruguay, where many characteristics of their regulatory donation systems were shared.

The second part of the scientific session looked specifically at organ trafficking. The first speaker was Dr. Ravindra Sitaram Wankhedkar, Past President of the Indian Medical Association, and current treasurer of the WMA. He talked about the current realities and said that organ trafficking and human trafficking for illegal organ transplantation was one of the biggest crimes on humanity, having international implications. It was rising due to high demand and low supply, economic inequalities, progress in transplantation techniques and increasing migration. Most vulnerable were women, children and migrants. He said govern-



ments, international organisations, NGOs and medical associations must join hands to fight this menace. No country was left unaffected by this black market organ trade. But some countries were known more for having doctors who would illegally transplant, while others were more known for citizens seeking out illegal transplants. He referred to those countries where people sought organ transplantation and said that the prevalence of black market organ trades in these countries stemmed from having doctors willing to perform the transplants, brokers willing to set up deals and citizens willing to sell their organ illegally. On a conservative estimate, 10 per cent of all registered transplants were illegal, approximately 14,000. But in reality, the figure was much more. He said that transplant tourism undermined waiting lists and safety regulations and often abused marginalised and oppressed people in order to gain the necessary organs. A lack of access to transplants and a lack of availability of organs were the driving forces behind this trade. He said the average age of a seller was 33.6 years, and their average income was \$15.4 US dollars. Many were migrants. Joint projects had been conducted to combat this trade, but often there was no power to back this up.

Dr. Wankhedkar concluded by saying that the solutions included developing better systems of deceased organ donations, encouraging altruistic living conditions, preventing needs for transplantation by treating diseases that led to organ failure and implementing laws that prohibited organ trading and trafficking.

The next speaker was Dr. Marta López-Fraga, the Scientific Officer in charge of the donation and transplantation activities at the European Directorate for the Quality of Medicines & Healthcare at the Council of Europe. Since 2011, she has been in charge of the European Committee on Organ Transplantation, the Steering Committee in charge of the donation and transplantation activities at the Council of Europe. The

committee actively promotes the non-commercialisation of organ donation, the fight against organ trafficking and the development of quality and safety standards in the field of organs, tissues and cells.

Dr. López-Fraga said that organ trafficking was a global phenomenon. It was estimated that up to 10 per cent of kidney transplants performed annually were the result of trafficking, a total of up to 6,800 kidneys per year. It was a highly lucrative business, with recipients usually paying between \$70,000 and \$160,000 for an organ. Healthcare professionals had opportunities to prevent these crimes through detection, reporting and then combating them. She said there were critical points at which healthcare professionals had a decisive role. These included the evaluation of prospective donors and recipients, the management of patients who were considering travelling abroad for transplants and managing patients who had received a transplant abroad and returned home for follow up care. At each stage, healthcare professionals had specific actions they could take. She said that health professionals and authorities could no longer turn a blind eye to these illicit practices. These activities needed to be regulated and health care professionals had an important role in preventing and combating these practices.

Dr. Dominique Martin, Associate Professor in Bioethics and Professionalism at Deakin University, Australia, spoke about the ethical duties that might influence professional participation in collecting and reporting data. Routine collection and reporting of data were a key issue, because there might be data indicating potential crimes. Professional duties towards individual patients included privacy and confidentiality, a person's right to autonomy in decision making and the prevention of harm. Professionals might face ethical uncertainty regarding their reporting obligations. Would reporting be legal? What data should be reported? Would reporting cause other harms? Dr. Martin said health professionals were

at the heart of transplant donation and the issue of trafficking. There was a clear necessity for them to be involved in collection and reporting. They were at the heart of patient care and were ideally placed to collect this information. They had ethical and professional duties to collect and report information about suspected transplant related crimes, especially where reporting was expected to reduce the risk of future harm to others. Tensions might arise between reporting duties and obligations to respect patient privacy and confidentiality. And the extent of reporting duties and their ethical weight would be dependent on the context in which reporting occurred and on the systems that were in place to ensure that information would be used effectively and that vulnerable individuals would be protected from harm.

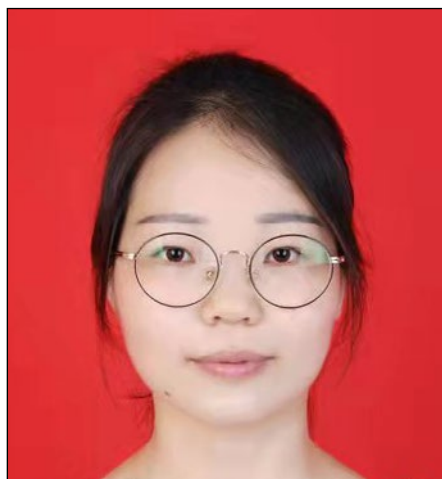
Prof. José Antonio Lorente, Professor of Legal Medicine at the University of Granada, talked about a programme called DNA-PRO-ORGAN that was launched in Granada in 2016 focusing on kidney transplantation. This promoted the creation of databases of biological samples helping traceability from donor to recipient and vice versa. It was expected to become a useful tool to investigate suspected cases of organs trafficking, a type of crime where the lack of documentation or the use of forged documents make investigation highly challenging.

In the closing session, two speakers summed up the day. Dr. Frank Ulrich Montgomery, Chair of the WMA Council, thanked the speakers. He said that combining ethics and organ trafficking in one session had been very fruitful. He was impressed by the phrase that if physicians did things badly their patients and their families would never forgive them, but if they did things well, they would never forget them. Dr. Tomás Cobo, President of the Spanish General Medical Council also thanked the speakers. He said the session had emphasised the fact that physicians were involved in the fight against this scourge of trafficking.

## Focus on COVID-19 Vaccine



*Jinjian Yao*



*Shuang-qin Xu*

The pandemic of COVID-19 caused by SARS-CoV-2 since December 2019 is still very serious and affects human life and health globally, and conventional pharmaceutical interventions are ineffective in controlling the disease progression and epidemic spread. Based on previous experience in combating the epidemic, the development of a safe and effective vaccine as soon as possible is a powerful measure to mitigate the epidemic shortly. Thanks to the active research and validation of COVID-19 Vaccines by several vaccine research and development institutions around the world, several vaccines have been administered worldwide currently. This article reviews the vaccines that have been put into use worldwide in terms of their development process, mechanism of action and safety, hoping to help people understand the production process and clinical effects of the COVID-19 Vaccine, and encourage more people to receive the COVID-19 vaccine in time to reduce the impact of the epidemic on global public health, economy and society.

### 1. Vaccination is a matter of urgency

According to a study from the University of Maryland School of Public Health, the global epidemic of COVID-19 is growing due to the emergence of highly infectious mutant strains such as the Delta strains, which are evolving in their ability to spread, with mutant viruses becoming increasingly airborne and increasing infections even in countries with vaccination rates of over 40%. As of October 17, 2021, the total number of COVID-19 infections worldwide is approaching 250 million, and the number of deaths is about to cross 5 million. In terms of the regional distribution of COVID-19 infections worldwide, the United States remains the country with the most severe epidemic, with more than 44.64 million confirmed infections, while the top four countries are India, Brazil and the United Kingdom, with 34.06 million, 21.63 million and 8.4 million confirmed infections, respectively.

Studies have shown that patients who recovered from COVID-19 infection after active

treatment produce antibodies to varying degrees, which neutralize the COVID-19 in vitro, creating a longer period of immunity so that the virus can no longer infect and spread [1]. The COVID-19 vaccine is a biological agent developed and authorized to combat the COVID-19. When a healthy population is fully vaccinated, their body's immune system produces a large number of neutralizing antibodies and thus gains the ability to fight the COVID-19 infection. In the absence of an effective tool to control the epidemic and in the absence of specific treatment for patients infected, widespread vaccination is currently an effective way of controlling the deterioration of the epidemic situation.

Herd immunity, which refers to the protective barrier of a larger population when a certain percentage of the population has acquired immunity through vaccination or previous virus infection, can reduce the spread of the virus [2]. For the proportion of the population needed to reach herd immunity, WHO gave a number of 60–70% in November 2020. As of 15 September 2021, vaccination rates have reached 70% in China, about 60% in European countries represented by the UK and Germany, slightly more than 50% in the US and Japan, and only 15% in India. However, the global epidemic is on the rebound as the delta variant emerges, and the delta variant could spread among those who have been vaccinated, causing “breakthrough infections,” in which vaccinated individuals test positive for COVID-19 more than 14 days after completing two doses vaccination. Studies have shown that vaccines are still effective against delta strains and disease progression, but that herd immunity can only be achieved with greater rates of vaccination. No vaccine provides 100% protection, and herd immunization does not provide protection for those with contraindications to vaccination. But through herd immunization, these people can be indirectly protected by the immunization from those around them, so vaccination can protect not only themselves

but also those in the community who are not eligible to be vaccinated. In addition, WHO Europe Director Kruger said that the COVID-19 could be around for years and that health officials must now “anticipate how to gradually adjust our vaccination strategy”, especially with regard to the need for additional booster shots to maintain immune protection against COVID-19.

## 2. Development of COVID-19 vaccines

Vaccines are designed to assist the body's immune system in safely recognizing and blocking COVID-19 viruses that enter the body, with antigens derived from the disease-causing components of the COVID-19, such as proteins or glucose, or possibly the entire virus after inactivation.

In addition, the vaccines sometimes contain other ingredients to maintain the safety and efficacy of the vaccine, such as preservatives (to prevent contamination of the vaccine after opening the glass vial), stabilizers (to prevent chemical reactions within the vaccine and to prevent the vaccine components from adhering to the vial), surfactants (to keep miscible all the components of the vaccine), diluents (to dilute the vaccine to the correct concentration of liquid before use), adjuvants (to retain the vaccine at the injection site for longer or to stimulate local immune cells), residues, all of those have chance to contribute to the allergic response.

The types of COVID-19 vaccines currently under development are: (i) whole inactivated or attenuated vaccines by inactivated or weakened viruses in the lab, which do not cause clinical signs and symptoms of COVID-19 pneumonia, could stimulate the body's immune response, with the advantages of mature technology, high safety, and easy storage and transport, and the disadvantages of a potentially short duration of immune protection and a single route of immunity (slightly less effective in the face

of delta variants). (ii) Recombinant protein vaccines, which use harmless protein fragments or protein shells that mimic the COVID-19 virus to safely trigger an immune response. (iii) Viral vector vaccines, which use safe viruses that do not cause disease and use them as a platform for producing coronavirus proteins to trigger an immune response, with the advantages of being safe and efficient, easy to store and transport, and less adverse effects, and the disadvantage is that the immune effect of a single dose is generally weaker than 2 doses, and the effect on mutated variants is diminished. (iv) RNA and DNA vaccines, a cutting-edge approach using genetically engineered RNA or DNA to generate proteins that can safely elicit an immune response by generating antigen proteins, with the advantages of rapid development and production, strong immunity and higher safety, and the disadvantages of immature technology, poor stability and high storage and transport requirements [3].

WHO and its partners are committed to accelerating the development of the COVID-19 vaccine while following the highest safety standards. The vaccine is subject to different stages of development and testing clinical trials typically consist of three phases, Phase I: vaccination of a small number of young and healthy adult volunteers to assess its safety, confirm that it produces an immune response, and determine the correct dose. Phase II: Vaccination of hundreds of volunteers to further assess its safety and efficacy in producing immune antibodies. This phase usually also includes a group of unvaccinated individuals as a control group to determine whether the changes in the vaccinated group are caused by the vaccine or occur by chance. Phase 3: Vaccination of thousands of volunteers and comparison with a similar group of people who were not vaccinated but received a control product to determine the effectiveness of the vaccine in the disease prevented and its safety in the broader population. The final phase is to evaluate the ability of the

vaccine to prevent disease, known as vaccine efficacy. After all, stages have been evaluated for safety, the vaccine is then reviewed by national regulatory agencies and policy committees, which determine whether the vaccine is safe and effective enough to be marketed and how it should be used.

In the past, the series of steps to develop a vaccine could take many years to complete. Now, however, the urgent need for a COVID-19 vaccine has led to a restructured approach for vaccine development with unprecedented financial investment and scientific collaboration. The development process is proceeding with a number of steps in parallel while maintaining strict clinical and safety standards. For example, a number of clinical trial programs are evaluating multiple vaccines simultaneously; strong financial and political support for vaccine development, etc., but this does not compromise the rigour standards of the research program.

At least 13 different vaccines (across four platforms) and more than 6.5 billion doses are currently in use. Of these, Pfizer/Bio- tech's Fupirtide vaccine (a nucleic acid vaccine with 2 doses administered at 3-week intervals apart) was added to the WHO emergency use list on 31 December 2020. On 16 February 2021, the Serum Institute of India/Covishield vaccine and AstraZeneca/AZD1222 vaccine (developed by AstraZeneca/Oxford and produced by Serum Institute of India and SK Biologics, an adenovirus vector vaccine, 2 doses total with an interval of 4-12 weeks apart) was added to the emergency use list. At March 12, 2021, Janssen/Ad26.COV 2.S vaccine (adenovirus vector vaccine, 1 dose total) developed by Johnson & Johnson was added to the emergency use list. On April 30, 2021, Moderna mRNA 1273 (nucleic acid vaccine, 2 doses total with an interval of 3 weeks) was added to the emergency use list. 2 doses with an interval of 3-4 weeks apart) was added to the emergency use list. On May 7, 2021, the COVID-19 vaccine (inactivated

vaccine, 2 doses in total with an interval of 3 weeks) was manufactured by the Beijing Institute of Biological Products Limited Liability Company, a subsidiary of China Biotechnology Corporation, was added to the emergency use list. On June 1, 2021, the Coxing-Kerrif vaccine (inactivated vaccine, 2 doses in total with an interval of 3 weeks) was added to the emergency use list. 2 doses in total, separated by 2-4 weeks) is added to the emergency use list [4].

### 3. Safety of the COVID-19 Vaccine

China completed the COVID-19 vaccine research, development and approval process in record time with unprecedented scientific collaboration, thereby meeting the urgent need for a COVID-19 vaccine while maintaining high safety standards. As with all vaccines, COVID-19 vaccines have undergone rigorous clinical trials to demonstrate that they meet international requirements for safety and efficacy. The COVID-19 vaccine is safe for most people 5 years of age and older, including those who already have a variety of diseases, including autoimmune diseases, that include hypertension, diabetes, asthma, lung disease, liver disease [5], kidney disease and chronic infections that are in a stable and well-controlled [6]. For people with compromised immune systems, who are pregnant or breastfeeding, who have a history of severe allergies, especially to vaccines (or any component of vaccines), and who are very weak, the decision to vaccinate should be made in consultation with a health care provider.

Like other vaccines, different kinds of COVID-19 vaccines may cause different side effects. Most of the reported side effects of the COVID-19 vaccine are mild to moderate and short-lived, including fever, fatigue, headache, muscle pain, chills, diarrhoea, and injection site pain, and will go away on their own within a few days [7]. In very rare cases, the vaccine can produce

more serious or longer-lasting side effects. The rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer membrane of the heart) have been reported after the second dose of COVID-19 mRNA vaccine, mainly in young men aged 12-29 years (40.6 cases of myocarditis per million-second doses), compared with 4.2 cases per million-second doses in women in the same age group, usually with milder symptoms, with rapid medication and rest can help avoid causing long-term damage or death to the heart, so the WHO believes the benefits of vaccines far outweigh the risks of myocarditis and pericarditis because they prevent hospitalization and death from COVID-19 [8, 9].

What we need to know is that no vaccine has 100% protection[10]. There may even be a small percentage of people who do not receive the expected protection after the COVID-19 vaccination. In addition, we still do not know well about how long the immunizing effects of the various COVID-19 vaccines last, and are subject to several factors, such as age, underlying medical conditions, or prior exposure to COVID-19, in addition to the specific characteristics of the vaccine, which may have an impact on the effectiveness of the vaccine itself [11]. Therefore, even with COVID-19 vaccination, we must continue to use all effective public health measures, such as maintaining physical distance, wearing masks and hand washing regularly [12].

### 4. Challenges

To sum up, the following are the main challenges to promote vaccination globally: Global NCC vaccination is unbalanced: different countries or regions are affected by various factors such as local economy and society, and currently the global vaccination is unbalanced[13], China has already achieved a 70% vaccination rate, although variant strains are emerging, but Zhong Nanshan, an academican of the Chinese Academy of

Engineering, said that China reached 83.3% vaccination rate is expected to establish herd immunity, however, the population in underdevelopment countries COVID-19 vaccination rate is far from the WHO proposed 60%-70% vaccination rate[14], as the time pass by, may be in the less vaccinated countries to appear more contagious the mutant strains, that is, the global need to face the challenge of the outbreak waves; mutated strains emergence: as it spread widely around the world, new variants continue to emerge, including B.1.1.7 (now named Alpha), first identified in the UK, B.1.351 (now named Beta) in South Africa, P.1 (now named Gamma) in Brazil, and B.1.617 (now named Delta), these variants tend to have multiple mutations and exhibit increased infectivity and immune escape [15-16], posing great challenges for future outbreak control; SARS-CoV-2-specific antibody of levels s continued to decline in serum of infection or vaccinated people [17] who need to a booster vaccination. Distribution imbalances limit the speed of herd immunization: in order for everyone around the world to benefit from a safe and effective COVID-19 vaccine, WHO has led the development of an equitable distribution framework that aims to ensure that successful COVID-19 vaccines and therapeutic drugs are shared equitably among all countries. The goal is to deliver at least 2 billion doses of vaccine by the end of 2021 and 1.8 billion doses to 92 low-income economies by early 2022 to protect those at the highest risk of infection and severe disease. And in some countries facing greater threats and vulnerabilities. The achievement of these goals will require technical assistance from more developed countries as well as economic assistance, and it is believed that with the unity of purpose of the global population, the epidemic will eventually crab.

### 5. Vaccination is imperative

Since December of 2019, people around the world have been tenaciously battling the



COVID-19 virus and have some progress in epidemic control. There is now a global consensus that vaccination against COVID-19 may be the most effective measure to address the epidemic in the future, and vaccination against COVID-19 has been actively promoted worldwide. However, the virus is still changing, and the phenomenon of immune escape has emerged from the mutated strains that keep evolving, which has brought new uncertainties to the prevention and control of the epidemic in future among countries, so the vaccine development and vaccination strategy should be more up-to-date and constantly improve the speed of research and development and vaccine types, faster than COVID-19 mutation, there is a long way to go in the prevention and control of the epidemic around the world, and the people of the world need to work together, we should be confident that with the jointed efforts around the world, the COVID-19 will eventually be defeated by humans, and the people of the world will usher in the final victory in this battle.

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The authors state that they have no conflicts of interest to disclose

Shuang-qin Xu<sup>1,3\*</sup>, Jin-jian Yao<sup>2\*</sup>, Jin Qian<sup>1,3</sup>, Qi Li<sup>1,3</sup>, Tang Deng<sup>1</sup>, QiFeng Huang<sup>1</sup>, HangFei Wang<sup>1,3</sup>, XinXin Wu<sup>4</sup>, Nan Li<sup>1,3</sup>, Ji-chao Peng<sup>1</sup>, Yang Yi<sup>1,3</sup>, Yue Huang<sup>1,3</sup>  
XiaoRan Liu<sup>1,3\*</sup>

1. The First Affiliated Hospital of Hainan Medical University, Hainan Medical University, Haikou 571199, China.
  2. Emergency Department, Hainan General Hospital Affiliated to Hainan Medical University, Haikou, 570311, Hainan, China
  3. Emergency and Trauma College, Hainan Medical University, Haikou, 571199, China.
  4. Hainan Medical University, Haikou, 571199, China.
- Chinese Society of Emergency Medicine,  
Chinese Medical Association

E-mail [liuxiaoran3192@163.com](mailto:liuxiaoran3192@163.com)

\*These authors contributed equally



## Embryo: Are Researchers Working to Protect It?



Paula Díaz-Herráez

The past few decades have seen the increasing speed of technological evolution. What seemed impossible a few years ago is now getting closer to becoming a reality. However, should we not consider if every technical possibility is ethically good, that it is something truly good for humanity?

In the book *The Art of Being Fragile* by Alessandro D'Avenia, we find an idea which aids reflection on this matter: "There is no time left: the chrysalids, the embryo, the seed are realities, all of them, which take too much time and too much effort to become fruit. We want everything now forever. We cover our fragility with a technological armor that allows us not to notice it" [1]. The world is full of fragility, but maybe instead of protecting that fragility, we are making it more vulnerable, disguising it with a layer of technology. As Alessandro D'Avenia mentions, one of the fragile realities is the human embryo, a fundamental reality that is in conflict with the evolution of technology.

Since the birth of the first test tube baby in 1978, the situation of the embryo in medi-



Pablo Requena

cal fertilization and research has changed progressively, increasing the vulnerability of the embryo because further applications of the technique have developed.

This article briefly reviews the historical outcomes of using embryos in medicine and research to show that a slippery slope is forming for the permissible uses of human embryos. The recent publication of the guidelines for Stem Cell Research and Regenerative Medicine of the International Society for Stem Cell Research (ISSCR) could be a good example of that [2].

### Historical Issues

In 1978 Louise Brown was born, becoming the first baby born by *in vitro* fertilization (IVF). Since then, according to data from the European Society of Human Reproduction and Embryology, more than 8 million children have been born by IVF through 2018 [3]. Nevertheless, the production of embryos is much bigger than the number of children born through IVF. The 2020 report

of the ISSCR on the clinical use of human germline genome editing, states that only 20% of the IVF procedures end in actual birth [4].

Following the birth of the first test tube baby, different countries developed legislation to determine how these embryos were being used, indicating rules that limit and regulate these techniques.

In 1979, the Ethics Advisory Board of the United States Department of Health, Education and Welfare proposed the 14-day limit, which was endorsed in the United Kingdom (UK) in 1984 by the Warnock Committee. In the UK, one year later it legalized human embryos for research use [4]. The statements, defined in these documents, covered various aspects such as: 1) no human embryo would be created by cloning; 2) no human embryo would be genetically modified; 3) no part of the human embryo could be created; 4) the use of human embryos in assisted reproduction and research would be regulated with the utmost care, and 5) no experimentation on human embryos would be permitted after 14 days [5].

In 1987, the World Medical Association (WMA) adopted certain statements regarding the field of IVF and embryo transplantation, mentioning that IVF was to be utilized for alleviation of infertility and to avoid genetic disorders [6]. In 1990, the UK Human Fertilisation and Embryology Authority (HFEA) established regulations for the creation and use of embryos in research and treatment [7].

We can observe that within the first decades, there were restrictive regulations for the use of the human embryo. But, since 1998, extensions of the limits were produced, as embryonic stem cells were used in research, resulting in the Donaldson Report in 2000.

The British Donaldson Report was drafted to assess the new area of research using hu-

man embryos. The report maintained the 14-day rule and indicated the “restricted” conditions for using human embryos in research. Nevertheless, 48,000 embryos no longer needed for IVF treatment were used in research between August 1991 and March 1998 and, in the same period, 118 embryos were created for direct research use [7], a number that is hardly limited. Moreover, the report indicates that the restrictions formulated were due to respect for the human embryo, stating that respect increases as it develops as a “potential” human being and not because of having “full” human status from the time of its fertilization. Another aspect reflected in the document was that the only ethical concern in embryo research was to create them by cell nuclear replacement.

One year later, in 2001, the US government placed a ban on the production of any human embryonic stem cell (hESC) line that requires the destruction of an embryo, limiting the research using hESCs lines that were already available at this time [8].

A further step was taken in 2008, as the WMA reviewed the statements of IVF and embryo transplantation. The Association became more permissive, as they considered the following: 1) the possible selective termination of multiple pregnancies to increase the chances of the pregnancy proceeding to term; 2) preimplantation genetic diagnosis (PGD) may be performed on early embryos to search for the presence of genetic or chromosomal abnormalities, discarding the embryos carrying the abnormalities and implanting those which appear normal; 3) not allowing PGD use for trivial reasons, since sex selection is only allowed where it is used to avoid a serious sex chromosome related condition or to select embryos to treat a seriously ill sibling; 4) the research using human embryos should be carefully controlled and should be limited to areas in which the use of alternative materials will not provide an adequate alternative, but never creating the embryos for research; 5) opposition to

the use of cell nuclear replacement with the aim of cloning human beings [9].

In 2009, the WMA adopted a statement for stem cell research. Its revision in 2020 indicates that the fields of stem cell research and therapy are among the fastest growing areas of biotechnology, allowing the use for the aim of “spare” or “excess” embryos from IVF but not producing them directly for research purposes [10].

In 2015, the US National Institute of Health (NIH) announced the suspension of further research funding for studies involving human pluripotent cells introduced into vertebrate embryos [11]. That same year, the use of mitochondrial replacement therapy (MRT) was approved in the UK [12]. Nevertheless, in 2016, a further step was taken when the UK Home Office issued a new guideline for scientific research involving using human material in animals. The guideline divided human-animal chimera and hybrid research into three categories and specified how to regulate each of them accordingly [11].

A crucial moment in the use of embryos for reproduction and research arose with professor He Jiankui’s experiment, which led to the first gene-edited babies in 2018. He used the CRISPR-Cas9 technique to modify the baby’s germline, arguing that it is faster, less expensive, and more precise than zinc-finger nucleases (ZFNs) or transcription activator-like effectors nucleases (TALENs). But this does not keep in mind that the targeting efficiency of CRISPR-Cas9 is still inadequate [13]. This experiment went against many well-established Chinese and international ethical norms relating to human germline editing and clinical research [13]. The international response was directly against conducting experiments in this field, arguing that this technology is still under development. The experiment highlighted the robust oversight in the developing global standards for governance and oversight of human genome editing by the World

Health Organization (WHO), who started working on it in March 2019 [14].

After years of work and debates, the 71<sup>st</sup> WMA General Assembly, held in 2020, approved a statement on human genome editing. The document reflects on the ethical issues regarding genome editing, identifying various concerns, such as: 1) using editing not for therapeutics but for enhancement purposes; 2) creating classes of individuals defined by the quality of their engineered genome; 3) eugenics; 4) leading to unpredictable epigenomic changes that may affect future generations, since once introduced into the human population, genetic alterations would be difficult to remove [15].

The same year, the ISSCR published the guidelines of the International Commission on the clinical use of human germline genome editing. The guidelines indicate that genomically edited human embryos should not be used to produce a pregnancy until genomic changes can be precisely made and without introducing undesired changes. It also emphasized the prohibition, for the time being, of modifying the nuclear genome of human embryos for human reproduction purposes [4].

Finally, in May of 2021, the ISSCR published its updated guidelines for stem cell research. The guidelines increased the permissible clinical use of embryos, arguing for “promoting an ethical, practical, appropriate, and sustainable enterprise for stem cell research and the development of cell therapies that will improve human health and should be available for patients in need” [2]. They include a division into three categories of different experiments that use human embryos, indicating what can be done in each situation and the reasons for this classification. The document also mentions that the research should use the minimum number of embryos necessary to achieve the scientific objective. But the 14-day rule has been expanded when research objectives make it necessary due to the development

of culture systems and based on the argument that it allows a better understanding of infertility, pregnancy loss, developmental disorders that occur after implantation, and for the sake of improving IVF pregnancies [2]. It also increases the possibilities in research of chimeric embryos, even reaching full gestation if it is among the well-justified goals of the research, and facilitates further research of MRT.

Additionally, these guidelines note that certain research activities are currently not permitted, adding that these approaches are “currently unsafe” or raise unresolved ethical issues, but that “may be valid in the future”. Under future perspectives, they include the genome-modified human embryos and embryos generated from human gametes that have had their nuclear DNA modified.

## Reflections

Bearing in mind all the documents developed since the use of human embryos started more than 40 years ago, we can observe that the advance of technology is opening new possibilities. The “restrictions” on using human embryos have diminished, with allowance for aspects that initially were completely banned but now seem reasonable because of the possible benefit of understanding the causes of infertility, why many pregnancies do not reach their end, improving IVF or contraceptive therapies, and more.

If we consider closely the evolution of the aforementioned documents, we see that technological possibilities seem to be considered more of value than the relevant ethical issues. Guidelines for reproduction and research using human embryos were developed because human embryos were not seen as “a simple group of cells”, even if they were not considered the first stages of a new human being. Consequently, all these documents mention some “kind of respect” the human embryos deserve. But this respect is

not the respect a human life deserves. Over time, we have seen that the myth of Pandora’s box has played out. Once the box is opened it is very difficult to choose a stopping point, as the research discovers new and further possibilities.

We live in a utilitarian society, seeing utility as the unique reasonable aspect to have in mind. But often utility is not a good parameter to think of what is really important. Making decisions within a utilitarian ethic could be useful in some contexts in which the value of the human being is not at stake. But utilitarianism is not able to reach answers that show the deep dignity of each human being. It is clear here how the choice of an ethical theory to decide what is appropriate or inappropriate is decisive for the practical ethical answers, and not all theories are able to avoid unjust discrimination. In this case, utilitarianism is not able to overcome age or developmental discrimination. It does so by hiding behind the concept of “potential human.” But it is enough to look at a current book on embryology to realize that what is in potential is not the human being but his or her anatomical structures and functions.

Technological possibilities cannot be the parameter to indicate what should or should not be done, because it gives technical and evasive answers to ethical questions. These two fields, technical and ethical, are at two different levels of reflection, even if they are connected. The ocean tides change depending on the phase of the moon, but the dignity of human embryos should not be mutable depending on the results of an experiment.

One of the limits in human embryo research that have remained most constant is the 14-day rule. But in the last few years, it has been questioned in various articles [16] and the ISSCR guidelines of 2021 have made it flexible [2]. The 14<sup>th</sup> day was selected because it is the moment when the embryo finishes implantation and begins

gastrulation, meaning that the embryo is individuated, making twinning impossible. Most importantly, it is prior to the formation of the primitive streak at which time the embryo can experience pain and suffering [16].

The argument to extend the limit up to 28 days indicates to the fact that up to that point no functional neural connections or sensory systems exist in the embryo [16]. Consider this extension as useful for learning more about the developing nervous system without any risk, for gaining a better understanding of the early development of cells into organs during early embryonic development, and for improving the safety and success rate of current IVF procedures [17; 18]. After the 2021 ISSCR guidelines were published, some articles commented on the rule flexibilization, like the one of Robin Lovell-Badge, who was the chair of the task force to elaborate the guidelines. In his article, Lovell-Badge says that “fourteen days is shortly before the stage at which the first signs of the central nervous system (CNS) appear, as the first neurons appear at day 42” [19]. Nevertheless, no limit date is indicated in the ISSCR guidelines, as they only mention that “currently it is not technically feasible to culture human embryos beyond the formation of a primitive streak or 14 days post-fertilization, but as culture systems are evolving it could be possible in the near future” [2]. This raises the question: what would be the limiting day of human embryo development for employing it in research? Say, 14, 28, or 42 days? Can we move on without any limit until the requirements of the experiment are met, or will the socio-cultural context not allow it?

The remarkable question is not which day could be the limit, nor to think that the 14 days was an arbitrary date selected. We think that the questions have to be focused on a different aspect such as what value we grant the human embryo. How can we define the human embryo? Are we relaxing not only

the limits but also failing to recognize the dignity of the human embryo? These are all aspects that some researchers have reflected on [5].

When the limits of ethics are not given more value than considerations of technological possibilities, we face a very weak ethic that can be changed at every moment. Everything would be open to discussion, and truth would be constructed by what technical knowledge shows to be the ultimate demand in that particular moment.

Curiously, the 2021 ISSCR guidelines are proposed as an international standard for scientific and ethical rigor as well as transparency in stem cell research. They establish the basis for the implementation of new regulatory frameworks in nation states and assure that research is conducted with integrity [20]. But what all these years have demonstrated is that the research limit is constantly reached.

It is frequently questioned if it is ethically allowed what seems to be the most pertinent aspect of doing research, making it necessary to elaborate new guidelines that will allow the previous limit to be crossed. If we had solid ethical principles, supported by an adequate anthropology, we would not need to ask ourselves so often about the limits, because they would be obvious.

Although it has been more than two decades since the first hESCs were derived, the controversy over their use in research and translational medicine has not diminished over time [21]. If for so long the ethical dilemma has come out in each small change that has been produced, maybe it is because we are not answering properly, or simply trying to justify ourselves for what we see as more beneficial to us, rather than thinking where we are going.

For some researchers, the ethical dilemma involving the destruction of a human embryo was and remains a major factor

that has slowed down the development of hESC-based clinical therapies [8]. The central moral question is whether the destruction of many early human lives is justified by the development of a therapy that may save many others. In other areas of moral reflection, it is clear that the answer would be negative. There is no justification for sacrificing one human life to save another, even to save many. The difference here is that the life sacrificed is a life that is in the early stages of its development, that we do not even know if it would be able to be born or not. But despite these differences, it seems to us that a society such as ours, with its particular sensitivity to the rights of the most fragile and vulnerable, should be more attentive when it comes to assessing how prenatal life is protected.

Since fertilization has taken place, there is a new biological entity with a unique genome and with the biological information and autonomous mechanism for the development into an adult human being. Each embryo is a unique individual of the human species that is starting its first steps of life; the embryo is also a he or a she, as this new entity has a determinate sex. Given all this, how could a human individual not be a human person? By explaining and showing how the human embryos from their beginning have a substantive continuity in human development, we provide a valuable reason to say that, since fertilization, we have a new human being [22]. "The reality of the human being for the entire span of life, both before and after birth, does not allow us to posit either a change in nature or a gradation in moral value since it possesses full anthropological and ethical status. The human embryo has therefore from the very beginning, the dignity proper to a person. In this way, the embryo deserves the protection that is due to a human person" [22].

Another problematic aspect is considering many embryos created through *in vitro* fertilization techniques to be "spare embryos."

No one would use such nomenclature to speak about human beings, as there is no human being that can be considered as a "spare." Basically, these techniques of manipulation and of the destruction of human embryos are based on a theoretical conception in which the embryo has no value whatsoever, even if one does not want to recognize it. Perhaps it is claimed that the value is greater than animal embryos value, but the actions show that this is not the case. Sometimes, there is mentioned a gradual value and dignity for the human embryo. But as soon as an embryo is allowed to be destroyed, it means it does not possess value and dignity at all.

## Conclusion

Without having a robust and consolidated ethic, it is impossible to establish guidelines that can truly protect the human embryo. The ongoing research that uses human embryos constantly shows that we face a vulnerable reality that demands protection and recognition of its true nature. To perform research employing utilitarian ethics does not reach the proper question, let alone its answer. Instead, this ethic moves us much further from reaching them, opening new and more complex questions.

That is why it is important to define solid ethical criteria that do not always change with technological development. These are criteria to guarantee the protection and dignity of all human beings – including the most vulnerable – both at the initial phases of life and as its end approaches.

Although the documents that have been written since human embryos started to be used either for reproduction or research were seeking to answer how and in which way these embryos can or cannot be "used," none of them have arrived at an answer that concerns the fundamental aspect which is the great value and dignity each human embryo possesses. Instead they have only



contributed to increasing the vulnerability of these embryos. That is why we appeal to researchers for a deeper understanding of the ethical aspects of their work so that they can do research that respects each human being.

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**Paula Díaz-Herráez, PhD (1)**

*Humanities and Medical Ethics Unit,  
School of Medicine, University of Navarra  
E-mail: [pdherraez@gmail.com](mailto:pdherraez@gmail.com)*

**Pablo Requena Meana, MD STD (2)**

*Professor of Moral Theology and Bioethics  
Pontifical University of the Holy Cross  
Vatican Medical Association  
Delegate to the WMA  
Pontifical Academy for Life, Rome (Italy)  
Clinical Ethics Commission, Bambin  
Gesù Pediatric Hospital, Rome (Italy)  
E-mail: [requena@pusc.it](mailto:requena@pusc.it)*

## The Environment & Healthcare: Do Our Choices Matter?

Do the environmental improvements we make in our clinics and offices really impact the big picture? This month, the World Medical Association's My Green Doctor answers this question and shares ideas for your practice (Reading time: 5 minutes): <https://mygreendocor.org/the-environment-healthcare-do-our-choices-matter-2/>

Register at My Green Doctor and save \$60 (U.S.) by using discount code, MGDWMA, making My Green Doctor a free membership benefit from WMA. My Green Doctor adds just five minutes of environmental sustainability business to each clinic staff meeting. Everything you need is in the "Meeting-by-Meeting Guide" so there's

nothing for the clinic manager or you to study. You will also be helping to prepare your patients for the health

threats of climate change. Please register today and ask your manager to register as well: <https://www.MyGreenDoctor.org/> or <https://www.MyGreenDoctor.es> (en espanol). That discount code is MGDWMA; please share this with members of your nation's medical organizations.





## A commentary on “Health is a Creative Adaptive Process”, C.R. Cloninger et Al



Kristina Stoyanova



Drozdostoy Stoyanov

The perspective on health as a creative adaptive process proposed in this paper [1] is largely psycho anthropological overarching the discussion of etiological influences behind various diseases, with inhomogeneous boundaries and insufficiently explained by ostensible clinical differences between them. The psycho anthropological background allows summarizing the complex influences of the demographic characteristics of people, their behavioural lifestyles and socio-cultural living conditions on health, in general, of evolutionary interaction between the person and its environment. In this sense, modern evidence-based medical models of categorical disease entities are rather nomothetic, when person-centred medicine is the predominantly idiographic paradigm.

We would like to compliment the ingenious approach of Cloninger and co-authors [1] with another, analytic perspective. New scientific discoveries eliminate the dichotomy between nature and society, health and disease (situated in diagnosis, or not). For example, there is clear evidence that bacteria, viruses and fungi in the human body “turn

into, or transform into the human body” – 43% of the body consists of human cells, the other 57% are bacteria, fungi, viruses or non-human organisms, and they are present in human corporeality and subjectivity. Recent research provides insights that certain dysfunctions of microorganisms in the human body are related to gastrointestinal disorders, allergies, autoimmune diseases, obesity. Furthermore, there is data on the relationship between various microorganisms and mental health in terms of anxiety, depression, obsessive-compulsive disorder, autism. Processes of transformation and adaptation are especially significant in the plan of evolution. The innate resilience of human beings is the focus of Cloninger’s main claim (leading to and strongly associated with, health, longevity, well-being, good life, and happiness) is interpreted as a form of *creative solidarity* – again through the example of coexistence and symbiosis between the microbiome and human body, lasting thousands of years. Why creative solidarity? Because solidarity (unanimity) is expressed in the ability of human beings to create supportive living conditions, to share

work, food, space, home, emotional and rational support [2]. Health and well-being are embodied in biopsychosocial learning abilities that allow the individual to share and adapt to ever-changing internal and external conditions [3].

Our research in the field of psychology during and before the pandemic, reports a trend of inter-correlative links between constructs such as emotional intelligence, sense of coherence and burnout among health professionals, physicians and teachers in Bulgaria. Emotional intelligence and a sense of coherence are defined as constructs of salutogenic functioning. This means that *they constitute mental health independently from disease and its pathogenic focus* (diagnosis, symptoms). They are negative predictors of proneness to burnout [4, 5, 6, 7]. Burnout is predicted by personality structure and influences of a specific professional context. For instance, the harm-avoidant person in conditions of pressure is more vulnerable to burnout, while the more persistent person is likely to be prone to burnout measured in terms of decreased personal accomplishment when exposed to an environment characterized by low levels of autonomy and innovation [4]. In other words, cognitive, instrumental and motivational components of the psyche moderate resilience and vulnerability – personality traits or abilities. This again returns us to the idea of innate resilience.

Emotional intelligence, for example, is another facet of human intelligence. Epigenetically, it is considered as a common variable – a mechanism of emotional regulation.

Only 10% of a person’s ability to show empathy is due to genetic characteristics. The remaining 90% are not encoded by genes but depend on early developmental factors, the environment and lifestyle [8]. Therefore, in the empirical field of evidence-based science, we can examine dependent variables, but it is difficult to measure specific causal factors. In our research, there have not been identified any particular factors explain-

ing resilience/vulnerability and behaviour of coherence, except personality traits. We have identified attitudes and personality structures that explain trends in human behaviour. The diversity of specific causal factors regulated by personality traits and intelligence resources in terms of health and diseases may be quantified and measured. However conventional scientific inquiry and practice in medicine are currently insensitive, or unprepared, to a philosophy and humanities driven approach and research outside their established instrumental and experimental framework. They traditionally belong to paradigms of treatment and health care, focused and hence restrained to intervention and study of pathological symptoms as representations of discrete disease entities.

C. Robert Cloninger notes that inclusion and exclusion criteria in clinical trials such as age and comorbid conditions aiming to avoid research confound actually extrapolate results to the general populations that they are not genuinely supposed to represent.

Rethinking, redefining modern approaches to treatment and health care, then integrating them into broader cultural, ideographic background has the potential to generate science-grounded cultural, epigenetic and personal variables, and can deliver and cultivate significantly more comprehensive scientific results for a better informed medical practice.

In conclusion, it is no exaggeration to define human creativity as a fact and an artefact of epigenetics. This also applies to health and attitude towards health and illness.

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**Kristina Stoyanova,  
Drozdostoy Stoyanov**  
Medical University-Plovdiv,  
Research Institute, Bulgaria  
E-mail: [stojanovpisevski@gmail.com](mailto:stojanovpisevski@gmail.com)

## Report from COP 26, Glasgow, Scotland, UK

The climate crisis is a health crisis. For the first time, this was one of the themes and often-repeated points made by participants in the health sector as well as some government officials at the Conference of the Parties (COP 26) in Glasgow, Scotland on 01-13 November 2021. Five members of the World Medical Association joined other health-related delegations to promulgate this message to participants and insert language in discussions/negotiations. There were numerous educational sessions and panel discussions in the World Health Organization pavilion, the first time ever that health had an ongoing voice and physical presence at the conference. In addition, on

06 November, our partner at the conference, the Global Climate & Health Association (GCHA) held an off-site live in Glasgow that was also live streamed specifically on the science of climate and health as well as advocacy and commitments from some nations.

The week began with Michelle Glekin, members of the International Federation of Medical Student Associations (IFMSA), and I meeting with several country delegations to 1) discuss the relationship between climate change and health, 2) why this relationship is negatively affecting citizens in that nation today and



*Ankush Kumar Bansal*

how that will likely worsen in the years to come, 3) review of their National Determined Contribution (NDC) for mention



of health, 4) discussion of the Healthy Climate Prescription (see below), and 5) including mention and/or proposed language of health in high-level negotiations. Most countries were highly receptive to these points, and some offered to present language or advocate for including such language in the documents coming out of negotiations. We had strong support from countries such as Bolivia, Iraq, and Pakistan in the first week. Collaborators reported strong interest from Côte d'Ivoire, Rwanda, and the European Union (including several member-states). The United States Government was also highly supportive. Dr. John Balbus, a physician and Director of the Office of Climate Change and Health Equity was supportive of including health concerns and equity in the discussions and to increase efforts to address these concerns in the U.S. Additionally, Dr. Rachel Levine, a physician and the Assistant Secretary of Health & Human Services, made a major announcement at the 06 November satellite conference in which she pledged that the United States would work to reduce carbon emissions at all federal healthcare facilities in the next 10-15 years. This is significant because, while the federal healthcare sector is just one part of the entire healthcare sector, the entire U.S. healthcare sector accounts for 8.5% of all carbon emissions from the United States. This commitment follows the previous commitment by the National Health Service (NHS) of the United Kingdom. In the second week, Dr. Haim, Dr. Ekpe Philips Uche, Dr. Innocent Achanya Otobo Ujah, Maira Sudabra, and I met with additional delegations. All in all, the WMA delegation met with around 15 nations. With our collaborators, the healthcare sector met with almost 50 nations. Attempts were also made to meet with Alok Sharma, the President of COP 26 to formally include language on health in the proceedings and commitments. Though this ultimately failed, there was strong interest from many countries and the COP 27 organizers in Egypt.





One of the key written messages of the WMA delegation and the health sector representation at the Conference was the Healthy Climate Prescription, <https://healthyclimateletter.net>. This document asks the government delegations to take action to meet the Paris Agreement commitments of stopping warming to the 1.5 C target by further reducing greenhouse gas emissions (GGE) particularly from high-income countries; include health in those plans; transition from fossil fuels to clean energy; transfer of funds from high-income to low-income countries towards

mitigation and adaptation; build climate resilient, low-carbon, sustainable health systems; and ensure that pandemic recovery investments support climate action and reduce social and health inequities. While many countries, particularly middle and low-income countries supported this and some are working towards these goals, unfortunately there was pushback from a few high-income countries, particularly in North America and Europe, on the transfer of funds. This was evident in the negotiations in the final days of COP as well. Regardless, by the end of COP, approxi-

mately 600 organizations representing 50 million healthcare workers signed on to this letter. This included World Medical Association and a few national medical associations.

Several Ministers of Environment, Climate Change, and/or Health from around the world are physicians. This was important in our meetings with these government delegations because they understood the importance of addressing health in climate change mitigation, adaptation, and political negotiations. Furthermore, there was almost unanimous support of the efforts of WMA and GCHA to bring health to the main discussions at COP 26. For example, the Deputy Minister of Environment & Health for Iraq, the Secretary to the Ministry of Environment for Sri Lanka, and the Director of National Climate Change for Colombia, as well as Drs. Balbus and Levine of the United States are physicians who understood and supported our position from clinical and public health perspectives. This highlights the importance of physicians in advocacy of our patients and public health in government and as citizens in our countries.

From an educational perspective, the WHO held approximately 65 sessions for participants including panel discussions, presentations, reports, and classrooms that were all live streamed during the two weeks. One of the important points made during the sessions and in the discussions with delegates was climate change response and health equity. These are in line with current WMA policies such as universal health care access and resolutions such as Protecting the Future Generation's Right to Live in a Healthy Environment, Climate Emergency, and Divestment from Fossil Fuels. In one of the sessions, the relationship between five of the COP aims and health aims was discussed; namely, adaptation and resilience, energy transition, clean transport, nature, and finance. This was also paraphrased in 10 recommendations to make the health



argument for climate change. There were several scientific summary presentations on specific harms to health by climate change such as energy and air pollution, food systems, and mobility. The importance of dietary modification/change and food system sustainability/resilience was mentioned in several sessions which again is line with WMA policy. Currently, health is not required in the NDC framework. However, some countries do include health in their NDC reports. The importance of formally including health in the NDCs that are published every 5 years was also presented and was one of our points in our meetings with delegations.

Ultimately, health was not made part of the formal COP reports despite multiple attempts by different sectors of the health community, including the WMA delegation. One of the biggest hurdles, primarily from the Global North was transfer of funds to lower income countries, primarily in the Global South, for climate mitigation and adaption, including health. This

involved other areas of discussion besides health resulting in impassioned speeches from leaders or representatives of small, lower-income nations. Despite this, both higher and lower income nations showed support for including health and addressing health inequity in their own countries now with hopes of international agreement at the next COP in November 2022 in Sharm el Sheikh, Egypt. Of note, 42 countries pledged during COP 26 to lower carbon emissions from their health-care systems with twelve pledging to go net-zero by 2050. These nations included high-income countries such as the United States, United Kingdom, and Germany. While the major part of the U.S. health-care system is privately-owned, the pledge by the Department of Health & Human Services and The White House to become net-zero in the federal system (Departments of Veterans Affairs and Defense, Bureau of Prisons, Indian Health Service, etc.) is significant because the entire U.S. healthcare sector accounts for over 25% of global healthcare carbon emissions.

The WMA delegation also made numerous contacts with other non-governmental organizations, universities, and climate change and health educational programs/courses for medical students, junior doctors, and practicing physicians to groom the next generation of physician researchers, policy makers, and advocates on the climate change and health intersection.

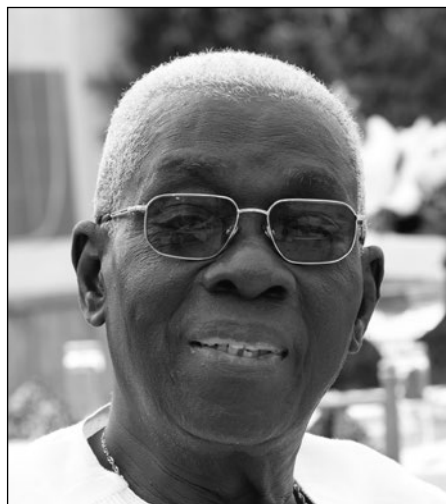
While all of the aims were not achieved, there was significant progress. The health/medical community is continuing these efforts in preparation for COP 27. There is excitement and hope for the future by many advocating for climate action and the involvement of physicians was welcomed by many during the meeting.

**Ankush Kumar Bansal,**  
MD, FACP, FACPM, SFHM, United  
States of America, Associate Member  
E-mail: [dr.akk1@gmail.com](mailto:dr.akk1@gmail.com)

**Michelle Glekin, MD**  
Israel Medical Association

## Obituary

*Dr. Albert Gyang Boohene (1933–2021), Past Chair of the WMA Council*



In 1976 Dr. Albert Gyang Boohene became Chair of the World Medical Association Council. A paediatrician from Ghana, he was uniquely suited to lead this international body through a professional career that started with a medical education in London. After working in his home country and teaching physiology at the Ghana Medical School, he returned to London for post graduate education.

In 1969 he returned to Ghana as a paediatrician and academic teacher. During his first and second periods of work in his home country he served in various functions in the Ghana Medical Association – as National Assistant Secretary from 1963 to 1966 and

as Honorary Secretary from 1970 to 1973. This engagement led him to the WMA as a delegate of the Ghana Medical Association. With the exit of most African medical associations from the WMA because of WMA's reluctance to join the international boycott of South Africa in the 1970s his participation in the WMA ended as well.

Despite this exit, Dr. Boohene achieved ground-breaking influence for sub-Saharan Africa at the WMA. In a letter to the family of Dr. Boohene, the WMA Secretary General wrote: "The World Medical Association will keep him, his achievements and leadership in our institutional memory. We remain grateful for the engagement he devoted to the global medical family."

Dr. Albert Gyang Boohen died on 29 November 2021 at the age of 88.



# 220<sup>th</sup> WMA Council Session, Paris 2022

**Start Date:** April 7, 2022

**End Date:** April 9, 2022

**Location:** Hôtel du Collectionneur, Paris, France

The WMA Council Session is open to all Constituent Members of the World Medical Association, to Associate Members, to observers and to other individuals by special invitation.

Although there are continued uncertainties and restrictions in place in response to the Covid-19 pandemic and its variants, the Council decided to hold the meeting as scheduled from 7 to 9 April 2022 but in hybrid format.

## JUST IN CASE...

The Secretariat will be closely monitoring the situation and in case that the situation becomes impossible to hold even a hybrid in-person meeting, the ExCo might decide to convert into virtual. In that case, the meeting dates will be from Tuesday 5 April to Friday 8 April and the time will be 11:00 to 14:00 UTC. Please note this alternative schedule in your calendar!

Registration and more details are available through the [members' area](#).



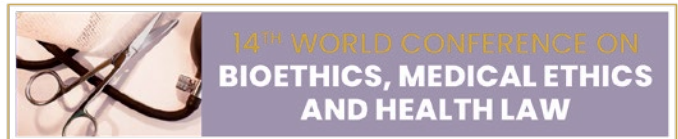
# 14<sup>th</sup> World Conference on Bioethics, Medical Ethics and Health Law

Dear Colleagues,

We would like to inform you of the postponement of the 14<sup>th</sup> World Conference on Bioethics, Medical Ethics and Health Law to a new date: 7–10 March, 2022 in Porto, Portugal.

The International Chair has decided on this postponement after lengthy discussions.

The decision to postpone from 2021 to 2022 stems from the need to preserve the participants' lives and health during this difficult period of the corona plague. We are pleased to inform you that the conference will take place under the same conditions and at the same venue. We are confident that you will remain loyal to the International Chair and the World Conference.



The Conference will undertake to retain the full rights you have acquired in the registration fee you have paid. This commitment applies both to your participation in the conference and to your accommodation at the hotel you booked (if at all).

**Bonus for participants:** The International Chair will hold a number of additional international projects virtually in 2021, which will be offered to **all participants**. This coming March and November, the Chair will host a virtual international conference dedicated to discussing ethical dilemmas which has arisen during the COVID-19 pandemic.

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