ETHICAL CHALLENGES DURING COVID-19 PANDEMIC

PERSPECTIVES FROM DIFFERENT COUNTRIES

WEBINAR BOOKLET

ETHICAL CHALLENGES DURING COVID-19 PANDEMIC PERSPECTIVES FROM DIFFERENT COUNTRIES WEBINAR BOOKLET

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TOBB ETU PUBLICATIONS

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PREFACE

The COVID-19 pandemic has been affecting our lives for more than a year now. It was not the first pandemic that humanity faced, and it will not be the last one. During the pandemic, we once more realized that science and ethics play a pivotal role in public health emergency management. It is beyond discussion that scientifically proven knowledge is primary to plan and implement preventive, therapeutic, and rehabilitative measures. Hence since the beginning of the pandemic enormous effort was put in by all researchers across the globe to enhance scientific knowledge on the SARS COV-2 virus and the course of the disease. This urgent need for knowledge raised questions about research integrity and the role and responsibilities of ethics review. However, research was not the only field where ethical and value-based questions emerged. The scarcity of resources raised questions about fair allocation of resources, the public health measure which limits individual freedoms provoked discussions about the ethical grounds for restricting autonomy for the greater good, and the unequal access to vaccines entailed moral issues about global inequalities in health.

The TOBB University of Economics and Technology International Chair in Bioethics/ WMA Cooperation Center (Former TOBB ETU UNESCO Bioethics Center) organized this webinar with these thoughts. Distinguished speakers from different regions of the world presented a rich contend regarding ethical issues in several aspects of the pandemic and constructive discussions were pursued possible solutions to these problems. I believe this webinar was an important contribution to our academy to advance our perceptions and conceptualizations of ethical issues in public health emergencies.

Prof. M. Nejat Akar M.D.

Dean of TOBB ETU School of Medicine

INTRODUCTION

Humanity's struggle with infectious diseases has a long history. The devastating plague pandemics in the early and Middle Ages, HIV AIDS, Zika, and SARS are the most well-known disasters which killed or injured millions of people. Catastrophes of plague pandemics during middle-age led human beings to think about the main paradigms of their times and question their rightness and validity and resulted in changes in the main paradigms of medicine. For example, humoral medicine, which had been the main discourse of medicine since Galen (129 AD-216), was challenged by the plague pandemics and was replaced by modern science despite the common trust for humoral medicine and the huge support from prominent religions.

Recent epidemics of the 21st century like AIDS, H1N5, H1N1 resulted in scrutinizing current understanding and response to communicable diseases and led to a new approach in developing pandemic preparedness plans at international, regional, and national levels. The International Health Regulations, an agreement among 196 members of the WHO for building capacities to detect and report public health emergencies, was one of the huge steps for early warning and response system development and developing an international structure for global health. However, the IHR regulation does not contain any reference to ethical principles or moral values that should be considered during pandemic preparedness or response. After the influenza pandemic some institutions, including the WHO, published ethical guidelines for pandemics preparedness and management. These guidelines did not play well to guide the management of the current C-19 pandemic. On the contrary, the current pandemic revealed the fact that neither public health authorities nor physicians and, the public, in general, are well-equipped for noticing and reflecting on moral issues and value-based decisions faced during the pandemic.

Like the plague of the Middle Ages, the COVID-19 pandemic is urging us to reevaluate and rethink the ethics of pandemic preparedness and response. Most of the existing literature addresses ethical issues of communicable diseases within the frame of public health ethics. This is understandable since communicable diseases are considered a problem for the public rather than individual patients. Hence, ethical questions circle around justice and legitimacy and the responsibility of authorities to implement measures. The discussions on justice emerge from the tension between utilitarian and egalitarian approaches to efficiency and equity, while individual liberty and duty of governments to protect public health constitute the main debate in terms of legitimacy.

The ignorance about the virus, its clinical manifestations, long-term effects, effective treatment and protection measures; urgency for decision making and acting; rapid worldwide dissemination of the infection and, imminent surge for healthcare services are the main features of the COVID-19 pandemic that precipitate uncertainty in decision making. Although public health ethics is essential for reflecting on moral issues in a pandemic or communicable disease in general, the current COVID-19 pandemic showed that it fails to reflect on and provide guidance for ethical decision-making at all levels and public health ethics discourse alone and is not enough to offer comprehensive ethical reasoning that embraces all aspects the phenomenon of the pandemic.

This webinar aimed to define ethical issues and ethical dilemmas that emerged during the pandemic. Since the resources and pandemic preparedness level was not the same for all countries, we assumed that different ethical problems might be encountered in different countries. However, the presentations and discussions once more showed that most of the struggle in terms of moral and ethical difficulties that came forward during current the pandemics and core values to guide the decision-making process at different levels of the health system and healthcare management were similar in most parts of the world.

Pandemic is a global health issue which requires global response. This webinar was a fruitful platform for realizing this fact and discussing grounds for enhancing our capacity for ethical decision making in pandemic preparedness and response. I express my sincere gratitude to all presenters, participants, and my students at the TOBB ETU International Chair in Bioethics/ WMA Cooperation Center Student Association for their contributions for making this webinar real.

Associate Prof. P. Elif EKMEKCI M.D. Ph.D.
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Deputy Dean School of Medicine
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INTRODUCTION BY TOBB ETU INTERNATIONAL CHAIR IN BIOETHICS/ WMA COOPERATION CENTER STUDENT ASSOCIATION EXECUTIVE BOARD

TOBB University of Economics and Technology International Chair in Bioethics/ WMA Cooperation Center (Former TOBB ETU UNESCO Bioethics Center) Student Association's goal is to expose the university community to bioethics. Our student association was established in January 2021, one year after the establishment of TOBB ETU International Chair in

Bioethics/ WMA Cooperation Center. Our association is achieving its aim through various platforms where we discuss ethics in various areas. We want to explore and discuss the world of ethics through different focus points. Our main study fields entail numerous aspects we tend to face in medical practice. We also hold the privilege of being the first bioethics student association in Turkey, we hope this field expands within students all around the world. In addition to the information above, with the lead of our advisor, Dr. P. Elif Ekmekci, we now had gathered to host a webinar in regard to the ethical challenges countries faced during the COVID-19 pandemic.

The first step of our preparation was to identify the speakers and get in touch with them who were kind enough to accept our invitation. The panelists were purposely selected from different regions across the globe. As the board of the student association, our further job was to prepare the symposium poster, social media posts and any written information regarding the event. We had divided the tasks within our group, hence we managed to avoid any possible delays. Lastly, the meeting platform was the hardest part to organize due to several reasons. We were lacking experience in terms of hosting a webinar meeting. Despite this problem, we found a solution with the help of our IT department, thus the event took place without any technical difficulties.

150 people from 24 countries attended the webinar. The speakers pictured a broad frame of the ethical challenges during COVID-19 pandemic. The discussion flourished with the active participation of attendees and the written Q/A section. We received several positive feedbacks which encourage us to enhance our works further in the field of bioethics.

We believe that we accomplished a great work by putting effort with the contributions of our advisors, precious panelists, and attendees, though we are a newly established association. Preparing this symposium helped us to enhance our perspectives and knowledge regarding ethical challenges countries faced during COVID-19 pandemic. We hope you enhance yourself by reading our book as much as we did.

TOBB ETU International Chair in Bioethics/ WMA Cooperation Center Student Association Executive Board

Begüm Güneş (5th year medical student)

Manolya Bergüzar Şekerlisoy (5th year medical student)

Mehmet Can Aksoy (4th year medical student)

Ece Deveci (3rd year medical student)

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Perihan Elif EKMEKCI was born in Ankara in 1971. After she completed her education in TED Ankara College, she graduated from the Medical Faculty of Ankara University in 1995. She had her PhD in History of Medicine and Ethics from Ankara University in 2014. Currently she is an associate professor and head of History of Medicine and Ethics department at TOBB ETU School of Medicine

She was a research fellow in Imperial College Tanaka Business school, London, UK in 2006. She has been a Fogarty Fellow at Harvard University and had her Fogarty/NIH Program Master's Certification in Research Ethics in 2014. She has been a fellow of WIRB International IRB Western Institutional Review Board Research Ethics Training Program, Seattle Washington (USA) in 2016.

She served as the head of EU relations department of Ministry of Health Turkey (2007-2016) and developed several projects in alliance with the EU. She was the Turkish representative for the European Center for Disease Control Advisory Board and served in this position between years 2011-2016.

Currently she is the chair of the International Unit in Bioethics/ WMA Cooperation Center and deputy dean of TOBB ETU School of Medicine. She is chairing the Intuitional Review Board of TOBB ETU, and she is a member of open science committee of TOBB ETU. She is a member of World Association for Medical Law and the International Forum of Teachers of the International Unit in Bioethics. She has several publications in distinguished journals on ethics and history of medicine. Dr Ekmekci is the co-author of the book titled "Artificial intelligence and Bioethics" published by Springer in 2020. She is teaching undergraduate and postgraduate courses on history of medicine and ethics.

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TOBB University of Economics and Technology School of Medicine Dean

Prof. Akar was born in Ankara in 1952. After he completed his education in TED Ankara College, he graduated from the Medical Faculty of Ankara University in 1977. He became a professor in 1995. He has conducted research in Italy and the USA in molecular genetics. He was awarded the Turkish Scientific and Research Council Research Award in 1989 and the Ankara University Research Award in 2000. He worked as a member of the Department of the Pediatric Molecular Genetics in the Department of Childhood Health and Diseases of the Ankara University Medical Faculty. He was also the Founding Director of the Biotechnology Institute of Ankara University. He is now working as a faculty member of TOBB-ETU Medical School, Pediatrics Department. He is a member of the editorial board of the several journals including Thrombosis Research, Egyptian Journal of Medical Human Genetics, Turkish Journal of Hematology. He published a textbook titled “Introduction to Clinical Molecular Pathology (1995 & 1998)” and also “Genome Project and The Turkish Press (2007)”. He published the following books in English: “15 years of Anatolia with Ord. Prof. Dr. Albert Eckstein, 1935-1950 (2017)”, “A Humane Mission: Dumlupınar (2017) and “Mother and Child Sculpture” (2005). A TV documentary based on his book “A Female Surgeon in Iğdır (2005)” was created. His other books are in Turkish : Turkey in the 1939 New York World Fair (2005), Biography of A Pediatrician: Bahtiyar Demirağ (2005), Portraits in My Pocket (2011). The First World War and Children, 2014. He is married to Ece Akar and father to two children and two grandsons.

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“Ethical Challenges During COVID-19 Pandemic: Perspectives from Different Countries” Symposium: Students’ Review

Begüm Güneş, Manolya Bergüzar Şekerlisoy, Mehmet Can Aksoy, Ece Deveci, Ebrar Gültekin, Irmak Güvenç, Ahmet Emre Demirkaya, Sümeyye Yoldaş

Introduction

The uncertain and unexpected nature of the COVID-19 Pandemic has added many layers of difficulty to the existing ethical problems of the health systems. Although some of these problems were common for most countries, others were specific to countries or regions. Moreover, the context and severeness of the arising ethical issues have varied throughout different countries and the Pandemic course. The international webinar titled “Ethical Challenges During COVID-19 Pandemic: Perspectives from Different Countries” was designed to discuss the main ethical issues of the COVID-19 Pandemic with particular attention to the challenges of various countries and examine these issues within a global frame of mind.

This paper aims to present the discussions that took place during the symposium “Ethical Challenges During COVID-19 Pandemic: Perspectives from Different Countries” on the 13th of March 2021 and to set out the medical students’ perspectives on them, who were part of the organizing student’s body of the TOBB University of Economics and Technology International Chair in Bioethics/ WMA Cooperation Center (Former TOBB ETU UNESCO Bioethics Center).

Main Part

The first presentation was by the key-note speaker Prof. Henry Silverman. He discussed inequalities in the context of research ethics in the COVID-19 Pandemic. One of his main points was to understand disparities, and we should describe the conceptual differences between two terms: equity and equality. Equity is to provide different opportunities to the people who have different contextualities to reach equal outcomes (1), where equality is to give people the same options regardless of their contextuality. In addition, according to equity, if identical results are wanted to reach, discrimination of more resources should be allocated to people in different circumstances. Ignoring equity while generating policies for preparedness and response to public health emergencies may cause some groups such as women, low-income people, minorities, migrants, and older people to be affected more negatively by the challenges of the Pandemic.

Discussing these unequal outcomes, the reasons for the different results may be various circumstances, efforts, or discriminatory mechanisms based on law, social status, and economics. Although some of those reasons can be part of biological determinants, they are not necessarily related to biology. Some public health measures directly impacting health may also have some collateral economic consequences that deepen inequality among various populations. These measures may disproportionately affect a broad range of vulnerable groups. The goal here is to be aware of the unwanted collateral impact of public health measures on other sectors and to minimize the disparities in COVID-19 mortality and morbidity rates that disproportionately affect disadvantaged people. Prof. Silverman sees research as a way of addressing these inequities. In this respect, he argues that health disparities research within the healthcare system should be advanced through a conceptual framework that provides detecting unequalness of vulnerable people, understanding contextual factors in different levels of society, reducing intervention, amending, and evaluating policy. Another factor in mitigating disparities in the healthcare system is community engagement; therefore, a high community engagement continuum should be one of the targets.

In the next part of the symposium, Professor Morenike Oluwatoyin Folayan discussed the ethical challenges faced in Nigeria and Africa during the COVID-19 Pandemic. Prof Folayan's first point was that Nigeria has been giving battles in several epidemic diseases such as HIV, Polio, Malaria, and Ebola. Some of these endemic diseases still have high mortality and morbidity rates; therefore, sparing extensive resources to COVID-19 instead of these fatal endemic diseases caused mistrust against the Nigerian health authorities. In addition, because of the lack of personal protective equipment (PPE) for health care workers and insufficient hazard allowance, some healthcare workers got infected by Coronavirus, and many of them died. Health care workers started a strike; however, it was terminated shortly because of the COVID-19 Pandemic. Considering the cause of the deaths, an ethical dilemma exposes because of the apparent risk of not having a government health insurance cover on health workers.

Another problem Nigeria faces during the Pandemic is the increasing gap between the wealthy and poor. The inequality of treatment causes this deepening due to decision-making according to financial status. The lockdown decision was another main reason, and it affected some sectors more negatively. The last ethical dilemma is the lopsided distribution of vaccines. While well-developed countries order vaccines more than their population need, some countries like Nigeria cannot even order sufficient vaccines for their people. Along with the other accompanying errors in the successful implementation of protective health measures, this is a solid barrier to reach health for people of underdeveloped countries, and it possesses the risk of delaying worldwide recovery. To conclude, there is a need to recognize the state's role and the importance of policy, and it is also essential to respond in an equitable way to global crises.

Another country discussed in terms of the ethical challenges faced during the COVID-19 Pandemic is Pakistan by Professor Farah Asif. Like many other countries, Pakistan has been facing some difficulties with supplying the ongoing need for primary health care during the current COVID-19 Pandemic. Hence, Pakistan's health system has been evolving to meet the demands of health provision and new and old research ethics reviews.

Prof Asif focused on research ethics and scientific integrity in Pakistan. All national-level research studies demand the approval of The Pakistan National Bioethics Committee (NBC), founded in 2002-2003, which is the primary formation to oversee and uphold the ethical principles in all health sectors in Pakistan. Also, there is the Local Research Ethics Committees (REC) that approve all institutional-based research studies. Additionally, NBC provides training for RECs via its national-level Research Ethics Committee (NBC-REC). There is no formal mechanism based on a competency level among these committees; hence there is no synchronized work between them, leading them to have separate procedures. There is no registry for ethics committees, so there is no registration process or accreditation, so it directs people to work unregulated.

Furthermore, some financial issues include lack of funding sources, limited administrative support, not getting paid, and the massive workload because of the COVID-19 overwhelmed and put pressure on REC members. It has been identified that there is a need for legislation. Hence, as Professor Asif says, we need to initiate a severe national-level dialog and find a common way to regulate the research for the integrity of the study, for the scientific validity of research, and to build the trust of our community. To eliminate these problems, we need comprehensive guidelines, to have a registry of ethics committees, and we need to have mechanisms for accreditation.

The place of ethics in our societies and how it is changed during the Pandemic is talked about by Professor Francis P. Crawley. During pandemic, contexts of our daily talks have changed, and science started to take part in them. Nowadays, many people know what a clinical trial is or how a vaccine or medicine is developed. Science and politics cooperate, and politicians mention the importance of science many times. Many countries formed special committees of scientists to guide political decisions. However, the extent to which politicians reflect the science is still questionable. COVID-19 Pandemic is not just a public health emergency; on the contrary, it affects many different areas of our lives. The effects of Pandemic are on social activities, such as the reasons for gathering or participants or the platform/place gatherings are done. We faced difficulties while gathering information, whether they are trustworthy or not. Religious, educational, social discourses have changed, and it caused a change in the perspectives of societies. Hence, when the lockdowns end, nobody is sure whether we could go back to the time before the Pandemic.

Regarding research methodologies, data sharing and science have changed. On the other hand, because it significantly impacts societies, social science studies and clinical trials are more related. Many other areas have their own ethics committees like business ethics. Pandemic is bringing ethics to our society and our lives. The main question left for us is whether we will provide an appropriate and well-defined place for ethics when the COVID-19 Pandemic ends.

Lastly, the effects of the COVID-19 Pandemic on children are talked about by Professor Rhian Thomas Turner. Some policy decisions taken during the Pandemic have a malign impact on children, such as; school closures and lockdowns, reduction in health services; for instance, appointments were being delayed, many types of research were closed and COVID-19 related research for children was postponed. Also, the Pandemic hit children differently depending on their socioeconomic status. There are studies of how schools affect virus transmission and school closures would affect the rate of transmission.(2) It is essential to understand the real impact of school closures on children, not only the impact on virus transmission. It has long-term health effects, such as more screen time, less exercise, and some economic effects on children, especially on shielding vulnerable ones—this reduced children's access to interventions on clinical trials. In general, children find it difficult to speak out about what they need. That includes the mechanism provides meaningful input into research to protect their rights during the Pandemic. The current policy decisions made on behalf of children have impacted many different rights, including their right to health, education, survival, and development, participation in, and benefit from scientific advancement. It is crucial to building an environment that is more receptive to the idea that the needs of children can be better served through research.

Discussion

After establishing the International Health Regulations by the WHO and the Influenza pandemic in 2009, the entire world, health authorities, and ethical committees assumed they were prepared for the next public health emergency until we faced the current COVID-19 Pandemic. WHO informed health systems regarding a possible pandemic; however, it is evident that most countries failed to prepare for an outbreak. As a result, some health systems worldwide have collapsed with a vast patient burden. COVID-19 has taken many lives and revealed several ethical problems and questions waiting to be resolved.

Furthermore, Prof Silverman delivered a question concerning the prosperity of society. We all agreed that the virus hits the poor and the rich equally. Diseases do not discriminate; thus, they would have similar impacts on the wealthy and underprivileged. However, this statement raises an ethical dilemma where preventive medicine must be considered. More Economically Developed Countries or High-Income Countries can develop their healthcare system in a much more rigorous way, enhancing their preventive medical structure. This development indeed indicates that High-Income Countries can be more protected from diseases and Low-Income Countries are more exposed to the virus. This example suggests the idea of national disparities within the pandemic. We are all aware that the virus cannot discriminate however, some countries are much prone to being negatively impacted by the pandemic. This disparity also applies to the society within any nation. Wealthy ones have the privilege of having high standard health care, hence they are less likely to suffer from any disadvantages. On the other hand, less fortunate ones tend to usually have difficulties accessing healthcare which creates this inequality within any society. To overcome this pandemic or any other health issues in the future, we must reduce the disparity and try to provide healthcare to any and everyone.

The vaccine, mask, distance, hygiene are our weapons against COVID-19. Their influence on the prevention of exposure increases with high community engagement. (3) Community Engagement is the process of working collaboratively with and through groups of people affiliated with similar situations to address issues affecting the well-being of those people. (4) Nowadays, the well-being of those people relies on the observance of COVID-19 precautions, restrictions, and treatment guidelines.

Six main community engagement actors are local leaders, community and faith-based organizations, community groups, health facility committees, individuals, and critical stakeholders. (5) These actors will play an essential role in directing society and controlling the epidemic. They should keep society up-to-date on new developments and prevent the spread of rumors and false information that could hinder the fight against the virus. While doing this, broad educational campaigns, television, and social media advertisements can be used.

We became more aware of how important ethics is during the pandemic process. From vaccine distribution to selecting the patient who would be hospitalized in the intensive care unit, we have been facing many ethical problems. Along with others, these challenges have taken their toll on the Nigerian healthcare system. Africa, especially Nigeria, has feeble health systems because of some epidemics, financial problems, and inadequate health workers and equipment. (6) Therefore, indeed COVID-19 Pandemic is unpreparedly faced the situation and hard to manage the situation for whole countries; process and burden of Pandemic are heavier for Nigeria and other African countries. (7,8) The invention of COVID-19 vaccines as an effective and scientifically proven prevention towards COVID-19 Pandemic brings together some problems such as fair and just distribution of vaccines. (7) Vaccine distribution is one of the essential issues in terms of three reasons. Firstly, this distribution is not according to the size of the community, and some of the well-developed countries such as Canada and the UK can order multiple times of their population; some of the countries cannot order even for their needs. (9,10) Therefore, we can say that high-income countries are getting access to COVID-19 vaccines earlier than countries with fewer sources. [11] It is estimated that in some low-income countries, widespread vaccination coverage will be achieved after 2023 [12,13]. According to given statistics, over 39 million vaccine doses had been given in 49 more prosperous states - but one developing nation had only 25 doses.[14] Unfortunately, this situation comes to mind with this question: Is the determined value of lives according to the country's degree of welfare? (13) Another is the financial burden of vaccines on these countries that have a feeble health system. Financial burden creates two options: not obtaining enough of a more effective and expensive vaccine or obtaining a less effective but cheaper one. (13) The solution for the second problem may be a donation of vaccines from the companies or foundations to these countries.(7) The last problem is the determination of priority vaccine distribution between countries. The vaccine needs of some countries should be preferred earlier than others because of the country's situation; for instance, Nigeria has delayed some of the critical vaccination, especially for children, such as polio, meningitis, and yellow fever. (15)

Also, there is another vast unfairness, and the head of WHO, Tedros Adhanom Ghebreyesus, explained it as follows: It was not fair for younger, healthy people in wealthier nations to get injections before vulnerable people in poorer states. Also, he considers it as a "catastrophic moral failure." He also notes that the unfair distribution of vaccines is a moral problem and an economically and epidemiologically self-destructive practice. He says that the more the virus is transmitted, the risk of occurring new variants puts the effects of vaccines at risk. Dr. Tedros noted that this imbalance in vaccination caused a false sense of security. [16] Ultimately, these actions will only prolong the Pandemic, the restrictions needed to contain it, and human and economic suffering. [17] Therefore, to have a global immunity towards the Coronavirus, the allocation of vaccines must be fair.

In addition, according to the IMF, International Monetary Fund, as bad as inequality had been before the Pandemic. As forcefully as the Pandemic has exposed the inequalities in our society, the post-pandemic world could experience even more significant inequalities unless governments do something. The reason is simple: COVID-19 will not go away quickly. [18]

The inequalities, unfortunately, do not end just with these unfairnesses. For instance, as we examined before in this article, the financial limitations in Pakistan cause even the basic need's absenteeism in ethics committees which is legislation. Furthermore, due to not having common legislation leads to not having proper communication between the committees. Hence managing the Pandemic is getting even more challenging for them.

All these unfairnesses have a considerable number of contradictions with the Declaration of Human Rights; according to the Declaration, everyone has a right to access health equally. [19] For instance, in 1948, article 25 of the Universal Declaration of Human Rights (UDHR 25/1) stated that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in the circumstances beyond his control."

Furthermore, International Covenant on Economic, Social and Cultural Rights (United Nations) also refers to the right of health as follows: Article 12/1, in 1966, stated: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." and in 12/1/c "The prevention, treatment, and control of epidemic, endemic, occupational and other diseases." and 12/1/d "The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

In 1999, the additional protocol to the American convention on human rights in the area of economic, social and cultural rights to health, the States Parties agreed to recognize health as a public good and, particularly, to adopt the following measures to ensure that right [...] Universal immunization against the principal infectious diseases; Prevention and treatment of endemic, occupational and other diseases [...] Satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable."' (11,19)

Given the a priori acceptance of the take-over of public health ethics during a pandemic, (20) we believe that the problems with the allocation of scarce resources, especially in a macro-allocation context, should be addressed within the unifying scope of public health rather than the practical approaches of various institutions or individuals. Additionally, they need to be dealt with with the transparency and attentiveness that communities require for any concordant action. (21)

The arising questions regarding allocation of scarce resources during a pandemic, including whether a fair allocation system should be mandatory, need elaboration. We agree with the previous papers that state the undeniable need for setting priorities and developing an adaptive triage system. Although many countries have developed various methods of using resources, we witness that all of them lead to various injustices. (21) This leads us to the idea that resources cannot be used fully equitably. As such, we think the main thing to discuss is to decide what is the fairest of our options. From this point of view, an emergency triage system should be established to stabilize the use of resources in the world. In this way, everyone can be guided by evaluating a more objective ground. Additionally, we believe there may be different considerations upon the characteristics of the resource and the community.

Ethics has become a topic that the whole world is talking about. Even those who are not health care professionals are informed or learned about how COVID-19 vaccines are developed and tested when it is looked at from an ethical clinical trial perspective.

Science and politics started to work hand in hand to solve the problems that we face. The committees of healthcare professionals, which are formed by ministries, guide politicians to take steps. It was a critical step in bringing the public together with professionals' suggestions and making them pay attention to their suggestions. Moreover, this situation caused issues such as treatment priority and vaccine distribution to be interpreted in terms of justice.

Conclusion

Ethics is a field that enables us to distinguish good from evil and right from wrong. It is a guide in every field where the subject is human. Ethics can guide us in every matter we have to choose from, as its consequences will affect us and others. It serves many purposes, such as ensuring ethical credibility, establishing a legal framework, being fair, and giving assurance. Especially if the subject is human, ethics is also there. It is for this reason that ethics now appear in every field.

Through our symposium, we analyzed ethical challenges during COVID-19. COVID-19 disproportionately affects the poor minority and a broad range of vulnerable populations, and social systems are not naturally inequitable. Still, they are rooted in discriminatory practices and beliefs, and providing equity by politics is a solution for addressing unjust imbalanced social systems. Therefore, global disproportions of using rights such as ordering vaccines to heal and being insufficient in policy to cover vulnerable groups and staff cause global and ethical issues. For instance, in Pakistan, the foundation of ethical committees is hardly old. There is no formal mechanism based on a competency level among these committees; hence there is no synchronized work between them and not to have qualified communication. Also, there are some financial issues that strict the studies of ethics committees.

On the other hand, some policy decisions taken during the Pandemic have had a malign impact on children, such as school closures and lockdowns and reduction in health services; these decisions disproportionately hit them in terms of their socioeconomic status. COVID -19 showed us that countries are not ready for a pandemic, but, as we mentioned, diseases hit the poor and rich both. While More Economically Developed Countries or High-Income Countries have the chance to eradicate the virus in their countries, undeveloped or developing countries cannot wipe out the virus. The same goes for the distribution of vaccines. More Economically Developed Countries or High-Income Countries to receive more vaccines than their needs emerge as an ethical problem. It is essential that developed countries should provide financial support to countries that cannot access the vaccine. The COVID-19 has created various ethical questions and problems. It will also continue to develop more. Decisions to be made during this period should be based on moral principles. Decisions made by ethical principles alleviate conscientious objections to consequences that may arise. (22) We hope that what we learn from the COVID-19 Pandemic will guide us through the next Pandemic.

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RESEARCH TO ADDRESS INEQUITIES CAUSED BY COVID-19

Henry Silverman MD, MA, Professor of Medicine

Introduction

This chapter will discuss health inequities caused by the Covid-19 pandemic and the types of research that can be performed to address these inequities. We will discuss the following:

- Distinguishing inequities from inequalities
- Health inequities among marginalized populations caused by Covid-19
- The value of implementation research in addressing these inequities
- The importance of community engagement with implementation research

Disproportionate Impact

Regarding the pandemic of 1918, the following is often said: "The virus does not discriminate, it hit the rich and poor alike".

In most polls that ask this question, almost two-thirds of the participants would "agree" with this statement, whereas a little over one-third of the participants would disagree with the statement. Surely the virus does not discriminate, so what would lead people to disagree with this statement?

The issue is what do we mean by the word "hit"?. Examining epidemiologic data from the 1918 pandemic reveals some insights. Figure 1 shows the incidence of influenza among persons of different economic status: Specifically, the "the poor and the very poor" and the "well-to-do and the moderate". We see that the incidence is much higher for the "poor and the very poor" compared with the other group [1].

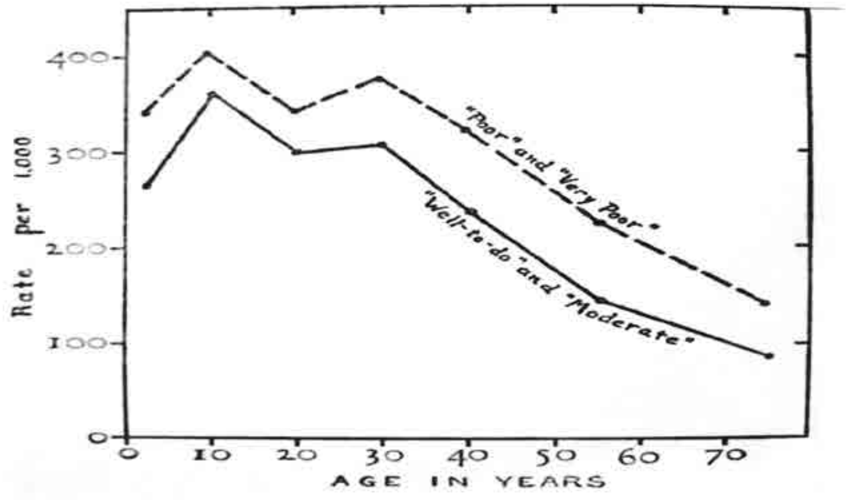
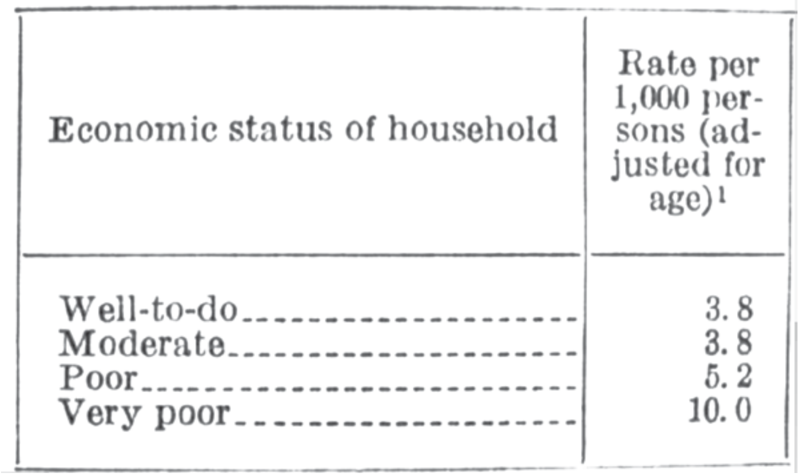


Figure 1 – Age incidence of influenza in the epidemic of 1918 among persons of different economic status: Adapted from Edgar Sydenstricker and Arthur J. Lawrence, Public Health Reports (1974-), Vol. 121, Historical Collection 1878-2005 (2006), pp. 190-204 URL: http://www.jstor.org/stable/20057068 .

Figure 2 shows data regarding mortality/1,000 persons from influenza and pneumonia during the epidemic of 1918 among white persons classified according to the general economic condition of the household: ranging between "very poor – poor – moderate – well to do. We see that mortality for the "very poor" is much higher compared with the other socio-economic groups. These data from 1918 are very similar to the data being generated in the Covid-19 pandemic 2021 insofar that groups representing the lower socio-economic strata are experiencing higher incidences of illnesses and mortality from Covid-19. What we need to do is to "unpack" the reasons why vulnerable populations are being "hit" harder than the other groups.



Economic status of household	Rate per 1,000 persons (adjusted for age)[1]
Well-to-do	3.8
Moderate	3.8
Poor	5.2
Very poor	10.0

Figure 2: Mortality from influenza and pneumonia during the 1918 pandemic according to the economic condition of the household

The issue pertains to the sources of disproportionate impact during pandemics. Figure 3 shows the sources of disparities during pandemics. There are differences in social position based on income, wealth, education, occupation, and race/ethnicity. These differences lead to three major causes of disparities [2].

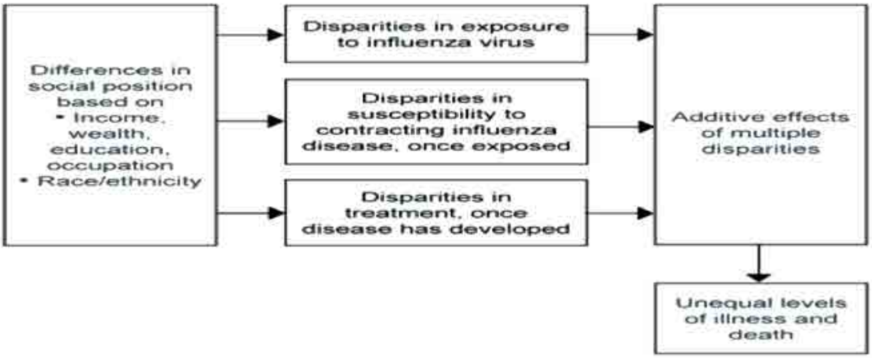


Figure 3: Sources of disproportionate impact during pandemics. Adapted from Blumenshine P, et.al Pandemic Influenza Planning in the United States from a Health Disparities Perspective. Emerging Infectious Diseases. 2008; 14:709

First, we have disparities in exposure to the influenza virus – for example, individuals from the lower economic strata of society would find it difficult to social distance either because they live in dwellings that are occupied by many family members or they have jobs where there is a high density of individuals (e.g., grocery stores). Second, there are disparities in the susceptibility to contracting influenza disease, once exposed. This effect emanates from individuals from the lower socio-economic strata as being more vulnerable to illnesses. This can be due to poor underlying health from either inadequate nutrition or chronic illnesses. Third. there are disparities in treatment once a disease has developed. These effects are due to disparities in access to health services, health care policies that exacerbate existing inequities, as well as unconscious biases of health care providers toward marginalized groups.

The additive effects of multiple disparities lead to unequal levels of illness and death. It may become evident during a pandemic that a particular demographic group or groups with compounded social vulnerabilities may prove them to be at exceptionally at high risk of death.

Based on experiences with previous pandemics it is reasonable to assume that pandemic influenza can cause case fatality rates for some groups that are significantly higher than the rates of high-risk groups.

Distinguishing between Inequities and Inequalities

What accounts for these disparities during pandemics especially if individuals have equal resources and also equal opportunities? However, each person encounters different circumstances that determines the allocation of their exact resources they will receive. It appears that vulnerability during pandemics is firmly rooted in preexisting vulnerability caused by inequities.

Inequities refer to unfair, avoidable differences arising from poor governance, corruption, cultural exclusion, or systemic racism that leads to differential access to health care services, employment, residential environment and other determinants of health. All of these factors are avoidable.

All of these factors explain the root causes of differential exposure to the virus that we discussed previously: higher exposure rates to the virus; greater severity of the effects of illnesses once exposed; and differences in access to health care services. In contrast, inequalities simply refer to the uneven distribution of health or health resources as a result of genetic factors or the lack of resources that are unavoidable.

Let's further explore the differences between inequities and inequalities. In Figure 4 we see three individuals with equal resources (i.e., standing on equal boxes in order to see the baseball game). But not everyone has the same circumstances. Ensuring that everyone have the same boxes is treating everyone the same but is not recognizing the reality of situations. Specifically, in this case there are differences in height. To address this difference in height, we give more resources to people who have different circumstances.

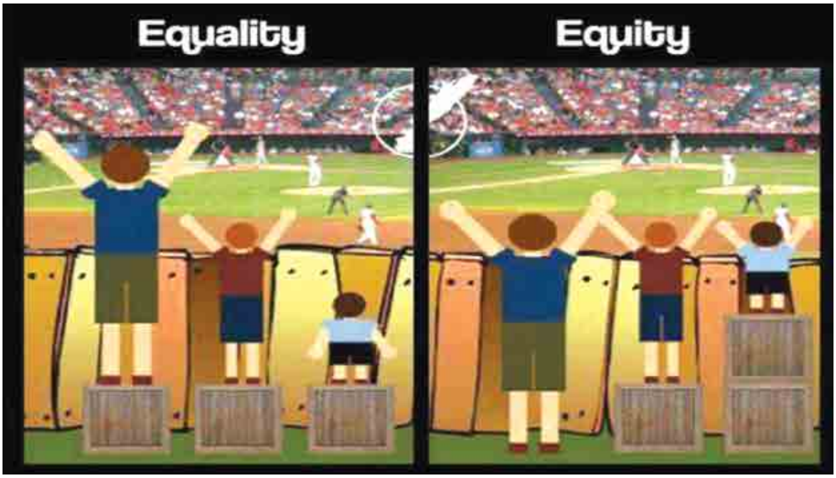
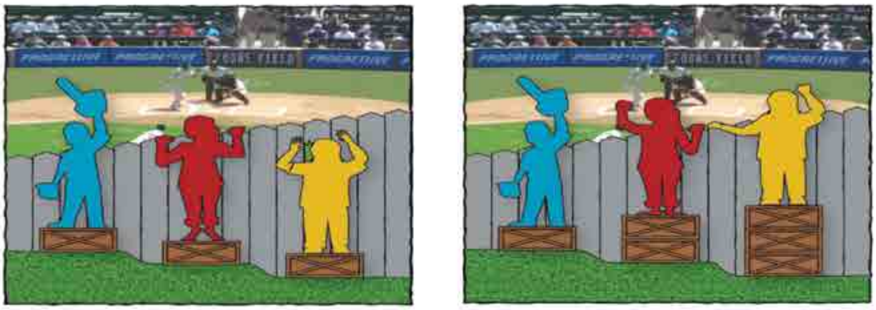


Figure 4: Equality vs. Equity

However, there is something misleading about Figure 4 insofar that the differences shown are caused by height differences. Height represents an inherent biological factor that is unavoidable. But such inequalities do not represent inequities, which refer to systemic avoidable factors that allows for differences in opportunities or factors that lead to vulnerability.

Figure 5 is better at demonstrating the differences between inequality and inequity. In Figure 5, all the children are of similar height and have equal resources. But the child on the right is at a disadvantage due to being on lower ground. Being on "lower ground" represents systemic barriers, biases, and unjust health policies based on race and ethnicity.



EQUALITY

EQUITY

Figure: 5 Equality vs. Equity – re-emphasized

The child on the right needs more resources not due to biology but due to previous unjust, avoidable social circumstances. Race disparities are due to social circumstances and policy and not biology. Social systems are not naturally inequitable but are rooted in discriminatory practices and beliefs.

Unequal resources due to social circumstances are due to avoidable social circumstances.

Equity is an absence of avoidable differences among groups of people. Equity is a solution for addressing unjust imbalanced social systems.

Racial equity is the elimination of unjust systemic barriers. Equity is the outcome when race will no longer be a predictor of health, education, income, etc. Due to the previous history of inequities, individuals subject to inequities now need more resources to achieve outcomes equal to individuals who have not be subject to systemic biases.

Further, figure 4 continues the dangerous narrative that achieving racial equity is "helping" people of color and communities of color because they are inherently and biologically deficient. In fact, the subtle and probably unconscious narrative reinforces the racists idea that "people of color are not as smart, not as motivated, and not as qualified, and need help to succeed."

A quote by Thich Nhat Hanh helps re-frame the usual thinking:

"When you plant lettuce, if it does not grow well, you don't blame the lettuce. You look for reasons it is not doing well. It may need fertilizer, or more water, or less sun. You never blame the lettuce." [3]

Why address Inequities?

Why should society address inequities? In other words, “What is fairness?”

If we fail to take steps to mitigate health disparities our society will look different at the end of the pandemic. Who will be missing because of disproportionate deaths?”

Martin Luther King said that “injustice anywhere is a threat to justice everywhere we are caught in an in escapable network of mutuality tied in a single garment of destiny. Whatever effects one directly affects all of us in directly.”

We should address inequities because they represent unfair systemic practices in our societies that have caused an unequal “playing field”. In addition to this deontological reason, we should address inequities because of a utilitarian based enlightened self-interest insofar that everyone’s health is dependent on the health of everyone, and this is especially true in times of pandemics.

What are the threats from the pandemic that causes unequal outcomes?

Let’s explore further the source of the health threats from the pandemic. Figure 6 shows the Triple Pandemic Threats, which include the direct effects of Covid-19, economic impacts, and unjust social practices. In each instance, the inequitable effects on vulnerable groups are due to either unjust practices inherent within the practice itself (e.g., social policy) or due to the differential effects of the “threat” on populations who are vulnerable due to pre-existing unjust practices (e.g., chronic illnesses due to inequitable access to health care services prior to the pandemic).

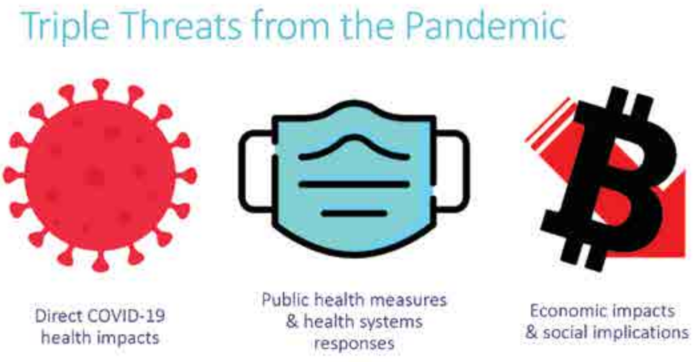


Figure 6: Triple Threats from the Pandemic.

Figure 7 also demonstrates the inequitable effects of the Covid-19 pandemic. This figure shows the changes in rates of employment or recovery of jobs between the wealthy and individuals from low economic strata. Essentially, during this past year the change in numbers of low-paying jobs in the service sector work were permanently lost among those in the lower socio-economic strata. As such, the return to employment has been slower for the bottom 25% of the work force. Individuals in the low paying jobs are due to a variety of reasons, e.g., biologic, social, or unequal educational opportunities due to unfair practices.

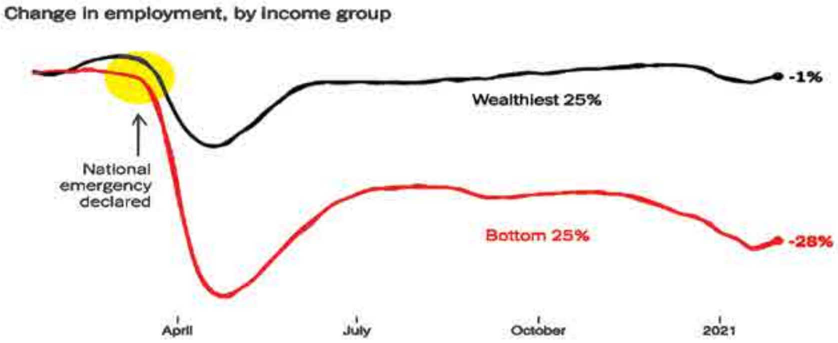


Figure 7: Recovery of jobs between wealthy and Bottom 25%: Source: New York Times

Unequal outcomes during pandemics are due to either unjust discriminatory practices that occurred pre-pandemic or during the pandemic.

- Based on experience with previous pandemics it is reasonable to assume that pandemic influenza can cause case-fatality rates for some groups that are significantly higher than the rates of other high-risk groups.
- It may become evident during a pandemic that a particular demographic group or group with compounded social vulnerabilities may prove to be at exceptionally high risk of death.

The Covid- 19 is disproportionately affecting the poor, minorities and a broad range of vulnerable populations. The collateral effects of the pandemic due to the global economic downturn and social isolation and movement restriction measures are unequally affecting those in lower power structures of societies [4].

Implementation Research

The goal is to decrease the disparities in COVID-19 case-fatality rates, which disproportionately affect vulnerable populations. Examples of what can disproportionately affect vulnerable populations include:

- Inability to social distance: "Social distancing is a privilege."
- Individuals live in multi-generational house.
- Inequities in testing
- Inequities in dissemination of information
- Social-Economic context Inequities in access to vaccines

To address the widening health disparities from Covid-19 what needs to conduct implementation research. Implementation research "is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health."[5].

Implementation research can help address the disproportionate impacts from the COVID-19: Such response can show that evidence-based interventions not being implemented well with contextual and implementation outcome barriers (feasibility, acceptability, adoption etc.). During the past year, several papers have exemplified how implementation research have addressed inequities that have proven to be successful within health care [6-8].

More broadly, implementation science focuses on how to apply research advances in real-world service systems [9]. Too often, however, evidence-based interventions are applied inequitably across various settings and populations, skewing application of best available practices toward communities and organizations with high capacity and resources.

There are three methodologic paradigms for conducting implementation research to address health inequity [5].

Paradigm #1: Use existing data or obtain new data to understand what drives disparities and how they can be overcome.

Paradigm #2: Include populations with health inequities in new implementation research.

Paradigm #3: Focus exclusively on populations experiencing inequities.

There are several ways in which implementation research can help address inequities and include the following:

- Provides framework to ***Identify*** the causes of gaps in care and outcomes.
- ***Understand*** Contextual factors which impact access, uptake and quality.
- Transform into ***actionable*** knowledge.
- Help adapt and ***scale*** interventions proven successful in addressing inequities in other settings.

Kilbourne and colleagues offer a framework that organizes the process of health disparities research into 3 sequential phases: detection, understanding, and reduction or elimination. Phase 1(detecting disparities) informs phase 2 studies (understanding disparities), which in turn informs phase 3 research (interventions to reduce or eliminate disparities) [10].

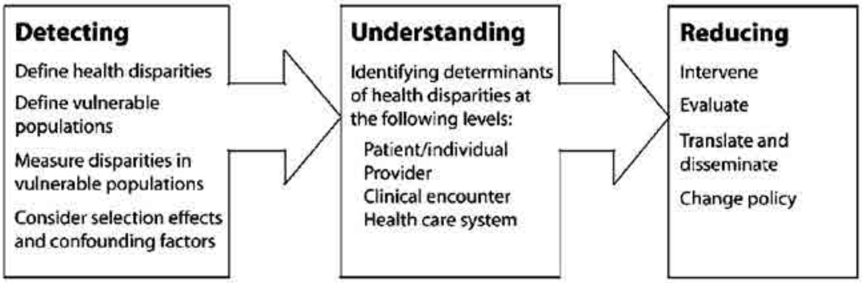


Figure 8 The 3 phases of the disparities research agenda.

In terms of identifying vulnerable populations, this can include women; older persons; adolescence; persons with disabilities; indigenous peoples, migrants, and marginalized minorities.

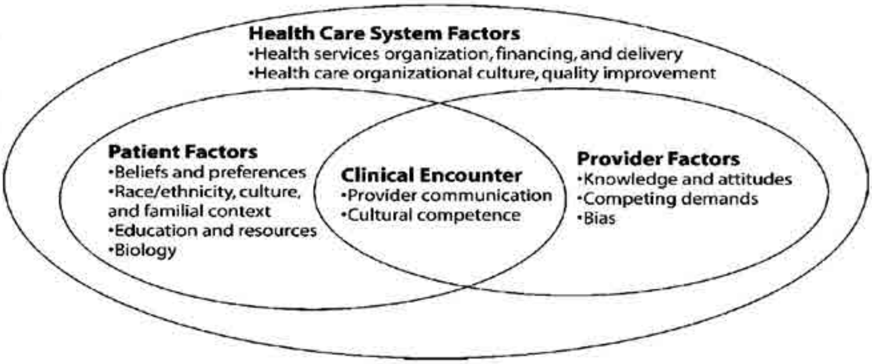


Figure 9: Understanding the origins of health and health care disparities from a health services research perspective: key potential determinants

of health disparities within the health care system, including individual, provider, and health care system factors [10].

Regarding understanding, we need to appreciate the contextual factors in the external environment, individuals and families and health systems and interventions which result in disparities on access, uptake and outcomes. We need to understand the origins of health in healthcare disparity at all different levels Regarding understanding, one needs to.

As shown in figure 9, these include patient factors, the clinical encounter, providers' factors and also the healthcare system factors. Appreciating healthcare system factors is important as "most existing strategies to reduce disparities target patients and/or providers and rarely target system level factors, even though they likely contribute to health disparities"[11] .

For example, is low testing due to access (cost, geography, place of work) or acceptability (fear of diagnosis)? Evidence-drive interventions have included expanding of test sites into community settings, contact tracing through community-based workers to overcome suspicion and address access.

Another example: is social distancing acceptable and feasible? Multi-generational and more crowded housing makes home isolation not feasible. Hence, one needs to access good strategies that include alternate sites for isolation, structural support (food packages).

Finally, an example of identifying and understanding disparities that lead to unequal health outcomes comes from issues occurring with vaccine distribution. We have developed strategies to distribute the vaccine; however, we need to understand why vulnerable groups are left behind, e.g., they don't have the means to access the vaccine in society [12].

Phase 3 of Kilbourne and colleagues' proposed research agenda is the development and implementation of interventions that reduce or eliminate disparities in health or health care. These authors mention four issues that are important at this stage:

(1) developing appropriate intervention strategies, especially for community-based settings that serve vulnerable populations,

(2) instituting appropriate evaluation techniques,

(3) determining whether a strategy for reducing disparities is ready for implementation and translation into routine care settings, and

(4) developing strategies that promote policy changes on the basis of the intervention.

Other issues to address include the following: Can a program be adopted, can providers deliver it with fidelity, will the program actually reach the intended populations and will organization sustain it over time? [13]

COMMUNITY ENGAGEMENT

The last topic to discuss regards the issue of building partnerships for health equity. Partnership building is a crucial strategy for implementation research [14, 15]. By building partnerships between key community and health system stakeholders, researchers can establish equal voices with legitimate power and oversight concerning the conduct of implementation research[15]. Partnerships are essential to addressing social justice issues that result from intentional and un-intentional discriminatory policies and social structures that create and perpetuate health inequities.

Involving the community exists on a continuum. On one end of the spectrum, we have community outreach, consult and involvement. We want to reach, however, towards the higher level of this continuum. One should strive for a relationship with the community that includes collaboration and shared leadership.

Community-based participatory research (CBPR) and community-partnered participatory research (CPPR) are two well-known approaches devoted to the development of processes for engagement and continued participation of communities in research [16].

The significance of community engagement was shown in a recent WHO "call" for proposals in which one of the areas of focus involved "mapping of Ethics Review Committee practices in in relation to the engagement of communities in research to enhance health care delivery [17]. This "call" for proposals was to identify good practices with engaging communities in research for implementation and in social innovation and low and middle and, countries.

To close, I want to discuss several thoughts from Jim Lavery who also ascribes to the importance of community engagement, but he stresses that such partnerships with the community needs to be fair. Fair partnerships serve as a determinant of effectiveness of global health campaigns and implications for research ethics [18].

In regard to the latter point about research ethics, Lavery believes that the current research ethics paradigm is insufficient to do the moral heavy lifting when partnering with communities. The present ethics framework, developed more than 50 years ago, is mainly focused on protections, e.g., safeguards for vulnerable populations and has an exclusive focus in individuals. The "dominant paradigm" of research ethics is silent on the importance of fairness as an ethical goal for the principal vehicle (partnerships) through which global health research and implementation programs are delivered.

Lavery believes that one needs to move to a newer paradigm of research ethics that includes stakeholder engagement and farness in research partnerships. Also, Lavery stresses on how one should create value for stakeholders. To address this issue of value, Lavery believes that one needs to borrow concepts of stakeholder theory from business [19]. Stakeholder engagement offers a more effective and realistic way to determine the value of research for relevant stakeholders than standard metrics, which are mostly about US metrics, such as publication and citation rates and impact factors.

The research fairness concept to enhance fair partnerships is ethically significant and the challenge is developing fair partnerships that involves the relevant stakeholders. The four pillars of this new paradigm involve: stakeholder engagement, fair partnerships, brokered design, and knowledge co-production.

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Comments from the audience:

"CONGRATULATIONS! THANK YOU FOR THIS GREAT SYMPOSIUM."

A DISCUSSION ON THE NEED FOR A GLOBAL ETHICAL STANCE FOR PUBLIC HEALTH EMERGENCIES: WHAT WE HAVE NOT LEARNED SINCE THE PLAGUE TO COVID-19 PANDEMIC?

Perihan Elif Ekmekci M.D. PhD. Associate Professor

Introduction

The COVID-19 pandemics has once more derived our attention to the concept of public health emergencies and how it is perceived in public health ethics. World Health Organization (WHO) defines public health emergency with international concern as an extraordinary, serious event that has the risk to spread internationally and therefore requires immediate, coordinated and, collaborative international response (1). This definition constitutes the essence of International Health Regulations (IHR) published by the WHO in 2005 and it is a product of the long history of communicable diseases which negatively affected huge numbers of people from various countries by causing millions of deaths, hindering international travel and trade.

Although IHR 2005 was a considerable milestone in the international preparedness and response to public health emergencies, several concerns were raised regarding its effectiveness during SARS and EBOLA pandemics (2,3,4). One of these concerns was the absence of core values and principles which would guide ethical decision-making during public health emergencies. The lack of an ethical framework has been one of the main concerns in terms of response and management of the COVID-19 both locally and globally.

This article begins with a short look at the history of international preparedness and response to infectious diseases and identifies the factors that led to IHR and its revision in 2005. Then the ethical shortfalls of the IHR 2005 which were identified in recent pandemics are discussed. The article ends with a discussion on the possibility of a global ethical stance to address the ethical issues of public health emergencies that threaten the sustainability of humanity.

A short history of infectious disease outbreaks and international response

The plague was the most significant communicable disease which caused public health crisis in medieval times. Individual states generated some public health measures like quarantining ships for 40 days before allowing them to draw close to the ports, ordering people to stay in their households, or robing physicians with special clothing that cover their body and face to avoid contamination with *miasma* (5).

However, it was soon understood that none of these measures were sufficient to stop the spread of the plague. Worse, new communicable diseases continued to emerge by letting humanity despairing about the limited effectiveness of the standalone local measures.

Epidemics of communicable diseases like cholera, yellow fever and, the plague with devastating consequences on many people could not be taken under control by national quarantines and continued to breach international trade. This situation urged the countries to collaborate to stop the transborder dissemination of communicable diseases. With this objective in mind, the first international sanitary conference was held in 1851 in Paris followed by thirteen other conferences. The main paradigm of thought in these conferences was that countries should be transparent about outbreaks of cholera, yellow fever and, the plague within their borders and inform each other to facilitate the surveillance and response (6).

Another common understanding among western countries was that most of the communicable diseases were originating from Asian countries. Depending on this understanding "Asiatic diseases" term was generated. The Italian scientist Pacini, who described the pathogen of cholera thirty years before Robert Koch, named his publication "Microscopic observations and pathologic deductions on Asiatic cholera" indicating that cholera was originating from Eastern countries (6). In 1892, The International Sanitary Convention was adopted. Among the measures listed in this convention, there were strengthening the quarantine in the Suez Canal, and the annual pilgrimage to Mecca to avoid the entrance of communicable diseases from eastern countries to the west (5,6).

In this context, it was thought that regional institutions might facilitate generating and implementing measures against communicable disease dissemination and response. Hence, some organizations were established to organize regional efforts like the Pan American Sanitary Bureau (1902) and Office International d'Hygie`ne Publique (1907). With the establishment of the WHO in 1948, these regional organizations became less significant, and the WHO became the leading actor for organizing the cooperation and coordination of CDs spread, and the regional offices of the WHO took over the functions of the regional institutions (6).

The first International Sanitary Regulations (ISR) were released in 1951 by the WHO. The name ISR was changed to International Health Regulations (IHR) in 1969. The main paradigm of thought was very similar to that of the 19th century which was based on the obligations of states to notify each other about outbreaks and restriction of international trade and travel in their territories in case of an outbreak. In addition to this historic perspective, the IHR had another drawback. It contained a very limited list of notifiable diseases which only included cholera, yellow fever, and the plague. Later two other communicable diseases were inserted into this list: smallpox -which was removed from the list in 1981 due to global eradication of the disease- and typhus. However, despite the new additions, the list was becoming more outdated by novel outbreaks the HIV-AIDS and re-emerge of archaic diseases like tuberculosis and malaria (6).

Another shortfall of the IHR was its limited perspective regarding complex social factors like migration, urbanization, social determinants of health, and economic inequalities which have a causal and reciprocal relationship with the spread of communicable diseases. In addition, with the beginning of the new millennium, the public health emergency term acquired a new dimension: bioterrorism. Microbiological agents were started to be used as means of terrorist attacks which had the capacity not only to kill or disable considerable numbers of people living in the region but also to risk the lives and wellbeing of individuals who live in remote areas (7). Public health was also threatened by nuclear disasters. The Chernobyl accident in 1986 was a warning to humanity that public health emergencies were not limited to communicable disease outbreaks. The existing IHR did not have any reference to these newly emerging threats.

With these in mind, the revision process for the IHR was initiated. A paradigm shift that aimed to portray public health emergencies as an issue of global health security guided the revision process. The new paradigm conceptualized public health threats as a set of risks to global health emerging from biological, chemical, nuclear, and environmental origins. With this paradigm shift, public health emergencies were no more limited to a set of communicable diseases originating from a particular geographic region -allegedly Asia and the Middle East- and can be controlled by transparent surveillance and limiting international travel and trade was left behind.

This paradigm shift and concept of global health security required a new global health governance system. The new governance system which was reflected in the revised IHR contained the following main differences in terms of ethical values and perspectives:

1. The agents who were responsible for providing information on surveillance of outbreaks were enhanced to include non-state actors such as NGOs, the private sector, and the media. This approach was indicating that maintaining global health security and managing preparedness and response to public health emergencies is a responsibility for all parties, including individuals. The extension of responsible agents for apprising outbreaks endorsed the principle of transparency and promoted the timely flow of information for public health threats.

2. The extend of measures enhanced. The old version of the IHR suggested implementing a *maximum* number of measures for international trade and travel where the new perspective endorsed a scientifically proven risk assessment to determine the limits of measures. This change highlighted the principle of proportionality, the essentiality of scientific knowledge in decision making, and a custom-made approach to each public health risk.

3. The list of diseases was replaced with the concept of global health security which focuses on public health risks of urgent international concern. The SARS epidemic in 2003 provoked this amendment which clearly showed that list of diseases or syndromes (as proposed in the draft in 1998) would not work when an outbreak with a novel agent is taking place. With the new GHS concept, the scope of the IHR expanded significantly to cover all possible sources of public health threats.

4. Balancing greater good for public health and individual human rights: The IHR 2005 intended to oblige parties to implement minimum interference with human rights and international trade and travel that is necessary to protect public health. The limits of infringements to individual rights were to be defined by scientifically proven knowledge.

The ethical shortfalls of the IHR 2005

Although the IHR 2005 had a wide perspective regarding global health security and preparedness and response to public health emergencies, epidemics of the 21st century like AIDS, H1N5, H1N1, EBOLA, and SARS led to scrutinizing its effectiveness. It was beyond discussion that the IHR 2005, an agreement among 196 members of the WHO for building capacities to detect and report public health emergencies, was one of the huge steps for developing a global early warning and response system and planning preparedness and response against public health emergencies (8).

However, the IHR 2005 had several limitations and among them, one particular deficiency precluded its effectiveness and practicability: The IHR 2005 did not provide any ethical guidance to decision making since it does not contain any reference to ethical principles or moral values that should be considered during pandemic preparedness or response.

The importance of this insufficiency was revealed during the influenza pandemic in 2007. Individual states and the global health community realized that decisions during a public health emergency were mostly value-based. These value-based decisions were essential in terms of building trust and compliance with public health measures during the crises. Having this in mind, some institutions, including the WHO, published ethical guidelines for pandemics preparedness and management (9).

In the "Ethical considerations in developing a public health response to pandemic influenza" report, the WHO defined critical ethical questions after influenza pandemic: the distribution of scarce essential resources like medications, vaccines, and intensive care unit beds, obligations of health-care workers to the community considering the risks to their health and the health of their households and balancing public health measures like quarantine, surveillance, and social-distancing, with individual rights and freedoms (9).

In this document, it was clearly stated that pandemic preparedness should include an ethical framework for decision-making to answer these questions since it would be too late to develop one during a public health emergency.

However, these guidelines did not gain enough attention from public health authorities. Hence, like the IHR 2005, none of them could offer proper ethical guidance during the current pandemic. On the contrary, the COVID-19 pandemic revealed the fact that the global health community and individual countries, regardless of their level of socio-economic development, were not well-equipped for noticing and reflecting on moral issues and value-based decisions faced during the pandemic. Humanity was caught unprepared and failed to respond timely and adequately and mitigate the devastating consequences and impact of the outbreak.

The ethical questions during the current COVID-19 pandemic

The current pandemic showed that the main questions which require a frame for ethical decision-making during a public health emergency arise in different settings and various decision-making levels.

The different settings vary in a wide spectrum, with healthcare facilities on one end and global health and international health governance on the other. Value-based decisions during the pandemic in a healthcare facility are listed as allocation of scarce resources such as medicines, preventive measures such as vaccines, or special treatment units like the intensive care beds (10,11). Apart from allocation of resources, there are other ethical questions: the limits of the ethical obligation of the healthcare workers to serve when there is scientifically proven high risk for their health and well-being, as well as the health of their families or people they live with; the breaches of physicians' freedom to choose the appropriate treatment for their patients because of the obligation infused by authorities to apply treatment plans with little or no scientific proof and obliged by public health authorities; the limitations on health care workers' freedom to quit or withdraw from their jobs because of high demand for their service; the obligation to serve in communicable disease treatment which may not necessarily be their area of expertise and the inevitability of overlooking their patients whom they were in charge of for the sake of COVID patients (10,11).

At the national level, public health authorities are in charge of making value-based decisions. The ethical tension at this level is usually between individual rights and freedoms and the greater good. The execution of public health measures that limit individual rights such as quarantine, social distancing, or wearing masks is justified because there is scientifically proven evidence that they will ease the dissemination of the outbreak. The legitimacy of such sanctions has been debated largely during the COVID-19 pandemic. The responsibility of health governing bodies to promote well-being, health, and security for all people and the transfer of some autonomy of individuals to public authorities in terms of the social contract were suggested as grounds for legitimacy of the authorities to overlook individual rights and freedoms in extraordinary circumstances like the pandemic. On the other hand, a considerable amount of people found it hard and unnecessary to comply with these limitations, and several public protests were done in various countries all around the world. These protests may provide empirical evidence that public health measures which infringe individual rights should be well-planned before a public health emergency takes place. While planning a response to public health emergencies, the authorities should be transparent about the possible measures that would limit individual rights but still will be needed to control and manage the emergency. Moreover, having community engagement in these preparedness plans would enhance public compliance and the effectiveness of these measures.

The shortage and unjust distribution of vaccines to some low- and middle-income countries has driven attention to the importance of ethical decision-making at the global level. Questions about the justification of the ethical responsibility of high-income countries to share their resources with low-income- low resource countries have been raised. Solidarity and justice are among the ethical themes which are argued for justification of this obligation (12). However, this ethical discussion is even more deepened with the arguments about vaccine passports. The lack of an ethical stance in terms of global health inequalities makes room for such proposals with the risk to worsen the conditions for low-middle income countries and increase global health inequalities.

There is also another particular decision-making level that has implications at both the healthcare facility level and national and global pandemic management level: research ethics. The vast need for scientifically proven knowledge urged the research community to conduct research immediately. This urgency provoked discussions about the role and responsibilities of institutional review boards (IRB) or ethics review committees (ERC) during a public health emergency (13). Again, several guidelines have been published to assist the ethical review process. However, the questions about IRB/REC working processes were still discussed widely during the COVID-19 pandemic.

Apart from these ethical questions, some other problems have ethical implications, therefore, require an ethical stance. The limited executive power of the IHR 2005 and the WHO in terms of leading international response and coordination, unawareness of changing and newly emerging vulnerabilities in a national and international context and, recognizing the right to health as a fundamental value of pandemic preparedness and response and failing to refer to the right to health of all human beings while advocating for mitigating inequalities are foremost issues in this context.

Discussion and conclusions:

Bioethics is a considerably new discipline that has been flourishing since Van Rensselaer Potter used the term bioethics in his book “Bioethics: Bridge to the Future” in 1971. The term “bioethics” has been welcomed broadly because it offered a wider perspective than the medical ethics discourse and invited an interdisciplinary approach to ethical issues which may have an impact not only on human beings but on all beings in the world. (14)

Potter listed five major factors which carry the risk of jeopardizing the sustainability of life. Poverty, population, war, pollution, politics, and negative side effects of progress. He plausibly argued that the new discipline of bioethics should bring science and philosophy together to produce wisdom which he defines as “the knowledge of how to use the knowledge.”

Revisiting Potter’s thoughts inspire us about the role of ethics in public health emergencies. Even decades ago, Potter pinned the idea that the issues which may jeopardize life and wellbeing were global. Note that his list constitutes of universal problems with socioeconomic and health consequences for all humanity. The phenomena in this list are global in origin and hence, can be solved with global awareness and response. The ethical questions which surfaced during the current pandemic have supported Potter’s perspective by underlining the need for a global ethical stance. However, considering the ethical questions and dilemmas that were faced during the COVID-19 pandemic revealed that humanity has difficulty understanding this fact even now when the SARS COV-2 virus is threatening the lives of millions of people all over the world.

Pandemic preparedness and response require bringing together science and ethics to generate the wisdom needed to guide policies and priority setting. (14) The COVID-19 pandemic made it clear that 1. the problems faced in different settings are universal and no country is immune to them regardless of their economic status, 2. Countries must cooperate and demonstrate acts of solidarity to overcome these problems, 3. Decisions during a pandemic are driven by science and ethics.

On the other hand, the idea of finding global solutions to global problems and request for a global ethical stance invokes criticisms about the dominance of western values in global settings and turning a blind eye to the ethical codes of communities and countries by imposing western values to them. Some critics call this a new form of neo-colonialism, hence refuse the concept of global ethics as it threatens their communal values and autonomy (15). The proponents of this critical state that western culture prioritizes individuality while their (non-western) culture finds inherent value in the community and the greater good. However, this criticism contains a paradox that refutes its basic argument about the impossibility of global ethics. The paradox lies in the general assumption that all individuals in western or non-western countries share the same values, and that community is a homogenous living being with a single set of ethical codes. This thought might have been pertinent for some closed communities without any access to effective communication means with the rest of the world, but not in the current time in which there is a continuous interaction among people regardless of where they live. This interaction makes it easier to understand and share values for individuals and communities and form a common understanding about problems and possible solutions to them. Hence, it is plausible to argue that the ethical values and principles of different communities might converge to agree on some common values. The high risk for all humanity's wellbeing brought by the pandemic can be a facilitator of this convergence.

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Comments from the audience:

"GOOD AND INFORMATIVE SYMPOSIUM."

WHAT WE LEARNED FROM THE SYMPOSIUM OF “ETHICAL CHALLENGES DURING COVID-19 PANDEMIC: PERSPECTIVES FROM DIFFERENT COUNTRIES”

Banu Buruk PhD. Assistant Professor

Introduction

Epidemics start suddenly in time, progress in a limited stage in terms of space and duration, follow a process of increasing tension, progress towards a crisis of individual and collective character, and eventually drift towards the closure of the pandemic process. It is known that in the historical process, many infectious disease epidemics that deeply affect life were fought. For example, the 1918 Spanish flu epidemic, which emerged in the struggle of humanity to survive in the early 20th century, is a major pandemic [1]. In the first quarter of the 21st century, we are facing the COVID19 pandemic, which has cut us off from our fast pace of life since the end of 2019 and has made us question the value of life deeply. When we look at the historical process, it is seen that the previous epidemic processes differ greatly from the current COVID19 epidemic. The World Health Organization (WHO) 20 April 2020 Situation Assessment Report describes this difference as “*The world has never faced a challenge of this scale before. COVID-19 is a truly global crisis and the only way to overcome it is to be in global solidarity together.*” [2].

Undoubtedly, this great challenge caused by COVID-19 has brought new ethical problems to both the treatment and research aspects of the health system. The increasing number of ethical problems has created various dilemmas in the delivery of both local and global public health services. Ethical problems stemming from COVID-19 have existed in different forms or amounts in different living conditions, different healthcare infrastructure arrangements, and different cultures. With this symposium we organized, we had the opportunity to listen to the perspectives and experiences of both local and international ethical problems from public health and ethics experts living in different geographical regions of the world. The discussions mainly focused on the issues such as inequality in terms of health care allocation among patients, community engagement during the inequality solution phase vulnerable groups, cultural and geographical differences, the responsible conduct of research (RCR) perception among public, the special condition of children's educational/social needs and the post-pandemic inequalities we should be aware of.

The Inequalities in the Integrated World Model

A century ago, there was no leadership mechanism that provided international coordination like WHO. There was also no 24-hour news cycle to inform the public about the pandemic21. In the 1918 Spanish flu, the measures were not applied on a global scale, but on a national and even local scale. Therefore, the experiences gained in the geography where the virus first showed its effect were not used in other geographies and the virus was starting a destruction process in every region it reached. However, it is also a fact that the slower the knowledge of the epidemic measures spread during the Spanish flu period, the slower the transportation of all other living / non-living things, including humans, was. The fact that we currently live in an integrated world order gives us the ease of going anywhere in the world or the ability to attract information about every place in the world to where we are. Therefore, both the coronavirus itself and all kinds of information about the virus are spreading many times faster than the pandemic period 100 years ago. However, the integrated world model could not be the solution for the the inequalities in terms of COVID-19 treatment and research ethics. The resource allocation among people from different countries or among the different groups of people (differences in age, living location, profession, in-come level ..etc.) put some of them in a vulnerable position. According to the discussions held in the symposium, we need new methods to measure the level of vulnerability caused by COVID-19 pandemic, by using the method of community engagement.

The difficulties vulnerable groups in Pakistan are facing are has two dimensions in relation to ethical dilemmas: first one is problems of primary health care system, and the second one is the problems about the critical role of local research institutions and IRBs. We focused on the urgent need for COVID-19 patients care and the ethics issues in the individual rights of the patient, physician - patient relationship, population needs & individual patient needs, the health risks physicians facing during COVID-19 patients in inadequate protective conditions, the distribution of scarce medical resources between the patients who need urgent & continuous treatment and the COVID-19 patients. The appropriate precaution to ensure that pandemia research are maintained within ethical standards is critical research & treatment distinction during pandemia circumstances. In these COVID-19 pandemia days, it is almost impossible to distinguish the research and treatment process with sharp lines. The second ethical dilemma was about research ethics and scientific integrity in Pakistan. Although there is a need for an IRB approval for clinical trails in Pakistan, there is no registry for different IRBs, no accreditation, causing a catastrophic research environment. Even in pandemia conditions, IRB review and oversight are indispensable to ensure the determination of scientific principles of clinical trials. It is for sure that exclusion of IRBs can create a slippery slope which would end in loss of trust for scientific knowledge. To avoid such drastic consequences of this slippery slope, IRBs may need to change some of their working styles into such as conducting on-line meetings suitable for their members' working shifts or inviting substitute members. And also, the members of the ethics committee need to overcome the problem of being independent of the stress caused by the emergency and to prevent scientific integrity.

The difficulties vulnerable groups in Nigeria are facing during COVID-19 pandemic are about quite different the ethical challenges than the ones in Pakistan. For decades, Nigeria has been fighting with epidemic diseases such as Ebola, HIV, and Malaria. Although it does not cause a global crisis as much as the COVID-19 epidemic, there have been some important epidemics concerning public health in the last 20 years. For example, SARS CoV-1, first reported in Asia in 2003, first spread to countries in Asia and then infected more than 8,000 people. In 2014, the Ebola epidemic caused by a highly contagious and deadly virus, especially in West Africa, progressed rapidly and caused high death rates. There was an outbreak of Middle East Respiratory Syndrome (MERS) in Korea in 2015 with a 20% mortality rate [3]. But the real difficulty about Nigeria is that some of these influential communicable diseases are endemic for African region. The endless endemic diseases trigger the thoughts that there is not enough struggle given by the authorized health institutions in the country. On the other hand, it is a fact that not only the public but also the healthcare care workers (HCW) are vulnerable to these endemic diseases. The inability to provide adequate personal protective equipment (PPE) to healthcare workers, or even a government-guaranteed health insurance, is the root cause of this vulnerability. The HCWs are expected to serve more which put their health and lives in excessive risk. Besides, this risk is not limited to their lives, since their households and loved ones are at risk too. These facts imply that, medical profession is a job in which workers are asked to sacrifice their health and their loved ones' health for the sake of serving others when needed. According to World Health Organization (WHO) "*workers with certain professional qualifications, such as physicians, nurses, and funeral directors, may have a duty to assume a certain level of personal risk as part of their professional or employment commitments*" [4] (WHO, 2016). The ethical grounds for this duty depend on the fact that in pandemics healthcare service is essential and HCWs are capable of providing healthcare more than anyone else [5] (Ruderman, 2006). This sentence is true; however, it does not imply the ethical obligation for serving if doing so exposes their lives or loved ones' lives. The second argument is about a hypothetical social contract between HCWs and the society [5] (Ruderman, 2006). This argument states that healthcare is one of the essential needs which is demanded more at times of emergency such as a pandemic. If HCWs will be demanded to serve on basis of this hypothetical social contract, then it would be plausible to think that the society/ health authority should have some responsibilities towards HCWs. Providing sufficient personal protective equipment (PPE) is the leading responsibility in this context.

Another problem Nigeria faces during the pandemic is the unjust distribution of vaccines, which is directly related with health diplomacy. The World Health Organization defines global health diplomacy as the ability to leverage the disciplines of public health, international relations, management and law as a tool to manage and shape positive change. Historically, health diplomacy has emerged for the purpose of humanitarian aid. This concept is used more by governments to positively influence the behavior of others for the public good and is remembered as soft power [6]. In modern history, there has not been such an urgent impulse to develop a vaccine as in the COVID-19 pandemic. It is seen that countries are investing to support research in vaccines developed for the COVID-19 pandemic. The question of how to find a successful vaccine as well as mass-produce it and distribute it evenly remains unanswered. Here, the lack of financial resources of low-income countries such as Nigeria constitutes one of the obstacles to preventing the pandemic [7]. However, on April 24, 2020, the World Health Organization, in partnership with humanitarian and private sector organizations, affirmed its commitment to "fair global access to safe, quality, effective and affordable COVID-19 diagnostics, treatments and vaccines [8].

Another issue about COVID-19 pandemic is how digitization has changed our lifestyles, it has brought the distant closer; facilitated access to information. So everything is more visible now. During the pandemic, science became one of the main chat topics. Scientific information produced anywhere in the world is now accessible as “information” without waiting for the outputs of that information to be formed and delivered to us. For example, we can see the scientific data on clinical studies in which the coronavirus vaccine is being developed, before the vaccine is developed and presented to us as a research output. On the Internet, we can monitor what high-tech companies, research groups in research institutes are working on on the treatment of virus infection [9, 10].

Lastly, the effects of the COVID-19 Pandemic on children was one of the main topics of the symposium talks. The pandemic has quarantined people and made social distance individual life mandatory. Despite many restrictions, especially transportation, the continuation of an integrated and global understanding of the world is actually due to our discovery that life continues to flow in this order. Our digitalized life, our working order, our education life, our shopping routines, our socializing habits are now almost entirely done through a computer screen. While learning to live with the coronavirus in the 21st century, it has also shown that many of the things we do in life can be achieved by using the possibilities of technology. Of course, in order to maintain individuality and the continuity of life at the same pace, the importance of isolated interpersonal communication has increased. Especially the transition to the distance education system triggered the children to meet the concept of individuality at the beginning of their lives. Since a child’s individualization through the advantages offered by technology depends on the socio-economic status of her family rather than her own abilities, it has become inevitable that this situation creates an unequal order among children. On the other hand, “individuality”, which can be a life alternative for adults, unfortunately had to be imposed on children in the challenging conditions of the pandemic and caused serious damage in their educational-social lives.

Discussion & Conclusion

COVID-19 Pandemic has affected almost all areas of our lives; from health needs to social activities, or from finance to education. We got used to live with the lockdowns, and almost forgot our routine before the pandemic. From our homes, we access all kind of knowledge about the current pandemic, including the scientific progress of vaccine research carried out by different scientists all around the world. Patients, family members of patients, healthcare professionals, researchers, and the general public can easily access information about publicly and privately supported clinical trials through the web-based resource “ClinicalTrials.gov” [11]. Similarly, WHO’s “international clinical trials registry platform (ICTRP)” also provides access to clinical trial data conducted in different countries [12]. Such web-based platforms provide summary information about research protocols and the title, definition and design of the study, disease, intervention (medicine studied, behavior or procedure, etc.), study locations and contact information, links to relevant information on other health websites such as PubMed for citations and summaries of scientific articles in the medical field, number of participants and demographic data, study outputs and It includes information such as a summary of adverse events experienced by study participants [13]. Making clinical studies related to coronavirus visible on web-based platforms, making simple or advanced scans about these studies; it provides an opportunity for anyone to learn how these studies are conducted and who can participate, or to view and analyze statistics on registered studies. In a sense, this situation supports the elements of transparency, accountability and therefore reliability.

Ease of access to information is directly proportional to the rapid increase in the speed of information production [14]. Accurate and/or verified information is needed today more than ever before. Abundance of information means that false or misleading information is as accessible as true information. WHO has defined this situation by developing a new terminology by analogy with the pandemic: “Infodemics: The excess of information – some true and some not – occurring during the pandemic”[15]. False information in the abundance of information is actually a kind of virus like the coronavirus. In this sense, COVID19 is a digital pandemic in which tension and chaos spread faster than the virus itself 3. downplaying the risks of COVID19, equating COVID19 with seasonal flu, questioning the effectiveness of mitigation and control measures (e.g. use of masks), promoting unproven treatments, politicizing vaccine development necessary for the ultimate control of the pandemic, or spreading various conspiracy theories on social media; each is an example of misinformation that spreads like a virus[16].

Beyond all these information access, there is still an inequality issue among high-income - low-income countries, HCW’s - vulnerable groups and children. As our lifestyles change, our perspectives towards life and what is important in life may change. This situation inevitably triggers the change of our value judgments. We are witnessing that the COVID-19 epidemic has dramatically affected our lives, with the change in our own value judgments. How are our values about life prioritized? This question has started to be questioned more with the COVID-19 pandemic. In order to ensure the continuity of life in a way that makes life valuable, value judgments such as equality, justice, honesty, cooperation and usefulness have become more visible. On the other hand, the scope of the COVID-19 epidemic was so wide that a global health mobilization was undertaken; the idea of how we can allocate limited resources to everyone in the fairest and most efficient way started to gain weight. This change of thinking has led the way in which the understanding of public health in the field of medicine is overtaking the understanding of individualized medicine, which has been prioritized too much recently [17]. Unfortunately, it has been seen that expensive and effective treatments developed for individuals suffering from rare diseases do not help the destruction caused by the pandemic. However, coronavirus hits the poor and the rich equally. Covid-19 has similar impacts on the wealthy people who can afford individualized treatment options and people who can not. At this point, the preventive medicine options, under fair allocation strategies which wealthy and financially incapable people both can access, gained importance. Of course, the number of infected patients has increased a lot, as the pandemic did not leave almost unaffected areas on the world. As a result, the process of finding a cure for the epidemic revealed the transition from individual labor to collective labor, that is, the importance of cooperation. At the moment, we experience that social health is at least as important as individual health. Therefore, social and class differences began to lose their importance even more.

Last but not least, although we have faced inequality in many issues during the pandemic, from protective equipment for healthcare workers to the public's access to vaccines, inequalities will continue to exist after the pandemic, as it was before the pandemic. We know that COVID-19 will not be completely out of our lives in a short time, and we will feel its presence for a long time, although its impact continues to decrease. One of the topics discussed at the symposium was that the presence of COVID-19 would change the size of the inequalities experienced before the pandemic or bring new inequalities after the pandemic. This preliminary determination is very valuable for predicting possible ethical dilemmas and taking necessary precautions by making justified ethical analyses.

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Comments from the audience:

"Actually, comments of Professor's on the ethical situation of the world and different countries are very directive and informative for our medical education. Thank you for this symposium."

RESEARCH ETHICS REVIEW IN PAKISTAN DURING COVID-19 PANDEMIC

Farah Asif

Shaukat Khanum Memorial Cancer Hospital And Research Centre (https://www.shaukatkhanum.org.pk/home.html) is first tertiary care cancer hospital of Pakistan and state of the art cancer hospital, which is unique as it has continued to treat more than 75% of all cancer patients seen completely free of charge. Its annual budget is Rs. 19 billion (Year 2021) and Philanthropic spending to date is Rs. 53 billion (US$ 514 Million)

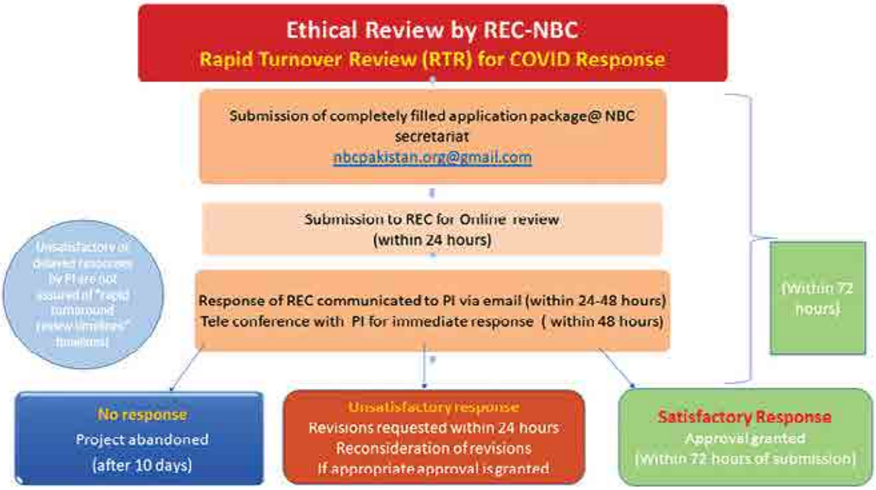
Hospital Mission Statement is "To act as a model institution to alleviate the suffering of patients with cancer through the application of modern methods of curative and palliative therapy irrespective of their ability to pay, the education of health care professionals and the public and perform research into the causes and treatment of cancer."

Shaukat Khanum Memorial Trust strives continuously to enhance Pakistan's capacity to provide the best possible care to as many cancer patients as possible, based on the principles of equity, transparency, and merit. Though a cancer hospital but it has capacity of doing all types of relevant research of highest scientific and ethical standard is part of our mission. Research offers a potential for change that is untapped for countries like us and we wish to be the instrument for that kind of change as reflected by the existence of comprehensive research guidelines and Institutional Review Board since 2005. SKMCH&RC has supported development of human resources, capacity, and other initiatives for this cause.

As a low-and-middle-income country with a population of 220892332 (1), surviving in a chronic state of underinvestment, Pakistan faced the challenges to meet the ongoing need for basic health care during the current COVID-19 pandemic, like many other developing and developed countries. In response, our health system witnessed adaptations to keep pace with rapid and huge demands of healthcare provision and new research challenges, as well as maintaining ongoing research and ethics review needs for healthcare conditions outside COVID-19.

The Pakistan National Bioethics Committee (NBC) is the official body to oversee and uphold the ethics principles in all sectors of health research in the country (2). All institutional-based research studies require prior approval by Local Research Ethics Committees or Institutional Review. National level research projects, as well as those projects with international collaborations, require NBC approval as well as local review by the appropriate IRB(s). Regulatory approval by the Drug Regulatory Authority of Pakistan (DRAP) is also required for clinical trials, following approvals by the appropriate IRBs and the NBC. The NBC provides guidance for ethics review and periodic trainings for IRBs via its national level Research Ethics Committee (NBC-REC).

During the current COVID-19 pandemic, the NBC-REC developed guidance primarily describing how it reviews COVID-19 research (3). This was essential considering the influx of new research related to COVID-19.



Source: *http://nbcpakistan.org.pk/rec.html*

This was an important resource which steer institutional ethics committees in the process of urgently needed adaptations. Local IRBs, however, have yet to be coordinated in this national response. Research ethics and regulations constitute a national matter. especially, the functioning of IRBs are globally principally dependent on national legislation, regulation, and guidance, which are of essential importance to enable them to work in local context.

IRBs in Pakistan are currently not registered or accredited by a national-level competent authority. Hence, they work independently according to their individual structures and procedures, reflecting significant differences across institutional approaches (4), however this may be true for developed world as well. There is a lack of coordination between the local IRBs as well as regarding their interaction with the NBC-REC. There is a tendency for a 'silo approach' to ethics review by local IRBs. This impairs an effective and coordinated response to PHEs. Finally, local IRBs in Pakistan found themselves suddenly overwhelmed during the COVID-19 pandemic with a need for fast-tracked reviews of research related to the pandemic. They found themselves pressured to consider clinical trials that had insufficient safety and/or evidence data on which to base reliable decision-making (5). The COVID-19 pandemic also highlighted the lack of coordination for review of COVID-19 multicentre research in Pakistan, which led to duplication of efforts and burden on ethics committees as well as research teams. Many countries adapted to coordinated ethics review during ongoing COVID-19 public health emergencies at national level (6). In summary, challenges unique to Ethics Review framework of Pakistan can be listed as follows:

- In Pakistan, Formal mechanisms to interact among IRBs, community and the NBC do not exist.
- IRB unregulated with wide variation in the competency level and working.
- A majority of IRB membership remains without any formal training for the work expected from them in ethical review.
- External pressures to influence deliberations, conflict of interest issues within board leadership and
- inconsistent application of review requirements all contributes to undermining the reliability of the process.
- Some of the most significant threats to independent and uninfluenced functioning of such boards arise from institutional leadership itself.
- National level guidelines, regulations and training resources are limited on key aspects related to research.
- In spite of previous emergencies, no agreed procedure for ethics review during PHEe exist.

It faced additional challenges, during COVID-19 PHE, which include.

- COVID-19 has led to a disruption of the normal IRB meeting times and even the procedures.
- The pressure to accelerate the review of COVID-19 related research protocols has only added to, and highlighted, existing challenges for Pakistan's IRBs and the national ethics review system. The IRBs, and even the NBCs, saw a large increase in workload as well as increase in expectations that threated to overwhelm their capacity and lead to burn out by members.
- There have been reported instances of insufficient and even questionable IRB review practices.
- Studies with questionable scientific validity

To address the need for a strong national ethics review framework that promotes a reliable preparedness and response to PHEs. A 'one country, one system' approach is sought that promotes institutional, national, and international collaborative health-related research that contributes to health for all within Pakistan. There is a need for continuity of core ethical values during PHEs, developing synergies in ethics review across Pakistan, more opportunities of education and training and a comprehensive mechanism to protect the vulnerable groups, and ways of community engagement.

COVID-19 PHE offers an opportunity for IRBs in Pakistan to learn from one another's experiences and, based on these learnings, look for a common way forward, and it calls for a dialogue to generate evidence-based recommendations intended to develop policy and guidance that creates an operational framework for a national and local approach to ethics review during a public health emergency (PHE) to ensure that research in current outbreaks can proceed without undue delays and yet protect the rights and welfare of human beings who are surveyed, whose blood is drawn, or who receive experimental or off-label drugs, in line with previous learnings and guidelines by leading bodies (7,8,9).

Way forward is to develop a national action plan including

- Comprehensive Guidelines and legislation for ethics review in Pakistan
- IRB registry and a process of accreditation
- A good governance system of ethics review requires a centralized body with sufficient funding, preferably providing a platform for coordination and communication between ethics committees, NBC and regulatory body.

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Comments from the audience:

"I enjoyed topic and presentations."

EXPERIENCES WITHIN THE UK DURING THE PANDEMIC

Rhian Thomas Turner

Introduction

The Children and Young Adults' Research Unit is situated in the Children's Hospital for Wales in Cardiff and is part of the NHS in Wales. Wales is part of the UK but as a devolved nation, health is the responsibility of the Welsh Government. The NHS in Wales is free at the point of use.

CYARU was set up three years ago and is the only clinical research space in Wales dedicated to delivering clinical research for children up to the age of 17. CYARU delivers clinical research across the disease specialities including paediatric oncology. My own research interests focus on children rights and whether international law can help build a more receptive environment for the development of medicines for paediatric unmet medical needs.

My presentation will concentrate on experiences within the UK during the pandemic and ask whether we decisions made on behalf of children were based on evidence generated through research and if not, whether States have a duty to conduct such research.

UK Headlines

There have been numerous headlines in the UK relating to the impact of COVID-19 and children.

We have seen the direct impact of the virus on them.

In April 2020, the UK report its first cases of what would become known as Pediatric Multisystem Inflammatory Syndrome (PIMS-TS or MIS-C in the USA) (Pediatric Critical Care Society April 2020). Some of the symptoms of this new syndrome overlap with Kawasaki's disease and toxic shock syndrome and can lead to children being hospitalized.

We have also seen what is being termed the 'collateral' damage of COVID-19 on children which includes the impact of school closures on a child's education, its support networks, mental and physical health. The impact of perceived inaccessibility of pediatric services in hospitals with serious conditions going undiagnosed.

Decisions behind the headlines

Behind the headlines are the decisions that Governments have made on behalf of children. School closures happened for many, including children in the UK, early in the pandemic. This was accompanied by lockdowns and orders to stay at home.

A reduction in health services available to children, routine appointments were delayed. Early in the first wave of the pandemic in the UK and a decision was made to close down research studies to new recruits. In our hospital we have seen the redeployment of staff and research space to other services, including nurses sent to adult wards (RCPCH 2020).

Initially there was a slow response to opening interventional COVID related research for children in comparison to the rate at which adult studies were developed and opened.

Are they evidence based decisions?

School closures – there have been numerous studies across the world looking at transmission of the virus in schools. Public Health England started the sKIDS study in June 2020 (Ismail et al 2020). The study, which was set up to look at outbreaks of the virus in England and what part educational settings played in this, was conducted when only a small number of children were in school. It took place when children from certain years were allowed to return to school but also when a high percentage of year groups were still learning from home. The study was not recommissioned for the start of the September 2020 when all children would have been back in school. In Wales we have been unsuccessful in securing funding for any type of schools' transmission work despite Welsh Government's Technical Advisory Group (Welsh Government 2020) recommending that further research of specific school cohorts was needed to address unanswered questions on the balance of school closures.

The UK still cannot offer a definitive answer on the impact of schools on transmission of the virus. Only recently, at a hearing of one of the Select Committees of the UK Parliament, on 16th February, Prof. Woolhouse, of Edinburgh University suggested that it was safe to reopen schools to all those under 16 (UK Parliament 2021). Whilst John Edmunds, a member of the SAGE Advisory Committee to the UK Govt, commented that opening schools could risk a resurgence of the virus. He also commented that without the younger population being yet vaccinated the risks of further variants of the virus mutating was also a cause for concern (Weaver 2021).

What we still have is a high level of uncertainty over the role that schools play. Prof. Russell Viner, President of the Royal College of Pediatrics and Child Health in the UK stated during an evidence session at the UK Parliament, referencing his research on the role of transmission that "*the point to the systematic review was that we can't just assume that anything we do will have an impact. We have to do it carefully.*" (UK Parliament 2021). With this I argue that we need to understand the whole impact of school closures and lockdowns on children, not just understand the impact of school closures on virus transmission.

We have seen numerous potential issues raised that are a result of school closures and lockdown measures, which includes the impact of more screen time and less exercise on the long-term health of children, the impact of a decrease of education on long term economic outcomes for children living through the COVID era (Viner 2021 WHO) and we are yet to understand the impact of shielding on the vulnerable populations.

What we have seen in our hospital, and I understand this has been seen elsewhere too, although we do not have specific Wales data on the admissions, is the increase in children being admitted due to mental health conditions during these periods (Tuthill 2021).

Reduction in Health Services and non-COVID research opportunities

As I have previously mentioned during the first wave of the pandemic in the UK we saw a reduction in routine services for children including cancellation of non-urgent surgeries and outpatient appointment delayed (RCPCH 2020). We saw delays in presentation to hospitals for children with temperatures after people were told to stay at home if they had a high temperature. From a research perspective we also saw a total shut down of all non-COVID related research to new recruits during wave one. This therefore reduced the opportunities for children to access interventions only available through trials. We had to turn away potential participants, knowing they would lose the opportunity to participate in 'time sensitive' studies. We also await evidence of whether there will be a knock-on effect is a delay in new medicines coming to the market because studies were paused.

A delay in commencing COVID related research for children.

Whilst we saw an early surge of research studies opening for adults, such as RECOVERY and REMAP CAP that was not true for pediatric studies. Early in the pandemic, children were finding themselves in the position that they could not access studies for conditions impacting on their lives but also, they were not including in the research response to the pandemic.

That's not to say that studies relevant for children have not since opened, and we as a site have been involved in a few including the pediatric arm of RECOVERY Trial which is looking at the treatment options for children with respiratory COVID (adolescents) and PIMS-TS (younger population). Also, the RAPID-19, a study looking at the 'Seroprevalence of SARS-Cov-2 infection in healthy children' (Waterfield et al 2020). 1000 'Covid warriors' from across the UK who have given up to 3 lots of bloods over the course of 7 months.

Now of course we have the vaccine trials commencing including Oxford/AstraZeneca study in the UK down to the age of 6 and also looking at the Pediatric Investigation Plans agreed by the European Medicines Agency (EMA, 2020), numerous other vaccine studies in the pipeline.

Do we have a duty to conduct research?

The International Covenant on Economic, Social and Cultural Rights at Article 15 (1) (b) states that States parties (of which the UK is one) must recognize the right of everyone to enjoy the benefits of scientific progress and its applications (UNCESCR, 1966).

To supplement this article, General Comment 25 was published in March 2020 (UNCESCR, 2020). This General Comment further sets out the obligations on the State regarding this Article 15 (1) (b). Within this General Comment is an AAAQ framework, which for those who have come across it sets out the criteria for Availability, Accessibility, Acceptability and Quality. The frameworks are used a lot in human rights jurisprudence. Although we do not have the time to go through the entire framework today, it clearly sets out what is expected of state parties. This includes that scientific progress should and is taking place. That the research infrastructure needed for it to take place is available, acceptable, and accessibly and of good quality. Also, importantly that every person, without discrimination, should have equal opportunity to participate in scientific advancement. This includes children.

This opportunity is of great importance where this also impacts on the enjoyment of other rights, such as, for children the right to an education under Article 28 of the Convention on the Rights of the Child.

Can we build back better for children?

Historically Child Health research has been neglected. Prevailing R&D models, especially with regards to medicines development are ill prepared to provide for the child population. Small numbers of patients make it difficult for industry to see a return on their investment (EU Commission 2004).

However, the UNCRC, the most ratified human rights treaty requires that state fulfil their obligations with regards to children's rights. The UNCRC has four core principles which must be considered when interpreting the rest of the Convention. These include Article 2 - non-discrimination, Article 3 – best interests, Article 6 – the right to survival and development and Article 12 – the right to have their views respected. (UNCRC 1989)

In addition, Article 24 of the UNCRC concentrates on a child's Right to Health, whilst General Comment 15 on the Right to Health requests that children have access to 'appropriate prevention, health promotion, curative rehabilitative and palliative services' (UNCRC 2013). Research aids in the development of these services.

Article 12 of the UNCRC requires that children are given the opportunity to have their view heard on all matters that affect them. The Children's Commissioner for Wales (Children's Commissioner 2021) has conducted a survey during the pandemic aiming to gather the views of children across Wales but in general children find it difficult to speak out about what they need. They rely upon adults to provide the necessary mechanisms to allow them to voice their opinions, needs and concerns. That includes a mechanism to provide meaningful input in the research needed to protect their rights during the pandemic.

The current policy decisions made on behalf of children have impacted on numerous human rights, including their right to health, right to an education, right to survival and development and their right to participate in and benefit from scientific advancement.

Can we learn from this pandemic and do better? At the start of the presentation, I questioned whether there is a duty to ensure that policy is based on evidence generated through research.

I think we can use obligations from international treaties to build a case that State parties to treaties have a duty, but I think we first need to build an environment which is more receptive to the idea that the needs of children can be served better through research.

For years we have considered it better to protect children from rather than through research. The concept of autonomy and children's ability to give informed consent to participate in research being one major obstacle. However, many incidents have not helped, including the 1996 CNEP trial in the UK where newspapers wrongly reported that babies were being used as "guinea pigs" (Hey 2006).

However, by attempting to protect children from research we have created an environment in which children are given medicines that are not appropriately tested for them or where we make decisions to close schools without a robust evidence base.

I would argue that we need to combine a more receptive environment, such as that provided by Joan Tronto's explanation of care ethics in her book 'Moral Boundaries' (Tronto 1994) with an understanding of the issues for children, an understanding that can be provided by using International Treaties and jurisprudence as a framework. Tronto discusses the five elements of an ethics of care:

1. Attentiveness – which includes the recognition of a need to be cared about.
2. Responsibility – which requires us to take care of the need.
3. Competence – that we are able to take care of that need.
4. Responsiveness – that we respond to the needs of the care-receiver, and
5. The integrity of care – that all of the four elements about fit together as a whole. That we are able to identify and deal with the conflict that

has been identified whilst we conduct our obligations under the first four elements.

In using this care ethics framework and the framework provided by the treaties we start to recognize that Child Health research is underfunded and under prioritized and that as a society we have an obligation to respond to that need and work to find a solution that fulfils state obligations and respects the rights that children have.

States, through ratification of treaties, have a legal obligation to respect, protect and fulfil the human rights of children. This will differ depending on the resources available to the State, but the starting point is a clear recognition that robust research is in the interests of children.

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Suggested further reading:

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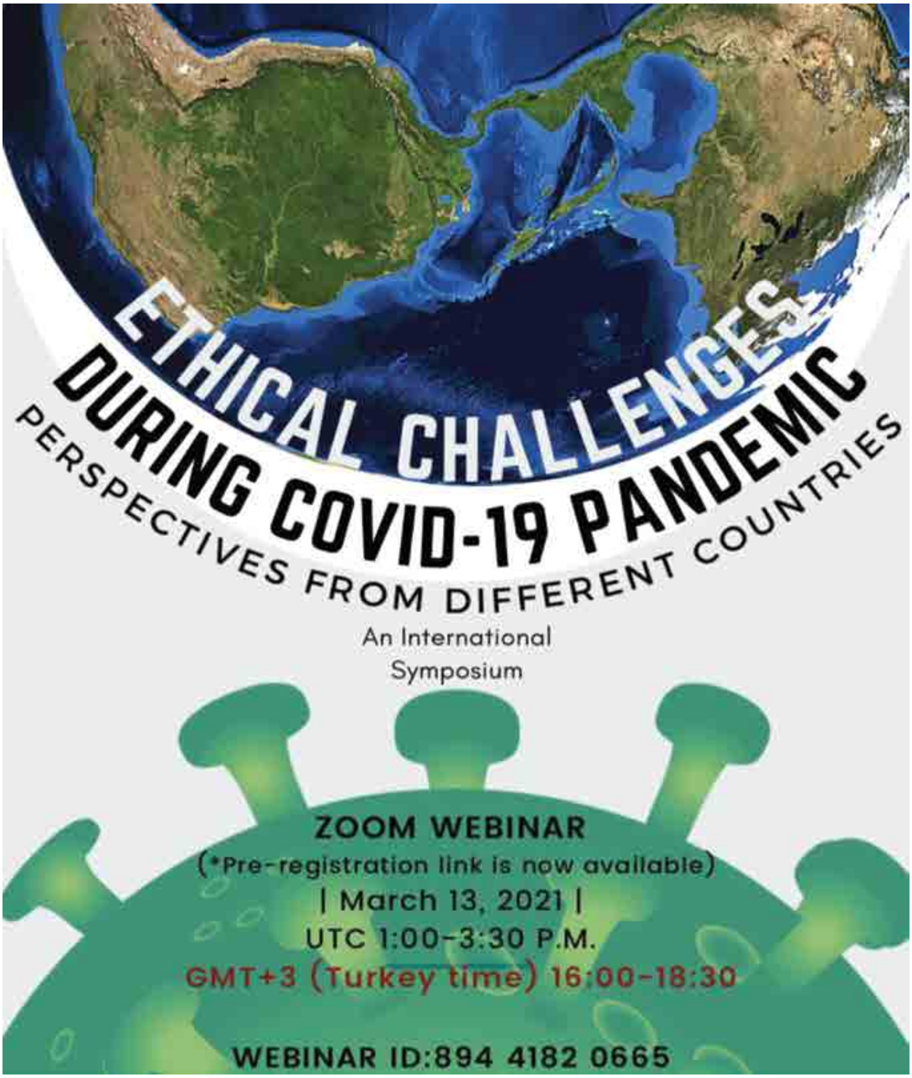
Appendix

WEBINAR POSTER



ETHICAL CHALLENGES
DURING COVID-19 PANDEMIC
PERSPECTIVES FROM DIFFERENT COUNTRIES

An International
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ZOOM WEBINAR
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| March 13, 2021 |
UTC 1:00-3:30 P.M.
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WEBINAR ID:894 4182 0665

WEBINAR PROGRAM

1:00-1:05 PM* 16:00-16:05**	**Welcome** Nejat Akar *TOBB ETU School of Medicine Dean*
1:05-1:15 PM* 16:05-16:15**	**WEBINAR Chair** Perihan Elif Ekmekci *UNESCO Bioethics Unit Chair,TOBB ETU School of Medicine Deputy Dean*
1:15-1:45 PM* 16:15-16:45**	***KEYNOTE SPEECH:* Research addressing health inequities during the COVID-19 pandemic** Henry J. Silverman *Professor of Medicine at the University of Maryland School of Medicine in Baltimore*
1:45-2:05 PM* 16:45-17:05**	**Ethical challenges faced in Nigeria during the COVID-19 pandemic** Morenike Ukpong *Clinical/Research Professor with the Obafemi Awolowo University, Ile-Ife, Nigeria*
2:05-2:25 PM* 17:05-17:25**	**Research Ethics Review in Pakistan During COVID-19 pandemic** Farah Asif *Clinical Research Administrator, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Lahore, Pakistan*
2:25-2:45 PM* 17:25-17:45**	**The Impact of Public Health Policy on Ethics During the COVID-19 Pandemic: Has Ethics Remained True to Itself?** Francis P. Crawley *Executive Director of the Good Clinical Practice Alliance - Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium*
2:45-3:05 PM* 17:45-18:05**	**Children, COVID-19 and research- Evidence based health policy during a pandemic; whose duty is it anyway?** Rhian Thomas-Turner *Research and Development Lead for Noah's Ark Children's Hospital for Wales, Cardiff and Operational Lead for the Children and Young Adults' Research Unit, Wales*
3:05-3:30 PM* 18:05-18:30**	**Q/A**

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** TIME ZONE:GMT +3 (TR)

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for their participation
in the "Ethical Challenges During COVID-19 Pandemic"
Symposium on March 13th 2021 .

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Head of TOBB ETU UNESCO
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