Review Paper

Bio Medical Ethics Issues in handling the Pandemic

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ABSTRACT

The current pandemic has brought to light a multitude of bio medical ethics issues with regard to handling the pandemic, highlight some of the major transgressions and suggest viable alternative measures that can be tried, to reduce the conundrum of risk versus benefit. The devastating pandemic that has struck the worldwide population induced an unprecedented influx of patients in ICUs, raising ethical concerns not only surrounding triage and withdrawal of life support decisions, but also regarding family visits and quality of end-of-life support. These ingredients are liable to shake up our ethical principles, sharpen our ethical dilemmas, and lead to situations of major caregiver sufferings. Proposals have been made to rationalize triage policies in conjunction with ethical justifications. However, whatever the angle of approach, imbalance between utilitarian and individual ethics leads to unsolvable discomforts that caregivers will need to overcome. With the above things in mind a detailed study has been made to identify the different Biomedical ethics involved in handling the pandemic especially in the area of Health care workers and hospital ICU and effort to contribute during the pandemic by using the engineering knowledge of HVAC laboratories have been designed in 3 weeks' time and handover to concerned have also been highlighted here.

Keywords: bioethics, biomedical ethics, pandemic, COVID-19.

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Ethics and COVID-19

From resource allocation and priority-setting, physical distancing, public health surveillance, health-care worker's rights and obligations to conduct of clinical trials, the COVID-19 pandemic presents serious ethical challenges. These in turn are complicated by the diverse health systems and unique cultural and socio-economic contexts of countries. Consequently, there is a great need for guidance to ensure ethical conduct of research, decision making in clinical care, and public health policymaking at every level of the global COVID-19 response [1].

Critical ethical choices with ICU and Caregivers

The paper aims to point out some critical ethical choices with which ICU caregivers have been confronted during the Covid-19 pandemic and to underline their limits. The formalized strategies integrating the relevant tools of ethical reflection were disseminated without deviating from usual practices, leaving to intensivists the ultimate choice of decision. The devastating pandemic that has stricken the worldwide population induced an unprecedented influx of patients in ICUs, raising ethical concerns not only surrounding triage and withdrawal of life support decisions, but also regarding family visits and quality of end-of-life support. These ingredients are liable to shake up our ethical principles, sharpen our ethical dilemmas, and lead to situations of major caregiver sufferings. Proposals have been made to rationalize triage policies in conjunction with ethical justifications. However, whatever the angle of approach, imbalance between utilitarian and individual ethics leads to unsolvable discomforts that caregivers will need to overcome [2]. The paper addresses issues with shortages of ventilators which have occurred in Italy and are likely imminent in parts of the US. These circumstances raise a critical question: when demand for ventilators and other intensive treatments far outstrips the supply, what criteria should guide these rationing decisions? Existing recommendations for how to allocate scarce critical care resources during a pandemic or disaster contain ethically problematic provisions, such as categorically excluding large populations of patients from access to scarce intensive care unit (ICU) resources. This viewpoint addresses these ethical concerns and provides a framework for making allocation decisions that incorporates multiple ethically relevant considerations, while allowing all patients in need to be eligible for access to critical care [2].

Healthcare Workers Under Extremely Stressful Circumstances

During the coronavirus disease 2019 (COVID-19) pandemic, some healthcare facilities have at times, reached the limits of their capacity to handle the surge in patient volume. Hospital beds and other medical resources became scarce as a consequence. Healthcare workers (HCWs), both clinical and non-clinical, were required to increase their workload, under extremely stressful circumstances.

HCWs are routinely exposed to numerous stressors, which results in high rates of burnout, post-traumatic stress disorder and suicide, especially among those working in high intensity environments. This has been especially true during the COVID-19 pandemic. Physically stressful working conditions and witnessing the suffering and death of large numbers of patients take a toll. Further, when resources cannot fully meet demand, HCWs may experience moral distress due to rationing decisions. In addition, being confronted with a highly contagious pathogen such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), there is also the fear of becoming infected oneself or spreading the infection to one's family (table 1).

This stress may contribute to physical exhaustion and feelings of fear and anxiety, sleep disorders and insomnia, or even burnout and depression. All of this is compounded in a situation like a pandemic where the effects are felt beyond the work environment, giving HCWs the sense that there is no way to escape the pressures outside the hospital. Anxiety is further heightened by the uncertainty about when the pandemic will end or how bad it will get. With all of this psychological trauma, some HCWs will need extra time away from the hospital; some may never return to their jobs. As a consequence, healthcare facilities and systems could lose HCWs precisely at a time when they are needed most, further aggravating the situation of scarcity created by the increased demand. Therefore, it is crucial to keep working conditions as safe as possible in times of crisis. As patient surge reaches critical limits, tasks not absolutely necessary for patient care should be reduced as much as possible, while preserving safety.

Table 1: Stressors for healthcare workers (HCWs) during the coronavirus disease 2019 [3]

Stressor	**Description**
Physical stress	Care for COVID-19 patients is particularly strenuous, since wearing of protective gear is required and specific interventions, *e.g.* prone positioning, are physically demanding for HCWs
Extra hours	When hospitals become overburdened by the number of patients and at the same time suffer from absenteeism of diseased HCWs, the remaining staff may require working serious amounts of extra hours

Stressor	**Description**
Fear of becoming infected or transmitting infections to non-COVID-19 patients, family or friends	Close contact to infectious patients poses a risk for HCWs of getting infected and also a risk for transmission of SARS-CoV-2 to non-COVID-19 patients
Restricted visitor policy	Visiting restrictions for relatives and friends of patients causing regrets and sorrow for HCWs
No conceivable spatial or temporal boundaries of the pandemic	No outlet to escape the situation because the pandemic as well as the stressors are not confined to the hospital, and not knowing when the pandemic is going to end
Social isolation	Family members of older age are at risk and cannot be seen, family celebrations cannot take place
Fear of losing family members, friends or colleagues	HCWs may care for many severely ill patients, constantly aware of the danger of a COVID-19 infection
Frustration with political leaders	Perceived or real inconsistencies and management failures of political leaders increase the feelings of helplessness and being at the mercy of others
Frustration with administration for not having enough equipment/PPE or failure to protect/testing equipment	Perceived or real management failures of administrative staff when equipment for self-protection is not sufficiently available increase the feelings of being sacrificed, thus causing anger
Uncertainty because of frequently changing information about COVID-19	HCWs are frequently asked about their opinion and for advice; they have to deal with a lot of uncertainty themselves and can be overwhelmed when facing individuals who do not understand social distancing and deny the danger of a pandemic spreading rapidly
Moral distress	Feelings of being left alone for rationing decisions on own moral standards when there are limited supporting structures a

Table 2: Reciprocal obligations for members of society with the goal of limiting the number of infected patients and reducing strain on the healthcare system.

Societal level	**Responsibilities**
All members of society	Social distancing Contact restrictions and avoidance of large group gatherings Wearing of facemasks in public Frequent handwashing Protection of healthcare workers from unjustified legal action due to providing crisis standard of care

Societal level	**Responsibilities**
Friends, family, colleagues and neighbours	Active listening Provide emotional support Encourage healthcare workers to seek help from mental health specialists Provide help for everyday duties (*e.g.* shopping, childcare)
Healthcare administrators and institutions	Ensure adequate personal protective equipment Limiting healthcare workers' workload by shifting tasks that are not absolutely necessary for patient care to non-clinical personnel Provide for counselling services Develop "work–life balance" programmes Promote self-care messaging Provide for education and teaching about recent scientific evidence related to the spread of SARS-CoV-2 and protective measures
Unions and professional organizations	Develop "work–life balance" programmes Promote self-care messaging Develop educational programmes about recent scientific evidence related to the spread of SARS-CoV-2 and protective measures Advocate for healthcare workers' needs to employers, hospital administrations and governments Protection of healthcare workers from unjustified legal action due to providing crisis standard of care
Local, regional, and national government	Ensure adequate access to personal protective equipment for institutions Support development of institutional and regional policies for rationing and triage Provide for financial protection of dependents of healthcare workers who become infected during their work Thorough explanation and public education regarding (scientific) rationale of restrictions and burdens Protection of healthcare workers from unjustified legal action due to providing crisis standard of care

Moral imperatives, and, similarly, the legal and professional obligations derived from them, cannot be a unilateral commitment by HCWs; they should instead be considered as part of a societal contract consisting of mutual interests, rights and duties. HCWs should be able to rely on reciprocal obligations from others [4]. The scope of these reciprocal obligations is similarly context- and situation-dependent. In the setting of the COVID-19 pandemic, HCWs must be able to rely on a wide array of support, as well as the responsible behaviour of other members of society (table 2). For instance, situations in which HCWs put themselves at risk due to the lack of personal protective equipment must be strenuously avoided. Similarly, reciprocal responsibility and solidarity also includes responsible behaviour of all members of society. Contact restrictions, social distancing, and the wearing of facemasks in public can help save HCWs, health facilities and health systems from being overburdened. Finally, compensation for surviving dependents of HCWs who became infected during their work and died should be part of these reciprocal obligations as a matter of solidarity.

When demand for resources overwhelms supply, the inability to provide standard of care due to lack of staffing or equipment raises not only moral but also legal questions [5]. HCWs, and in particular physicians, may be at risk for being sued for not providing a normal standard of care despite being in a crisis for which they themselves could not reasonably be held responsible [6]. Working under a crisis standard of care that may, of necessity, be well below the ordinary standard of care, can be a source of extreme stress for all HCWs. This stress should not be compounded by the fear of legal prosecution, whether civil or criminal. The reciprocal responsibility of society at large should therefore entail the protection of HCWs in general from legal action based on a failure to provide an impossible-to-achieve standard of care in times when clinicians are forced to practice under crisis standards of care [5].

It is also very important to acknowledge the psychological impact of these decisions by hospitals on health workers. The mental and physical strain is significant and frequently debilitating. Workers are under constant pressure to test and successfully diagnose, isolate and treat patients – all while under intense scrutiny by the people, the press and the administration. The fundamental workforce consists of junior residents and intern doctors. However, executives and medical superintendents often fail to understand that they are learners and clinicians-in-training, not full-time employees. Constantly pushing them without encouragement or guidance is bad for health. There is also an entrenched conviction that treating patients is the sole duty of doctors – a belief that has allowed some administrators to take advantage and excuse themselves from addressing doctors' needs. Specifically, during the pandemic, itself, workers are also beset with long working hours, inadequate supply of PPE, more clerical work and lack of accommodation to quarantine or isolate themselves. Even when PPE is available, using it is not easy because it limits opportunities to wash oneself or use the toilet, leading to physical and mental fatigue. In these circumstances, workers are expected to work for 8-12 hours on paper but often work for longer, and often with high quality and attention. This can and does get agonizing [6].

Preserving the lives of HCWs may help preserve one of the scarcest resources in this pandemic and thereby potentially save more lives through their work at the bedside. However, prioritization of HCWs will disproportionately benefit the educated and thereby aggravate existing social and racial disparities, which may be in conflict with egalitarian principles and equity. Several prioritization guidelines for the distribution of COVID-19 vaccines have acknowledged prioritization of frontline HCWs. However, other guidelines avoid taking a position with regard to favouring HCWs over elderly patients by awarding both groups the vaccine with equal priority. Both approaches have merit but considering all arguments we advocate for prioritization of frontline HCWs for SARS-CoV-2 vaccines [7].

Ethics In Handling the Pandemic and ICU

In everyday medical practice, a therapeutic decision to admit a patient to the intensive care unit (ICU), including various stages of care escalation (intubation, circulatory support, dialysis, extra-corporeal membrane oxygenation), requires a medical indication and incorporates the patient's will. Where resources are not limited, this decision is generally made with a focus on the potential benefit to the individual patient, unless the patient opts out of the treatment. If a therapeutic goal cannot, or is unlikely, to be achieved within the framework of the ICU, it is possible to not start (withhold) or to end (withdraw) the therapy. For example, a decision to withdraw ventilation or dialysis may be acceptable if there is little or no expected benefit. Such decisions should be made in a team with the involvement of the patient and relatives. Intensive care teams around the world have adopted these standards over the past decades and have found ways to implement them, often with input from clinical ethicists [8].

In crisis situations, such as pandemics, the admission and decision-making processes can change significantly if there are insufficient resources for care, as each decision taken for one patient may affect the decision-making for other patients. Triage in crisis situations comprises the selection of patients who will receive treatment, meaning that those not selected may not receive treatment from which they could benefit. The basic values underlying triage decisions in crisis situations generally include prioritization of medical urgency, capacity to benefit and fairness. For COVID-19, various guiding principles have been suggested, in particular the maximization of benefit and justice, including considerations such as treating people equally, promoting instrumental value, and giving priority to the worst-off. Triage decisions thus include medical factors, such as the severity of the health condition and likely outcome, as well as fairness in resource allocations and ethical issues [9-10].

Maximizing benefit

Maximizing benefit under conditions of scarcity can mean different things: it could refer to saving as many people as possible, to saving the greatest possible number of life years, or to saving the greatest amount of quality-adjusted life years (QALYs), with the resources available. Depending on which criterion is applied, resource allocation will look quite different. Saving as many life years as possible would favour young people, whereas maximizing QALYs would favour those with a capacity to lead long, healthy, independent lives [11].

Maximizing benefit gives back a sense of control in a desperate situation: although it may be impossible to help all patients, it is still possible to save those who will benefit most. The application of this guiding principle is not straightforward, however, and depends not only on how the medical assessment of benefit and its probability are operationalized but also on sociocultural and ethical norms concerning which benefits matter [12]. Defining benefit for application in triage in a pandemic, for instance, requires weighing short-term against long-term prognosis, including the impact of age and comorbidities as potential triage criteria. The question of whether people who are of instrumental value (e.g., healthcare workers) should be prioritized6 is an additional consideration compatible with the overall idea of maximizing benefit. In order to enable the necessary therapeutic decisions to be made consistently and fairly, criteria for maximizing benefit in triage situations must be clearly and transparently defined.

Although the focus here is on triage, it is important to note that in crises such as the SARS-CoV-2 pandemic, benefit can most effectively be maximized not at the level of triaging those who have fallen seriously ill but at the population level, where disease prevention in the general and vulnerable populations, and in the healthcare workforce is key. This includes ensuring that measures are in place to protect the most vulnerable in society, who have often traditionally been marginalized or in whom the social determinants of health have enhanced their vulnerability, as well as to support treatment teams with appropriate protective equipment (PPE) and potential prioritization for vaccinations, if available. A reward for individual commitment, such as prioritization of vaccination for healthcare workers, or allocation of the most effective masks (FFP2, N95) to those with greater exposure to respiratory droplets, can motivate people to contribute to a crisis [13].

Justice

The principle of justice in triage can be understood to mean that all patients with a comparable prognosis should have equal access to necessary medical care in the event of a crisis, based on predefined medical and ethical criteria. There is some controversy as to how to proceed in a next step, regarding the allocation of limited therapy to patients with the same prognosis. Whereas some have argued for a ‘first come, first served’ rule, others favour a lottery or randomization in order to avoid disadvantaging those who arrive later for reasons that are beyond their control (e.g. a delayed diagnosis) [14].

Other criteria for distribution, such as preferential treatment based on merit, are often rejected based on objections such as arbitrariness and the societal implications of connecting survival to certain distinctions or social roles [15]. Giving priority to the worst-off, another potential distribution criterion, is hard to reconcile with the idea of maximizing benefit, assuming the worst-off are not or at least less likely to benefit. Triaging guided by benefit maximization would rather favour the group that is severely affected and needs treatment urgently but is still well enough to be likely to profit from treatment. In fact, the conventional triaging process (e.g., in mass disaster) explicitly advocates excluding those who are least likely to benefit from treatment as well as those not in urgent need of care if resources are constrained.

Whereas justice in general invokes equality, meaning that everyone should receive the same treatment, equity—another concept relevant to triage—emphasizes the need to avoid discrimination, and to address ‘remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification’ [16]. Equity may mean different treatment for different needs, which is challenging to achieve in the context of triage, where advanced age and comorbidities may impact survival and benefit maximization.

Given the multitude of potential criteria for operationalizing justice in concrete allocation decisions, procedural approaches have been suggested, to work towards a consensus that is acceptable to all those affected by the decisions to be taken [17].

Overall, two major principles constitute the normative basis of triage guidelines: benefit maximization and justice. For the purpose of our analysis, we will focus on equity and fair process, and list any additional considerations mentioned in the guidance texts [18].

Triage Guidelines for the Sars-Cov-2 Pandemic

Italy was one of the first countries to experience a large number of patients who were critically ill at the same time, which led to a shortage of ventilators and intensive care resources [19].Although there may be nuances to this claim and more evidence is needed, access to ventilation therapy in COVID-19 was by default perceived as a matter of life or death, so that scarcity of respirators and ICU beds received special attention [20]. In the initial stages, overwhelmed by the acute crisis, care allocation decisions had to be taken in the absence of formal triage guidelines. This led to much distress on the part of individual clinicians and teams who continuously had to make allocation decisions at the bedside. Under conditions of scarcity, stress and fatigue, there may be errors and inconsistency in the decisions taken [21]. Not all countries have had to face the dire scarcity faced by Italy, but over the past months, in anticipation of demand escalation, triage guidance has been developed or adapted from former influenza pandemic guidelines in various countries [22]. This body of guidance documents aims to facilitate the decision-making process in triage situations, enhancing transparency and objectivity, and lifting some of the moral responsibility from individual clinicians' shoulders.

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All guidance documents mention that the patient's wishes regarding ICU therapy must be elicited and if possible respected. For instance, Australia/New Zealand guidance calls for 'discussions about goals of care, patient and family preferences, and the acceptability to the patient of critical care interventions if offered' [25]. Other guidance, such as from the United States, points to the deviation from the typical informed consent scenario in which all possible options are laid out to a patient [26]. In triage situations, not all treatment options can be offered to all patients who might benefit from them. The focus on patient will in the triage guidance is therefore on the patient's or surrogate's right to reject intensive therapy. Some guidance recommends promoting advance directives, so that reflection occurs calmly before an individual has fallen ill.

Conclusions

The COVID-19 pandemic has brought unprecedented, major challenges to the ethical conduct of research including challenges for the rapid and robust ethical review of biomedical research. No other humanitarian emergency to date posed similar global concerns to all research stakeholders. Governments around the world are trying their best to put in place sound governance mechanisms for urgently needed research. The coordinated efforts of all the Ministries of the government of India are trying their best to keep the pandemic under control.

The Indian Council of Medical Research's "National Guidelines for Ethics Committees Reviewing Biomedical and Health Research during COVID-19 Pandemic" is one such effort. Ethics committees, which are themselves under pressure from lockdown measures, are encouraged to be innovative in their support for researchers; to approve studies rapidly but simultaneously ensure that informed consent is not endangered; that vulnerable people are only involved in research that is relevant to their health; that healthcare workers are protected, including from assault; that communities are approached in such a way that they can build trust with researchers; that the media accept their responsibility for avoiding fake news; and that researchers whose ongoing studies suffer from missing data and low sample sizes are supported.

The road to normalcy being remote, all the recent changes made in the system may become the new normal for the future. It is difficult to predict whether the situation for research will stabilize soon or whether we are sitting on a volcano which can erupt at any time causing more damage than we ever expected. Only global collaborative efforts will help to tide over in the present crisis. During the pandemic an effort made to design Laboratories for COIVID testing has been made and 2 laboratories has been developed and few designed, sufficient efforts have also been made to spread awareness of COIVID 19 through posters.

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