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Editorial

COVID-19 and Equitably Sharing of Benefits and Burdens of Research

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An important key principle of research ethics is that the benefits and burdens of research with human participants should be equitably distributed [1]. The question of where COVID-19 clinical trials will be conducted is relevant to both the burdens and benefits of research. On the burdens side, there have long been concerns about the "off-shoring" of studies to low- and middle-income countries (LMICs) to take advantage of looser regulation and of populations eager to participate in research because they have no other good options for accessing health care [2]. This concern explains the outrage sparked by a French doctor's statement that COVID-19 trials should be conducted in Africa to take advantage of the fact that "there are no masks, treatment, or intensive care" (which would presumably make it easier to determine whether the experimental intervention was working) [3]. World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus condemned the comment as "a hangover from a colonial mentality" [4]. This principle has important implications for questions about where research will be conducted, how participants will be recruited, what questions will be investigated, and who will control the distribution of any innovations that result. In the rush to initiate clinical trials of treatments and vaccines for COVID-19, careful attention to these questions is particularly important. If clinical trials are not designed with equity considerations consciously in mind, the response to the pandemic may exacerbate disparities in health status between population groups. These substantiate that the principal of benefits and burdens of research with human participants should be equitably distributed.

At the same time, excluding LMICs from COVID-19 research is clearly not the solution, as doing so would reduce the potential benefits of research for persons in those regions. This is because the results of clinical trials conducted in one part of the world are not necessarily applicable to persons living elsewhere, due to differences in genetic makeups, the prevalence of comorbidities, and local health care infra structures [5]. It is therefore discouraging that the WHO's Solidarity Trial, which is comparing the safety and efficacy of four treatment options for COVID-19, currently includes only a few sites in Africa, Latin America, and South or Southeast Asia [6]. The global community must commit to supporting clinical trials in LMICs that contribute to the development of locally relevant interventions, while also ensuring that these efforts do not take resources away from other critical clinical and public health needs.

The manner in which participants are recruited into studies also raises equity considerations. For example, in the United States, there is substantial evidence that African American and Hispanic and Latinx patients are underrepresented among clinical trial participants [7]. This is a problem because, just like people from different parts of the world, people from different racial and ethnic backgrounds may respond differently to medical interventions [8]. While the reasons for racial and ethnic disparities in clinical trial participation are complex, one factor is reliance on recruitment strategies unlikely to generate significant minority enrolment, such as direct recruitment by physician-investigators at academic medical centers [9]. Proven strategies to increase the diversity of clinical trial participants include the development of culturally and linguistically appropriate communication materials, in-person recruitment at free clinics, and the careful use of financial incentives [10]. These and other strategies to overcome racial disparities in research will be

particularly important in Covid-19 clinical trials, given that the disease is infecting and killing African Americans at a disproportionately high rate [11].

Also important is support for research specifically focused on the unique needs of certain subpopulations. For example, residents of nursing homes and group homes for the developmentally disabled have been especially hard hit by the COVID-19 outbreak [12]. Because these populations have suffered a disproportionate share of the burdens of the pandemic, equity requires support for research specifically designed to reduce risk and improve outcomes in these institutional settings. Similarly, studies should focus on the unique needs of other populations that may be excluded from large-scale clinical trials, such as patients who are pregnant.

The looming issue with respect to research on treatments and vaccines for COVID-19 relates to control over any medical products that are developed. In most cases, companies that develop new medical products are entitled to patent them, even when the research is supported in part by government funds. Patents enable companies to exclude competition and charge high monopoly prices, which effectively blocks large portions of the global population from access to these products. This means that, even when individuals assume risks by participating in research that leads to the development of a medical product, they have no guarantee that, once the product is on the market, it will be made available in their community at a price they can afford.

Efforts are already underway to ensure more equitable access to COVID-19 treatments and vaccines. The WHO and some prominent government and industry leaders recently pledged to work together to ensure that "all people have access to all the tools to prevent, detect, treat and defeat COVID-19" [13]. Some companies have committed to making any such products that they develop available on a nonprofit basis [14]. One idea that will be considered at this year's World Health Assembly is a proposal to establish a mechanism for companies to "pool" patents and other intellectual property rights over COVID-19 products, making it easier for developers to access new technologies and for generic manufacturers to produce needed products at an affordable price [15].

Yet, while these are encouraging developments, they remain insufficient. The Trump administration has made clear that it has no interest in supporting any WHO-led initiatives, and, in any event, the WHO lacks the authority to override national intellectual property laws. While voluntary corporate philanthropy is admirable, with more than 100 vaccine candidates currently in development, there is no assurance that the companies making philanthropic pledges will be the ones whose candidate vaccines ultimately succeed.

What is needed is an international governance system to oversee access to COVID-19 vaccines and treatments. Given the fundamental ethical principle of equity in research, advocating for such a system should be a priority for everyone involved in designing, conducting, and funding clinical trials.

Ethical Issues in Placebo Controlled Trials for COVID-19 Vaccines

Multiple candidate vaccines for coronavirus are being evaluated scientifically in a process of unprecedented speed, and thousands of individuals around the world have volunteered to participate in placebo-controlled phase III field trials. If, or when, one of these candidate vaccines is proved to be safe and effective and receives an emergency use authorization by the Food and Drug Administration, will it continue to be ethical to enroll participants in other coronavirus trials that randomize half of them to a placebo? Some statements in the news media have claimed that it would be unethical to randomize anyone to a placebo control in a coronavirus vaccine trial once a vaccine is proven effective. This stance might be mistaken.

There are arguments that the use of placebo controls in candidate vaccine trials in the face of proven effective vaccines for a given disease is unethical because it violates the ethical principle of equipoise, held by many to be a fundamental norm for clinical trials. The equipoise principle requires that no patient should be randomized to a treatment or control intervention in a clinical trial that is known to be inferior to standard medical care. Clinical trials contrary to equipoise are alleged to violate the right of patients to medical care and the duty of care owed by clinicians. Some argue and contended that equipoise is fundamentally flawed in several published articles. The most general problem with equipoise is that it conflates the ethics of clinical research with the ethics of medical care. Ethical standards that govern medical care need not necessarily govern

ethics of clinical trials. However, even if equipoise is a valid norm for clinical research, it doesn't pertain currently to underway or planned coronavirus vaccine field trials.

Subjects in the coronavirus vaccine trials are healthy volunteers, not sick patients seeking treatment in the context of a clinical trial. Health care professionals who administer candidate vaccines within these clinical trials are functioning as researchers, not as clinicians providing standard treatment. Accordingly, randomizing trial participants to placebo when a proven effective vaccine exists does not violate equipoise or their right to medical care. Nor are trial participants in this situation denied a proven effective vaccine when they volunteer and give informed consent for participation in a placebo-controlled trial. After the first, or the first few, coronavirus vaccines have been demonstrated to be safe and effective, it is likely to take a considerable period of time before they become available for most people. Some individuals in the highest risk groups will likely receive priority access once an authorized or approved vaccine is available. This means that insofar as trial participants are unable to access a coronavirus vaccine outside the research setting, they will not be made worse off by trial participation. Indeed, they may be better off in view of a 50% chance of receiving a potentially effective vaccine. Those individuals who do have access to an effective vaccine outside the research setting are free to receive it instead of opting for vaccine trial participation. Others might choose to participate in a placebo-controlled vaccine trial for altruistic reasons despite their ability to otherwise receive access to a vaccine [16].

Some might argue that research participants become patients just by virtue of rolling up their sleeves to receive a shot of a candidate vaccine. While this is implausible, even if true, it doesn't follow that randomizing the individuals to placebo when a proven effective vaccine exists and is accessible violates their right to medical care. The right to medical care (more specifically, the right to receive an effective vaccine), like nearly all rights, is not an absolute, inalienable right. That right can be waived autonomously by individuals giving informed consent to participate in a clinical trial which randomizes them to either an experimental intervention or placebo. This is another reason why the equipoise principle is flawed, as it does not recognize that the right to medical care can be validly waived. Once a proven effective vaccine for coronavirus is developed, part of the disclosure to prospective participants in a placebo-controlled coronavirus vaccine trial is to inform them about this fact and the possibility that they might be able to get access to a vaccine outside the context of research [17].

The ethics of clinical research has generally been understood as essentially a matter of protecting the rights and well-being of research subjects. But this is too narrow an ethical focus. Also central to research ethics are the potential societal benefits from the knowledge to be gained from rigorous clinical research. Continued, socially valuable, placebo-controlled vaccine trials in the face of a proven effective coronavirus vaccine adequately protect subjects when they are designed and conducted in accordance with standards of scientific validity and the participants provide informed consent. The informed consent process affords these individuals the opportunity to decide whether they want to contribute to ethically sound clinical research with significant potential to contribute to population health. In the wake of the coronavirus pandemic raging around the world, it is highly desirable to develop multiple safe and effective vaccines. The most rigorous way to evaluate vaccines is by means of placebo-controlled trials. To put a stop to placebo-controlled vaccine trials once a single vaccine has been proven effective would be detrimental to population health [18].

REFERENCES

1. Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-Related Research Involving Humans (Geneva: CIOMS, 2016), guideline 3.
2. National Bioethics Advisory Commission, Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries (Rockville, MD: National Bioethics Advisory Commission, 2001).
3. Folley A. French Doctor Apologizes after Suggesting Africa for Coronavirus Tests. The Hill (blog), April 7, 2020.
4. Ibid.

5. Presidential Commission for the Study of Bioethical Issues, Moral Science: Protecting Participants in Human Subject Research (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2011).
6. Roussi A, Maxmen A. African Nations Missing from Coronavirus Trials. Nature 2020:4.
7. Loree JM, Anand S, Dasari A, Unger JM, Gothwal A, Ellis LM, Varadhachary G, Kopetz S, Overman MJ, Raghav K. Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018. JAMA Oncology 2019;5(10):e191870.
8. Racial and Ethnic Minorities in Clinical Trials, U.S. Food and Drug Administration, March 18, 2020, https://www.fda.gov/consumers/minority-health-and-health-equity/racial-and-ethnic-minorities-clinical-trials.
9. Borno HT, Bakke BM, Kaplan C, Hebig-Prophet A, Chao J, Kim YJ, Yeager J, Cinar P, Small E, Boscardin C, Gonzales R. A step towards equitable clinical trial recruitment: a protocol for the development and preliminary testing of an online prostate cancer health information and clinical trial matching tool. Pilot and Feasibility Studies 2019;5(1):1-8.
10. Taani MH, Zabler B, Fendrich M, Schiffman R. Lessons learned for recruitment and retention of low-income African Americans. Contempor Clin Trials Commun 2020;17:100533.
11. Thebault R. The Coronavirus Is Infecting and Killing Black Americans at an Alarmingly High Rate. Washington Post, April 7, 2020.
12. Hakim D. It's Hit Our Front Door: Homes for the Disabled See a Surge of Covid-19. New York Times, April 8, 2020.
13. Global Leaders Unite to Ensure Everyone Everywhere Can Access New Vaccines, Tests and Treatments for COVID-19. World Health Organization. April 28, 2020. https://www.who.int/news-room/detail/24-04-2020-global-leaders-unite-to-ensure-everyone-everywhere-can-access-new-vaccines-tests-and-treatments-for-covid-19.
14. Our Efforts to Develop a Vaccine and Identify Therapies for COVID-19. Johnson & Johnson, accessed April 28, 2020, https://www.jnj.com/coronavirus/prevention-and-treatment.
15. Hoen E. How the World Can Put Sharing above Profits in the Race for a Vaccine. Barrons, April 16, 2020. https://www.barrons.com/articles/a-vaccine-for-all-not-if-these-companies-and-countries-have-their-way-51586976476
16. Monrad JT. Ethical considerations for epidemic vaccine trials. J Med Ethics 2020;46(7):465-9.
17. Wendler D, Ochoa J, Millum J, Grady C, Taylor HA. COVID-19 vaccine trial ethics once we have efficacious vaccines. Science 2020;370(6522):1277-9.
18. Strassle C, Jardas E, Ochoa J, Berkman BE, Danis M, Rid A, Taylor HA. Covid-19 vaccine trials and incarcerated people—The ethics of inclusion. New Engl J Med 2020;383(20):1897-9.

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Review Paper

Karma and Corona: A Philosophical Perspective on COVID-19 As An Outcome of Cruelty Towards Animals By Humanity

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ABSTRACT

In the wake of a global pandemic called COVID-19, the world is enduring drastic human suffering in the form of deaths, draconian rules such as social-distancing, and country-wide lockdowns to combat this pandemic. What gave rise to this pandemic? This paper takes the position that COVID-19 is an outcome of cruelty committed by humans towards animals. In support of its position, this paper will make references to two Hindu cardinal laws, namely Paramātmā, and Karma, contained in the sacred Hindu epic, Bhagavad-Gita (the Gita).
This paper is presented in five parts. Section I will trace COVID-19's background. Section II will provide scientific proof that the pandemic originated in wildlife. In Section III, Zoonotic transfer from live animal markets as a source of infectious diseases will be explored. In Section IV, Karmic repercussions: The Hindu cardinal laws contained in The Gita will be explored. To this end, two Hindu cardinal laws, namely IV(A) Paramātmā, and IV(B) Karma will be discussed. In Section V, this paper will take the position that animal cruelty is the grossest kind of human ignorance, for which there are grave consequences. This paper will conclude that COVID-19 is an outcome for cruelty committed by humans towards animals, a response from the universe.
Key words: Karma, Corona, COVID-19, Animal Cruelty, Animals, Humanity.

Note: *COVID-19, Pandemic, and virus will be used throughout the paper as transposable terms***.**

Background
The world watched in horror as COVID-19 devastated China in early December. After witnessing massive growth in human fatalities spreading from China to all over the world caused by COVID-19, The World Health Organization (WHO) declared it to be a pathogenic pandemic on March 12th, 2020 [1].
COVID-19 is a type of virus that has symptomatic characteristics of a common cold such as fever, dry cough, continuous cough, and in severe cases, respiratory complications. It is believed to have originated from animals, and is believed to be zoonotic, i.e. it was transmitted from animals to humans. It is believed to have originated from either a live animal market or a laboratory in Wuhan, Hubei province, in China and has, up to date, caused an epidemic growth in human fatalities worldwide.

Scientific proof that COVID-19 originated in wildlife
As the world tried to cope with, and contain the catastrophic pandemic, it also simultaneously wondered in perplexity as to how it all started, i.e. the origins of the pandemic. Multiple theories,

some more conspiratorial than others, pointed its origins to a live animal market in Wuhan, a province in China, or that it may have been bioengineered in a laboratory in the same province, and that the virus infected humans, through an intermediary host animal. However, there is no confirmation from China as to the precise origin.

Nonetheless, this paper's research found an article published by The Lancet, in which 27 health scientists, from 9 countries, claimed, backed by reams of scientific proof, that the virus has a "natural origin," that it "originated in wildlife," and therefore, was not bioengineered.

Advocating full transparency, the health scientists claimed that the sources were researched by other health scientists, not only from China, but also "multiple countries," and they (the other health scientists) have analysed the genomes of the virus's causative agent, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and have found "overwhelming" conclusions that the virus "originated in wildlife [2].

If COVID-19 is a bat coronavirus, how did it infect humans? While initial research study results pointed to pangolins having a range between 85.5% and 92.4% genetic match to the virus, another study found the bat to have the closest match at 96%, making COVID-19 a bat coronavirus [3].

If COVID-19 originated from a bat, how did it infect humans, resulting in a global pandemic today? Or more appropriately, how did humans get infected by bats? Whether an animal infected a human or a human infected himself/herself by coming into close contact with the virus was the question. It was clear, however, that it was not the bat's fault! As one scientific researcher, Sara Platto from Jianghan University in Wuhan astutely noted [4]:

"The problem is not the animals, it's that we get in contact with them,"

This paper takes the position that cruelty towards animals is the reason why humanity is facing a global pandemic.

Zoonotic transfer from live animal markets as a source of infectious diseases

Many articles traced COVID-19 to a live animal market in Huanan, a province in China. This paper will focus on one article that succinctly summarizes the human activities in these live animal markets that have caused the virus to spread from animals to humans. According to this article, COVID-19 transferred to humans through close contact with many different wild animals *"being held together in confined spaces and small cages"* [5]. This close contact was brought about by "a variety of human activities [that] allow for consistent and regular interaction" such as *"hunting, butchering and farming (husbandry), as well as the global trade of animals and domestication of exotic animals as pets."*

It is no secret as to what happens in live animal markets. In these markets, animals face gruesome last moments in their lives before being mercilessly slaughtered for human consumption. Many mainstream media outlets have provided first-hand accounts of this practice. This paper chose two instances that follow:

In the first instance, a reporter for The National Review recounted:

"Terrified dogs and cats [are] crammed into rusty cages. Bats and scorpions [are] offered for sale as traditional medicine. Rabbits and ducks [are] slaughtered and skinned side by side on a stone floor covered with blood, filth, and animal remains." [6]

In the second instance, in The New York Post, the blood-spattered conditions in which the animals lived their last moments, side by side other dead and skinned animals, before being mercilessly slaughtered, was recounted by a reporter:

"In stall after stall, a mix of live and dead animals, which run the gamut from the known (pig, ox, duck, chicken) to the rare or unknown due to the condition of the carcass (,) stare back at you. In the wet areas of the market (,) usually reserved for fish and sea creatures and where the ground is slick with water and often blood (,) the stink is worse. The animals that have not yet been dispatched by the butcher's knife make desperate bids to escape by climbing on top of each other and flopping or jumping out of their containers (to no avail). At least in the wet areas, the animals don't make a sound. The screams from mammals and fowl are unbearable and heart-breaking." [7]

It is also important to note that while global pandemics such as SARS have also been linked to live animal markets in China, it is not the only country that maintains, and practices live animal

markets. In fact, the concept of live animal markets is hardly a novel revelation, but an ancient practice. Many countries around the globe, have historically maintained live animal markets for centuries. They still do. In many cities in the USA, live animal markets are maintained. In Minnesota, a study was conducted that showed a connection between live animal markets maintained there and the zoonotic transfer of viruses to humans [8]. Other countries that maintain live animal markets include Ghana, Nigeria, Mexico and Brazil, Hong Kong, Singapore and Malaysia, among others.
The cruelty faced by animals in the last moments before they are slaughtered by humanity comes back as karmic repercussions to haunt humanity for inflicting pain on animals. Animals suffered, so now humans suffer, for what humans did to animals.

Karmic repercussions: The Hindu cardinal laws contained in The Gita
In Hinduism, one of the oldest religions in the world, animal cruelty is perceived as one of the grossest kinds of ignorance and will give rise to serious karmic repercussions for humanity. In order to explain these karmic repercussions, this paper will discuss the most important cardinal rule of Karma alongside Paramātmā, both contained in the Bhagavad-Gita (the Gita).
For the purpose of clarity, the Gita is a Hindu scripture that is part of the Hindu epic, Mahabharata (The Great Dynasty). In Mahabharata, the struggles between two groups of cousins, the Kauravas and the Pandavas, in the age of the Bharata dynasty is recounted. Mahabharata, along with Ramayana, forms the two great epics in Hindu philosophical history.
The Gita, also referred to as the "song of god," is a conversation between the Supreme Soul, Krishna, and a human warrior, Arjuna, who is one of the Pandava brothers. In a deeper sense, the conversation is about an inner conversation that a human being has during his life with his or her belief in a higher power, i.e. the universe.
Cruelty towards animals is strictly condemned in the Gita, due to the belief that all life is sacred. In fact, the Gita goes further in its condemnation of animal cruelty by stating that it is not only the grossest form of ignorance, but it summons grave karmic repercussions for the killer from the universe:
"Slaughtering poor animals is also due to the mode of ignorance. The animal killers do not know that in the future the animal will have a body suitable to kill them. That is the law of nature. In human society, if one kills a man he has to be hanged. That is the law of the state. Because of ignorance, people do not perceive that there is a complete state controlled by the Supreme Lord. Every living creature is the son of the Supreme Lord, and He does not tolerate even an ant's being killed. One has to pay for it. So, indulgence in animal killing for the taste of the tongue is the grossest kind of ignorance." Bhagavad Gita 14:16 [9].

In the above quote, Krishna warns that if we live in ignorance of a higher power, that exists in all living things, and continue to mercilessly slaughter animals, we will pay for our actions.
In addition, Krishna warns that in the law of a state (state here means the material realm), we have laws to charge a man for killing another man, but in the law of the state controlled by the Supreme Lord (state here refers to the metaphysical realm), there are additional laws. These are the laws of Paramātmā and Karma, which advocate that all lives are equal, and all laws are therefore equal.

The Hindu cardinal law of Paramātmā
In Gita, we learn that all life is sacred in the universe, because of a cardinal law, namely, the existence of the Paramātmā or the Supreme Soul.
In Chapter 5, Text 18, Krishna says:
The humble sages, by virtue of true knowledge, see with equal vision a learned and gentle brahmana, a cow, an elephant, a dog and a dog-eater [outcaste]. Bhagavad Gita 5:18 [9].
In essence, Krishna as the Supreme Soul teaches us that while we as bodies are material production of different modes of material nature, we as living bodies, have souls within these bodies. All living things, animals or humans come under the premise of these living bodies. While each living body has its own soul, it is the Supreme Soul that lives in all living bodies. In this sense, Krishna as the Supreme Soul lives in all of us, humans and animals, "without distinction."

Therefore, we must treat each other with the due respect that we accord the Supreme Soul himself. It is due to this belief that Hindus accord animals equal respect and status as they would humans. It is due to this belief that they go further and accord the status of divinity to animals. Cruelty towards animals is seen as a grave sin, incurring grave karmic consequences in the cycle of samsara.

The Hindu cardinal law of Karma in the cycle of Samsara

The law that all life is sacred in the universe, because of the existence of a Supreme Soul is closely tied to another cardinal law, namely Karma. Karma does not simply mean action; it means more than that. Karma is an action that will always incur a reaction. If we commit bad actions such as rape, murder, we will incur bad reactions from the universe, such as life sentence and death penalty. If we commit good actions, such as engage in charitable activities or save someone's life from misery, we will incur good reactions such as good health, happiness, wealth, and beauty from the universe. Simply put, bad actions incur bad reactions. This is Karma.

The complexity about Karma is that these human actions, good or bad, and the ensuing reactions from the universe, good or bad, happen not in just one lifetime, but in multiple lifetimes. The karmic process in an ongoing and continuing process throughout the soul cleansing cycle (Samsara) of birth, life, death and rebirth (reincarnation), until the soul is cleansed of bad karma and attains Moksha (liberation of the soul) from material bondage to this world.

Following the laws of Paramātmā and Karma, then what has happened are actions so grave that they have incurred equally grave reactions from the universe in the form of a pandemic that is now causing an epidemic growth of human fatalities. This is the response from the universe churning out its own revenge on mankind, for treating animals with cruelty [9].

Conclusion: COVID-19 as a response from the universe on cruelty towards animals

"The greatness of a nation and its moral progress can be judged by the way its animals are treated."
Mahatma Gandhi

We live in a world where there exists a profound form of human hypocrisy. While most of us advocate that all lives are equal, the reality is that all lives are not treated equal. Therefore, all laws are not equal pertaining to humans, and animals.

How can we protect animals from cruelty? Who speaks for these animals? Who speaks for living things that have no voice to speak for themselves? Where is justice for these animals? If we see the deadly effects of COVID-19 on the world, the universe has spoken for the animals, and has provided a voice for the voiceless. As mentioned in section III, humanity will suffer if it inflicts suffering on animals. The Hindu laws speak for themselves. This is a response from the universe, which is handing out its own justice for cruelty towards animals.

As of November 8th, 2020, the COVID-19 resource centre of The John Hopkins University of Medicine has registered 49,968,373 global cases of COVID-19, with global deaths registered at 1,252,427 [10].

This is a massive number of global deaths that humanity can stop by preventing animal cruelty. There is hope, since animal activists and groups, including the Humane Society of the United States, People for the Ethical Treatment of Animals, and Animal Wellness Action, have started to pressure Asia, and other countries to stop the unsavory practices at live animal markets, and to close them completely [11].

In July 2020, in the state of Washington, a legal petition for rulemaking was filed with the U.S. Surgeon General to "shut down" live animal markets to prevent another zoonotic transfer and a global pandemic that could cost millions of lives worldwide [12].

The world is becoming aware of why we humanity is suffering through a global pandemic. COVID-19 is what humanity is paying for, in the form of deaths. for cruelty towards animals. The world has in fact noticed that maybe, this is a message from the universe.*

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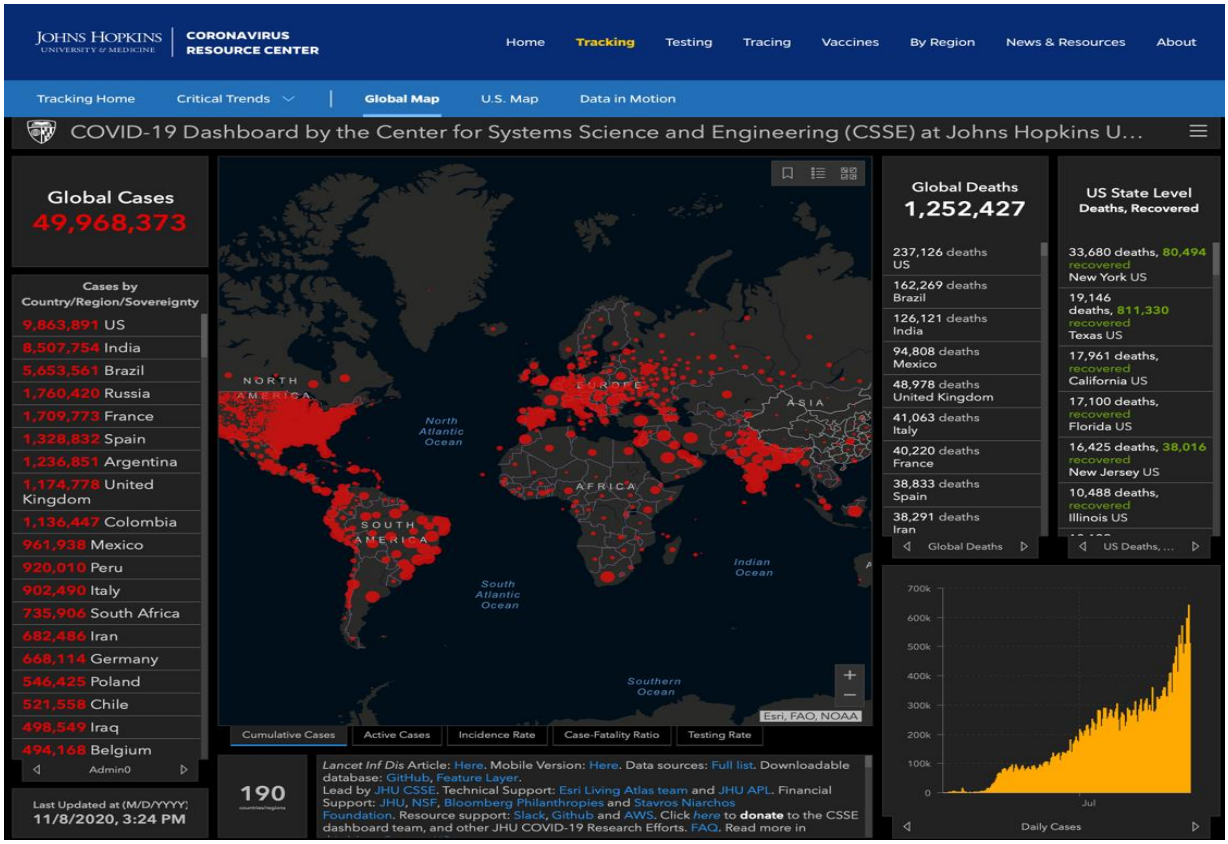

Figure 1

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**(In Hindu mythology, "Churning of the ocean of milk" is an expression to denote the perpetual battle between the devas or gods and the asuras or demons).*

REFERENCES

1. WHO announces COVID-19 outbreak a pandemic. (2020, March 12). Retrieved March 17, 2020, from http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic2
2. Calisher C, Carroll D, Colwell R, Corley RB, Daszak P, Drosten C, Enjuanes L, Farrar J, Field H, Golding J, Gorbalenya A. Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19. The Lancet. 2020 Mar 7;395(10226):e42-3.
3. Zhou P, Yang XL, Wang XG, Hu B, Zhang L, Zhang W, Si HR, Zhu Y, Li B, Huang CL, Chen HD. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature 2020;579(7798):270-3.
4. Cyranoski D. Mystery deepens over animal source of coronavirus. Nature 2020;579(7797):18–19.

5. Jandu, N. (2020, September 06). Human activities are responsible for viruses crossing over from bats and causing pandemics like coronavirus. Retrieved November 05, 2020, from https://theconversation.com/human-activities-are-responsible-for-viruses-crossing-over-from-bats-and-causing-pandemics-like-coronavirus-134226
6. Scully, M. (2020, April 15). China's Wet Markets, America's Factory Farming. Retrieved April 15, 2020, from https://www.nationalreview.com/2020/04/chinas-wet-markets-americas-factory-farming-both-violate-moral-common-sense/
7. Froelich, P. (2020, January 25). Inside the horrific, inhumane animal markets behind pandemics like coronavirus. Retrieved April 15, 2020, from https://nypost.com/2020/01/25/inside-the-horrific-inhumane-animal-markets-behind-pandemics-like-coronavirus/
8. Choi MJ, Torremorell M, Bender JB, Smith K, Boxrud D, Ertl JR, Yang M, Suwannakarn K, Her D, Nguyen J, Uyeki TM. Live animal markets in Minnesota: a potential source for emergence of novel influenza A viruses and interspecies transmission. Clin Infect Dis 2015;61(9):1355-62.
9. Bhaktivedanta Book Trust. Bhagavad Gita As It Is: with the original Sanskrit text, roman transliteration, English equivalents, translation, and elaborate purports. Los Angeles; 1986.
10. Johns Hopkins Coronavirus Resource Center. (2020, Nov 8, 2020). Retrieved Nov 8, 2020, from https://coronavirus.jhu.edu/
11. Ani. (2020, April 7). Broad coalition forming in US to pressure China to close wet markets. Retrieved April 9, 2020, from https://www.business-standard.com/article/news-ani/broad-coalition-forming-in-us-to-pressure-china-to-close-wet-markets120040800021_1.html
12. Doctors Urge Surgeon General To Shut Down U.S. Live Animal Markets. (2020, July 4). Retrieved November 05, 2020, from https://www.pcrm.org/news/news-releases/doctors-urge-surgeon-general-shut-down-us-live-animal-markets

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Position Paper

Nursing & Health Care Ethics Related to the COVID-19 Pandemic: Policy Guideline Recommendations Based on UNESCO's Universal Declaration of Bioethics and Human Rights

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This document was finalized in March 2021 at/near the one year anniversary of the initial declaration of the COVID-19 disease as a pandemic. First identified as 2019 novel coronavirus in China, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has circled our globe and further mutated along the way. While presenting individuals, teams, organizations, sectors and systems with significant challenges and difficult ethical burdens, it has also resulted in tremendous efforts toward collaboration and solidarity in ways that otherwise may never have been considered or realized. It is the sincere hope of members of the global nurse leaders panel that

lessons learned from COVID-19 will catalyze much needed changes in health care worldwide and not be simply forgotten. We respectfully honour those who have lost their lives to COVID-19; our family members, friends and loved ones, and colleagues.

UNESCO's Universal Declaration of Bioethics and Human Rights

In 2005, the United Nations Educational Scientific and Cultural Organization (UNESCO) adopted a *Universal Declaration of Bioethics and Human Rights* with fifteen core ethical principles. Further, the Declaration provides details about the scope, aims, application of principles, promotion of the declaration, and final provisions [please see https://unesdoc.unesco.org/ark:/48223/pf0000142825.page=80 for full text]. The core ethical principles offer guidance and a pragmatic lens for nursing practice and ethical decision-making across many sectors of health care around the world, and include:

- Article 3- Human dignity and human rights
- Article 4- Benefit and harm
- Article 5- Autonomy and individual responsibility
- Article 6- Consent
- Article 7- Persons without capacity to consent
- Article 8- Respect for human vulnerability and personal integrity
- Article 9- Privacy and confidentiality
- Article 10- Equality, justice and equity
- Article 11- Non-discrimination and non-stigmatization
- Article 12- Respect for cultural diversity and pluralism
- Article 13- Solidarity and cooperation
- Article 14- Social responsibility and health
- Article 15- Sharing of benefits
- Article 16- Protecting future generations
- Article 17- Protection of the environment, the biosphere and biodiversity

Additional Ethical Principles to Consider

Working with a framework of ethical principles, nurses strive to uphold a standard of care that meets professional, legal, and personal moral requirements for responsibility, accountability, and advocacy. While specific aspects of these ethical principles may vary based on social, cultural, and ethnic norms of a given country, the core ethical principles are largely consistent and ought to be adhered to in clinical, educational, and research practices.

- **Non-maleficence:** Nurses ought to promote and protect decisions and/or actions that will minimize, mitigate, or prevent harm. Risk management and harm reduction with and for the patient is a key responsibility of nurses, however, this includes advocacy for least restrictive and coercive measures.
- **Autonomy:** Nurses ought to respect and support a person's right to their own decision making process and choices. Respectful attention to and application of known past wishes and desires should be adhered to on behalf of patients who are not competent or capable of decision making. There are generally three conditions that are necessary for autonomy, including full disclosure of information, comprehension of the information, and a voluntary decision that is made without undue influence. Autonomous decision making may be achieved by an individual alone or by an individual with selected collaborators, including community members who may or may not be blood-related or considered to be close family members/kin.
- **Justice:** Nurses ought to be aware of the social determinants of health and promote fairness through the equal and/or equitable distribution of health burdens and benefits. Nurses ought to understand the barriers to achieving social justice within structures/systems and recognize factors unique to vulnerable and marginalized populations. Further, nurses

ought to seek knowledge about how the intersection of race, class, gender, and culture relate to health disparities, structural and systemic violence, oppression, and poor health outcomes. Also, justice includes issues of appropriate allocation of the right resources at the right time to patients who need care, in the spirit of proportionality. Even in emergencies, there is a need to deploy the right nurse/provider-to-patient ratio, with the right qualification and experience/expertise to protect and promote patient safety. In clinical research, nurses need to ensure that inclusion and exclusion criteria are justified, even in pandemics [1].

- **Beneficence:** Nurses ought to promote and protect decisions and actions that will maximize or restore benefits and good health outcomes. Further, nurses ought to promote and protect an individual's right to dignity at all times. In the interpersonal and therapeutic, professional relationship between a patient/client and a nurse, there must be a primary focus on helping and healing the patient. However, nurses often must navigate competing relational obligations to promote beneficence.
- **Truthfulness:** Nurses ought to seek to uphold a commitment to openness, honesty, integrity, and transparent decision making. Nursing care of the patient/client must be grounded in the best available scientific evidence and professional knowledge. Each patient/client must be cared for as an individual and at a level that seeks to address their needs and interests for further information.
- **Trust:** Nurses are among the most trusted health care professionals [2] and as such ought to seek to maintain and uphold this principle with patients, families, and communities. The public's trust in nurses is closely woven with an expectation for a high standard of ethical practice and compassionate care.

International Council of Nurses- Code of Ethics

First established in 1953, the International Council of Nurses' (ICN) *Code of Ethics* acts as a supranational model for ethical standards in nursing practice [3]. The latest version of the revised code (ICN, 2012), highlights four core nursing responsibilities [4]:

- Promote health
- Prevent illness
- Restore health
- Alleviate suffering

The ICN's code of ethics (2012) indicates that nurses must advocate for the human rights of patients, families, and communities. Therefore, nurses must work to address social issues through their practice in systems and within interdisciplinary teams. The ICN's code is currently under revision and it is expected to have a number of key additions, namely, the inclusions of nursing duties and obligations for challenging unethical behaviours and considerations for impacts to nursing related to technology, digital communications, and artificial intelligence [3]. An in-progress draft of the ICN's most current suggested revisions to the code of ethics for nurses is available online (https://www.icn.ch/system/files/documents/2020-10/CoE_Version%20for%20Consultation_October%202020_EN.pdf).

UNESCO's Chair in Bioethics Education Department's
Global Nurse Leaders Panel: National Codes of Ethics for Nurses

Australia: Australian College of Nursing/Australian Nursing Federation/Nursing and Midwifery Board of Australia, *Code of Ethics for Nurses in Australia* (2002; pp. 1-11) https://waubrafoundation.org.au/wp-content/uploads/2015/05/New-Code-of-Ethics-for-Nurses-August-2008.pdf

Canada: Canadian Nurses Association (CNA), *Code of Ethics for Registered Nurses* (2017; pp. 1-60) https://cna-aiic.ca/en/nursing-practice/nursing-ethics

India: Andhra Pradesh Nursing Council (APNMC), *Code of Ethics for Nurses in India* (n.d.; pp. 1-5) http://hmis.ap.nic.in/APNMC/pdfs/ethics.pdf
Israel: Israeli Nurses Federation - Ethic Division, *The Ethics Code of the Israeli Nurses* (2018; pp. 1-15) https://www1.health.gov.il/nursing/work/toolkits/code-of-ethics/
Hong Kong: The Nursing Council of Hong Kong, *Code of Ethics and Professional Conduct for the Nurses in Hong Kong* (2015; pp. 1-15) https://www.nchk.org.hk/filemanager/en/pdf/conduct.pdf
Kenya: National Nurses Association of Kenya (NNAK), *Code of Conduct and Ethics* (2009; pp. 1-20) https://eacc.go.ke/default/wp-content/uploads/2018/08/nnak-code.pdf
Sultanate of Oman: Ministry of Health, *Principles of Code of Professional Conduct for Nurses in the Sultanate of Oman* (2019; pp. 1-41) https://www.moh.gov.om/documents/106926/2918442/Principles+of+Code+of+Professional+Conduct+for+Nurses+in+the+Sultanate+of+Oman/d452d811-c765-473b-90b7-66d4761a028d
United Arab Emirates (UAE): Nursing and Midwifery Council, *Nursing and Midwifery Code of Conduct* (2013; pp. 1-17) http://www.uaenmc.gov.ae/Data/Files/Code%20of%20Conduct.pdf
United Kingdom (UK): Nursing and Midwifery Council, *The Code* (2015; online) https://www.nmc.org.uk/standards/code/read-the-code-online
United States of America (USA): American Nurses Association (ANA), *Code of Ethics* (2015; pp. 1-48) https://www.nursingworld.org/practice-policy/nursing-excellence/ethics/#:~:text=The%20American%20Nurses%20Association%20(ANA)%20Center%20for%20Ethics,rights%20at%20the%20state,%20national,%20and%20international%20levels

International Year of the Nurse and the Midwife Campaign 2020

Together, nurses and midwives represent almost a ¼ billion health care providers worldwide. To honour the important contributions of these professional carers, the World Health Organization designated the year 2020 as the *International Year of the Nurse and the Midwife.* This coincides with the 200th anniversary of Florence Nightingale's birthday. Known as the 'lady with the lamp' during the Crimean war, Nightingale was a nursing pioneer and leader whose thoughts and actions were far ahead of her time. Nightingale stood for "the value of stories, sensitivity, solidarity, space, scholarship and sustainability" [5]. These key concepts are still integral to the work of contemporary nurses who are committed to improving patient health outcomes, facilitating family-involved care, and integrating evidence-informed, best practices.

It is ironic that the *International Year of the Nurse and the Midwife* should coincide with the start of the COVID-19 pandemic. Further, the opportunity to reflect on the historical role of a nursing icon can offer (perhaps unexpectedly) important strategic priorities for nursing that have not changed very much over two centuries. Nurses still ought to seek the stories of patients, families, and interdisciplinary members of the health care team. Stories are an invaluable source of knowledge and understanding that can improve ethical decision-making, contextualize responsiveness, and contribute to better quality of care. Care interventions ought to be appropriate for the individual and their circumstances and delivered in compassionate ways (even during a global health crisis), with a sensitivity to contextual needs and factors. As nurses, we ought to serve in solidarity with each other and as key stakeholders in the health care organizations and systems that we are an integral part of. In the spaces and places that nurses work and live, we must promote and protect health, well-being, and safety for individuals and communities. Finally, scholarship and sustainability are ongoing commitments that nurses ought to continue to assertively pursue, as experts with unique knowledge and perspectives to creatively respond to our most difficult issues. This can only be attained if nurses speak up and speak out, not only in the contexts of courage, resilience, and hope, but also to boldly acknowledge and identify the harsh realities and sources of amenable suffering. In 2020, we were reminded about the many important historical contributions by Florence Nightingale, nurses, and midwives. Moving forward, let us not forget all that nurses and midwifes have to offer toward our combined efforts to achieve better health outcomes in our shared global village.

During the COVID-19 pandemic, a panel of global nurse leaders gathered in August of 2020 to participate in two international webinars (#18- https://www.youtube.com/watch?v=a6OGi-

1qZFk ; and, #19- https://www.youtube.com/watch?v=ieBxXj3eqWQ) hosted by the Education Department of the UNESCO Chair in Bioethics. The title for the sessions was "Medical ethics in the wake of the COVID pandemic: International panel discussion- Nurses, bioethics, and the response to the COVID-19 pandemic." Specifically, the global nurse leaders were tasked to address *Article 13- Solidarity and cooperation.* The panelists discussed their experiences and extraordinary challenges with COVID-19 in the context of their own countries and contexts, across 10 different nations. Shared goals, common experiences, and significant differences were identified and explored. From the fulsome panel discussions that occurred during the webinars, a manuscript was prepared and published in the international academic journal of the UNESCO Chair in Bioethics:

Jones-Bonofiglio, K., Arulappan, J., Brown, A., Cassells, K., Cooper, V., DiGangi Condon, K., Gurevich-Gal, R., Jeyasingh, R.C., Kalaimathi, S.A., Kezia, J.R., Leung, S., Titus, S., Neumann, J., & Atieno Wagoro, M.C. (2020, Dec) 'We are all in this together': Nurses and ethical issues during the COVID-19 pandemic. *Global Bioethics Enquiry, 8*(3), 177-181. https://globalbioethicsenquiry.com/wp-content/uploads/2021/02/VP2-NURSING-1.pdf

Therefore, members of the panel of global nurse leaders had opportunities to participate in *global social witnessing* through acts of solidarity and cooperation, by coming together as a community of nursing practice for the webinar series and through ongoing collaborative work to produce a publication. *Global social witnessing* allows for mindful attention and embodied awareness of global events, such as the COVID-19 pandemic. Such collective and individual social witnessing brings a shift from linear mental processing to an active compassionate response from mind, heart, and body (The Pocket Project, n.d.).

Purpose

The purpose of this document is to present a call to action and propose international health care ethics policy guideline recommendations in response to the COVID-19 pandemic from a global nursing perspective, in the context of *UNESCO's Declaration*. Specifically, these recommendations will follow the Declaration's Application of the Principles, namely:

- Article 18- Decision-making and addressing bioethical issues
- Article 19- Ethics committees
- Article 20- Risk assessment and management
- Article 21- Transnational practices

UNESCO's Chair in Bioethics Education Department's Global Nurse Leaders Panel: A Call to Action

The value of nurses has been recognized as essential during the coronavirus/COVID-19 pandemic. However, the value of nurses has not been upheld within global health care systems during this recent and ongoing crisis. Experiences of nurses during the pandemic indicate extreme psychological distress (e.g., fear, anxiety, grief, powerlessness, desperation, despair), stigma, inadequate access to personal protective equipment (PPE), unsafe infection control protocols, delayed testing and reporting, erratic messaging, understaffing, and reduced trust in employers, health care organizations, and governments [6]. Accurate numbers are not yet available to discern how many nurses' lives have been lost to the SARS-CoV-2 virus.

Members of the panel of global nurse leaders, which represents 14 individuals and 10 nations around the world, calls on governments, health care organizations, and other stakeholders to renew their commitments to more fully value and directly support nurses and their essential work with interdisciplinary teams across diverse health care practice settings.

The important contributions of nurses in our world's health care systems have defined nurses as much needed partners and key stakeholders in global health, both during crisis and beyond. As such, the panel members recommend the following call to action to be immediately implemented and to continue in an ongoing basis:

- Protect and promote the physical and mental health, well-being, and safety of nurses working in various health care areas/environments around the world.
- Recognize nurses as key stakeholders with the need for equal partnerships in local, national and global health care domains.
- Support leadership opportunities, continuing ethics education, and leadership training/development for nurses in various roles with organized efforts to garner nurses' engagement and meaningful consultation on direct and indirect matters of patient and family care, community and public health, and health policy/legislation development.
- Increase the number of nurses in formally designated leadership positions with decision-making power in health care organizations and government, especially those roles traditionally and exclusively held by medical doctors only.

Additional Calls to Action for Consideration:
American Nurses Association call to action report:
https://www.nursingworld.org/~4907b6/globalassets/docs/ana/ana-call-to-action--exploring-moral-resilience-final.pdf
American nurses call to action: https://www.aacn.org/~/media/aacn-website/policy-and-advocacy/the-fight-against-covid-19-joint-statement-4-10-20.pdf?la=en
ICN call to action: https://www.icn.ch/system/files/documents/2020-04/ICN%20briefing_COVID19_Top_priorities_ENG.pdf
Immigrant nurses call to action (Philippines/Pakistan):
https://onlinelibrary.wiley.com/doi/10.1111/jan.14432
Public health nurses call to action (USA):
https://onlinelibrary.wiley.com/doi/full/10.1111/phn.12733
WHO call to action: https://www.who.int/campaigns/world-aids-day/2020/key-messages

UNESCO's Chair in Bioethics Education Department's Global Nurse Leaders Panel: International Health Care Ethics Guideline Recommendations

Article 18- Decision-making and addressing bioethical issues

Ethical decision-making can be promoted and enhanced through activities that support nurses to uphold their obligations (duty of care) as professionals and their personal moral values as individuals and community members. Ethical issues in practice can be addressed with appropriate knowledge sharing and ongoing, engaged dialogue with stakeholders who represent diverse perspectives. As key stakeholders in health care systems globally, nurses must be included in all levels of planning and protocol development, including stewardship and allocation of resources. Even in crisis conditions, such as the COVID-19 pandemic, nurses must not be excluded from ethical decision-making activities.

Article 19- Ethics committees

Ethics committees in various health care settings support and guide research, clinical decision making, policy development, and/or ethics education and awareness. Within these important roles and responsibilities is the need for the voices of nurses, as the largest component of the global health care workforce and a vital part of the multidisciplinary cohort, in partnership with the organization and in alignment with essential mission, vision, and values statements. Even in crisis conditions, such as the COVID-19 pandemic, ethics committees must continue to be judiciously utilized to make evidence-informed decisions on protocols, policies, and practices.

Article 20- Risk assessment and management

Assessment, management, and mitigation of risk in various health care settings requires access to up-to-date, comprehensive, and timely information that is delivered via multiple modalities for communication. Risk must be assessed for all individuals within the health care setting including frontline care providers, administrative staff, management, senior leadership, patients, families/caregivers, and the community. Reasonable expectations for health protection and promotion of the many must be measured against legal and human rights of individuals, and through a lens of equity. Communication strategies must seek ongoing collaboration and coordination among and between health care organizations, public health, communities, and nations. Frontline nurses and other health care worker personnel must have their concerns about safety, protection, and adequate support addressed.

Article 21- Transnational practices

Transnational practices, in the context of the Declaration, largely refers to research endeavours and appropriate ethical and/or legal review and oversight. Within research endeavours, there are opportunities for much needed reciprocity through systematic and global approaches to facilitating data gathering, access, sharing, and utilization that may provide important and responsive benefits to urgent global health issues. Further national nursing organizations should have an engaged role in supporting research contributions, promoting education, and facilitating the uptake and utilization of evidence-informed findings, engaging all members across all health care sectors to respond in solidarity and cooperation. Such actions recognize and value the importance of the global efforts of nurses as a world-wide community of practice and enhance much needed access to quality information to inform decision-making.

Appendix A

Recommended Readings

1. Canadian Nurses Association (2020). *Nurses' ethical considerations during a pandemic.* https://cna-aiic.ca/-/media/cna/covid-19/nurses-ethical-considerations-during-a-pandemic_e.pdf
2. Berlinger, N., Wynia, M., Powell, T., Hester, D. M., Milliken, A., Fabi, R., & Jenks, N. P. (2020). Ethical framework for health care institutions responding to novel Coronavirus SARS-CoV-2 (COVID-19) guidelines for institutional ethics services responding to COVID-19. *The Hastings Center*, *12*. https://www.mentice.com/hubfs/COVID-19/White%20paper%202020%20-%20Hastings%20Center%20COVID%20Ethical%20Framework.pdf
3. Bursztajn H, & Levy-Carrick N. (2020, Dec 21). A pandemic of false choices. *Psychiatric Times*. https://www.psychiatrictimes.com/view/a-pandemic-of-false-choices
4. Hamilton, D. & Gallagher, A. (2020, Apr 16). COVID-19: nursing in a pandemic and how to apply ethical decision-making in practice. https://rcni.com/nursing-standard/opinion/comment/covid-19-nursing-a-pandemic-and-how-to-apply-ethical-decision-making-practice-159996
5. Huang, L., Lin, G., Tang, L., Yu, L., & Zhou, Z. (2020). Special attention to nurses' protection during the COVID-19 epidemic. *Critical Care, 24,* 120. https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-2841-7
6. International Council of Nurses. (2020, Sept 14). Protecting nurses from COVID-19 a top priority: A survey of ICN's national nursing associations. Author. https://www.icn.ch/system/files/documents/2020-09/Analysis_COVID-19%20survey%20feedback_14.09.2020%20EMBARGOED%20VERSION_0.pdf
7. Kreh, A., Brancaleoni, R., Magalini, S. C., Chieffo, D. P. R., Flad, B., Ellebrecht, N., & Juen, B. (2020). Ethical and Psychosocial considerations for hospital personnel in the COVID-19 crisis: Moral Injury and Resilience. *MedRxiv*. https://www.medrxiv.org/content/10.1101/2020.11.18.20232272v1.full
8. Jones-Bonofiglio K. (2020). *Health care ethics through the lens of moral distress.* Springer.
9. McGuire, A. L., Aulisio, M. P., Davis, F. D., Erwin, C., Harter, T. D., Jagsi, R., ... & COVID-19 Task Force of the Association of Bioethics Program Directors (ABPD). (2020). Ethical challenges arising in the COVID-19 pandemic: An overview from the Association of Bioethics Program Directors (ABPD) task force. *The American Journal of Bioethics*, *20*(7), 15-27.

10. Monforte-Royo, C., & Fuster, P. (2020). Coronials: Nurses who graduated during the COVID-19 pandemic. Will they be better nurses? *Nurse Education Today*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7387935/
11. Phelps, A. and Lawrence-Wood, E. (2020). The morals and ethics of the COVID-19 frontline. *Health & Wellbeing.* https://pursuit.unimelb.edu.au/articles/the-morals-and-ethics-of-the-covid-19-frontline
12. Shakya, D. R. (2020). Stress management-A way ahead. *Journal of BP Koirala Institute of Health Sciences*, *3*(1), 1-8. https://www.researchgate.net/publication/343239323_Stress_Management-_A_Way_Ahead
13. Shakya, D. R., Mishra, D. R., Gyawali, R., Rimal, S. P., Lama, S., Yadav, A. K., ... & Sapkota, N. (2020). COVID-19 Pandemic and BPKIHS: our situation, endeavors and future direction. *Journal of BP Koirala Institute of Health Sciences*, *3*(1), 39-49. https://www.researchgate.net/publication/343239404_COVID-19_Pandemic_and_BPKIHS_our_Situation_Endeavors_and_Future_Direction
14. The SARS Commission. (2006). *Executive summary: Spring of fear (volume 1).* http://www.archives.gov.on.ca/en/e_records/sars/report/v1.html
15. Ulrich, C. M., Rushton, C. H., & Grady, C. (2020). Nurses confronting the coronavirus: Challenges met and lessons learned to date. *Nursing Outlook*, *68*(6), 838-844. https://www.sciencedirect.com/science/article/pii/S002965542030659X?casa_token=9mwJrpc5BOYAAAAA:Lldv7pRKMQTkXCQwzMYB84HR3fMNMu_Lhsg7fACZDsSrhepB-S5kSt9Vuc8IpDd5P12s-kSg4Go
16. Vahidy, F. S., Bernard, D. W., Boom, M. L., Drews, A. L., Christensen, P., Finkelstein, J., & Schwartz, R. L. (2020). Prevalence of SARS-CoV-2 infection among asymptomatic health care workers in the greater Houston, Texas, area. *JAMA Network Open*, *3*(7), e2016451-e2016451. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768707
17. Wagoro, M. C. A**.,** Omondi, E.A., Cheptum, J.J., Munoru, F.M. &Nyansikera, R. (2020). Nursing patients with COVID-19 in Kenya: Balancing duty of care and fear. *Journal of Association of Kenyan Physicians, S14,* 3(2), s10- s17. https://www.researchgate.net/publication/341775142_Nursing_Patients_with_COVID-19_in_Kenya_Balancing_Duty_to_Care_and_Fear
18. World Health Organization, International Council of Nurses, & Nursing Now. (2020). State of the world's nursing 2020: Investing in education, jobs, and leadership. World Health Organization. https://www.who.int/publications/i/item/9789240003279
19. World Health Organization. (2020, Sept 17). Charter. Health workers safety: a priority for patient safety. Author. https://www.who.int/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf
20. Wright, D. K., Peterson, W., & Gifford, W. (n.d.). *Nurses ethical considerations during a pandemic.* Canadian Nurses Association. https://cna-aiic.ca/-/media/cna/covid-19/nurses-ethical-considerations-during-a-pandemic_e.pdf

REFERENCES

1. Wagoro MCA**,** Omondi EA, Cheptum JJ, Munoru FM, Nyansikera R. Nursing patients with COVID-19 in Kenya: Balancing duty of care and fear. J Assoc Kenyan Physicians 2020;3(2):s10-7.
2. Edmonds JK, Kneipp SM, Campbell L. A call to action for public health nurses during the COVID-19 pandemic. Pub Health Nurs 2020;37:232-4.
3. Stievano A, Tschudin V. The ICN code of ethics for nurses: a time for revision. Int Nurs Rev 2019;66(2):154-6.
4. International Council of Nurses (ICN). (2012). The ICN code of ethics for nurses. https://www.icn.ch/sites/default/files/inline-les/2012_ICN_Codeofethicsfornurses_%20eng.pdf
5. Gallagher A. Learning from Florence Nightingale: A slow ethics approach to nursing during the pandemic. Nurs Inquiry 2020;27(3):e12369.
6. Brophy JT, Keith MM, Hurley M, McArthur JE. Sacrificed: Ontario healthcare workers in the time of COVID-19. New Solutions: A Journal of Environmental and Occupational Health Policy 2021;30(4):267-81.
7. Jones-Bonofiglio K, Arulappan J, Brown A, Cassells K, Cooper V, DiGangi Condon K, Gurevich-Gal R, Jeyasingh RC, Kalaimathi SA, Kezia JR, Leung S, Titus S, Neumann J, Atieno Wagoro MC. We are all in this together': Nurses and ethical issues during the COVID-19 pandemic. Global Bioethics Enquiry 2020;8(3):177-81.

8. Gallup Politics. https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx
9. The Pocket Project. (n.d.). Global social witnessing. https://pocketproject.org/global-social-witnessing/?inf_contact_key=0a2a694a2ad63780e8c38c999156cb5acc0558ed5d4c28cbfab114022b1ec50d
10. United Nations Educational Scientific and Cultural Organization (UNESCO). (2005). Universal declaration of bioethics and human rights. https://unesdoc.unesco.org/ark:/48223/pf0000142825.page=80

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Original Research Paper

Ethical Oversight of Implementation Research In Rural Settings Of A Developing Country During The COVID-19 Outbreak

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ABSTRACT

Ethical oversight of the Institutional Review Boards (IRB) could facilitate the beneficial impact on the conduct of implementation research in rural settings during the public health emergency of international concern (PHEIC). There is a knowledge gap in the application of implementation research ethics to uphold the impact on the planning of community surveys during the COVID-19 outbreak in remote rural settings. This study aimed to underscore the implementation research ethics principles incorporated in the IRB review practice at the Department of Medical Research, Myanmar by examining the records of three implementation research proposals submitted between April to October 2020. These records targeted the self-help groups, malaria volunteers, and nutrition-support groups who will introduce the innovative interventions in the remote rural areas, malaria-afflicted communities and the households of women with young children in their first 1,000-days respectively. Given that social, economic, and local administrative issues contribute for the acceptability, adoption, and effectiveness of interventions, the IRB has seriously considered the strategic plan for community engagement at vulnerable sites during PHEIC in addition to the contextual equipoise. It is also imperative to introduce the protective measures to mitigate the transmission among the research team members and the target audience in the COVID-19 period. Safe data collection modes without any interpersonal contact are desirable. The improved awareness of implementation research ethics principles and the applications is crucial for further capacity strengthening of IRBs as next steps to fit their reviews with PHEIC in a resource-constrained environment
Keywords: Ethical oversight, Implementation research, contextual equipoise, community engagement, public health emergency, COVID-19

INTRODUCTION

A multidisciplinary nature and the involvement of multiple stakeholders are keys to implementation research in a real-world setting. It aims for sustainable health gains resulting from

successful interventions [1]. Throughout the implementation research process, there is a need for comprehensive and meaningful stakeholder engagement. Features of implementation research mainly include the relevance and responsiveness to local health priorities [2-3]. Along a similar vein with health policy and systems research, the Institutional Review Boards (IRB) raise several ethical issues in research design while reviewing the implementation research (IR) proposals. The Global Health Ethics Team at WHO, in collaboration with TDR, elucidated the important knowledge gap concerning the ethical implications of implementation research [4]. Ethical oversight of the Institutional Review Boards (IRB) could facilitate the beneficial impact on the conduct of implementation research in rural settings during the public health emergency of international concern (PHEIC) [5-10].

In late March 2020, Myanmar has reported its first confirmed cases followed by the effective response of the State to the public health emergency condition to curbing disease spread. Introducing non-pharmaceutical interventions coupled with the regulatory measures are in place. These interventions engender contact-tracing, testing, quarantine, mask-wearing, the prohibition of mass gathering and the official closure of religious and recreation sites, universities and colleges, schools, food establishments, the release of stay-home orders, and travel restrictions etc. Until mid-August, there were only 374 reported cases and six deaths. From then on, the number of positive cases among the tested increased up to over 1,000 every single day till the end of November 2020 according to the official reports [11]. Some of the public health interventions with or without the partnership with the International Non-Governmental Organizations (INGOs) and the development agencies temporarily halted at the beginning of the pandemic but resumed later by observing the universal precautions for mitigating COVID-19 transmission. Between April to October 2020 within the COVID-19 pandemic period, the IRB at the Department of Medical Research (DMR) in Myanmar has assessed five implementation research proposals with more than minimal risk under the full board review meetings [12]. Of these proposals, three studies included the innovative approach in rural settings through a myriad of volunteer groups in which only one study focused COVID-19 socio-behavioural aspect. Those groups reflected the most desirable form of community engagement to control non-communicable diseases, malaria and to prevent nutritional deficiencies in their specific project sites. Importantly, the selected proposals also demonstrated the unique feature of the collaborative research within the public health programs [13] launched by the Department of Public Health in partnering project management and supervision, sharing resources and technology with the International Non-Governmental Organizations (INGOs) in line with their official agreement (a memorandum of understanding) with the Ministry of Health and Sports (MoHS), Myanmar.

Particular ethical considerations in implementation research should cover about from whom and how informed consent can or should be obtained; balancing of risks and benefits that could accrue to different groups; the responsibility of researchers to address ancillary findings, especially where health systems are weak; and appropriate dissemination of results to ensure timely uptake and scale-up of successful interventions [2,3,13]. In times of public health emergencies such as infectious disease outbreaks, ethics guidelines for implementation research together with other forms of public health research become more stringent than before to safeguard the project team as well as the target beneficiaries [6]. Apart from the contextual equipoise, it is imperative to seek for ethical concerns linking to implementation research outcomes. As such, the focus will be on access, acceptability, reach, adoption, and utilization of health interventions and sustainability and scaled-up [14-15] within the weak rural healthcare infrastructure of the developing country amid pandemic restrictions and regulatory measures. In this connection, there is limited knowledge available to date in all parts of the world in relation to how IRBs respond to and appraise implementation research during the PHEIC with implications for further capacity building. Therefore, this study aimed to underscore the ethical challenges of implementation research proposals reviewed and considered during the COVID-19 pandemic from April to October 2020 at the IRB of the DMR.

METHODOLOGY

We performed the case-based reviews of three IRB records of implementation research related to public health interventions using the inclusive self-help groups (ISHG), trained malaria volunteers and the nutrition support groups. For each research project reviewed at the IRB, the analysis informed the project description, and a brief account on ethical considerations without revealing the actual title of the research projects and partner organizations (INGO A, B and C) to observe anonymity and confidentiality in line with Helsinki declaration. The methodology in constructing case studies followed a previous paper [16]. Ethical challenges in this study referred to ethical issues related to implementation research that needed to take into account during the IRB review process that were difficult to deal with, in the absence of clear guidelines or known precedents [4]. The IRB (DMR) exempted the review of this research. The administrative authorities provided permission to review the records for further analysis.

RESULTS

All three research projects provided strong justification to introduce IR in the selected contexts: target beneficiaries of primary health care services in rural areas, villages targeted for malaria elimination and low-income households of women with young children in their first 1,000-days. The national counterparts of the ongoing public health programs in Myanmar planned those research in collaboration with the respective INGOs.

The proposed study designs of three implementation research projects were variable. These included a pre-test and post-test quasi-experimental intervention study without a control group (case study 1), an open step-wedged cluster-randomized controlled trial (case study 2), and a mixed-methods study with serial cross-sectional surveys (case study 3). Brief project descriptions were shown in text boxes 1 to 3.

Text Box 1: Brief project description of viable inclusive self-help groups in rural areas

Case study 1

Implementation research for viable inclusive self-help groups to enhance strategies in primary health care coverage in rural households

Despite the increasing burden of non-communicable diseases (NCDs), significant gaps and inequalities in the healthcare delivery system pose as barriers in accessing and sustaining care and treatment. Furthermore, evidence of effective interventions targeting diabetes and hypertension as major NCDs in rural areas remains limited. A set of cost-effective interventions are planned at the village level in country X in collaboration with the INGO (A). The implementation research includes further scaling up and training of Inclusive Self-Help Group Volunteers (ISHG) to deliver health knowledge through health promotion sessions. Also, they will do basic screening service to refer to the primary health care (PHC) facilities, as well as to deliver ancillary services for the vulnerable groups and to establish the linkage with their closest PHC facilities.

Ethical considerations

In case-study 1, community engagement through intensive advocacy meetings with village authorities, influential persons, and the rural health centre staff are critical for trust-building to ISHG volunteers, and for creating mutual respect between them and PHC workers at the village level. The guidelines of the MoHS to prevent COVID-19 transmission should be in place when conducting the advocacy meetings for community engagement. Moreover, community consent is the appropriate choice rather than individual informed consent which should initiate from the inception of the project. Importantly, timely referral to the nearest PHC facilities for ancillary care

is crucial in line with instructions of MoHS after detecting any abnormality in screening that might include suspected COVID-19 cases. Expected benefits such as an increase in health knowledge, and understanding of feasibility, acceptability, and effectiveness of the proposed intervention will outweigh the risks thus encouraging the access of vulnerable households in the rural community to NCD-related primary health care services. During the process and end-evaluation, arrangements for data curation, data sharing, and data confidentiality between implementing partners requires careful deliberation particularly in the COVID-19 outbreak period.

Text Box 2: Brief project description of malaria volunteer groups in an endemic rural setting

Case study (2)

Implementation research to strengthen the malaria elimination strategies in the rural communities of country X

Despite the rapid expansion of the malaria program coverage, an emergence of artemisinin resistance and the existence of pocket areas of residual infection deter the National Malaria Control Programmes (NMCP) to meet the targets for malaria elimination goal by 2030. In this context, the NMCP in country X partnered with the INGO (B) to identify and implement the new package of malaria interventions. The innovative community-based integrated model will encompass strategic interventions through the deployment of trained malaria volunteers. Project villages are to be included by a step-wedged pattern that differs from the traditional model. The new model focuses on the expansion of the scope of activities of malaria volunteers as opposed to the conventional model. It will include the additional screening for dengue, filariasis, TB and HIV/AIDS. Moreover, appropriate referral service will provide more opportunities for them to test malaria by RDT among rural householders who are not in easy access due to their mobile nature of livelihoods.

Ethical considerations

For case-study 2, it is the responsibility of the health systems while engaging and working with vulnerable populations in villages with the potential for pockets of residual malaria and prone not only to the risks of outbreaks but also to other vector-borne diseases such as dengue and filariasis and major killers like TB and HIV/AIDS. There is the uncertainty of how the proposed intervention package will be accepted and be effective within the given context that is 'contextual equipoise'. While implementing the intervention, the responsibility for the provision of ancillary care for illnesses other than malaria is required. Expected benefits such as an increase in understanding of feasibility, acceptability and improved access to the proposed intervention will outweigh the risks to enhance the malaria elimination activities. For trust-building to newly equipped malaria volunteers, community engagement through intensive advocacy meetings with village authorities, influential persons and the rural health centre staff is critical. To avoid the invasion of privacy and discomfort by interviewing the community members and village authorities by the trained malaria volunteers of the same locality, separately trained interviewers by the research team should perform the recruitment and taking the informed consent and the evaluation of the proposed intervention activities. In times of public health emergency, it would be essential for malaria volunteers to practice the universal precautions to prevent COVID-19 transmission. Data sharing and data confidentiality process between implementing partners of the proposed intervention requires careful deliberation.

Text Box 3: Brief project description of nutrition support groups in poverty stricken rural sites

Case study (3)

The add-on mixed methods study of implementation research by the nutrition support groups concerning COVID-19 risk perceptions and risk mitigation behaviours in households of women with young children in their first 1000-days

The poverty-stricken rural communities of Regions A and B of Country X have reported a high prevalence of malnutrition in under-five children due to low exclusive breastfeeding, improper infant and young child feeding practices, lack of dietary diversity, and food insecurity as an impact of insufficient agricultural resources. As guided by the National Nutrition Center, the INGO (C) has introduced the "Enhanced Homestead Food Production Program" with emphasis on the behavioural change communication aimed at correct feeding practices for young children in their first 1000-days combined with the arrangements of adequate water supply for hygiene and sanitation in these areas. During the COVID-19 pandemic period, the nutrition support groups of INGO (C) have distributed preventive materials to project households. They would like to assess the risk perceptions of householders and their risk mitigation practices for COVID-19 as an add-on study. The study covered the EHFP program beneficiaries and the respective health and local authorities and purposively selected community members. Due to the semi-lockdown conditions, the research team planned two-rounds of quantitative and qualitative data collections through mobile phones.

Ethical considerations

In case-study 3, community engagement through comprehensive advocacy meetings to be arranged for village authorities and other influential persons is critical in the enhancement of trust-building between the nutrition support groups and the community regarding the use of COVID-19 preventive measures and to avoid confusion between the on-going nutrition project and the add-on research study using mixed methods. Since the researchers have planned to use the phone-based data collection, there is an unequal chance of selection for the households without mobile phone access. Also, passing on the phone among the household members might pose increased health risks that might outweigh the benefits. The data collection planned by the responsible staff of the implementing organization of the particular locality might create undue influence and conflict of interests. The validity of verbal consent by the selected respondents during the stressful time is questionable. The research team should inform the respondents about their right in refusal to participate in this research that could not affect the program benefits obtained. Respondents could receive mobile money for their phone bills, not more than three USD is considered appropriate as an incentive for participation which is equivalent to the daily minimum wages as of 2019 in Myanmar. Keeping the survey short by avoiding lengthy and ambiguous questionnaires is to reduce the cost, time, and frequency of phone calls as well as to avoid the discomfort of research participants. Data confidentiality and data sharing among the implementing partners is highly desirable to support the dissemination and utilization of salient findings to the target beneficiaries that aims to support sustainability.

DISCUSSION

The claim of this present study mainly addresses the role of IRBs to perform thorough scrutiny in implementation research ethics during the pandemic period in remote rural settings without adequate healthcare infrastructure to achieve quality ethics oversight. One study from India provided a strong evidence to foster ethical biomedical and health research during the COVID-19 pandemic [17]. Each proposal fulfilled the specific components in designing the implementation research study [4]. Table 1 summarized the specific ethical challenges encountered in each proposal.

Table 1: Summary of ethical challenges in implementation research during COVID-19 pandemic in Myanmar (April to October 2020)

Ethical challenges	Case 1 Inclusive self-help groups for primary health care	Case 2 Malaria volunteers	Case 3 Nutrition support groups (add-on mixed methods COVID-19 perception survey)
Study design	-	*	-
Study context/relevance	*	*	*
Acceptability of intervention	*	*	*
Equipoise	-	*	-
Sustainability	*	*	*
Incentives	*	*	*
Quality control	*	*	*
Group/community consent	*	*	-
Selection of community representatives	*	*	*
Ancillary care	*	*	*

*Source: Adapted from- Ethics in implementation research. Facilitator's guide. Geneva: World Health Organization; 2019. *- denotes the specific ethical consideration*

Ethical challenges in implementation research particularly in time of PHEIC as noted in three case records varied in terms of the study design, contextual equipoise, recruitment, and community consent. There is an argument on the necessity of special consideration on ethical issues in the design and conduct of stepped-wedge cluster-randomized trials in both high- and low-resource settings in terms of the justification for using the design, and the classification of the study as research or non-research [18-19]. Unlike the intervention study without a control group (case study 1) and a mixed-methods study with rounds of cross-sectional surveys (case study 3), the step-wedged cluster randomized controlled trial (SW-CRT) (case study 2) raised some ethical considerations together with methodological constraints. In a low-resourced setting, the application of SW-CRT was feasible and relevant particularly related to a delay in rolled out of the intervention package for malaria elimination to some control villages. Nevertheless, in terms of risk-benefit assessment, the risks in delay should be considered as important as the intervention is perceived to be superior compared to the standard of care [18].

Adequate protection of human research participants in selected villages to mitigate ethical challenges relied upon the application of specific ethical guidelines by the research team as suggested by the IRB. Furthermore, the IRBs should scrutinize for the underlying reason in the choice of clusters (villages) as the first step to introduce interventions by targeting the mostly needed ones as described in case study 2. However, SW-CRTs are less efficient, more prone to bias, and expose more people to harm than conventional RCTs. Practical and logistical reasons for using a CRT or SW-CRT should be weighed against the possible advantages of more rigorous methods such as conventional RCTs [18]. In addition, observing the contextual equipoise of the proposed implementation research is the real challenge for IRB members due to uncertainties and unexpected events like disasters and public health emergencies [5,6,9]. It is particularly true in case study 2.

Given that social and economic and local administrative issues contribute to the acceptability and effectiveness of interventions in all case studies in this research, the IRB has seriously considered the strategic plan proposed by the research teams for community engagement in their project sites during public health emergency where vulnerable communities existed with health inequities [6, 10]. The IRBs need thorough scrutiny of the transparent recruitment procedures fit to pandemic restrictions as well as the informed consent forms to observe autonomy [20] either in the form of

community consent to reach vulnerable households or the individual ICF used during the initial, mid-term, and end-evaluation surveys as noted in case study 3 with an addendum of two rounds of COVID-19 perceptions survey. Balancing risks and benefits and plans to provide ancillary services by the implementing partners or the appropriate referral service could pave the way to the ethical conduct of implementation research [2,21]. Data sharing platforms varied by the source of data and methods of data collection thus creating difficulty to maintain data confidentiality also noted by other studies [11].

In the context of the COVID-19 pandemic, IRBs need to consider specific elements of research proposals during the ethics review process. An ethics oversight should focus on the compliance of each and every study with the international and local laws, rules, and guidelines for responses towards disasters and public health emergencies and strict adherence during the actual conduct [8, 22]. Moreover, during the unprecedented COVID-19 pandemic period, it was imperative to introduce protective measures/strategies to safeguard against and to mitigate the transmission and risk of acquisition of infection for both research team members and the target audience [6]. Optimizing uptake of evidence-based interventions such as using personal protective equipment is mandatory already included in the ethical considerations of the provided case studies in this research. The adherence to COVID-19 restrictions enhances the use of safe data collection modes without any interpersonal contact such as using mobile applications, and telephone interviews to avoid undue risks as noted across all case studies. Also, ethics reviews should focus on transparency during recruitment [9,23]. The arrangements for ethical dissemination of salient findings by virtual means during the PHEIC mainly depend on the complex nature of implementation research being based upon multi-stakeholders' involvement at different levels of the healthcare system [7].

Strengths and limitations

This is the first study reported from the IRB of a developing country where there is successful planning for implementation research projects of various designs in rural communities during the pandemic period. All of these proposals require appropriate modifications for ethical conduct during the period of PHEIC after paving their way through the IRB review process. However, in this study, we could not explore ethical issues/challenges involved in all types of implementation research designs.

Conclusions

Reviewing and appraisal of the implementation research proposals by IRBs in low-constrained settings is not an easy task. Current IRB review forms may require revisions to fit with epidemic ethics as well as for an implementation research incorporating public health interventions. Besides, IRBs should attempt for an after-review process and remote monitoring during the pandemic period by guiding the researchers to submit the progress reports regularly for the fulfilment of quality ethical oversight. The formidable challenges raised in implementation research ethics are manifold that requires attention to develop specific ethics framework and indicators in low resource settings. The evidence informed IRB policy and procedures for implementation research ethics is a necessity to improve awareness and meaningful applications. It is crucial for further capacity strengthening of IRBs as next steps to fit their reviews with PHEIC in a resource-constrained environment.

REFERENCES

1. Hales S, Lesher-Trevino A, Ford N, Maher D, Ramsay A, Tran N. Reporting guidelines for implementation and operational research. Bull World Health Organisation 2016;94(1):58–64
2. Macklin R. Ethical challenges in implementation research. Public Health Ethics 2014;7(1):86–93.
3. David H. Peters, Nhan T. Tran, Taghreed Adam. Implementation research in health: a practical guide. Alliance for Health Policy and Systems Research. World Health Organization.2013.
4. Ethics in implementation research. Facilitator's guide. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

5. World Health Organization. Guidance for managing ethical issues in infectious disease outbreaks. Geneva. Switzerland 2016.
6. WHO. Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R & D. 2020. https://apps.who.int/iris/bitstream/handle/10665/331507/WHO-RFH-20.1-eng.pdf.
7. WHO. Guidance for research ethics committees for rapid review of research during public health emergencies. 2020. file:///C:/Users/User/Downloads/9789240006218-eng%20(3).pdf
8. Research in Global Health Emergencies: Ethical Issues. Nuffield Council on Bioethics, 2020.
9. Yeoh KW, Shah K. Research ethics during a pandemic (COVID-19). International Health 2020:1-2.
10. McGuire AL, Aulisio MP, Davis FD, Erwin C, Harter TD, Jagsi R, Klitzman R, Macauley R, Racine E, Wolf SM, Wynia M, Wolpe PR & The COVID-19 Task Force of the Association of Bioethics Program Directors (ABPD) Ethical Challenges Arising in the COVID-19 Pandemic: An Overview from the Association of Bioethics Program Directors (ABPD) Task Force. Am J Bioethics 2020;20(7):15-27.
11. MoHS. COVID-19 Surveillance Dashboard. Ministry of Health and Sports, Myanmar 2020. https://www.mohs.gov.mm
12. Database of the Institutional Review Board, Department of Medical Research. 2020.
13. Wai KT, Aye N.S. Collaborative Research in Health Sector. In: Wai KT, Aung W, Oo ZZ. (eds). Principles of Responsible Conduct of Research and Research Ethics: A Handbook. Department of Medical Research, Ministry of Health and Sports, Myanmar, 2020. https://www.mohs.gov.mm
14. Win HH, Wai KT. Implementation Research Ethics. In: Wai KT, Aung W, Oo ZZ. (eds). Principles of Responsible Conduct of Research and Research Ethics: A Handbook. Department of Medical Research, Ministry of Health and Sports, Myanmar, 2020. https://www.mohs.gov.mm
15. Proctor E., Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et.al. Outcomes for implementation research: conceptual distinctions, measurement challenges, research agenda. Adm Policy Mental Health 2011;38:65-76.
16. Gopichandran, V., Luyckx, V.A., Biller-Andorno, N. et al. Developing the ethics of implementation research in health. Implementation Sci 2016;11:161.
17. Kumar NK, Muthuswamy V. Fostering ethical biomedical and health research in India during the COVID-19 pandemic. Research Ethics 2020;16(3-4):1-10.
18. Joag, K., Ambrosio, G., Kestler, E. et al. Ethical issues in the design and conduct of stepped-wedge cluster randomized trials in low-resource settings. Trials 2019;20(703).
19. Hemming K, Taljaard M. Reflections on modern methods: when is a stepped-wedge cluster randomized trial a good study design choice? Int J Epidemiol 2020;10;1043-52.
20. van der Graaf, R., Cheah, P.Y. Ethics of alternative trial designs and methods in low-resource settings. Trials 2019;20:705.
21. Leadbeater, B.J., Dishion, T., Sandler, I. et al. Ethical Challenges in Promoting the Implementation of Preventive Interventions: Report of the SPR Task Force. Prev Sci 2018;19:853–65.
22. Tindana PO, De Vries J and Kamuya D. Ethical challenges in community engagement practices in research during the COVID-19 pandemic in Africa. AAS Open Res 2020;3:23.
23. Mathur, R. Ethics preparedness for infectious disease outbreaks research in India: a case for novel coronavirus disease 2019. Indian J Med Res 2020;151(2 & 3):24–31.

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Original Research Paper

Awareness Of Patient's Responsibilities Amongst the Patients Admitted in Various Hospitals in Belagavi City

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ABSTRACT

Background: Successful medical care requires ongoing collaboration between patients and physicians. Their partnership requires both individuals to take an active role in the healing process. Autonomous, competent patients control the decisions that direct their health care. With that exercise of self-governance and choice, comes a number of responsibilities. These responsibilities are presented to patients in the spirit of mutual trust and respect. Hence the objective of this study is to assess the awareness of admitted patients in various hospitals in Belagavi about their responsibilities.
Methodology: A cross sectional observational study was conducted amongst the admitted patients of various hospitals in Belagavi, for a period of three months. Data were collected using pre-tested questionnaire forms. The collected data was analyzed with SPSS V.20software. Analyzed Results were expressed as percentage using appropriate tables and figures.
Results: 140 IPD patients accomplished the questionnaire on the awareness of patient's responsibilities of which 76.14% patients were aware and 23.86 % were unaware of their responsibilities towards the health care.
Conclusions: This study concludes that a large number of IPD patients are aware of their responsibilities and also signifies the importance of educating the remaining small number of IPD patients about their responsibilities.
Key words: patient's responsibilities, awareness, responsibility, Belagavi

Introduction

The American Medical Association has provided a list of patient responsibilities, said to be derived from patient autonomy [1]. What are the basic responsibilities which patients should be aware of [2] :

- Providing accurate and complete information.
- Asking questions
- Following instructions given by doctors

- Following facility, rules and regulations
- Showing Respect and thoughtfulness
- Meeting financial commitments
- To follow treatment plan.

Madhok from India has reported doctors being, thrashed and abused by lay public for a trivial fault. According to them the causes of violence were lack of communication between doctor and patient, poor image of medical profession, lack of faith in judicial system and police, besides insufficient security for doctors [3].
A report from Bangladesh also throws light on fact that violence in healthcare system has been increasing at alarming level [4]. A national survey in Australia revealed that 58% of General Practitioners had experienced verbal abuse and 18% experienced property damage [5]. The medical profession and medical ethics currently place a greater emphasis on physician responsibility than patient responsibility. This imbalance is not due to accident or a mistake but, rather is motivated by strong moral reasons. As we debate the nature and extent of patient responsibility it is important to keep in mind the reasons for giving a relatively minimal role to patient responsibility in medical ethics [6].

Factors Influencing Patient Participation in Health Care Decision-Making are affected by individual factors, such as

- Demographic characteristics [7-8];
- Personal characteristics (reads a lot, is mentally ok, can express himself) [6,9];
- Level of acculturation [7],
- Cultural knowledge and beliefs [9],
- Values and practices concerning health and care [7],
- Having physical ability, cognitive and emotional relation with others [9-10],
- Knowledge, beliefs, values and experiences in regard to mainstream health care services [7]

This study is to find out whether inpatients are aware of their responsibilities or they have to be educated in ethical and effective counselling methods for understanding their role and duties which will contribute to increasing patients' involvement in their care and also factors affecting their awareness of in patient's responsibilities. The study was aimed to study the awareness of inpatients responsibilities towards hospital, doctors and their treatment

METHODOLOGY

Source Of Data: The patients admitted in IPD of various hospitals of Belagavi city, with willingness to participate in survey were taken. Informed written consent was taken from the patients after obtaining detailed history. Evaluation was done with the help of performed parameters.

Research Design: Case series observational study
Study Period: 3 Months
Sample Size: 140
Tool: Pretested validated questionnaire
Inclusion Criteria

- In patients who are conscious and can understand and speak
- Either sex
- Age from 18 and above

Exclusion Criteria

- Unconscious ICU patients

- Patients less than 18 years
- Patients suffering from terminal illness

Method of collection of data

Patients were selected on the basis of inclusion & exclusion criteria. Minimum sample

RESULTS

Table 1: Gender based awareness: Descriptive Statistics

Gender	Average Awareness	Std. Dev. of Awareness	Min Awareness	Max Awareness
F- 48	6.9	3.0	0	10
M- 92	8.0	2.4	0	10
Grand Total- 140	7.6	2.7	0	10

Graph 1: Occupation based awareness among male and female

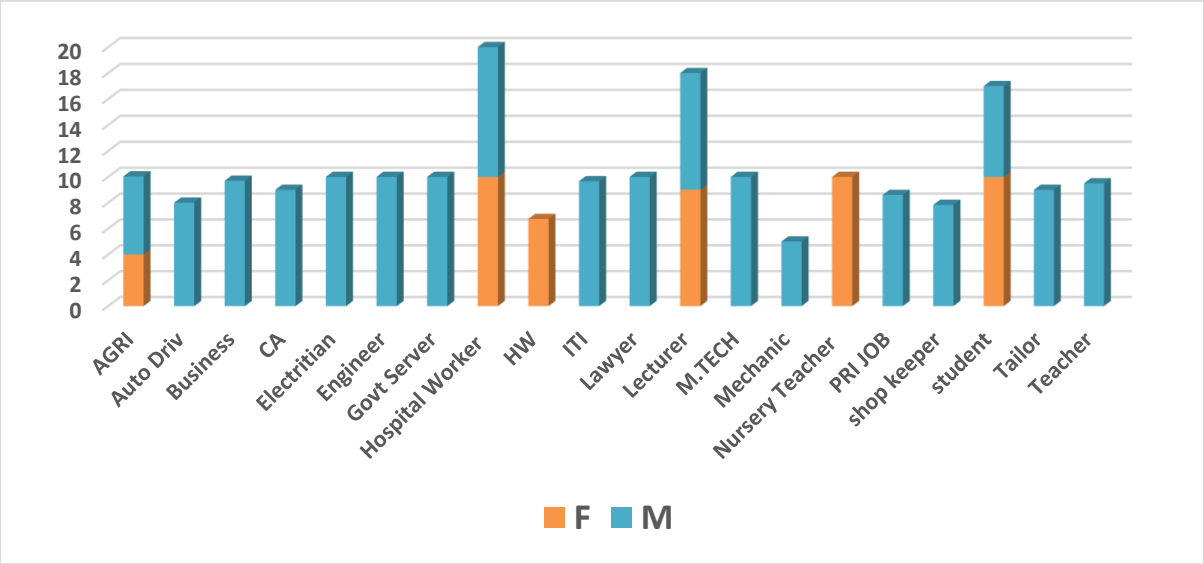

Table 2: Awareness among various age groups: Descriptive statistics

Age group	Average of Aware	Std Dev of Aware	Min of Aware	Max of Aware
18-30	7.5	2.859006	0	10
30-50	7.8	2.399863	1	10
50-70	7.5	2.856091	0	10
70-90	6.8	3.259175	0	10
Grand Total	**7.6**	**2.673035**	**0**	**10**

Table 3: Awareness based on education and gender

Education	Age group				
	18-30	30-50	50-70	70-90	Grand Total
Graduate+	9	9	10	10	9
High school	6	7	8	5	7
Higher secondary	7	8	9	7	8
Primary	8	6	7	10	7
Informal	7	7	5	6	6
Illiterate		7	5		6
Grand Total	8	8	8	7	8

Table 4: Chi-Squaretest for significance

Chi-square Test for significance

Variables	Pearson Chi-Square	P-Value	@5% level of Significant
Occupation	176.16	0.756	Insignificant
Age	32.81	0.331	Insignificant
Education	85.41	0.000	Significant
Gender	20.77	0.023	Significant

140 IPD patients accomplished the questionnaire on the awareness of patient's responsibilities of which. 76.14% patients were aware and 23.86% were unaware of their responsibilities towards health care. Factors influencing the awareness according to this study are as follows -
Education: Is significant association factor
Gender: Has significant association where males were more aware than females.
Age: Has no significant difference as awareness was equal among all the age group of IPD patients
Occupation: Has no significant association with awareness.

DISCUSSION

Patient responsibilities are important towards health care and hospital and are required in health care ethics, but is not followed up to the mark by patients as they are more inclined towards rights than responsibilities. Our modern societies have always given special prominence to patients' rights, but rarely acknowledged the existence of their responsibilities. However, rights have to be fully balanced with obligations. Patients are not only duty-bound by the traditional relationship they have with medical professionals, but also by their role in society through healthcare. Nowadays, as societies cannot afford irresponsible behaviour from the public in health care systems, more attention has been paid to patients' duties. These do not just have moral consequences, but also legal ones. Can a patient be held responsible for a bad outcome in a medical treatment? Recent debates have shown that this question is a global problem, and it therefore

requires an international overview. Such a study will help to clarify patients' duties and show how the legal system deals with them and what has been done so far to engage more patients in their own health. This survey helped me to understand the views of inpatients responsibilities towards hospitals and doctors. In our study we found out that 76.14% patients were aware and 23.86% were unaware of their responsibilities towards health care. No such studies were conducted on patient's responsibilities amongst the inpatients hence; this study reveals a valid data about the Awareness of inpatients responsibilities in various hospitals.

What can be done?

- In hospital-to identify less educated patients with help of questionnaire format and educate them.
- Globally this questionnaire can be filled online and applied globally.
- Mobile app can be developed on questionnaire and can be analysed.
- General rules and regulation can be displayed in the form of videos

What can be the outcome?

- Some services may be free in hospitals which can be brought to notice
- Medicines can be replaced and taken.
- Maximum benefits can be taken like ESI scheme and govt policy where even uneducated patients can be identified and informed.
- For all the above, good communication between admin department, PRO and Doctors with patients will help to take maximum benefits from the hospital.

The study was conducted only on inpatients of few hospitals in Belagavi city. An extensive study should be done including greater number of hospitals in more geographical regions. Further studies are needed to analyze the Awareness of patient's responsibility with the broader scope including various hospitals in different geographical locations.

REFERENCES

1. Gauthier CC. The virtue of moral responsibility and the obligations of patients. J Med Philos 2005;30(2):153-66.
2. https://www.arnothealth.org/patients-responsibilities
3. Madhok P. Violence against doctors. Bombay Hospital Journal 2009;51(2):301–2.
4. Ham Nazmul Ahasan, Aparna Das. Violence against doctors. J Medicine 2014;15:106-8.
5. Rasul CH. Violence towards doctors. Bangladesh Medical Journal. 2012;43(1):3-5.
6. Thompson AG. The meaning of patient involvement and participation in health care consultations: a taxonomy. Soc Sci Med 2007;64(6):1297–310.
7. Johnstone MJ, Kanitsaki O. Engaging patients as safety partners: some considerations for ensuring a culturally and linguistically appropriate approach. Health Policy 2009;90(1):1–7.
8. Davis RE, Jacklin R, Sevdalis N, Vincent CA. Patient involvement in patient safety: what factors influence patient participation and engagement? Health Expect 2007;10(3):259–67.
9. Bastiaens H, Van Royen P, Pavlic DR, Raposo V, Baker R. Older people's preferences for involvement in their own care: a qualitative study in primary health care in 11 European countries. Patient Educ Couns 2007;68(1):33–42.
10. Larsson IE, Sahlsten MJ, Sjostrom B, Lindencrona CS, Plos KA. Patient participation in nursing care from a patient perspective: a Grounded Theory study. Scand J Caring Sci 2007;21(3):313–20.
11. American Medical Association.1847."Code of Ethics, Chapter 1, Article II, Obligations of patients to their physicians. Reprented in J.Kartz."In the silent world of doctor and patient,231-233.New York: Free Press,1984.

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Original Research Paper

Ethical Issues Raised for Public Health and Socio-Behavioral Research Focused on Containment of the COVID-19 Pandemic

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ABSTRACT

In response to a global public health emergency, it is critical to focus ethical considerations in public health and socio-behavioral research proposals concerning COVID-19 containment. A desk-based review during October 2020 analyzed two mixed methods studies and three quantitative observational studies submitted to the Institutional Review Board (IRB) of which one study emphasized the Case Report Forms (CRFs) and the rest were online surveys. Main tools intended for primary data collection in the submitted research proposals covered the google forms, Facebook messenger, and mobile phones to access the general public, healthcare providers, and civil society organizations. The waiver of the documented 'Informed Consent' to decide for filling the online google forms, intensive pretesting and data collector training for interviews via digital platforms, and data security issues were priority ethical concerns addressed during the IRB appraisal in addition to preserve anonymity in retrieving and reporting the findings in CRF. The virtual dissemination plan is acceptable during the pandemic. A regional networking scheme of IRBs could foster ways to deal with ethical dilemmas during the public health emergency especially when using the internet and other digital platforms for data collection.
Keywords: Ethical concerns, COVID-19 pandemic, IRB, public health, Socio-behavioural research, Containment

INTRODUCTION

In the upsurge of COVID-19 infection which is unprecedented as a global public health emergency, the research questions in public health and socio-behavioral dimensions are essential for the containment in a real-time support of evidence-informed decisions [1-3]. In light of uncertainties in vaccines and therapeutic agents as well as expanding community transmission of COVID-19

infection, researchers focus to generate data on non-pharmaceutical interventions to follow the example of earlier pandemics [4]. The local Institutional Review Boards (IRB) might face some difficulties in reviewing those researches during public health emergency in response to pressure from the authorities concerned [5-8]. In the context of COVID 19 pandemic, WHO has introduced the standard operating procedures for rapid reviews by research ethics committees [9-10].

As stated in the Belmont report, the rights of research participants related to safety and beneficence must be considered first [11]. Research has to follow the ethical principles even in the crisis of public health aspect. The explicit ethical concerns for public health and socio-behavioral research depend upon the choice of study design, recruitment approaches and data collection portals, data curation, data sharing and dissemination. Scientific justification, assessment of risks and potential benefits, consultation and engagement, coordination, participant selection, expert review and informed consent were the key factors [12]. The underlying reasons for limited exploration of ethical concerns in IRBs for socio-behavioral research in COVID-19 included lack of familiarity and limited capacity of IRB members and potential solutions exist such as efforts in capacity building [13]. Given that the IRB should consider whether the proposed informed consent taking process is most appropriate to conduct in the situation, it is crucial to seek for any other requirements being justifiable to express the respect of participants [14]. An IRB could waive the informed consent and modify the elements such as the requirement of signature of participants in the context of minimal risk study, if waiving of the informed consent could not severely affect the participant's welfare [15].

Myanmar has reported the first two confirmed cases of COVID-19 on 23 March 2020. Thereafter in April, the accelerated health sector responses covered the guidelines for the healthcare providers for prevention and containment measures. Other strategic approaches covered the establishment of the national volunteer steering unit, community fever clinics in Yangon and Mandalay cities and the National Call Center at the Department of Medical Research [16]. In response to the fulfilment of knowledge gaps for the strengthening of policy and procedures, the research proposals target the perspectives of healthcare providers towards compliance to guidelines, and public understanding of rapidly evolving COVID-19 related information mainly essential for changes in preventive behaviors and to promote early help-seeking for suspected symptoms. The IRB of Department of Medical Research (DMR), Myanmar has received a total of 108 applications for the full-board meetings, expedited reviews and exemption between April to October 2020 during the pandemic period. The new SOP introduced for expedient reviews assisted the IRB members to prepare for quality reviews. Above all, socio-behavioral and public health research contributed for 45% (49/108) of which 24% (12/49) were COVID-19 related proposals. The turnaround time from the date of review to approval by the IRB was as quick as six days in terms of the expedited review process of the COVID-19 related proposals [17].

As such, the IRBs face ethical challenges in balancing the community and individual risks and benefits in newly developed proposals submitted for review during the pandemic period with an emphasis on containment measures. It is imperative to seek for specific ethical considerations to protect human research participants during public health and socio-behavioral research in time of public health emergency response. Both researchers and IRBs are responsible for ensuring the justifiable risk-benefit ratio, social justice, and social values [15]. Studies are limited or none in Myanmar and elsewhere according to the PUBMED literature search in addressing the problem concerning ethical considerations of public health and socio-behavioral research during the COVID-19 pandemic. Moreover, there is a need to fulfil the knowledge gap in research ethics reviews. Therefore, this current study aimed to analyse the ethical concerns in reviewing the COVID-19 related public health and socio-behavioral research proposals submitted to the IRB (DMR), Myanmar between April to October 2020.

METHODOLOGY

Study design and study population

A cross-sectional study that included a desk-based record review of IRB at the Department of Medical Research (DMR), Myanmar was carried out in October 2020. Five out of 12 records of

public health and socio-behavioral research related to COVID-19 containment measures were retrieved from the IRB (DMR).

Sampling and data analysis

The records at the IRB were purposively selected for the brief review and analys ofed the key features in form of case studies that encompassed the proposal summary and ethical considerations. The contents of the proposal review form by the standard operating procedures of the IRB (DMR) covered: both technical and ethical issues to strengthen scientific integrity.

RESULTS

Two studies were intended for mixed methods and the remaining three were quantitative observational studies of which one study focused on Case Report Forms (CRFs) of hospitalized COVID-19 patients for secondary data collection and the rest planned online surveys for primary data collection. All were stratified as the minimal risk and were eligible for the expedited review at the IRB. The researchers aimed to use google forms, Facebook messenger, and mobile phones to access the general public, healthcare providers and civil society organizations

Case study 1 emphasized the preparedness and response of health care providers in both public and private sectors related to COVID-19 outbreak in country X (Text box 1).

Text box (1)

Case study on COVID-19 preparedness and response among public and private health care providers

Project summary

A cross-sectional quantitative online survey is planned for rapid assessment of the preparedness and response to COVID-19. The target population will be 30,000 public and 5,000 private health care providers in country X. The proposed recruitment is by the announcement in the Facebook page along with the provision of a valid URL to download Google Forms in a local language to collect the individual responses. This study will identify the types and sources of information for COVID-19, common and preferred channels among health care providers, and with implementing partner organizations for disease response, awareness on prevention of COVID-19 focusing on physical distancing, about quarantine, signs, symptoms, severity of the disease, reporting and referral procedures of suspected cases and personal preventive measures, perceived needs and the availability of essential equipment support for COVID-19 response and the perceived challenges during COVID-19 response, and their suggestions for improvement.

In case study 1, the IRB has identified the ethical concerns to:

- Add the recruitment procedure in brief in the form of an announcement/advertisement in Facebook to participate in the online survey before description of the study tool (online google form) in Methodology section;
- Include the announcement in Facebook concerning the general information of research, eligibility to participate, valid survey period, strict confidentiality measures to be undertaken and a valid URL that linked to the survey;
- Submit the waiver request for the signature requirement in the ‘Informed Consent' before participating in the minimal risk online survey that is ‘a waiver of documentation of consent'.
- Submit the ‘Informed Consent' (without any signature) in form of an introductory letter to decide whether agree or disagree to proceed in filling the provided online google form.
- Move the question to fill up the telephone number and the email address to the end of the google form and add the guarantee for strict confidentiality.
- Include the dissemination plan to the target audience, policy and program planners to promote immediate utilization of research results to strengthen the health systems

Case study 2 focused the compliance with prevention guidelines and messages informing the general public about COVID-19 risks (Text box 2).

Text box (2)

Case study on compliance with prevention guidelines and messages informing the public about COVID-19 risks.

Project summary

It is a cross-sectional quantitative online survey among the general public using google forms to access the compliance with prevention guidelines for COVID-19 transmission. It aimed to find out the magnitude and predictors of public compliance with guidelines and information sources accessed by the public for prevention of COVID-19 transmission. The study population will be people 12 to 75 years old using Facebook and various social media and will collect the required data by requesting to complete the google survey form. The estimated sample size will be 171.

In case study 2, the IRB has identified the ethical concerns to

- Consider the inclusion of minors (12-17 years) in this online survey. However, it does not raise a big ethical concern due to not requiring privacy, not addressing the illegal issue or stigmatizing event and non-sensitive nature of questionnaire addressed in the google form. The questionnaires are mainly based upon government instructions widely available in the public media.
- Prepare and submit the 'Informed Consent'/'Assent' (without any signature) in form of an introductory letter to decide whether agree or disagree to proceed in filling the provided online google form.
- Submit the waiver request for the signature requirement in the 'Informed Consent'/'Assent' before participating in the minimal risk online survey that is a waiver of documentation of consent'.
- Include the dissemination plan of research results to the target audience, policy, and program planners to promote immediate utilization of research results to strengthen the healthcare infrastructure.

Case study 3 focused on epidemiological distribution and clinical characteristics of COVID-19 patients in country X (Text box 3). COVID-19 patients should be included in the vulnerable population especially when hospitalized and progressing into severity. However, this submitted proposal was categorized as a minimal risk study due to the use of secondary data extracted from case report forms (CRF).

Text box (3)

Case study on epidemiological distribution and clinical characteristics of Coronavirus disease (COVID-19).

Project summary

A cross-sectional quantitative study aimed to identify the epidemiological distribution, to describe the clinical and laboratory and radiological findings, to determine the proportion of symptomatic cases among COVID-19 cases, to evaluate the disease outcomes and to contribute the understanding of transmission of infection by assessing outcomes and management of the COVID-19 patients. It will analyse the publicly available secondary data of the Central Epidemiological Unit and case report forms recorded at the hospitals in Yangon Region which currently treat the COVID-19 confirmed cases.

The IRB further identified the ethical concerns in case study 3 to:

- Consider the waiver of the informed consent as the data will be collected from the existing medical records covering the whole period of hospital stay;
- Observe anonymity while retrieving, analysing, and reporting the essential findings available from individual case report forms. However, it is critical to record the name of the patient in terms of numerical codes in a password protected computer and to allow the patient to request for corrections or suppression of the collected information before discharge.

Case study 4 focused safe and effective use of chemical disinfectants by general public and volunteers in non-healthcare settings of country X in the context of COVID-19 (Text box 4).

Text box (4)

Case study on safe and effective use of chemical disinfectants by general public and volunteers in non-healthcare settings in the context of COVID-19

Project summary

It is a cross-sectional mixed methods study to promote safe and effective use of chemical disinfectants among the users of online social media and volunteers in non-healthcare settings in the context of COVID-19. For quantitative data collection, general public and volunteers of civil society organization (CSO) will be recruited for self-reported structured questionnaires including knowledge, risk perception and practiced related to chemical disinfection and related health problems. For qualitative portion, telephone interviews will be done for 10 representatives of CSO about current practices, challenges of chemical disinfection in non-healthcare settings, and potential solutions for safe and appropriate use.

The IRB identified the ethical concerns in case study 4 to:

- Submit the 'Informed Consent' (without any signature) in form of an introductory letter to decide whether agree or disagree to proceed in filling the provided online google form;
- Submit the separate waiver request letter for the signature requirement in the 'Informed Consent' before participating in the minimal risk online survey that is 'a waiver of documentation of consent'
- Submit the request for verbal consent only for telephone interviews in collecting the qualitative data;
- Include in the consent for qualitative interview as: "It may need more than one call if any interruption or disturbance occurs meets during the call."
- Train data collectors for telephone interviews especially introduction, tone, and respect;
- Educate the volunteers on how to use the disinfectant properly after interviewing and refer to clinicians if they have any health problems related to disinfectant use.

Case study 5 focused on healthcare providers at the district level of healthcare infrastructure and their perceptions towards the feasibility of establishing community fever clinics by using mixed methods. (Text box 5).

The IRB identified the ethical concerns in case study 5 to:

- Consider the online data security via a video call on the Facebook messenger for qualitative interviews and to pay attention to the feeling of discomfort of being identified on Facebook;
- Maintain the confidentiality of collected data
- Prepare the 'waiver of documentation of informed consent'
- Disseminate through the virtual platform concerning the salient findings in form of aggregate data with concealment of personal identifiers

Apparently, by participating in online surveys, none of the study participants could attain direct and immediate benefits. Nonetheless, the major benefit is the opportunity to contribute new knowledge. As for the incentives provided for participation in online surveys, four case studies in this research did not offer direct cash payment. However, interviewees through mobile phones and the Facebook messenger will be offered top-up phone bills to compensate their time.

Text box (5)

Case study on perception of health care providers on operational feasibility of community fever clinics

Project summary

A cross-sectional mixed methods study will identify the perception of both public and private health care providers on operational feasibility of community fever clinics in the district Y. For quantitative data collection, online Google forms will be used for 245 medical personnel. Altogether 14 key informants will be reached out for interviews via the video call using the face-book messenger.

DISCUSSION

The planned study design by the research team vis-a-vis their choices in the data collection portal (online system vs. conventional system) might have ethical implications for socio-behavioral and public health research [18-20] which is also true for research proposals related to COVID-19 infection [6-7]. In this research, all case studies illustrated the cross-sectional observational study design, and four out of five case studies involved digital platforms. Most of the researchers introduced the google forms via Facebook social media, and interviews through mobile phones. The internet research as a new avenue that has gained popularity in recent years is not without ethical challenges [21]. Among others, one case study preferred secondary data collection only by extracting the medical records to avoid the conduct of face-to-face interviews during the pandemic restrictions such as lock-down and semi-lock down measures and social distancing. Ethical concerns in record reviews highlight the importance of observing the anonymity [22]. It is emphasized as essential to keep the identifiers confidential in retrieving and reporting the findings in case study 3 through the extraction of available records of CRF at the study hospitals.

For digital data collection, the recruitment and eligibility criteria are important that requires an initial online announcement of the survey. The written informed consent procedures are not fit were not appropriate in this condition and an alternative form are was needed as evident in this brief review which is in consistency with other studies [23-25]. Therefore, as expressed in case studies, the IRB has suggested the researchers for the waiver request of the documented *'Informed Consent'* in form of an introductory letter to decide whether agree or disagree to proceed in filling the online google forms. The IRB has to check the alternative consent taking procedures whether all the required information related to the study are informed provided to participants before data collection and proper archiving of consent like documentation in google data collection form and recording [26-28].

As reported by other studies, there was an increasing trend in using the social media platforms in the field of socio-behavioral research. This context may bring in complex ethical issues associated with using social media for data collection [29]. The IRB strongly recommended data collection training and pretesting for telephone interviews and other online media, to educate the participants about control measures of COVID-19 and to arrange for proper referral to those with reported physical or mental problems. The IRB needs to consider both ethical and technical issues affecting scientific integrity carefully in this situation by reviewing the data collection method and the inclusion of proper interviewer training. Data security was the priority for online research involving either active or passive data collection and also for mitigating the discomfort felt by participants being identified either in the social media platform or during the interviews with a

video call from the Facebook messenger as noted in case study 5. Ethical issues were central to anonymity and confidentiality apart from data security. Within the European Union, studies need to comply with the General Data Protection Regulation (GDPR) in addition to country specific data protection regulations (In: EU Data Protection Rules and U.S. Implications, 2020) [30]. It is highly important to maintain the confidentiality of COVID-19 related data due to the possibility of stigmatization and violence. Therefore, the IRB needed to ensure thoroughly describing data storage and maintenance in the submitted proposals [30-32].

The dissemination of salient findings as an input to formulate new strategies for behavioral change communication, develop innovative public health interventions or to strengthen the existing policy and program guidelines are critical in public health and socio-behavioral research [32-33]. The IRB also suggested for the timely dissemination plan by virtual means during the pandemic to the target audience and the policy and program planners to promote immediate utilization. It is essential to check the involvement of dissemination plan about the study findings to relevant stakeholders, affected population and, the global community as necessary so that the greatest impact of the socio-behavioral and public health related research can be obtained. This fact has been supported by the COVID-19 Research Roadmap social science working group being established following the Global Research and Innovation meeting held in Geneva. Among others, one of the important responsibilities of the expert group members is to provide feedback on *'state of the art'* COVID-19 evidence in priority areas [33-34]. As such, effective dissemination is critical to accelerate the timely access of stakeholders to evidence-based messages in locally relevant language supportive to mitigate the spread of corona virus.

Conclusions

A real-time evidence generated from this study could support the effective and efficient reviewing of research concerning public health emergency response by local IRBs, thereby promoting scientifically and ethically sound studies in similar scenarios. The IRBs need to handle the timely implementation of COVID-19 related studies by fulfilment of scientific integrity within a short processing time. In the long run, the enhancement in networking the IRBs in the Region could foster sharing of ways to deal with ethical dilemmas especially when using internet-based research and digital platforms in support of COVID-19 related socio-behavioral and public health research entity.

REFERENCES

1. Honey-Rosés J, Anguelovski I, Chireh VK, Daher C, Konijnendijk van den Bosch C, Litt JS, Mawani V, McCall MK, Orellana A, Oscilowicz E, Sánchez U. The impact of COVID-19 on public space: an early review of the emerging questions–design, perceptions and inequities. Cities & Health 2020;8:1-7.
2. World Health Organisation. Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D. WHO/RFH/20.1.2020
3. Nuffield Council on Bioethics. Research in Global Health Emergencies [Internet], 2020. https://nuffieldbioethics.org/publications/research-in-global-health-emergencies.
4. Kantor BN, Kantor J. Non-pharmaceutical Interventions for Pandemic COVID-19: A Cross-Sectional Investigation of US General Public Beliefs, Attitudes, and Actions. Front Med 2020;7: 384.
5. Van Bavel JJ, Baicker K, Boggio PS, Capraro V, Cichocka A, Cikara M, Crockett MJ, Crum AJ, Douglas KM, Druckman JN, Drury J. Using social and behavioural science to support COVID-19 pandemic response. Nature Hum Behav 2020;4(5):460-71..
6. Qi,C, Zhu YC, Li CY, Hu YC, Liu LL, Zhang DD, Wang X, She KL., Jia, Y, Liu TX, Li XJ. Epidemiological characteristics and spatial-temporal analysis of COVID-19 in Shandong Province, China. Epidemiol Infection 2020;148:e141.
7. Wright KS. Ethical research in global health emergencies: making the case for a broader understanding of 'research ethics'. Int Health 2020;12(6):515-7.
8. Indian Council of Medical Research. National Guidelines for Ethics Committees reviewing Biomedical and Health Research during COVID-19 Pandemic. 2020. Available at:

https://main.icmr.nic.in/sites/default/files/guidelines/EC_Guidance_COVID19_06_05_2020.pdf
9. World Health Organization. Guidance for managing ethical issues in infectious disease outbreaks. World Health Organization. 2016. https://apps.who.int/iris/handle/10665/250580
10. Guidance for research ethics committees for rapid review of research during public health emergencies. World Health Organization. 2020.
11. Department of Health, Education, and Welfare; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. J Am Coll Dent 2014;81(3):4-13.
12. Saxena A, Horby P, Amuasi J, Aagaard N, Köhler J, Gooshki ES, Denis E, Reis AA, Ravinetto R. The ALERRT-WHO Workshop. Ethics Preparedness: Facilitating Ethics Review during Outbreaks – Recommendations from an Expert Panel. BMC Med Ethics 2019;20:29.
13. Kumar NK, Muthuswamy V. Fostering ethical biomedical and health research in India during the COVID-19 pandemic. Research Ethics 2020;16(3-4):1-10.
14. Mathur R. Ethics preparedness for infectious disease outbreaks research in India: A case for novel coronavirus disease 2019. Indian J Med Research 2020;151(2):124.
15. Wassie L, Gebre-Mariam S, Tarekegne G, Rennie S .Enhancing ethics review of social and behavioral research: developing a review template in Ethiopia. Research Ethics 2019;15(3-4):1-23.
16. MoHS. Updates on National COVID-19 Containment Strategies. In: Myanmar Health Sector Contingency Plan on COVID-19 and Other Emerging Respiratory Illnesses. 2020. http//:www.mohs.gov.mm
17. Pwint KH, Aung HM, Yadanar P, Aye NS, Show KL, et al. Expedient Reviews during the Covid-19 Pandemic Period: Concept to Current Practice of the Institutional Review Board in the Resource-Constrained Scenario. J Bioethics Appl 2020;1(1).
18. Marshall PA. Ethical challenges in study design and informed consent for health research in resource-poor settings. (Special Topics in Social, Economic and Behavioural (SEB) Research report series; No. 5) (2007) TDR/SDR/SEB/ST/07.1
19. Zimmer M. But the data is already public: on the ethics of research in Facebook. Ethics Inf Technol. 2020.12(4):313–25.
20. Hunter RF, Gough A, O'Kane N, McKeown G, Fitzpatrick A, Walker T, McKinley M, Lee M, Kee F. Ethical Issues in Social Media Research for Public Health. Am J Pub Health 2018;108(3): 343–8.
21. Moreno MA, Goniu N, Moreno PS, Diekema D. Ethics of social media research: Common concerns and practical considerations. Cyberpsychol Behav Soc Network 2013;16(9):708–13.
22. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) CIOMS Geneva 2002.
23. Whitaker C, Stevelink S, Fear N. The use of Facebook in recruiting participants for health research purposes: a systematic review. J Med Internet Res 2017;19(8):e290.
24. Russomanno, J, Patterson JG, Jabson Tree JM. Social Media Recruitment of Marginalized, Hard-to-Reach Populations: Development of Recruitment and Monitoring Guidelines. JMIR Pub Health Surv 2019;5(4):e14886.
25. Osterrieder A, Poomchaichote T, Cuman G, et al.: Online survey questions: Social, ethical and behavioural aspects of COVID-19 (Version 1.0 24 April 2020). Zenodo. 2020. 10.5281/zenodo.3764913.
26. Keller HE, Lee S. Ethical Issues Surrounding Human Participants Research Using the Internet, Ethics Behav 2003;13(3):211-9.
27. Buchanan EA, Hvizdak EE. Online survey tools: ethical and methodological concerns of human research ethics committees. J Empir Res Hum Res Ethics 2009;;4(2):37-48.
28. Roberts LD, Allen PJ. Exploring ethical issues associated with using online surveys in educational research, Educ Res Eval 2015;21(2):95-108.
29. Markham A., Buchanan E. Internet research: Ethical concerns. In Smelser, N. J., Baltes, P. B. (Eds.), International encyclopedia of social and behavioral science (pp. 606-613). Amsterdam, The Netherlands: Elsevier. 2015.
30. EU Data Protection Rules and U.S. Implications. Updated July 17 2020.Congressional Research Service.https://crs reports.congress.gov
31. Gupta S. Ethical issues in designing internet-based research: Recommendations for good practice. J Res Pract 2017;13(2).
32. Facca D, Smith MJ, Shelley J, Lizotte D, Donelle L. Exploring the ethical issues in research using digital data collection strategies with minors: A scoping review. PLoS One 2020;15(8):e0237875.

33. McVay AB, Stamatakis KA, Jacobs JA, Tabak RG, Brownson RC. The role of researchers in disseminating evidence to public health practice settings: a cross-sectional study. Health Res Policy Syst 2016;14(1):1-9.
34. WHO R&D Blueprint. Novel Coronavirus COVID-19 Social Science working group. World Health Organization, Geneva, 2020.

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Ethical Viewpoint Paper

Ethical Aspects of Informed Consent in Dementia

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Introduction
Informed Consent is an ethical and legal obligation that a medical practitioner or researcher must take in order to explain the treatment plan or enrol a participant in a research trial. In this process the participant or patient is informed about all the aspects of the treatment or trial in detail, which are important for the participant or patient to decide after studying these aspects in detail whether they want to voluntarily confirm their participation in the trial or is willing to undergo the said procedure or treatment. The concept is based on the principle of the Nuremberg Code, The Declaration of Helsinki, and the Belmont Report [1-5].
The informed consent is described in ethical codes and regulations for human subject's research. The goal of the informed consent process is to provide sufficient information to a potential participant, in a language which is easily understood by him/her, so that he/she can make the voluntary decision regarding "to" or "not to" participate in the research study. The same is applicable when an Individual undergoes a medical procedure, surgery or takes certain medications. No individual has the right to infringe a person's fundamental right, thus "Informed Consent" is an important and ethical tool [1,3].

Components of an Informed Consent
An Informed Consent can only be considered to have been given if a person or his/her legal representative have been completely informed about the trial/procedure and having understood the provided information, freely agrees to participate in the study or undergo a procedure.
Thus, the person must possess competence, must be voluntary and not been having to be forced to make a decision, the provision of information must be clear truthful and cover entire details of the said procedure or study, only then will the consent be valid.

Ethical Aspects of Informed Consent in Dementia
In obtaining an informed consent in patients suffering from Dementia we are faced with a significant challenge, as obtaining a consent depends on the competence and mental capacity of the individual. Certain symptoms of dementia like difficulty in concentration and understanding, problems in short term memory, makes their ability to give informed consent questionable. Furthermore, as age progresses the symptoms may worsen. However, it cannot be assumed that people with dementia are incapable of giving consent. Patients with mild to moderate dementia can interpret, evaluate, and derive meaning from their lives. The law assumes that all Individuals are capable unless there is evidence to the contrary [6-7].
The capacity has to be assessed in reference to the particular decision an individual needs to make at that particular time the decision needs to be made. A person can be deemed to be without capacity if, at the particular time when the decision needs to be made, he or she is unable by reason of mental disability to make a decision on the matter in question or is unable to communicate a decision owing to his or her altered consciousness or any other reason [8]. Also, capacity is not global in scope. Most decisions are made individually by a person, these decisions are often constrained by personal choice, values, socio-cultural influences, education, and occupation, thus,

they may not be always based on logic or deliberation [9]. Understanding, appreciation, reasoning and expression of a choice are the decision-making abilities that characterise capacity. This ability is not static [10]. Treatment of certain reversible conditions can also improve capacity, fluctuations, medications, delirium, infections, drowsiness, sundowning also effects the ability to make decisions [6-11].

It is established that capacity is required for valid informed consent, although capacity is dependent on cognition, it is not the same as cognition. It is also different from functional activities, for example, a person who is unable to do a certain task may be capable of deciding who can assist them to do the task [6].

Studies have found that impaired decision making was found in 44-69% residents in nursing homes and nearly all patients with mild to moderate Alzheimer's dementia were impaired at making decisions (component of understanding) but could still perform well as controls on appreciation, reasoning, and choice. Thus, with the preserved ability of making choice and providing reasoning, they can make a decision about daily care but not about complex treatment choices [12-15]. Patients with behavioural variant of frontoparietal dementia may perform well on standard neuropsychological tests but have impaired judgement and decision- making [16]. Patients with amnestic mild cognitive impairment were able to express choice but had impaired appreciation, reasoning and understanding [17].

Assessment of Capacity

A semi structured direct interview with the patient is used to assess capacity. The patient must have adequate, relevant information regarding the matter to be discussed and an approach of open-ended questions can be used to evaluate the aspects of decision-making abilities (understanding, choice, appreciation, and reasoning). Reassessment should be done which should be consistent and stable over time [6-18]

The clinician has an ethical responsibility to accurately assess the decision-making capacity of a patient, as it has various ethical, legal, and moral implications. In obtaining a consent the clinician must strike a balance between respecting the autonomy of the patient and acting in their best interest. It can also be possible that this decision be reviewed critically in the court of law. Thus, the process must be rigorous. The capacity is a point along the continuum, which can be rated adequate, inadequate, and marginal. The clinician must also be tactful to communicate the need for further assessment and maintain adequate records [6].

Certain tools can be used for assessing competence to name a few:

1. **MacArthur Competence Assessment Tool Treatment:** It is frequently used to assess competence and has been validated in patients with dementia which scores for four domains of capacity [19].
2. **Assessment of Capacity for Everyday Decision-making:** Useful to understand if a person who has a functional deficit understands an appreciates the problem, the risks and benefits of solutions to the problem and can reason through choices about solving it [20].
3. **Role of Neuropsychological Tests:** The help understand the neural basis of the decision-making ability, indicate interventions, and also act as a tool to assess capacity. Bedside tests like executive interview, formal tests like test of conceptualisation, Trials A and fluency test can measure executive functioning. Verbal memory tests are also important to recall information. [6,14, 21-23] The cognitive level of cognitive function and decision ability varies from individual to individual, but it has a significant impact on the patient's judgement regarding their capacity. The Mini Mental Status Examination (MMSE) is a widely used tool of cognition in clinical practice, it is easy to administer and requires no formal training. If used in conjunction with other neuropsychological tests it can improve patient's comprehension of the task to be done [13].

There is currently no single test, which could be considered a gold standard test for capacity assessments. In clinical practice, a combination of clinician's judgment with a structured capacity interview and neuropsychological tests that include executive function tests would be ideal. [6,24]

Alternatives In case of Incompetence to give Informed consent

A person who fully lacks the capacity to consent to research or a procedure could be for or against participating in research or undergoing the procedure in general. But that does not mean that in informed consent cannot be taken. In such cases 2 alternatives can be considered:

1. **Advanced Directives:** These are written by competent individuals who wanted to express in writing their wishes about medical treatment they might eventually need in the event of an accident or illness which rendered them incapable of exercising self-determination. In this way, a person's autonomy could be extended into the future well beyond the point that they were able to exercise it. The concept of the advance directive has been further extended to the research situation in some countries but not in most. Advance directives may be legally binding or simply advisory depending on their legal status in each country and sometimes on the nature of the decisions to be made [6].
2. **Proxy Decision Making:** It is usually in context of healthcare decisions and may be covered with laws or deontological codes. In certain countries proxy decision makers can also consent on behalf of the patient with dementia. In certain situations, the proxy decision maker is made by the means of an advanced directive. In other cases, it could be the patients' relative in the form of spouse, adult child, sibling, or lawful guardian [25].

Conclusion

A person's capacity to decide and make choices is an important part of who they are and how they wish to live. A person has the right to have an informed consent. Dementia can pose unique challenges in obtaining informed consent. As clinicians it is important to not just assess but ensure that the conditions provided were optimal for level of functioning of the individual to enable them to make a decision. We need to spend time to educate the person and their family, reduce their anxiety, take into consideration the lucid intervals, treatable causes, physical conditions which can interfere with capacity. Overall, the patient's best interests need to be focussed on. All persons irrespective of age enjoy the same liberties, however patients with dementia are more vulnerable and need proper attention. The complexities of their assessment and implications of their judgments need to be taken into consideration to ensure that their interests are protected. Informed consent in dementia requires a fine balance to be ethically and morally correct and preserving the autonomy of the patient.

REFERENCES

1. International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. Guideline for good clinical practice E6(R1) June. 1996.
2. Nuremberg Military Tribunal. The Nuremberg Code. JAMA 1996;276(20):1691.
3. Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N, Musmade PB. Informed consent: Issues and challenges. J Adv Pharmaceut Technol Res 2013;4(3):134–40.
4. World Medical Association declaration of Helsinki. Ethical principles for medical research involving human subjects. 2012.
5. The Belmont Report ethical principles and guidelines for the protection of human subjects of research. The National Commission for the protection of human subjects of biomedical and behavioral research; April 18. 1979.
6. Hegde S, Ellajosyula R. Capacity issues and decision-making in dementia. Ann Indian Acad Neurol 2018;19(Suppl 1):S34–9.
7. Wong JG, Clare IC, Gunn MJ, Holland AJ. Capacity to make health care decisions: its importance in clinical practice. Psychol Med 1999;29(2):437-46.
8. British Medical Association. Assessment of Mental Capacity. The Law Society; 2015 Dec 8.
9. Kim SY, Karlawish JH, Caine ED. Current state of research on decision-making competence of cognitively impaired elderly persons. Am J Geriatr Psychiatry 2002;10(2):151-65.
10. Appelbaum PS. Assessment of patients' competence to consent to treatment. New Engl J Med 2007;357(18):1834-40.
11. Grisso T, Appelbaum PS. Assessing competence to consent to treatment: A guide for physicians and other health professionals. Oxford University Press, USA; 1998.

12. Kim SY, Karlawish JH, Caine ED. Current state of research on decision-making competence of cognitively impaired elderly persons. Am J Geriatr Psychiatry 2002;10(2):151-65.
13. Pruchno RA, Smyer MA, Rose MS, Hartman-Stein PE, Henderson-Laribee DL. Competence of long-term care residents to participate in decisions about their medical care: a brief, objective assessment. The Gerontologist 1995;35(5):622-9.
14. Royall DR, Cordes J, Polk M. Executive control and the comprehension of medical information by elderly retirees. Experiment Aging Res 1997;23(4):301-13.
15. Marson DC, Ingram KK, Cody HA, Harrell LE. Assessing the competency of patients with Alzheimer's disease under different legal standards: A prototype instrument. Arch Neurol 1995;52(10):949-54.
16. Manes F, Torralva T, Ibáñez A, Roca M, Bekinschtein T, Gleichgerrcht E. Decision-making in frontotemporal dementia: clinical, theoretical and legal implications. Dement Geriatr Cogn Disord 2011;32(1):11-7.
17. Okonkwo OC, Griffith HR, Belue K, Lanza S, Zamrini EY, Harrell LE, Brockington JC, Clark D, Raman R, Marson DC. Cognitive models of medical decision-making capacity in patients with mild cognitive impairment. J Int Neuropsychol Soc 2008;14(2):297-308.
18. Karlawish J. Measuring decision-making capacity in cognitively impaired individuals. Neurosignals 2008;16(1):91-8.
19. Grisso T, Appelbaum PS. Comparison of standards for assessing patients' capacities to make treatment decisions. Am J Psychiatry 1995;152(7):1033-7.
20. Lai JM, Gill TM, Cooney LM, Bradley EH, Hawkins KA, Karlawish JH. Everyday decision-making ability in older persons with cognitive impairment. Am J Geriatr Psychiatry 2008;16(8):693-6.
21. Marson DC, Sawrie SM, Snyder S, McInturff B, Stalvey T, Boothe A, Aldridge T, Chatterjee A, Harrell LE. Assessing financial capacity in patients with Alzheimer disease: A conceptual model and prototype instrument. Arch Neurol 2000;57(6):877-84.
22. Bassett SS. Attention: Neuropsychological predictor of competency in Alzheimer's disease. J Geriatr Psychiatr Neurol 1999;12(4):200-5.
23. Marson DC, Cody HA, Ingram KK, Harrell LE. Neuropsychologic predictors of competency in Alzheimer's disease using a rational reasons legal standard. Arch Neurol 1995;52(10):955-9.
24. Etchells E, Darzins P, Silberfeld M, Singer PA, McKenny J, Naglie G, Katz M, Guyatt GH, Molloy DW, Strang D. Assessment of patient capacity to consent to treatment. J Gen Intern Med 1999;14(1):27-34.
25. Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. Arch Intern Med 2006;166(5):493-7.

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Ethical Viewpoint Paper

Ethical Aspects of Sexuality in Old Age

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Introduction
Human sexuality is recognized as a fundamental driving force but is frequently misunderstood and particularly in the elders it is neglected [1]. A marked increase in life expectancy over the past century has meant that individuals over the age of 65 years form an increasingly large proportion of our population [2]. Human beings are actually never too old to enjoy a happy and healthy sex life. Despite this, many people, young and old alike, are astounded at the idea of people remaining sexually active in their sixties and beyond. It is frequently assumed that elder persons lose their sexual desires or that they are physically unable to perform. For the elders, the ability to remain sexually active is a major concern in their lives. Fear about the loss of sexual prowess in older males is common. Older women also express sexual desire, but may fear their interest is undignified and disgraceful. Some elder persons may even freely accept their interests in sex, but their children or grandchildren may disapprove, making them feel guilty. The elder often view sexuality as an expression of passion, affection, admiration, and loyalty, a renewal of romance, a general affirmation of life, especially the expression of joy and a continuing opportunity for growth and experience. In addition, sexual activity is a means for the elder to affirm physical functioning, to maintain a strong sense of identity and establish self-confidence, and to prevent anxiety. It remains a mode of pure physical pleasure as well. However, not all elder persons have positive attitudes about sexuality. Like all persons, elders may experience sexual dysfunction due to boredom, fear, fatigue, grief, or other factors (e.g., intrinsically low sexual desire, physical disability). Sexuality in the elder is particularly affected by problems that are common in this age group, for example, depression, medical disorders, or incapacitation or death of a partner [3].

The concept of ethics
Ethics or moral philosophy is a branch of philosophy that "involves systematizing, defending, and recommending concepts of right and wrong behaviour" [4]. The field of ethics, along with aesthetics, concerns matter of value; these fields comprise the branch of philosophy called axiology [5]. Ethics seeks to resolve questions of human morality by defining concepts such as good and evil, right and wrong, virtue and vice, justice and crime. As a field of intellectual inquiry, moral philosophy is related to the fields of moral psychology, descriptive ethics, and value theory [6].

Ethics, sexuality and old age
Availability of partners plays a major role in how older adults experience sexuality. It is well documented that the majority of women outlive the majority of men in the United States. In contrast to older women, older men have significantly more opportunities to pursue opposite-sex relationships [7]. Approximately four out of five women who are seventy-five or older do not have a male sexual partner. In contrast, over 60%of the men in this age group do have a partner (AARP). The consequences of this gender gap have both personal and public health ramifications. With the advent of prescription drugs (for example, Viagra) that aid male erections, older men are more sexually active than in past generations. Drug-enhanced stamina paired with the gender gap makes it likely for partner-sharing to occur, such that each older man may have two or three female sexual partners who are within his peer group. Public health problems are magnified when older men

seek out the services of prostitutes and bring sexually transmitted diseases, including HIV, back to their senior partners [8]. The problems in older aged people increases when they have dementia. When a spouse is affected by dementia, moral and ethical views eventually can come into play. Healthy partners, more and more frequently, are going outside of marriage as the unmet emotional needs begin to increase. In addition to their own feelings of guilt, disapproving family members, friends, or physicians with little awareness of how to deal with this sensitive aspect of life with dementia may exacerbate the problem [9]. If relationships are the private arena in the struggle with sexuality and dementia, then long-term care is the public arena. With increasing frequency, assisted-living and skilled-care nursing facilities as well as older adults' family homes are walking a blurring line between guarding against neglect and abuse of residents, particularly those with dementia [9]. Specifically, when it comes to sexuality in long term care, not permitting residents to express their sexuality constitutes neglect, while failing to protect residents from unwanted sexual expression by another constitutes abuse. Abuse may range from criminal predation of a staff member or resident to a simple case of mistaken identity in a confused dementia patient.

Many of the staff members are young and may have little experience that prepares them for sexual behaviours in confused patients. Families may have differing religious or cultural backgrounds, giving way to differing views. The demand to fill nursing home beds may exert pressure from corporate mandates on facility administrators, encouraging the admission of prospective new residents with known inappropriate sexual behaviours that are likely to create difficulties [9].

Intimacy and sexuality expressed by nursing home residents with dementia remains an ethically sensitive issue for care facilities, nursing staff and family members. Dealing with residents' sexual longings and behaviour is extremely difficult, putting a burden on the caregivers as well as on the residents themselves and their relatives [10].

Ethical dilemma also occurs for use of drugs to increase or decrease sexual urge in old age. One study found that overall sexual activity showed a declining course with increasing age but still continued in individuals above 50 years of age. They also found that women were less interested and also less involved in both coital as well as non-coital activities. Sexual function is generally better in an active and working lifestyle in old age. Increasing age generally comes with reduction in quality of erection, ejaculate volume, vaginal lubrication, orgasmic pleasure and overall sexual functioning. Most individuals do not seem to be distressed with these changes. They frequently have more incidence of co-morbid illness in cases with worsened sexual function and sexual activity. People with old age have *significant* increase in the time required for sexual arousal. This study also quoted that love and intimacy stayed the same for majority of their subjects [11].

Moral and cultural values can interfere with the normal process of sexuality in old age. A sexually active old age female may want to have some drugs that can help her subside her sexuality as she may find it culturally inappropriate for her age. The ethical dilemma here falls on the doctor. Respecting the patients' autonomy takes priority but prescribing drugs or undergoing any kind of medical procedures has at old age has its own negative implications. Taking the high levels of comorbidity into account it might be as well be risky. For example, Sildenafil citrate has been shown to be an effective and well-tolerated oral agent for treating ED in the general population of adult men with ED of broad-spectrum aetiology. Elderly men are more likely to have concomitant medical problems than the general population of men with ED [12]. There is an incidence of 18% headache, 8% flushing, 8% dyspepsia, 5% nasal congestion and 2% visual changes of adverse effects among the older age group. No overt cardiovascular events are reported. So, sildenafil is an effective agent in elderly men, but it had a lower efficacy rate with increasing age, especially in men aged >80 years [13].

Sometimes when a person in old age, especially with dementia is sexually active, there are concerns about whether the person has the mental capacity to consent. This may be a concern both in existing relationships and in new relationships. All health and social care staff have a vital role to play in protecting vulnerable people from abuse and exploitation [14]. However, it is essential to be aware that the first statutory principle of the Mental Capacity Act 2005 is that 'a person must be assumed to have capacity unless it is established that he lacks capacity'. A diagnosis of dementia alone does not automatically mean that a person lacks capacity to consent to sex [14]. The Mental Capacity Act also tells us that a person must be given help with decision-making. This could

involve developing some awareness, if possible, of a person's past sexual preferences and habits and reminding them of wishes they have communicated previously. It also needs to be recognised that consent to sex will often be communicated non-verbally rather than verbally. Patients with dementia cannot be assumed to have impaired capacity. Even a patient with moderate or severe dementia, with obviously impaired capacity may still be able to indicate a choice and show some understanding. Four key components of decision-making in a capacity evaluation include understanding, communicating a choice, appreciation, and reasoning. Assessment of capacity requires a direct interview with the patient using open-ended questions and may include both informal and formal approaches depending on the situation and the context. A baseline cognitive evaluation with a simple test to assess executive function is often useful in capacity evaluation. All capacity evaluations are situation specific, relating to the particular decision under consideration, and are not global in scope. The clinician needs to spend adequate time with the patient and the family allaying their anxieties and also consider the sociocultural context. The area of capacity has considerable overlap with law and the clinician treating patients with dementia should understand the complexities of assessment and the implications of impaired capacity. It is also essential that the clinician be well informed and keep meticulous records. It is crucial to strike a balance between respecting the patient autonomy and acting in his/her best interest [15]. If somebody does have the capacity to consent to engage in a sexual relationship with another consenting adult, then they have the right to do so regardless of whether other people approve and their privacy must be respected [14].

Older aged people with LGBTQ face different issues. Older LGBTQ people are marginalised by: a) younger LGBT people, because of ageism; and b) by older age social networks because of homophobia, biphobia, transphobia, heteronormativity (the assumption that everyone is heterosexual, heterosexism (the privileging of heterosexuality), prejudice and discrimination towards LGBT people. Stigma against sexual expression in LGBTQ older adults may cause concealment of sexual orientation from family or care providers due to fears of rejection [16]. When compared with their heterosexual cisgender (non-transgender) counterparts, LGBTQ+ older adults are more likely to delay or not seek medical care, often due to fear of real or perceived discrimination from healthcare providers [17].

This topic is rarely talked about or discussed in the public. A geriatric person may have or may not be sexually active but the ethical aspects associated with it need to be discussed more vividly.

REFERENCES

1. Walker BL. Sexuality and the elderly: A research guide. Annotated ed. Westport, CT: Greenwood Press; 1997.
2. Tien-Hyatt JL. Self-perceptions of aging across cultures: Myth or reality? Int J Aging Hum Dev 1986-1987;24:129–48.
3. Pfeiffer E, Verwoerdt A, Davis GC. Sexual behavior in middle life. Am J Psychiatry 1972;128:1262–7.
4. Ludger V, Susanne K, Franz-Josef E. Die Literaturrundschau. Communicatio Socialis. 2015.
5. Internet Encyclopedia of Philosophy. [cited 2021May24]. Available from: ttps://iep.utm.edu/ethics/
6. Flexner SB. Random House unabridged dictionary. New York: Random House; 1993.
7. Carr D. The Desire to Date and Remarry among Older Widows and Widowers. J Marriage Family 2004;66:1051-68.
8. Nack A. Sexuality over the Lifespan--Social Trends Pose Moral Dilemmas for Communities of Faith. Intersections 2006;22:5
9. Wornell D. Sexuality and dementia: compassionate and practical strategies for dealing with unexpected or inappropriate behaviors. 2nd ed. Vol. 7. New York, NY: Demos Health; 2014.
10. Mahieu L, Anckaert L, Gastmans C. Intimacy and Sexuality in Institutionalized Dementia Care: Clinical-Ethical Considerations. Health Care Anal 2017;25(1):52-71.
11. Kalra G, Subramanyam A, Pinto C. Sexuality: desire, activity and intimacy in the elderly. Indian J Psychiatry 2011;53(4):300-6.

12. Fujisawa M, Sawada K. Clinical efficacy and safety of sildenafil in elderly patients with erectile dysfunction. Arch Androl 2004;50(4):255-60.
13. Müller A, Smith L, Parker M, Mulhall JP. Analysis of the efficacy and safety of sildenafil citrate in the geriatric population. BJU Int 2007;100(1):117-21.
14. The expression of sexuality in dementia [Internet]. Social Care Institute for Excellence. [cited 2021May24]. Available from: https://www.scie.org.uk/dementia/living-with-dementia/difficult-situations/sexual-expression.asp
15. Hegde S, Ellajosyula R. Capacity issues and decision-making in dementia. Ann Indian Acad Neurol. 2016;19(Suppl 1):S34-9.
16. Srinivasan S, Glover J, Tampi RR, Tampi DJ, Sewell DD. Sexuality and the Older Adult. Curr Psychiatry Rep. 2019;21(10):97-108.
17. Alvarado LA, Dorsen C, Jere C, Woerner L, Jones E, Miner SM. Designing a Program to Serve Older Adult LGBTQ+ Populations in Home Healthcare. Home Healthcare Now 2020;38(4):209-14.

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Ethical Viewpoint Paper

Ethical Issues in Psychological Research in the Wake of COVID-19

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Introduction

The advent of this pandemic has caused researchers all over the world to study various aspects, from the virus itself, to factors that are affected by it. Psychological research in the wake of COVID-19 is no such exception. While mental health concerns during this pandemic are sources of further study for future considerations, we must take into account ethical issues. Privacy and security concerns are of utmost importance, as research in this field often involves sensitive data such as a patient's medical records and psychiatric history. In case of in person research, the researcher should follow all COVID-19 related protocols like masking, social distancing etc. The researcher should also ensure the research participants are following protocol as well. Sensitivity during this pandemic with respect to data is also an important issue. Individuals are going through highly stressful periods, experiencing a downward spiral of mental health, grief, and financial stress. A lot of families have not only had to deal with the loss of their loved ones but have been deprived from saying their last goodbyes and carrying out their funeral rites. Researchers must keep in mind this vulnerable mental state. Health care systems around the world have been crumbling with work pressure and hence it is very important for researchers to be sensitive while conducting research and not press health workers to give out confidential details. Ethical committees must set clear cut guidelines with respect to psychological research, to ensure that the rights of the participants are given utmost importance.

Sensitivity during data collection

Research during the pandemic brings about the concern about sensitivity towards participants. For purposes of research, the researcher's sample could involve grieving families, patients who have been on the ventilator, and vulnerable populations such as those who have serious mental illnesses. It is especially important that the researcher keeps in mind that the participants' mental state has to be protected and taken care of. For example, wording of questions in surveys and interviews should be such that the questions themselves don't trigger a downward spiral of emotions, or make symptoms of their mental illness worse. The researcher must ensure that participants are not reminded of the stressful period that they went through, as it can bring about memories of the traumatic experience. It is imperative that researchers draw the line between the quest for data collection and the very sensitivity that is required on the part of humanity during these times.

Experienced researchers must train their assistants in how to collect data from the population, when the topic of study is sensitive. An atmosphere of trust and emotional support should be built above all, rather than the mechanical collection of data.

In the Indian context, the Indian Council of Medical Research (ICMR) has released ethical guidelines for research during COVID-19. It highlights the possibility of stigmatizing patients who have tested positive, as well as disadvantaged communities. Additional guidelines have been mentioned for those individuals who have gone through particularly stressful experiences. There have been specific guidelines for research on psychology and mental health, and they involve aspects such as the provision of psychosocial support, empathy, and utmost respect.

Privacy and data storage concerns

Privacy and security concerns are one of the main ethical issues to be accounted for when undertaking any form of research. Online research raises a lot of concerns of privacy and safety of data. When researchers use online platforms, they must ensure the apps are secure and end to end encrypted and aren't stealing data for marketing, selling data etc. Data collection methods done via video conference platforms such as Zoom, Google Meet, or WhatsApp video calls must ensure that the recordings are stored with utmost safety. Other platforms such as Google Forms must ensure that data is not shared by multiple researchers, to avoid data leakage. The number of people who have access to the data should be kept minimal as greater the number of people who have access to the data, higher the risk of data leaking. When participants take part in a research study, they are trusting the researcher with their information.

In today's world data is extremely valuable and data theft is widespread. Sensitive data, related to both physical and mental health must be protected. In the age of digital leaks and hacking, such data needs to be especially protected. The next issue related to privacy involves the storage of data. Hackers in the past, have been able to get access to patients' medical records at hospitals in a bid to extort money from the hospital. Especially keeping in mind, the context of COVID-19, researchers who have access to patients' medical records must ensure that data is saved with utmost safety and security, using encryption. Researchers need to be careful and make sure their data is stored securely and is hack-proof. A lot of COVID-19 patients have been facing a lot of stigmatization and discrimination. When research studies are conducted, participants often disclose very personal details and hence it is crucial these details stay confidential and the participants are protected from any kind of discrimination or stigmatization. It is the researcher's responsibility to maintain confidentiality and safeguard the participants' information.

Details about a patient's mental health disorders, ranging from anxiety, to schizophrenia must be saved with utmost privacy, after the participant, or the caregiver has provided consent about their data being used for a research study.

To ensure that privacy and confidentiality is maintained at all times, researchers must set clear guidelines on data collection and storage procedures before anything else. Especially if all the data collection is done remotely online, extra security measures should be added wherever possible.

While researchers might be motivated to publish the most recent findings related to the impact of the pandemic on mental health, caution must be taken in ensuring that privacy is not breached. Anonymity must be provided wherever possible.

Safety of researchers and participants in case of in person research methods

Mental health research is predominantly through face-to-face interview methods, or through observational methods. However, these methods generally involve the researcher and participant being in an outdoor setting which could be potentially dangerous to both as they are risking exposing themselves to the virus. As far as possible, researchers should try to switch to virtual platforms as an alternative medium for conducting research as that greatly mitigates their risks. Since participants could get wary about giving personal data for research through an online medium, researchers could reassure them by addressing privacy concerns by providing them with evidence that the platform they are using is safe and end-to-end encrypted.

In cases where virtual research methods aren't possible, researchers must strictly follow all COVID-19 related protocols like wearing a mask, face shield, maintaining social distance etc. As far as possible, while going to conduct research, the researchers should avoid public transport and try to travel in a private vehicle so that they cut down their exposure. If a group research is involved, it is very important to schedule it in a way that prevents overcrowding and stick to the schedule. While conducting any form of interactive research, the researchers must also ensure the research participants are also following all safety protocols. If participants are found not following safety protocol, for example, lowering their face mask, it is important for the researcher to correct them and immediately request them to follow the safety protocol.

Research with Vulnerable Populations

Children and adolescents

The biggest ethical issue while doing research with children and adolescents is that of consent. Especially with young children or those who are differently abled, it is imperative that the consent of these participants is taken before anything else. UNICEF has released guidelines on ethical considerations while conducting research on violence against children during the COVID-19 pandemic, where they emphasise that the requirement for gathering data should not override the consideration of the risks involved. These ethical guidelines include the possibility of gathering data remotely to eliminate face to face contact, lockdown rules and restriction measures to name a few. Further, many children have lost their parents due to COVID, and are in a particularly vulnerable mental state. Care needs to be taken that such groups are handled with utmost care and sensitivity, with experienced researchers in the field of paediatric research. In many cases, especially with infants and toddlers, the consent of caregivers is mandatory. Education settings like pre-schools, non-governmental organisations, orphanages, and child development clinics will have ethical guidelines of their own which researchers have to keep in mind.

Sensitivity and safety with the geriatric population

Majority of the geriatric population are not technologically savvy and hence while conducting research with the geriatric population, researchers may be forced to conduct in person research. However, the older population is a high-risk population for Covid-19 as they have a range of comorbidities and weaker immunity than younger people. It is crucial for the researcher to follow safety protocol especially while interacting with the older population.

One of the many ethical issues that come up while conducting research with the home-bound geriatric population is the researcher's role conflict. Parsons has provided a structural account of roles in his notion of the sick role. Merton has also provided information about how role conflict is a sociological construct, in his construct of role-sets. Researcher's role conflict occurs when the researcher is performing two roles with different and sometimes opposing sets of expectations. As a researcher, the normative role expectation is to be someone who is supposed to remain objective and not biased. However, while conducting research, if the researcher comes across something that could be potentially harmful to the participant, the researcher would feel an obligation to act in response to the perceived threat, abuse or neglect of the study participant while at the same time, the researcher would feel the need to remain objective and not do anything that would interfere with the study and dilute the validity of the results.

There are also many ethical issues while conducting research with the geriatric population that suffers from disorders like Alzheimer's. If researchers are conducting research on patients who have recovered from COVID-19, and any of the participants are suffering from Alzheimer's they may have no recollection of it and as a result it may scare them and heighten their paranoia. Many old age related psychological problems like Alzheimer's diminish a person's understanding and decision making abilities. Hence, it is unethical to conduct research on them as they may not fully understand the consent process and their willingness to participate may hence not be entirely consensual.

Ethical issues while doing research on healthcare workers

Health care systems around the world have been crumbling with pressure due to the COVID-19 pandemic. Health care professionals are being faced with challenges they have never seen before. Besides working themselves to the bone with extra shifts and increased patient load, they also have to worry about their own exposure to the virus and carrying the risk back home to their families. Health care workers also feel a lot of helplessness like in situations where they have to turn patients away, or when a particular treatment isn't working and they are losing the patient. A cross-sectional study on the impact of mental health among medical and nursing staff in Wuhan during the 2019 COVID-19 outbreak confirmed two-thirds of mental health disorders, especially in young women. Health care workers form a major cohort for COVID-19 related research, however, there are certain ethics researchers must keep in mind. Researchers should respect confidential data like

a patient's personal details and not press doctors, nurses etc. for giving out this type of sensitive data while conducting a research.
Around the world there have been shortages of medical resources and hospitals have had to turn away patients as they couldn't cope with the numbers. Globally, a lot of medical staff have reported feeling a moral dilemma while providing care for some patients where they know there is minimal medical benefit for the patient as they are nearing the end. In these cases, they feel particularly conflicted in turning away healthier patients who come in for treatment and have a much stronger chance to survive. All of these added pressures are definitely causing an impact on the mental health of healthcare workers and hence it is extremely important for researchers to acknowledge that these are different times and while conducting research on health care workers they must be very sensitive and respectful.

Suicide
Suicide in general, is a mental illness where research data is particularly sensitive. Whether it is related to the family of the individual who committed suicide, or the individual themselves who attempted to end their life, sensitivity and an atmosphere of social support is extremely essential. India witnessed a number of suicides related to COVID-19, and Japan saw its rates of suicide increase in 2020, for the first time in over a decade. Research on the topic of suicide is an important aspect of psychological research during COVID-19, as its findings could be particularly important in providing social support and mental health services to suicidal individuals. That being said, the ethical considerations must not be ignored. It is researcher must be extremely sensitive while gathering data, especially in the case of a suicide attempt. Any wrong wording can cause the individual to be reminded of the traumatic experience, and might make matters worse. It is imperative that the victim and the victim's family is given utmost respect and anonymity.

Studies on grief and death ethics
COVID-19 has taken the lives of millions and left families devastated. A study about the ethical issues in the study of bereavement examined the theoretical opinions of bereaved adults about ethical issues. Participants felt positively about bereavement research, although opinions about timing and method of recruitment were varied. The results also suggest that bereaved individuals should be considered competent to consent to bereavement research participation.
Not only have families struggled with the loss of loved ones, they haven't got closure as many families were not even allowed to meet their deceased relatives and carry out their funeral rites. A documentary study was done to study the effect of suppressing funeral rituals during the COVID-19 pandemic on bereaved families. Based on the analysis of the reports collected, they found that in addition to serious harm to the mental and physical health of those affected, Covid-19 also imposes challenges that need to be considered when planning psychosocial interventions. Families suffer due to being impeded from accompanying their loved ones during their final days in the hospital. After a lonely and helpless death, the suspension of funeral rites makes the mourning of the family members even more painful and incomplete. Hence with families dealing with loss and without getting to say their final goodbye, it is crucial for researchers to be extremely sensitive while conducting any kind of study and maintain grief and death ethics. They must also maintain dignity and avoid asking the family to repeat painful details about their loved one's death.

Ethics committees and their role during COVID-19
Psychological associations all around the world have ethical committees for research. These committees have to create a set of guidelines to protect the rights of the participants, and ensure that the research studies undertaken do not violate any ethical norms set by the committees. In addition, healthcare facilities such as hospitals also have their own ethics committees. These committees might consist of doctors themselves, who come up with a set of clear guidelines. However, in the wake of COVID-19, these doctors are busy on duty, and their focus is entirely shifted to patient care during this time. At a time when researchers want to understand the mental health impacts of the pandemic, these doctors and members of ethical committees might not give the attention required. Therefore, unknowingly or knowingly, researchers might bring in ulterior

motives and violate the ethical guidelines of the facility, potentially putting their participants at risk.

The WHO has released guidelines for research ethics committees for rapid review of research during public health emergencies in order to ensure that research as well as ethical standards are not compromised. The report states that such guidelines must come into place once a public health emergency is declared, and brings up an important point of conducting virtual meetings to review research processes in the event that face-to-face meetings are not possible. The report also mentions that individuals who are experts in the field of ethics must be contacted in advance to ensure that there is no shortage of committee members. All-in-all, researchers must ensure that they take all the required approvals from the ethical committees of the healthcare facilities whose patients they are using as a part of their sample. Be it mental hospitals, old age homes or psychiatric units, the researchers must ensure that they are not violating any ethical norms of that facility.

RECOMMENDED REFERENCES

1. Indian Council of Medical Research. National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic. 2020. https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf
2. Collier K. (2021, February 5). Hackers post detailed patient medical records from two hospitals to the dark web. NBC News. https://www.nbcnews.com/tech/security/hackers-post-detailed-patient-medical-records-two-hospitals-dark-web-n1256887
3. Choudhury S, Ghosh A. Ethical Considerations of Mental Health Research Amidst COVID-19 Pandemic: Mitigating the Challenges. Indian J Psychol Med 2020;42(4):379–81.
4. Research on violence against children during the COVID-19 pandemic: Guidance to inform ethical data collection and evidence generation. UNICEF DATA; 2020
5. Locher JL, Bronstein J, Robinson CO, Williams C, Ritchie CS. Ethical Issues Involving Research Conducted With Homebound Older Adults. The Gerontologist 2006;46(2):160–4.
6. Kang L, Ma S, Chen M, Yang J, Wang Y, Li R, Yao L, Bai H, Cai Z, Xiang Yang B, Hu S., Zhang K, Wang G, Ma C, Liu Z. Impact on mental health and perceptions of psychological care among medical and nursing staff in Wuhan during the 2019 novel coronavirus disease outbreak: A cross-sectional study. Brain Behav Immun 2020;87:11–7.
7. Wingfield-Hayes BR. (2021, February 18). Covid and suicide: Japan's rise a warning to the world? BBC News. https://www.bbc.com/news/world-asia-55837160
8. Beck AM, Konnert CA. Ethical Issues in the Study of Bereavement: the Opinions of Bereaved Adults. Death Stud 2007;31(9):783–99.
9. World Health Organization. (2020). Guidance for research ethics committees for rapid review of research during public health emergencies. https://apps.who.int/iris/bitstream/handle/10665/332206/9789240006218-eng.pdf?ua=1

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Ethical Viewpoint Paper

Critical Issues in Child Sexual Abuse

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Child sexual abuse is an extremely important, yet underreported and inadequately acknowledged problem in today's world. That this is a colossal problem not only in the developed world, but also in underdeveloped and developing nations of the world, cannot be overstated. It also contributes to significant medical and psychological morbidity in the victims, who are innocent children and find it difficult to process the abuse that they are going through [1]. Here we will review the scope of the problem, causes, effects, symptoms, medical and psychiatric problems and approach to the solution of this massive problem.

It is paramount to understand that this problem is underreported in both Western and developing nations. Why is this so? For one, victims of sexual abuse find it very difficult to admit to their friends or relatives or even therapist that they have suffered from sexual abuse. This is because the victims feel that they are responsible for the trauma they have undergone, and sometimes feel that they have invited and attracted the abuse [2]. In our country, there is this ill-founded belief that victims of rape and sexual assault are the ones who are asking for it, because of their behavior, clothing etc. This utterly backward and sick thought process puts additional stress and trauma on rape victims and hence they do not admit what has happened to anyone.

The second point is that children sometimes do not fully understand what is happening to them. Young children are not fully cognizant of what sex and sexuality means, what is the importance of consent, and how physical and sexual attraction and intimacy are linked to feelings of love, trust and connection. At the same time, it does not require knowledge or wisdom to understand that their freedom and their bodies have been violated without their consent because of the criminal mind of someone else. So, emotionally the children are in a very confusing position of feeling cheated and betrayed yet not fully understand why this feeling has arisen [3]. Moreover, they are not able to express this to their caregivers, and the trauma gets internalized. This is the worst thing that can happen because over the course of time the internalized trauma manifests as diseases of the mind and the body.

Another important reason for sexual abuse of children is the fact that they are vulnerable, both physically and mentally. A woman in her twenties will not get into a room with an unknown person or even with a known person if she feels that something is off, but children and innocent and trust everybody. It is only after the act that the horrendous nature of the assailant's plan becomes obvious to them, and sometimes even then it may not! [4].

Then there is the bigger and more real issue- even if a child who has been sexually abused reports it to his parents, quite often the parents brush it under the carpet and behave as though it never happened. Again, these are linked to so called societal values of honour and standing of the family. There is the pervading belief that hiding an episode of rape is better than reporting it (even if it brings justice, closure and treatment of the child) and dealing with 'loss of honour of the family' or 'inability of the child to get married in the future'. When this happens, the victim does not get the medical and psychiatric treatment that he or she needs. On top of this, the parents' refusal to even acknowledge the crime mentally devastates the child and puts him (or her) into a never ending

spiral of guilt, depression, hopelessness, failure and persistent attraction of abusive partners and spouses.

One more cause for the improper handling of this problem is the lack of initiative and apathy shown by the authorities towards victims of sexual abuse and their families. The police mistreat and make fun of these victims and try to dissuade them from making police reports and court cases, again citing the excuse of honour of the family and unwanted media attention. The legal system in this nation is also broken. By the time the case reaches the courts and a verdict can be delivered, years or even decades pass. Moreover, rich and influential people are able to bribe police officers and judges to make sure there is never a case, or even if there is, that there is never a verdict against them [5].

Bonds between parents and children are not always the best. Effective communication is often absent between parents and children. Children are not comfortable discussing even routine issues like school and friends with their parents, so something like sexual abuse is really out of the question. There is also some element of fear in the parent child relationship. The child feels that if he says such things like sexual assault, the parents will physically beat him or throw him out of the house. So, it is easy to understand why the child prefers to keep quiet rather than tell the parent what has happened.

Another important issue is that men (and even women) are not taught from a young age that women should be respected, and children are angels of God and should be given only love and positivity. They believe women and children are easy targets for sex. Since they are physically weaker, they cannot even resist. It is the responsibility of every parent to raise a child with the values of respecting women and children, honouring consent and never forcing anyone to do anything against their will.

A major factor which facilitates the abuse and also impedes the early reporting of such abuse is the fact that in most cases, the accused is someone known to the victim. More often than not, it is usually the father, uncle or in most cases a figure with whom the child is generally comfortable and thus can be easily persuaded to give in to such ghastly acts.

The issue of children being used for sex trafficking in many parts of the world is huge. Street children, school dropouts, children from poor families and children who run away from homes are prime targets for sex traffickers. Once into the system, it becomes almost impossible to get out of it. Many times, the police and politicians are also involved with these criminals in order to satisfy their financial desires. In the bargain, the children's lives get devastated [6].

The impact sexual abuse has on children can never be overstated enough. They are physically and mentally broken and become a shadow of their former selves or potential future selves. Depression is probably the most common effect of being a victim of this horrendous and sick crime. The child loses interest in life and comes to believe that there is no meaning in life. Their strong belief in God or a creator is lost. After all, which God would create humans who rape and torture innocent children? Suicide is an eventuality that must be considered in every such case [7].

Anxiety is another common complication. There are continuous feelings of anxiety, restlessness and nervousness. There is constant replaying of the traumatic experience in the mind which causes sympathetic over-activation, inability to sleep and again, a suicidal tendency. Psychotic behaviour consisting of illusions, delusions and hallucinations can also occur. A sexual abuse event can be a trigger for the development of schizophrenia. The onset of depression, anxiety disorder and psychotic disorder is fertile ground for the development of substance abuse. Moreover, substance abuse can be a form of escape from the reality of being a sexual abuse victim. A number of cases suffering from conversion disorder and psychogenic non epileptic seizures have also been diagnosed in children who have been sexually abused [8].

Children also face abandonment abuse from their families. They lose trust in their parents and distance themselves from them. It is also quite common for such children to leave their homes and completely cut off ties with the family. They become lonely and unhappy souls, always irritable and on the verge of suicide. It also becomes extremely difficult for them to form intimate relationships in the future. They bring patterns of guilt and victimhood into every relationship, constantly fearing that they will be abandoned, hurt and abused by their partners. Many of these children also enter the world of crime, becoming murderers, thieves, rapists and drug distributors.

They may also sexually abuse another person in the future as a form of revenge and hence this vicious cycle continues. It becomes extremely difficult to stop such cycles unless drastic interventions are done.

Such victims of sexual abuse are often reluctant to procreate and have children because they feel their children can also become victims of sexual abuse. There are also medical issues at stake here. Sexually transmitted infections (STIs) are common when sexual abuse occurs. HIV is likely to be transmitted to recipients of sexual intercourse rather than the active partner. Also there is spread of other STIs like syphilis, gonorrhea, herpes etc. There can also be trauma to the genital tract in forced abuse, leading to tears, fistulae with the urinary or gastrointestinal tracts or even gastrointestinal perforation. Any of these conditions can lead to death. Another worrisome issue is that of childhood or teenage pregnancy which can be a grave result of the sexual abusive act. Realizing that the child is pregnant as a result of abuse can have devastating effects on the child who might not be able to grasp the gravity of the situation and also on the parents of such child who would now have to manage not only the fragile mental state but also the unwanted pregnancy [9].

When such victims of sexual abuse suffer from a psychiatric disorder, their general health and nutrition suffers. Hence, they are prone to develop malnutrition, vitamin and mineral deficiencies and diseases like tuberculosis. Human Papillomavirus infection, if transmitted during sexual intercourse, can lead to malignancies of the cervix, vulva, vagina and anus.

It is also well known that memories of traumatic diseases are stored in the cells. When intense emotional trauma occurs, there are also epigenetic changes in the cells like DNA methylation and histone acetylation and de-acetylation. This leads to changes in the pattern of gene expression which can lead to weakening of the immune system and susceptibility to infections. It also has been purported to have a role in the development of hypertension, diabetes mellitus, autoimmune diseases and cancer [10].

What can we do to address the humungous problem of child sexual abuse and its attendant consequences? For one, there should be awareness of this problem even in the remote rural areas. Government and voluntary organizations should take efforts to educate the people about the existence of this problem. It should be introduced into the curriculum of schools so that children are aware of this problem from an early age and are able to recognize it when it happens to them or to their peers.

It is important to have grassroots level health workers at every Primary Health Centre who can be approached about this problem, and who can coordinate with higher medical services and also with police and legal authorities. The police and courts should be made more efficient and sexual abuse cases should be made a priority. They should be processed in Fast Track Courts and verdicts should be given as soon as possible. Sentences for rapists should be extremely strict. The identity of the victim should be kept hidden as much as possible from the press.

It is important to inculcate into people that children and women should be respected and treated as equals. Rapists should be looked upon with disdain and reported to the pol ice, rather than protected.

Psychiatric help is essential for the proper management of victims of sexual abuse. It is important for them to have a therapist with whom they can talk, express their feelings and emotions, and achieve catharsis. Drug therapy also has a role in the treatment of depression, anxiety and psychotic disorders. It is also important for the patients and their families to continuously follow up and be in touch with the system. Failure of follow up can lead to relapse. It is also important to have a team of social workers at every level who can help both the patient and the family with the consequences of sexual abuse. They will help the patient to get a job, earn money and become independent. They will also help the family to slowly integrate itself to the society without feelings of guilt or remorse [11].

There should be proper legislation which is very clear and explicit to deal with matters of sexual abuse. There should be a positive expression of such issues in the media, newspapers, films and movies. These can be a source of empowerment for victims of sexual abuse and marginalized groups. If the courts can convict high ranking officials and rich people who are guilty of rape rather

than protecting them, it will set an example and infuse life into this country and the world, giving it hope that we can finally overcome the problem of child sexual abuse.

REFERENCES

1. Murray LK, Nguyen A, Cohen JA. Child sexual abuse. Child Adolesc Psychiatr Clin 2014;23(2):321-37.
2. Crosswhite JM, Kerpelman JL. Coercion theory, self-control, and social information processing: Understanding potential mediators for how parents influence deviant behaviors. Deviant Behav 2009;30(7):611-46.
3. Blakemore T, Herbert JL, Arney F, Parkinson S. The impacts of institutional child sexual abuse: A rapid review of the evidence. Child Abuse Negl 2017;74:35-48.
4. Sanjeevi J, Houlihan D, Bergstrom KA, Langley MM, Judkins J. A review of child sexual abuse: Impact, risk, and resilience in the context of culture. J Child Sex Abuse 2018;27(6):622-41.
5. Mathews B, Collin-Vézina D. Child sexual abuse: Toward a conceptual model and definition. Trauma Viol Abuse 2019;20(2):131-48.
6. Browne-James L, Litam SDA, McRae L. Child Sex Trafficking: Strategies for Identification, Counseling, and Advocacy. Int J Adv Couns 2021;43(2):113-25.
7. Douglas M, Schatte D, Harper RA. The Aftermath of Childhood Sexual Abuse: A Case Report and Review of the Literature. Adolesc Psychiatry (Hilversum) 2011;1(3).
8. Vincentiis S, Valente KD, Thomé-Souza S, Kuczinsky E, Fiore LA, Negrao N. Risk factors for psychogenic nonepileptic seizures in children and adolescents with epilepsy. Epilepsy Behav 2006;8(1):294-8.
9. Fortin-Langelier E, Daigneault I, Achim J, Vézina-Gagnon P, Guérin V, Frappier JY. A Matched Cohort Study of the Association Between Childhood Sexual Abuse and Teenage Pregnancy. J Adolesc Health 2019;65(3):384-9.
10. Hindin P, Btoush R, Brown DR, Munet-Vilaro F. Intimate partner violence and risk for cervical cancer. J Family Viol 2015;30(8):1031-43.
11. Sawrikar P, Katz I. Barriers to disclosing child sexual abuse (CSA) in ethnic minority communities: A review of the literature and implications for practice in Australia. Children Youth Serv Rev 2017;83:302-15.

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