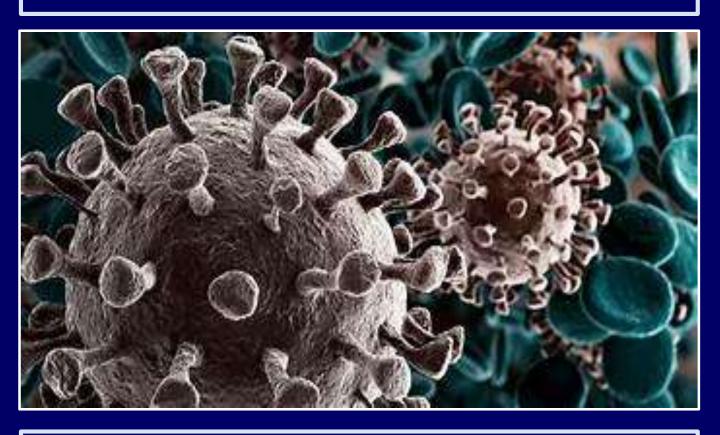


# Global Bioethics Enquiry

The Scholarly Publication of the UNESCO Chair in Bioethics



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## The scholarly publication of the UNESCO chair of Bioethics

# GLOBAL BIOETHICS ENQUIRY

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**Editorial** 

## Ethical Issues in Psychotherapy with Adolescents

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Psychotherapy for adolescents with psychological problems has made rapid progress in the last few years. Alongside this progress, there has been the emergence of ethical issues that need to be addressed in various clinical settings. The involvement of parents in adolescent psychotherapy often fuzzes therapeutic boundaries and issues related to confidentiality. The mental health professional working in a hospital or school setting is fraught with multiple problems. The advent of tele-psychotherapy and online psychotherapy has resulted in newer ethical dilemmas for mental health professionals with ethical issues related to communication via that medium. The issues related to parenting, culture and development patterns are also elucidated with a focus on ethical issues for psychotherapy with adolescents [1].

When a psychiatrist / psychotherapist comes face to face with treating an adolescent the aims are in doing what lies in the best interest of the adolescent like protecting the privacy of communication and respecting the adolescent as and the family while promoting and supporting the highest level of development and autonomy for the adolescent in question [2]. The practice of adolescent psychotherapy needs the therapist to achieve and establish rapport with both the adolescent and his/her parents or guardians. Psychotherapy in this special group is a complex and difficult challenge with multiple stakeholders like the child's development in the context of family dynamics, involvement of the school to evaluate the child's educational strengths and weaknesses and sometimes the social work and legal system to look after the needs of the adolescents [3]. We now look at some ethical dilemmas in this domain.

#### Therapeutic Boundaries and Adolescents

During any psychotherapy process, subtle instances arise that may pose a risk for boundary problems. Adolescents may challenge boundaries by posing personal questions, such as those about marital status or whether we have children and the career choices that our children have made. Such questions may be purely inquisitive and are potential opportunities to understand the child further. Motivations for these questions can be explored without necessarily having to provide an answer to them. They may also want to connect with us personally via messaging on social media and on various platforms. Therapeutic neutrality can be a helpful guide for making our way with an adolescent in the psychotherapeutic process [4]. Neutrality does not mean that the mental health professional does not care about the child or does not react with feelings to the evolving process. The therapist will neither encourage nor condemn the adolescent or his/her parents and their behavior, but remain interested, wanting to understand their meaning for the adolescent. Mental health professionals have to realize that therapeutic issues with adolescents may be beyond transference and counter-transference and that the adolescents' perceptions of the therapist and vice versa can greatly inform us about the conflicts involved [5].

#### Autonomy in adolescent psychotherapy

There is growing recognition of the adolescent to contribute to decisions based on understanding and objectivity. There remain many clinical and ethical indications for adolescents to participate in the decisions about treatment including psychotherapy. The working alliance is strengthened

when the adolescent feels that he/she has participated in an informed decision to pursue psychotherapy, rather than experience it as imposed on him/her [6]. In today's era where adolescents are quite well read and aware, they must be involved in treatment decisions concerning them when they have the insight and acumen to decide while they have the ability to give assent rather than consent which shall be given by their parents. All decisions in adolescent psychotherapy must be made in the light of parental attitudes, socio-cultural factors, religion and the underlying psychiatric diagnosis and psychopathology [7].

#### Confidentiality in adolescent psychotherapy

The psychotherapist dealing with adolescents has a strict responsibility to protect information about the adolescent and his/her family. These principles also serve as the underpinnings of the psychotherapeutic relationship between the adolescent and the mental health professional involved. It is only with the establishment of trust and confidence that a therapeutic space can be created. Within this space, the adolescent can feel sufficiently safe to trust the freedom to reveal all without being judged, retaliated, condemned and reprimanded [8].

In India, more so than the west, we face problems with regard to confidentiality issues when treating adolescents. First, as most of them are accompanied by their parents for consultations and therapy sessions, parents feel that they have a right to know what is going on within the minds of their adolescent may not agree with the confidentiality theory always. Also, many of the times parents pay for the therapy and hence expect the therapist or clinician to listen to them as well as reveal all that transpires within therapy between the therapist and their adolescent.

In school settings, it is even more difficult as a referral to the school counselor without parental approval is often scorned upon by many parents. Professionals conducting psychotherapy with adolescents encounter unique challenges in their efforts to protect their patient's privacy. They rarely operate in a vacuum sealed from interaction with parents and guardians [9].

In Indian society more so than the west, the belief is that a child hides nothing from his parents and that parents must know all when it comes to their child's problems. In fact, it often hurts the parent's ego when the adolescent thinks of going to counselor as parents feel that he has no confidence in them. They believe that he prefers to take problems to an outside party than keep them at home. In the west, psychotherapy for adolescents is better accepted and there are strict laws about confidentiality and almost every issue in psychotherapy, which is lacking in developing countries [10].

In one situation, the child and adolescent psychiatrist may be challenged to protect the privacy of the psychotherapeutic process from parents or guardians who are too intrusive and meddling. In some cases, the therapist may appeal for greater involvement and openness from parents who are perceived as too cold and aloof [11]. Parents and guardians have rights to be informed about any form of treatment conducted for their child, including psychotherapy, and have to be updated on their child's progress. A psychotherapy process with a child or adolescent that is too opaque to the parents may cause dissatisfaction and distrust with the therapist resulting in premature termination of therapy.

Adolescents must be able to trust that he or she has sufficient privacy for the process to be effective. They may not reveal vital information in therapy if they do not perceive this privacy as they may view the therapist as a middle man who just is waiting to reveal information or complain about them to their parents [12]. The psychotherapist has to review with parents the structure of the psychotherapy frame, the type of therapy, interventions in mind and importantly, their rationale. Issues relevant to privacy and confidentiality should be addressed. Parents can be reassured that shall be informed about the process and effects of interventions intermittently. The parents also can be reassured that information suggesting imminent danger to their adolescent or others would not be withheld from them.

#### Third party communications during adolescent psychotherapy

There may be multiple requests for information about an adolescent in psychotherapy or treatment progress. This is more so in the school mental health where teachers or the principal may want to know about the adolescent. Sometimes a written report about the same may be demanded. The

therapist becomes the gatekeeper of information and guardian of the adolescent's privacy. The therapist should respond to any request for release of information with consideration of its appropriateness and necessity and the potential impact of what is released on the adolescent and the psychotherapy process. When considering written or verbal communication to a third party, one should discuss the request with the adolescent and the parents or guardian. Reports requested by schools, courts or hospitals should be reviewed carefully, scrutinizing whether the content is congruent with the needs of the request and whether the reports contain information about the adolescent beyond what is needed. The therapist always should consider the long-term fate of what is released, including whether the setting receiving the material will be able to guard the privacy of these records in ways appropriate for their content [13].

#### Telepsychotherapy and adolescents

There are issues which come up with adolescents in that they may quite digitally aware and happy with a telepsychiatry model, while again prescribing medication and monitoring the same gets difficult in these populations. Parents may times want to be around children and adolescents during telepsychiatry counseling sessions and may thus not allow the privacy that is otherwise possible in a clinic setting. Apart from these confidentiality issues, the loss of essential elements of the therapeutic action seen in face to face sessions may be lost compromising the therapist-patient relationship. Talking to children and adolescents via blogs or social networking sites is strictly prohibited for the therapist. The same holds true for chats via messenger or talk networks as the security of these sites itself raises significant concern. It is also prudent that any therapist on a social networking sites refrains from adding the adolescent client as a friend as this involves breach of the therapist-patient relationship. A reliable time and place for contact and therapeutic work is exchanged for telepsychotherapy. Video call is always preferred to audio call to allow face visibility and emotional understanding [14].

#### Encounters outside the therapeutic space and in public places

Public encounters with patients pose challenges to privacy and confidentiality and to the adolescent. Although often unpredictable, some public encounters can be anticipated and avoided. When a therapist is aware that an adolescent may be at an event that he or she attends, one may choose to avoid the event or discuss the potential encounter with him or her ahead of time. In general, it is best for therapists to explain to the adolescent and his or her parents that, in the case of encounter outside of the office, one will err in the direction of not acknowledging them unless they initiate an acknowledgment [15].

#### Counter-transference in adolescent psychotherapy

Countertransference has been defined as feelings and attitudes toward a patient derived from earlier situations in the analyst's life that have been displaced onto the patient and may include all emotional reactions to the patient, conscious and unconscious, especially those that interfere with understanding and technique. The relevance of counter-transference and neutrality to the ethics of conducting psychotherapy lies in the critical importance of the child and adolescent psychiatrist's attention to his or her emotional reactions to one's patient and one's patient's parents or guardians. Common warning signs in the behavior of the therapist include recurrent lateness to sessions, extensions of sessions, touching of patients, gifts to the patient, and contact with the patient outside of scheduled sessions, especially outside of the office setting [16].

#### **Conclusions**

As noted above there are many ethical issues governing the conduct of psychotherapy with adolescents. Advances in development, globalization, the technology age, variations in parenting, religion, cultural factors, social and economic factors, legal requirements, the therapy setting and the therapist's own judgment should stimulate consideration of how these ethical principles apply to various situations. However, the most pivotal remains the psychotherapist's obligation to create and protect the integrity of the psychotherapeutic space to provide the adolescent the freedom to identify, examine, explore, and hopefully resolve the issues that bring one to treatment.

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# Ethical Issues in Patient Care in the current COVID-19 Pandemic

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#### **ABSTRACT**

The COVID pandemic continues unabated. Management of COVID patients have brought about huge ethical dilemmas to the fore. There are several concerns and conflicts that afflict the care of these patients. The various ethical issues that have been brought up by the COVID pandemic and measures to mitigate them have been highlighted in the manuscript. Rationing of resources, however clinically justified, is against the ethical principle of Justice which demands equitable distribution of resources and consideration of needs of all patients even while caring for an individual patient. Protecting the patient may be guided by the altruistic principles for the healthcare workers but the price paid by their families is another ethical concern. Diversion of resources to the COVID services compromises care of patients with non-COVID diseases including life threatening conditions like cardiac problems and malignancies. Neglecting these patients once again questions the ethical premise of Justice and equitable distribution of resources. Cardio-Pulmonary Resuscitation and End of life decisions bring about another important ethical concern. The mental anguish of the healthcare workers is another area of concern. The pandemic has also led to an explosion in research. Conduct of these studies and retraction of some major manuscripts highlight further ethical concerns.

Key words: COVID-19, ethics, pandemic, patient care

#### Introduction

The severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) or Corona-Virus Disease (COVID-19) continues unabated. Countries where the initial peak and trough was reached are now facing newer cases. In the absence of a major breakthrough with Vaccines and "herd immunity" still not being reached it is likely that the pandemic will continue for many more months. This is bound to put a strain on healthcare establishments in terms of infrastructure and manpower perspectives. When resources are limited the distribution of these resources are often influenced by ethical considerations. The imbalances in resources often lead to an emotional disquiet which is difficult to assess objectively but nevertheless are influenced by ethical concerns. While development of evidence-based treatment protocols for COVID -19 patients as well as meeting the critical care needs of non- COVID patients and procedures are essential we also have

to ensure that the care is provided within ethical principles. Moreover, these ethical principles apply not only to the patients but also to the caregivers and the institution and most importantly to those to who are denied the care owing to the pandemic. The pandemic because of its novelty has brought about a deluge of publications and because of the clinical needs most institutions have relaxed the ethical scrutiny for research. In this review we highlight the main ethical concerns the current pandemic has raised for all the stakeholders.

#### **Ethical Dilemma in Resource Allocation**

Almost 20% of patients infected with COVID-19 may require critical care support [1]. Mechanical ventilation is the commonest reason for ICU admission [2] and among patients requiring mechanical ventilation the mortality is in excess of 80% [3]. There are less than one lakh critical care beds in the entire country of which almost 60% are provided by the private hospitals. Only half of these critical care beds are supported with a ventilator and once again almost two-thirds of these ventilators are provided by the private sector [4].

Irrespective of the source of the critical care beds and the ventilators, the fact remains that these are grossly inadequate to meet the demands imposed by the pandemic. Experience from other centres in the world suggests that almost 20% of patients infected with SARS-CoV-2 virus may eventually require critical are admission [1]. As a result a strategy has to be developed to appropriately allocate these beds and ventilators to patients. The strategy though clinically relevant imposes serious ethical dilemmas. This is because, the concept of rationing, however clinically justified it may be, is against the ethical principle of Justice which demands equitable distribution of resources and consideration of needs of all patients even while caring for an individual patient [5]. The current pandemic makes this almost impossible in any health care system. Decision to selectively allocate or deny ventilators and resources pose an ethical dilemma. Denying elderly people the care they require at this stage of the their life reeks of "ageism" whereas denying a younger more fit person a ventilator would not only nip a young life in bud but would also indirectly may ruin an entire family that may be dependent on him. The choice is between a rock and a hard place. This dilemma has been witnessed by several western countries too and in general the consensus was to dedicate the scarce resource of critical care beds and ventilators to those who have the highest chance of surviving. This is very similar to the medical and ethical principles used during previous pandemics and other disaster management protocols [6]. When care is provided based on rationing it is inevitable to draw a backlash from society. It is therefore important to develop an ethical framework that reflects the expectations and priorities of the society with respect to resource allocation [7]. It has been pointed out that in a pandemic the focus should shift from a patient-centred provision of healthcare, to a community-centred model of health provision [8]. Prompted by the situation in Lombardy, Italy, the Italian College of Anaesthesia, Analgesia, Resuscitation, and Intensive Care (SIAARTI) recommended a combination of "clinical reasonableness" as well as a "soft utilitarian" approach to deal with the issue of limited resources and dilemmas in resource allocation [9]. The rationality of clinical reasonableness often failed to justify the emotional dilemma and these decisions prompted several physicians to seek ethical counsel.

#### The price paid by non-COVID patients

Another important problem and ethical issue brought out by the pandemic is the treatment of patients who do not have COVID. In order to deal with COVID patients there has been significant restructuring of services across the globe with different bodies providing recommendations as to how this reorganisation of services can be carried out [10-12]. However, the focus of these measures taken is the COVID patient and the non-COVD patients have unfortunately been neglected to a large extent.

Cardiac surgery for instance has seen a massive reduction in performing life-saving procedures. The hospitals are dictated by tiers they fall in and the treatment that can be offered to non-COVID patients is influenced by the COVID workload. For instance, in cardiac surgery, hospitals have been classified into 4 tiers with a proposed reduction in operative capacity. Tier 1 (0-30% inpatient COVID-19 Load, mild reduction in operative capacity); Tier 2 (30-60% inpatient COVID-19 Load,

moderate reduction in operative capacity); Tier 3 (60-80% inpatient COVID-19 Load, severe reduction in operative capacity) and Tier 4 (>80% inpatient COVID Load, minimal operative capacity) [11].

Similarly, Primary Percutaneous Coronary Interventions (PPCI) which is the mainstay of treatment of ST-elevation myocardial infarction (STEMI) has been affected severely. The duration between occurrence of pain and the intervention being carried out is the key to successful treatment. It has been seen during the pandemic the number of STEMI cases treated were significantly reduced. It is unlikely to be due to a sudden decrease in the occurrence of STEMI but is more likely to be an outcome of redistribution of resources. Further credence to this theory is found by the fact that even when patients were diagnosed with STEMI there was a significant delay between the onset of symptoms and PPCI [13].

Apart from cardiac patients, other specialities like Orthopaedics, Gastroenterology, Dermatology, Urology and many other chronic conditions have all seen significant drop in patient numbers presenting to the hospitals [14]. Endoscopies were reduced dramatically all across the globe due to concerns over it being an AGP. Some countries reported a 90% reduction in the endoscopy rates [15]. Screening tests for important conditions like diabetes and dyslipidemia have also witnessed a dramatic dip. While undoubtedly these screening tests are less urgent than cancer and other emergencies the cumulative risk of undiagnosed diabetes and dyslipidemia tends to be much higher. If nothing it mirrors the general neglect of non-COVID conditions which has led to an unaccountable suffering. Some of these neglected areas like screening for diabetes and dyslipidemia may have long term impact and may present as significant economic and health burden in future [16]. Once again, these measures question the ethical premise of Justice and equitable distribution of resources.

#### Cancer services and the conflict between Beneficence and Maleficence

Cancer patients are a very vulnerable cohort as concomitant infection with COVID-19 carries a high risk of mortality. However, delays in diagnosis, surveillance or treatment all have serious implications towards the overall prognosis [5]. In the wake of the pandemic, several changes have been brought about regarding screening and treatment modalities. Regimens for surgery, chemotherapy, radiotherapy have all been altered.

Re-allocation of resources has led to reduction or in some instances, complete suspension of cancer screening services. This has serious implications. Urgent referrals of cancer patients have seen a drastic reduction in many countries that invariably leads to lesser number of cancers being diagnosed [17]. Chemotherapy protocols are being modified to minimize the frequency of visits and degree of immunosuppression. Maintenance therapy is not recommended in order to reduce hospital visits. The role of radiotherapy has expanded with COVID-19, as radiation therapy is being used to replace or delay surgery. For instance, a radiotherapy has been advised to delay surgery in patients with rectal cancer [18]. This may have implications on the prognosis and also puts extra demand on radiotherapy services eventually leading to selective allocation.

Surgical care of cancer patients has suffered during the pandemic. Patients previously treated with or designated for surgery are being treated with other form of therapies [19]. With the focus mainly on emergency care almost all the countries, took measures to delay or defer non-emergency surgeries. The delay in cancer surgery has potential for serious harm. Delaying certain cancer surgeries by few weeks can result in an increase in tumour size and may even convert an operable case into an inoperable one changing the prognosis completely [20]. For example, certain patients with head and neck tumours have excellent prognosis after surgical resection and denying them the surgery and the cure in face of the pandemic is against ethical principles [21].

The recommendations of the European Society for Medical Oncology to classify certain cancer as low or medium priority for follow-up may have serious implications for most cancers in terms of depending on risk of disease and complications. Also, face to face consultations have been replaced with online consultations. Breaking bad news or stating the poor prognosis of the cancer is difficult at best of times. To do so online is going to be even more challenging [10]. Studies have shown that there was significant concern among patients with cancer both about acquiring COVID as a

nosocomial infection as well as with regards to disruption of their standard prescribed care due to by COVID-19 [22].

## Protecting the patient at the cost of the family of the Healthcare worker- another ethical concern

One ethical dilemma that is rarely talked about is the conflict between serving the population at large and protecting one's family. The dedication and devotion of healthcare workers (HCW) is a prime example of altruism [23]. However, the HCW's working in the critical care areas designated for patients infected with COVID-19 are at risk of acquiring the infection. Not only that they are at risk of passing it on to their family members especially if it consists of elderly parents and young children. Various HCW's are resorting to stay away from elderly parents and sending children away to grandparents to protect them. Others choose to stay together and live under constant fear of infecting their loved ones. It is not just the health of the family of the HCW at risk but also there are significant psychological and financial factors that come into play making this an extremely difficult dilemma to address. To make it worse this is not even discussed or thought about either by the institution they work for or by the society at large. Most health care institutions do not provide automatic insurance cover for the family of the HCW. Thus, purchasing the right insurance that covers the elderly family members is the onus of the HCW and in the current scenario is extremely difficult and expensive. This coupled with the fact that most HCW's are receiving a reduced pay from the healthcare establishments make this ironical. It is not at all surprising that the HCW's are under psychological distress and burnout [24].

This is another area where the ethical responsibility of the healthcare establishment comes into focus. There is no doubt that hospitals should consider proper residential and refreshments for those directly involved in critical care services looking after COVID patients. The bigger question is should the healthcare establishment go any further and provide free healthcare if the HCW or any of the family members of the HCW contracts COVID? On surface it may be tempting to suggest that they should. However, this is also questionable. How does the hospital establish that the family member was staying with the HCW? How can it be assessed that the family member was infected by the HCW? While these are difficult questions and the answers will vary from region to region and hospital to hospital however at the bare minimum the hospital should think of these ethical issues. The HCW should be given a choice to stay in the hospital during the period of duty and longer if they prefer to stay away from their family for a while to ensure they are not infected [25]. It is not just the frontline workers, like doctors and nurses but also the support staff like the receptionists, managers, housekeeping, that face this dilemma. HCWs, in other areas like laundry and facilities, often feel left out and disillusioned [26].

Several measures can be taken to deal with the concerns and dilemmas of the HCW. Communication and leadership and empathy are the key to respond adequately to the concerns of the HCWs. Besides, reduction of noncritical work, information on managing stress, sessions to provide psychological support either as a group or individually will help [27-28].

#### Patient's Family- Another un-quantified ethical concern

Most families in current times are nuclear and once a person is diagnosed with COVID and needs admission in a critical care area it throws a multitude of issues on the family front. Emotional stress brought out by the uncertainties of the prognosis is further magnified by the added anguish of physical separation [29]. Financial constraints and stress on children are other issues that are major concerns.

The emotional trauma to the patient and the families during this pandemic is of unthinkable proportions. The inability of family members to stay next to their loved ones during their last moments generates emotions that cannot be recorded in words. Having the person, with whom you have shared most of your life, next to you, when you are breathing your last, is the best palliation. Denying the basic need to bid farewell to loved ones results in depression, and guilt in the surviving family members that can last a lifetime. The patients themselves have a social craving and a primordial need to see their families [30]. Despite the HCW's doing their best the critical

care environment during current pandemic is greatly dehumanized with members of the caring team covered in their PPE [31].

Dying from COVID-19 in isolation has existential as well as social consequences for both patients and families [32]. In many countries like India the funeral rites of a COVID patient is performed by the state with the family not having access to the dead body. In fact in some states, they are not even allowed to the cremation site. Funeral rituals are fundamentally ingrained in our culture and rites are important to signify the end of life. Several cultural and religious beliefs are inherent to the last rites of a person and serve as a closure for the families. Religious rituals are considered as the final dignity that can be offered to the departed and is deeply entrenched in our psycho-social and religious and cultural beliefs. The pandemic and the preventive measures taken deny this basic need of families and is a major ethical concern [31]. Changes should be instituted to allow family members participate in the last rituals of the deceased patient in a safe way. Other methods to maintain communication like video calls and supervised short visits with adequate precautions should be considered.

#### Cardio-Pulmonary Resuscitation and End of life decisions

Cardiopulmonary resuscitation poses another important ethical dilemma. At one end there is a very short window of opportunity to resuscitate a patient with COVID-19 who has arrested on the other hand there is a highly increase risk of contamination to the HCW.

Both chest compressions and endotracheal intubation of bag and mask ventilation are aerosol-generating procedures (AGPs). As a result, cardiopulmonary resuscitation has a huge potential to generate aerosols [33]. HCW's are used to instituting immediate chest compression and airway control algorithms but are now confronted with the dilemma between wearing personal protective equipment and instituting immediate CPR protocols. The current recommendations made by the European Resuscitation Council COVID-19 guidelines suggest that a minimum a FFP3 mask (FFP2 or N95 if FFP3 not available), eye and face protection, long-sleeved gown, and gloves should be donned before undertaking CPR. However, DC cardioversion can be attempted prior to gaining airway control and chest compressions [34].

More importantly however hard it may be a careful assessment has to be made to identify those where CPR would be inappropriate [34]. Patients with severe COVID-19 respiratory failure and multiple organ failure who undergo a cardiac arrest may not be candidates for CPR. While the decision for not attempting CPR used to be taken in the past too they have assumed far greater importance in the current pandemic and have significant emotional and ethical challenges for the health care workers as well as the family members.

Some of the other measures that can be taken to mitigate the ethical concerns to a certain extent regarding CPR include using mechanical compression devices in COVID-19 as well as performing CPR with the patient in the prone position. These measures can potentially limit the number of required people during the CPR and also limit viral exposure [35-36].

Some patients are because of age and other co-morbid conditions may have a much poorer outlook. In these patients initiating mechanical ventilation may not prove to be of much use. While the patient is rapidly deteriorating, with family members not around the doctor invariably decided on the best possible option. However, that option may not be the preferred option by the patient who at the time of decision making may not be in a state to exercise or inform his wish. The fact that end of life decisions and care even in a pandemic is primarily a patients choice it is important that decision-making is shared and communication with the patient and the family in advance should remain central to clinical practice [37].

It has been witnessed that end of life discussions with COVID patients are significantly lower compared to pre-COVID times. Also, in only 1 in 4 cases a relative was present at the time of death in the hospitals [32]. The role of advance directives thus has assumed greater importance especially in the Western world.

Virtual intensive care unit (vICU) is another novel measure that has been taken to allow family for patients with COVID-19. Patients are able to virtually see and hear their family members which helped with the mental strength to fight through the crisis. It also serves as a boon for the families who have expressed gratitude for the ability to see and speak with their loved ones [38].

Tele-palliative medicine is a similar measure implemented to allow family members the ability to interact with their loved ones during the end of life. It helps with care and end of life discussions, provides contact and closure for both patients and their families [39].

#### **Vulnerabilities of Health Care Workers**

The pandemic has brought about not only health concerns but also a psychosocial burden on the healthcare workers. Healthcare workers are at high risk of acquiring nosocomial acquisition of SARS-CoV-2 and are also predisposed to burnout, anxiety, fear of transmission, depression, substance abuse and strategies that aim to prevent and treat vicarious traumatization in medical staff have to be developed [40].

#### **Ethics and COVID research**

It is important to engage in research in the current pandemic as important answers regarding the treatment and prevention can only be obtained through meticulous study of the infected patients. While the studies may or may not benefit the participants, it can be deemed to serve the population at large. In order to facilitate important research in an expeditious fashion many health authorities have adopted fast track policy for ethics approval in COVID research [41]. Majority of journals are also relaxing the requirements of peer review in order to provide important scientific information in the public domain in a timely fashion. However, one of the unprecedented fallout of the COVID pandemic and encouraging research is the perverse explosion in the number of publications using COVID patients as "subjects' of research.

Broadly there are two important ethical concerns with regards to research in COVID patients. Firstly, to ensure that the basic principles of research ethics are adhered to and secondly that in the mad rush to publish, the quality and sanctity of the research is not compromised. The age old adage of "Bad research is Bad Ethics" has to be adhered to. With regards to the first concern there are some thought provoking data that has come to light. A significant proportion of studies are recruiting or reporting patient data include patients who are more than 65 years of age and one in six participants in these studies are children [42].

A cursory search on PubMed alone using the search term "COVID" resulted in 58,740 results. This is an absurd amount of publication generated in less than 9 months that translates into more than 6500 publications in PubMed indexed journals every month. Most of these publications have been rushed through and there are concerns over the quality of peer review in many of those. A recent publication on the subject confirmed that almost 4000 papers were made available on preprint servers, a number that is only likely to increase. By 31<sup>st</sup> of July 2020, 33 manuscripts had been retracted or withdrawn or concerns had been raised regarding them. 12% (4 out of 33) were retracted in high profile journals like Lancet and New England Journal of Medicine [43-46]. Of the studies where an issue was flagged there were six which were due to consent issues and 3 had research ethics committee implications. These studies may just be the tip of the ice-berg only identified because of being published in journals with higher impact factor and more analytical readership.

One of the most obvious and practical concerns over research in COVID patients centres around informed consent. As researchers are usually not allowed in the restricted COVID designated zones the sanctity of informed consent is realistically under question. Delegating the consent responsibility to the frontline health workers is now recommended as one of the strategies for consenting [47].

However, concerns remain over the efficiency and due diligence exercised by the overworked frontline worker in obtaining the consent. Obtaining informed consent through alternative means like mobile apps and tele-consenting makes good reading but the use is limited to very limited healthcare sectors and remains a very theoretical proposition in most institutions.

This is a very coarse ethical issue and much more subtle concerns regarding the mental well being of the participant or the legally acceptable representative (LAR) is not often accounted for. A person in critical care fighting for his life in a dehumanized environment confronted with the prospect of being a research participant is bound to have significant mental issues. Similar implications exist for the LAR consenting on behalf of the patient and are perhaps not accounted

for. It is recommended that the impacts of COVID-19 on mental well being of participants and relatives should be considered even if these studies are not designed to evaluate mental health issues [48]. Ethical concerns also exist with conduct of RCTs in COVID patients. It is inevitable that participants in the control arm would receive the best alternative medical or supportive care and may be denied the opportunity to have the investigational drug or vaccine and a favourable outcome [49]. It is obvious that research in patient with COVID, especially those in critical care present a huge challenge from the ethical perspective. In order to mitigate these concerns, it is imperative for researchers to adhere to guidance provided by national bodies [50]. Besides, the WHO has listed ethical standards that is expected to be followed by researchers during this pandemic [51].

Answers for ethical dilemmas are never right or wrong, but are just difficult ones. Protecting patients with COVID infection as well those who have other chronic illnesses is equally important and in line with the ethical principles of distributive justice and beneficence and non-maleficence. The respect of the wishes of the patient and their families has to be respected and should be guided by respect for autonomy. In doing so it is important to protect the healthcare workers to safeguard the principle of fairness and human rights.

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## Altered Human: A Moratorium on Human Germline Editing as a fundamental violation of the rights of The Unborn, our future generations

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#### **ABSTRACT**

With the advent of CRISPR-Cas9, Clustered regularly interspaced short palindromic repeats (Crispr), touted to be the best gene editing tool by the scientific and medical community, it is currently possible to practice human germline editing with efficiency, accuracy, and affordability, to eradicate fatal diseases, and correct faulty gene mutations, for future generations. If human germline editing becomes law, it will have the power to create humans without fatal diseases and faulty gene mutations. However, International organizations such as UNESCO, and The Oviedo Convention have placed a moratorium on human germline editing because of its capability to end the heritage of humanity itself.

This paper will take the position that human germline editing will not end the heritage of humanity. On the contrary, it will bring forth not just the preservation of humanity, but the preservation of better specimens of humanity. As such, a moratorium on human germline editing should be lifted, and in its place, solid legal guidelines put in place to conduct further research in this field. In support of its position, this paper will extend two arguments. The first will be based in Galton's eugenics "better to be good rather than bad specimens of their kind" argument, while the second will be based in a humanistic "for the benefit of future generations" argument, already contained within the premise of the Oviedo Convention itself.

This paper is divided into 5 sections. The first section will explore human germline editing as a scientific innovation that can alter unborn humanity. In section two, a revolutionary gene editing technology, Crispr will be explored. In section three, this paper will explore international organizations, and their laws, that have placed a moratorium on human germline editing as, according to them, it has the capability to end the heritage of humanity. In section four, this paper will extend two arguments, one based in eugenics, and the other based in human rights, in favour of lifting a moratorium on human germline editing. In its fifth section, this paper will take a humanistic stance that while preserving the heritage of humanity is important, such a preservation cannot be maintained at the expense of benefits that can be conferred upon our future generations brought upon by science and technology such as gene editing technologies, and human germline editing. Preventing such benefits to our future generation, is a fundamental human rights violation of the unborn, the voiceless in our society.

Key Words: Human Germline Editing, Crispr Cas-9, Eugenics, Human Rights, Unborn

#### Human Germline Editing as a scientific innovation that can alter unborn humanity

Genome editing technologies enable changes to be made to the DNA of living organisms such that physical traits, and the risks of fatal diseases, and faulty gene mutations, in these living organisms can be altered [1]. For the purposes of this paper, the focus will be on human genome editing. In human genome editing, it is important to distinguish between somatic and germline editing. Somatic gene editing "affects only the patient being treated (and only some of his or her cells)...[while] germline editing affects all cells in an organism, including eggs and sperm, and so is passed on to future generations."2 In germline editing, the entire genome is altered. As per the National Human Genome Research Institute, somatic editing targets non-reproductive cells [2] and affects the human edited...while germline editing targets reproductive cells (sperm, eggs, embryo) and are passed down from generation to generations [3].

If human germline editing becomes law, it will become possible to not only manipulate the genetic makeup of humanity, with efficiency, accuracy, and affordability, but also to design, produce, and pass on the best heritable human population, with efficiency, accuracy, and affordability. Currently, Crispr is seen as a revolutionary tool that can facilitate human germline editing with efficiency, accuracy, and affordability. More importantly, Crispr, if used to edit germline, is seen as a revolutionary scientific innovation that can alter unborn humanity.

#### CRISPR, a revolutionary gene editing technology

It is important, therefore, to explore Crispr. Crispr was popularized by Dr. He Jiankui, a scientist from Southern University of Science & Technology. Dr. He was condemned for using Crispr to genetically modify human embryos to make them immune to HIV, and then implanted them into a real live woman, who gave birth to twins. While Dr. He was severely condemned by the Chinese government, and punished with 3 years of imprisonment, and a hefty fine, the world did take notice of the revolutionary capability of Crispr to alter unborn humanity.

Simply put, it is a gene editing tool that works by means of a homing device guiding a molecular scissors (cas9 enzyme) to a target a section of DNA. Together, the device, and the scissors, work to insert, delete, modify, replace disable, repair, or insert something new to the area that was cut. In medical terms, the words often used are "disable.... repair.... insert...." [4].

As noted in section I, Crispr is considered a revolutionary scientific innovation as it trumps older gene editing tools in terms of efficiency, accuracy, and affordability. With its potential to be efficient, accurate, and affordable, if human germline editing using Crispr becomes legal, it will become accessible to all of humanity, to not only eradicate heritable fatal diseases, and correct heritable faulty gene mutations, but to also modify and perfect the genetic makeup of humanity itself. As a result of its capability to alter future unborn humanity, some international organizations, in the name of human rights, have placed a moratorium on human germline editing for fear that it will alter the heritage of humanity itself. For the purpose of this paper, the two organizations' international laws that will be discussed in this paper are UNESCO, and The Oviedo Convention, respectively.

## International laws: Human germline editing as an end to the heritage of humanity, A morphed moratorium

The first act of international law that has placed a moratorium on genetic editing of the human germline was found in UNESCO's Universal Declaration on the Human Genome and Human Rights. Quoting 29 C/Resolution 17 entitled: "Implementation of the Universal Declaration on the Human Genome and Human Rights," the organization stated in no unclear terms that if human germline editing is allowed, it will be the end of the "heritage of humanity".

Through the declaration, they pointed out the need to "protect and pass our heritage to future generations and protect human rights." Human genome editing should only be allowed for "preventive, diagnostic, or therapeutic reasons and without enacting modifications for descendants" [5-6].

It is crucial to understand that "modifications for descendants" should be interpreted to mean germline modifications, which can only be made to human embryos. As such, the declaration was referring specifically to a moratorium on human germline editing.

Likewise, The Convention on Human Rights and Biomedicine (Oviedo Convention), which is part of the council of Europe (an international organization based in human rights, democracy, and rule of law), the only internationally legally binding instrument on the protection of human rights in the biomedical field, has placed a moratorium on human germline editing, using an almost verbatim ad literatim phrase:

Under Article 13: "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and *only if its aim is not to introduce any modification in the genome of any descendants*". This is interpreted as judiciously permitting human somatic gene editing, while imposing a "complete ban" on human germline editing.

It is crucial to understand that "any modification in the genome of any descendants" should be interpreted to mean germline modifications, which can only be made to human embryos. As such, Article 13 was referring specifically to a moratorium on human germline editing.

## Arguments in favor of lifting a moratorium on human germline editing: Eugenics and Human Rights

While this paper agrees with the two organizations above that preserving the heritage of humanity is to protect fundamental human rights, it questions the failure of these human rights organizations to protect the human rights of humanity not yet born, our future generations. It, therefore, takes the stance that in line with the same reasoning, that is to protect human rights of the unborn, the voiceless in our society, a moratorium on human germline editing, should be lifted.

In support of its stance, this paper will offer two arguments, one based in Galton's eugenics, and the other in human rights itself.

#### Argument 1: Galton's "Better to be good rather than bad specimens of their kind"

Eugenics is a set of beliefs, and practices that focus on producing a human population with the best genetic makeup [7]. In an attempt to define the essentials of eugenics in his 1904 article, Galton referred to a fable in which animals in a zoological garden, agreed that:

"...it was better to be healthy than sick, vigorous than weak, well-fitted than ill-fitted for their part in life; in short, that it was better to be good rather than bad specimens of their kind, whatever that kind might be [8]."

Most of humankind will agree with this definition. In fact, it will be irresponsible to humanity not to agree with the above statement. Most of us aspire to be mentally, and physically fit. Being indisposed mentally, or physically, not only carries with it the burden to oneself, in the form of pain and suffering, but a burden to others, who will have to take care of the indisposed, and witness the pain and suffering. In addition, the cost of medical care, and the financial drain on society at large to take care of the indisposed cannot be ignored. Ultimately, we must suffer the pain of losing loved ones, when death ensues from fatal diseases, or faulty gene mutations.

We cannot possibly aspire to be "bad specimens" of our kind. As such, it can be safely concluded that a human who will be born in the future will most probably not wish to inherit fatal diseases, and faulty gene mutations, even from his or her own loved ones. In conclusion, unborn humanity will most probably be in favor of germline editing, as performed on them.

It is important to note that human germline editing can only be performed on humans not yet born, and as such, it will be futile to discuss informed consent here as it cannot be given.

#### Argument 2: Human Rights' "Solely for the benefit of future generations"

This paper could not ignore the fact that while the two international organizations mentioned above have placed a moratorium on human germline editing as a way to preserve the heritage of humanity as a fundamental human rights, they seemed to have failed to adequately defend their decision based in human rights, for future generations. While human genome editing should be allowed for "preventive, diagnostic, or therapeutic reasons...", the fact that "any modification in the genome of any descendants" should be excluded from this equation should be interpreted to mean that there are no protections for our future generations, which is a human rights violation in itself. Hypothetically, if an already born human, wishes to have children, and has a fatal predisposition in his or her genetic makeup, according to these organizations, he or she must simply refrain from

having children. There will be no option, despite scientific innovations, such as Crispr, to be able to correct this predisposition at germline. There are other possibilities of course, such as Preimplantation Genetic Testing (PGT) that can facilitate the selection of good genes to be implanted into the uterus in order to correct the fatal pre-dispositions. However, fertility treatments such as PGT are costly. While the elite will have no issue with expensive medical treatments, the rest of the world will not be able to afford these treatments, opting for no children at all. If we follow the human rights argument, it can be argued that placing a moratorium on germline will have the opposite effect of not preserving the heritage of humanity but contribute towards its extinction.

Interestingly, it is crucial to note that Article 13 is "in contradiction with one of the motivations of the Oviedo Convention, that progress in biomedicine would be used solely for the benefit of future generations" [9].

#### Conclusion: A voice for the voiceless

This paper is cognizant of the fact that germline editing can open a floodgate of nonmedical, non-essential, and cosmetic enhancements into play. Humanity in its natural form can aspire not only to be healthy, but to be beautiful too. While there is nothing wrong with wanting to be healthy, and be beautiful, it is important to focus human genome editing, and human germline editing especially, in the eradication of fatal diseases, and faulty gene mutations. In protecting human rights, we must at the least, consider the right to be healthy, and placing a moratorium on human germline editing takes away that fundamental right for the unborn, our future generation.

Additionally, when we consider human rights, it is important not only to consider humanity that exists but also humanity that will exist in the future. In particular, it is important when we consider human rights to pay attention to the most vulnerable in our society, the ones without voices, such as the unborn. In placing a moratorium on human germline editing, we have completely ignored our future generations. Any scientific innovation that has the capability to better the genetic makeup of humanity, should not be compromised in the name of protection of human rights, when such a protection has the effect of violating the fundamental human rights of the unborn, the ones without voices. In fact, it is more important to protect the rights of those without a voice, the voiceless, the unborn in our society. This paper rests its case

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 Review Paper

## Online Fellowship Exit Examination During the COVID-19 Pandemic

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#### **ABSTRACT**

The COVID-19 pandemic, also known as the coronavirus pandemic, ongoing pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The COVID-19 pandemic requires minimizing close human interactions its aero digestive tract secretions serve as a carrier for this disease. During the early stages of the pandemic, when the nature of the coronavirus was still unknown, most institutes made the decision to temporarily avoid all in-person contact and close their campuses completely. For many higher education institutions, this resulted in the cancellation of upcoming examinations. Without a clear understanding of how the coronavirus operated and the most effective measures to prevent its spread, collecting students into one room for a prolonged period was no longer considered safe. However, examinations are a critical part of the higher education process and a necessary step in providing medical trainees with accurate grades. Online exams are still a new phenomenon at higher education institutions, so there's a lot to learn regarding the wide-spread implementation of these new exam processes. However, during a period where in-person contact comes with many risks, online exams are a great way of maintaining momentum in higher education and to ensure the learning process doesn't ground to a halt. Conducting online examinations is based on the Artificial intelligence (AI) designed databases and software. It reduces the use of paper and other resources. For medical trainees, online structural clinical examination (OSCE) can also be conducted online on software based video call applications.

This review article deals with four different patterns which have been followed in India. Based on this experience we consider that conducting online examination is a feasible option during pandemic situation.

**Keywords:** Examination, online, pandemic, education, corona virus, COVID-19

#### Introduction

An examination is a process of evaluating an individual's knowledge, ability, or skill in a particular subject. It is a systematic process of collecting, analyzing, and interpreting the information to determine the extent to which trainees are achieving and understanding instructional objectives [1]. The examination is used as a measuring tool to convert qualitative data (knowledge, skill, or ability) into quantitative data (rank, grade, etc.). An academic course aims to provide the source of knowledge in a particular subject during a pre-defined period. The examination is also used as a yardstick to assess the trainee's knowledge on a predefined scale of ranks and/or grades. It is a method of cross-sectional examination of knowledge as it relates to a particular subject matter applied either to a single individual or a group of individuals participating in this process. Historically, the examination process started when humans came into existence. In India, notes on the tradition of guru shishya (teacher and student) can be recognized in the great epics of the Ramayana and the Mahabharata where trainees are assessed regularly by a teacher through examinations. The teachers assessed their teaching skills through the achievement of their trainees. Takshashila (150-180AD) and Nalanda (450-850AD) are the ancient universities of India with a structured educational system with proper evaluation methods [2].

An examination/assessment can be a closed book type where the examinee depends on memory to respond to the questions. In an open book, system reference material is allowed to be used to give a response to a question. The examination can be conducted formally with a pattern of questions as indicated, and be supplemented for example, with an exit exam after a certification course. It may also be conducted informally for example, evaluating a trainee's ability to rate a story or read a paragraph. For those who have undergone training in health education, an examiner may observe the candidate's complete interaction with the patient and the team. An examination may be conducted orally either in person or digitally (virtually, online), securely on paper, using technology. The health care trainee evaluation may require the use of animals where indicated, volunteer model human actors, or by using high-fidelity simulation technology.

The effective delivery of healthcare needs not only didactic knowledge and technical skills but also good analytical and communication skills, interdisciplinary teamwork and care, counseling, evidence; problem-based learning and system-based practice. This requires our assessment systems to be thorough, sound, and robust enough to evaluate the requisite attributes along with testing for the required knowledge and skills. An individual assessment has a powerful positive steering result on learning and completion of the curriculum. It imparts what we value as important and is the most cogent motivator of student learning [3].

#### Why an online examination is required?

The Corona virus disease 2019 (COVID-19) global pandemic requires minimizing close human interaction and the use of appropriate distancing and physical barriers to prevent the spread of this disease especially between asymptomatic but contagious folks and unexposed individuals. The aero-digestive tract secretions serve as a carrier for the virus causing disease. COVID-19 being a highly contagious viral illness has been responsible for inoculating individuals by aerosol generation, loud speaking, sneezing, and coughing. The use of a face-mask and social distancing has become a new public norm [4]. Many cities and academic campuses across the world are under lockdown. Public transport is scantily available and social gathering could be a punishable offense. In many places, the standard form of education with a physical presence in a classroom is no longer allowed nor encouraged. Medical trainees are receiving digital didactic and simulator-based education with proper distancing and face-mask and face-shield protection. Direct learning from physical contact with patients is limited but gradually increasing as the dynamics of virus spread and its confirmation in patients are becoming available. At the University of Minnesota in the U.S. medical students and graduate trainees in anesthesiology have now been allowed to return and resume clinical work with the wearing of facemasks, hand-washing with detergent, and use of appropriate personal protective equipment (PPE) when required. The didactic teaching, grandrounds, and morbidity and mortality discussions are still largely conducted on a digital platform. However, trainee evaluation and examination remain an essential part of the curriculum. The current unprecedented situation poses a great challenge in conducting assessments as per the past

protocols. The risk of contracting COVID-19 between the examiner, the candidate, and mock-patients is considerable. Unless all three groups of individuals are tested for the absence of COVID-19 the manual involvement in a room between personnel imposes a significant risk. Many candidates are usually clustered in a room for the required monitoring during the written examination. Similarly, during the viva portion of the exam there will be a close interaction between the examiner and examinee, not only a time-consuming process but also requires significant interaction with other individuals for the proper conduct of the examination process. Also, there are limitations in the number of candidates that may be able to take the live examination at a single physical place. The following changes that have occurred both in teaching and conduct of examinations are now reviewed as follows:

The technological advancement in communication has revolutionized the method of conducting examinations. The concept of online examination is not new to our medical community. Many overseas examinations are conducted using digital online media. They have proven to be efficient, less time consuming, and effective. COVID-19 posed social barricades for conducting manual examination that may thus be overcome by judicially using online examination systems [5].

At present, a wide range of methods are available not only for assessing but also addressing patient care issues including modification of essay type questions (MEQs) checklists, Objective Structural Clinical Examination (OSCE), student projects, simulated surgeries, Constructed Response Questions (CRQs), critical reading of papers, rating scales and scores, tutor reports, portfolios, short and long case assessment, essay type questions, use of logbooks, trainer's reports, the conduct of audits, video assessments, simulator use, self- assessment, peer assessment and use of standardized patients.

Measuring progress in ascertaining deep knowledge and competencies may be a problem if the exams are designed to measure multiple integrated abilities, such as factual knowledge, solving problems, synthesis, and analysis of information. Trainees may delve into one's ability and ignore other options making it difficult to conduct holistic evaluations. Therefore, progress tests that are designed to measure growth from the beginning of learning until graduation should measure distinct abilities.

If a large amount of knowledge is required to be tested, MCQs should be used. Long and short cases should involve the use of clinical scenarios. Objective Structured Clinical examination (OSCE) consisting of multiple stations where each candidate is instructed to perform a defined task such as taking a focused history or performing an attentive clinical examination of a particular system needs to be performed. A standard grading scheme that is specific for each case has to be used. It is an effective alternative to unstructured short cases. The assessment is a basic component as part of the whole educational system. The assessment should be designed prospectively along with learning outcomes. It should be purpose-driven. Assessment methods must provide valid and usable data. Methods must yield both reliable and generalizable data.

Multiple assessment methods are essential to gather most aspects of clinical competency and any single method is not adequate to do the job. For knowledge, ideas, application of that knowledge ('Knows' and 'Knows How' of Miller's conceptual pyramid for clinical competence) context-based Multiple-choice questions, elongated matching items, and short answer questions are suitable. For 'Shows How' multi-station OSCE is useful. For performance-based assessment ('does') mini-CEX (Mini Clinical Evaluation Exercise), DOPS (Direct Observation of Procedural Skills) is appropriate. On the other hand, clinical work sampling or logbook may be used. Assessing a trainee is a comprehensive conclusion making process with many important indicators beyond the measure of a student's success. Trainee assessment is also related to program evaluation. It gives important data to determine the effectiveness of the program, improves the teaching program, and helps in the development of educational ideas.

The online examination system (OES) uses client/server architecture. A database is used to save the exam information. An instructor or administrator can add or delete questions; set the correct answer, set the time limit of the exam, can register, or delete a student name. They can show the questions randomly to registered trainees calculate the results automatically and show the results immediately. The information of questions displayed to trainees, their response to the question, the correct response, the score of the student are archived in a database, so it can be reviewed

anytime later [6]. All of this is done confidentially by the examiners with secure systems in place to avoid leaking of the examination.

The examinations will be split out in:

**Written Exams**: The written examination consists of Multiple-choice questions. Multiple choice questions may be administered in one of two ways:

- (1) Single location: All candidates in an urban area will need to reach and assemble in an examination center. The candidates will be allocated to an examination room where the multiple-choice questions are projected on the screen and the examinees are asked to choose the correct answer and write it on the answer sheet. By the end of the day, marking will be assigned based on the answers provided by the candidates. Another way to do this is using individual computers with specific safety log in criteria (e.g. Prometric). Here, the candidates are thoroughly frisked along with verification of their identity before allowing them to enter the exam hall equipped with multiple computers. They are randomly made to sit on different computer desks and are allowed to log in to the exam with their unique login and password.
- **(2) Multiple locations:** In this type of examination, the MCQs are transmitted electronically to several centers in a particular region.

Practical Exams: Practical exams are further divide into 3 parts –

- (1) Objective structural clinical examination
- (2) Cases discussion based on clinical scenario @ viva Stations

1). FORMATIVE ASSESSMENT: 2). SUMMATIVE ASSESSMENT: · Informal & Formal tests taken during ·Evaluate competence at the end of learning process. instructional unit. • This identifies strength & weakness & • This helps the examiner to determine if the help target areas that need work. candidate has assimilated the knowledge or e.g.: Internal exams conducted monthly. skill to the required standard. 3). NORMS REFERENCED TESTS: 5). CRITERIA REFERENCE TEST: ·Helps in comparing a student's TYPES OF · This is designed to measure student's performance against a national or other performance against a fixed set of **ASSESSMENT** 'norm' group. criteria & learning standards. e.g.: National level entrance exam. 4). PERFORMANCE BASED ASSESSMENT: 5). AUTHENTIC ASSESSMENT: • This requires student to solve real · In this type of assessment, measurement problems or produce something with real of accomplishments that are worthwhile world application. compared to multiple choice standard • This assessments allows the educator to tests. distinguish how well the student thinks critically & analytically.

Figure 1: Assessment Types

#### **Online Examination System**

An online examination system is a computer-based test system that can be used to conduct computer-based tests online. This examination system uses fewer resources and reduces the need for question papers and answer scripts, exam room scheduling, arranging invigilators,

coordinating with examiners, and more. Objective structured clinical examination (OSCE) can also be conducted on the online platform using various video call applications. The examiner staying far can see the candidate performing at each virtual station using virtual patients. An oral examination (viva-voce) also may be conducted using video conference applications [7].

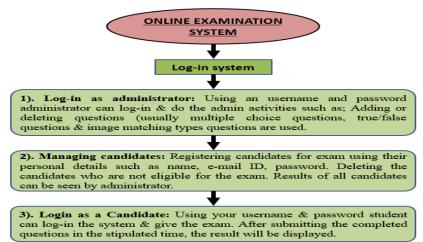


Figure 2: Flowchart depicting the components of online examination system (OES) Role of Artificial Intelligence

Artificial Intelligence (AI) is a computer's ability to mimic human intelligence. In practice, it is a segment of computer science that involves designing computer applications to perform tasks that typically have required human intelligence such as visual perception, speech recognition, and decision making [8].

Due to the increasing scale in the number of patients with COVID-19, the education system has suffered in many aspects. As per the guidelines released by the central government, the institutions are not allowed to conduct regular examinations for the trainees and fellows until the COVID-19 situation is declared as controlled. In this situation, Artificial Intelligence (AI) can play an important role in many ways.

#### Online examination system with AI

Online examination system is software via a portal with one added artificial intelligence that is it even checks brief answers manually typed by a student along with the option of ticking and providing appropriate marks to the user. The online examination system first accepts a login id and password and then allows authenticated users to appear for the exam. The exam is of a limited time span as pre-determined and provides a set of questions in a random order for each user appearing for the test. Along with the option of selecting answers, some questions may even have the answer to be written as a brief. This answer was manually written by the examinee is graded by AI and given appropriate marks by the system. This is done by comparing the user's written answer with the real answer stored in the system database. When the test is completed the total marks are calculated and displayed to the user at the same instant.

#### **Advantages of OES**

- 1. **Safer during COVID-19 pandemic:** Manual examination system involves close contact of candidates with each other, with the examiner and the mock patients. As the COVID-19 virus spread by aerosol, this system poses a greater risk of infection spread to candidates, examiner, and the patients. Whereas the OES allow appropriate social distancing among candidates, the examiner need not have to travel to the exam center and avoids direct contact with candidates and patients, a standardized virtual patient can be used instead of real patients [9].
- 2. **Environment friendly:** The usage and thus wastage of paper is reduced by OES significantly. The ongoing environmental crisis caused by climate change can be reduced by effective and eco-friendly steps like OES.

- 3. **Time saver:** The time taken for the whole manual examination process is significantly reduced by OES. Manual preparation of questions and printing is avoided by OES. The exam can be conducted in batches with more students in each batch, thus the whole duration of the exam is reduced by OES.
- 4. **Reduces expenditure:** As the stationery cost and printing charge are not involved in OES, this system reduces the cost of examination considerably. OES also avoids the necessity of booking examination halls and invigilators needed to conduct the exam.
- **5. Increased privacy and security:** Because of a secured login facility, unauthorized individuals cannot manipulate the system, thus the conduct of the exam and publication of results provides additional security. The results can be used by using a username and password and call-back double security, thus maintaining the privacy of the candidate.

#### **Disadvantages of OES**

- 1. **Open book exams:** OES becomes an open book exam as it provides freedom for candidates to access online subject related materials. But careful selection of questions and time restriction can avoid this negative effect of OES.
- 2. **Infrastructure requirement:** Technical requirements such as a desktop computer or laptop with a good quality internet connection, built-in or external webcam, microphone, and speaker must be arranged by the candidate or the institute. The candidate will require a clean desk and a lonely room for participation in the exam. The present era of technological advancement has allowed these facilities that are typically easily available in every household.
- 3. **Newer technology needs training** It is a mind-boggling job for those who are not used to the regular usage of the online platform. It needs multiple trial runs before actual exams. To avoid confusion, a model exam can be conducted for all candidates before the real exam. It avoids anxiety and improves the performance of the candidate and examiner [10].
- 4. **Unanticipated system failure:** Unanticipated system failure could foil the online exams which could result from power failure, inability to fulfill system requirements, lack of continuous high-speed internet facility, and unanticipated security issues. Any glitches in computer performance or internet connection must be accommodated contemporaneously.

#### Indian College of Anesthesiology (ICA)

Since March 2020 due to the lockdown, the routine academic schedule has become disrupted. Trainees enrolled for a year fellowship program in Cardiac Anesthesia and course coordinators have faced an unprecedented challenge of continuing the academic activity and were much more perplexed about the method to conduct the summative examination. Taking advantage of the significant advancement in communication technology, we propose a rapid shift to utilizing online teaching platforms that to date have helped the academic program to continue without any interruption. In a recent pilot, multiple-choice questions have been used to test the knowledge of candidates while decision-making skill has been assessed using OSCEs, problem-based learning and case discussions. Similarly, the performance skill was assessed by reviewing the logbook maintained by the candidate over the academic year. Interactions between the examiner and candidate have been successful via an online platform. A Time-limited display of MCQs has been performed. OSCE stations were arranged with 2 or 3 questions about a particular device/drug/images e.g. ECG, trans-esophageal echocardiography videos/images. A series of up to five stations were arranged and the images or videos shared with the candidate's desktop or laptop computer using a webcam and a microphone were provided.

The short and long case discussion has been conducted with a face-to-face interaction between the examiner and student using an online video system. In a two-week follow-up, none of the candidates developed COVID-19 symptoms. About 82% of candidates felt the online platform a better alternative to routine classroom examinations. Proper planning of the exam blueprint, a stable high-speed internet connection, a properly working microphone, and a web-camera are the minimum requirements to conduct a successful online examination. Though an examiner missed

the direct interaction with trainees, the examiner was able to evaluate the candidate's at par with the routine examination system. Examiners spent an average of three hours for the whole online exam while it used to take two days' preparation including travel and stay. The online exam is economical too. It reduced the money spent on stationeries, transport, and accommodation of examiners.

#### ICA Protocol for Exit examination during Covid- 19 Pandemic:

- 1. All candidates must report to the center at 8.00 am after breakfast. No breakfast will be provided but packed lunch will be provided. Candidates are advised to bring their own bottled water for drinking.
- 2. Candidates are advised not to sit for the examination if they suffer from fever, cough, or any other symptom suggestive of possible COVID-19; but no COVID-19 test will be necessary.
- 3. Temperature and SpO<sub>2</sub> will be checked before entry to the examination hall.
- 4. Hand sanitizer must be used before entry and at two-hourly intervals till the exit after the examination.
- 5. Safe distancing must be maintained at all times.
- 6. Face Mask (surgical mask or N95 (covering the face & mouth) must be worn all through); No PPE needed but face mask must be worn.
- 7. Cough and sneeze etiquette must be followed.
- 8. No thesis nor logbook verification is included in the evaluation.
- 9. Must bring Government-issued ID and admit card.
- 10. There will be no live patients for practical examination; instead case scenario will be provided case discussion.
- 11. A written exam with 50 MCQ pattern questions plus 25 OSCE pattern questions need to be prepared in PowerPoint presentation.
- 12. The practical examination will include viva-voce at 4 stations of 10 minutes each, and 2 virtual cases of 15 minutes each.
- 13. All examiners will be on a laptop screen and connected through Wi-Fi. Examiners are not required to travel to the center.
- 14. Candidates are advised to bring their laptops which are working; connectivity will be provided but there will be strict vigilance. If someone is found browsing the internet/books/notes during the exam, they will be debarred from the examination.
- 15. The candidates are prohibited from entering the clinical areas of the hospital.

#### ICA Fellowship Exit examination during Covid- 19 Pandemic:



A) Written exam with MCQ's being projected on screen with safe distance; B) OSCE on a screen; C) External examiners from distant location; D) Candidate interacted with external examiners online; E) Candidate face to face with internal examiners; F) Tabulation of marks at the end of the exam

#### The Simulation Society (TSS) pattern:

#### An online clinical examination for fellowship certification during the COVID-19 pandemic

The TSS platform, over the years has been doing online fellowships as shown in Figure 1A, 1B, 2 and table 1. An online solution was needed in which multiple cases and scenarios could be presented in a structured clinical vignette format and the students learn on simulators to enhance their clinical skills. This format was taken care by an information technology portal entitled "Buzz4health". The academic partnership between The Simulation Society and Buzz4health, is now four years old, bearing fruitful results.

#### Digital E-learning TSS fellowships in COVID-19 pandemic

The virtual e-learning platform is well known since 2015<sup>(11)</sup>. The simulation society has been doing Digital e-learning fellowships since 2016. But in COVID-19 pandemic, the governments, all over the world are recommending shifting to online learning as transient arrangements to prevent any academic disruptions. TSS was ready for it, already with a batch ready for training enrolled in September 2019 and exam-going in August 2020. But, COVID-19, digital technology availability made it so much easier than before (Fig 1A and 1B)

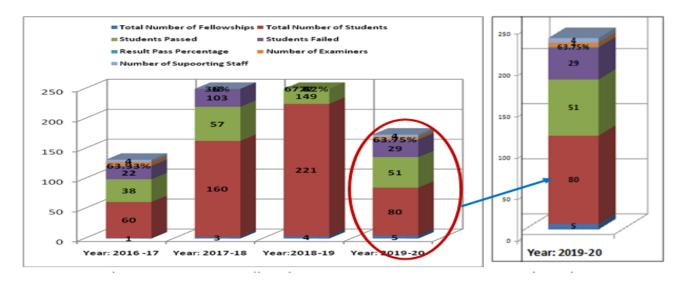


Figure 3A and 3B; 3A: JCCC-TSS Fellowships Statistics; 3B: Statistics in COVID pandemic TSS examination

Table 1: TSS fellowships statistics year wise					
	2016 -17	2017-18	2018-19	2019-20	
Total Number of	1	3	4	5	
Fellowships					
Total Number of Students	60	51	221	80	
Students Passed	38	50	149	51	
Students Failed	22	1	72	29	
Result Pass Percentage	63.33%	98%	67.42%	63.75%	
Number of Examiners	6	13	8	4	
Number of Supporting Staff	4	8	6	4	

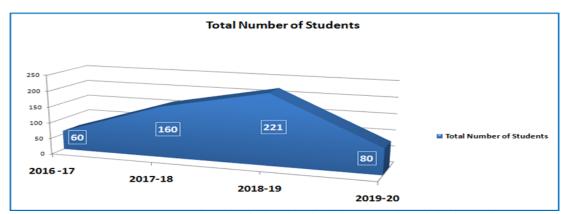


Figure 4: Number of student's year wise in TSS Fellowships

In response to the COVID-19 pandemic, following lockdown and social distancing norms, The COVID-19 pandemic and TSS, there was a boom in digital E-learning platforms. The simulation Society (TSS), already had an existing 4<sup>th</sup> year batch of fellows – 80 of them, enrolled in five different fellowships since September 2019. They were to be final exam going in August 2020 scenario (Figure 3A and 3B).

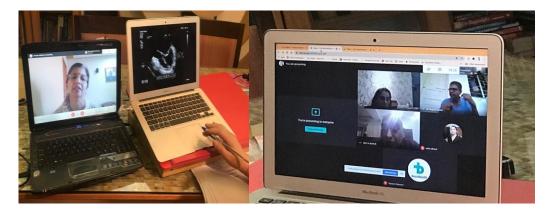


Figure (5A and 5B): Exit Examination of TSS Fellowship, a screen shot of the online methodology

During COVID-19 pandemic, the content for fellowships in Echocardiography, Cardiac Critical Care, ECMO, ECMO specialist and Cardio diabetes were given in even a more diligent and sincere manner. The recent information quality, user satisfaction, communication between information technologies, all TSS fellows and faculty improved tremendously, mainly due to more time available, for most. The information technology, system quality too has improved with Zoom, Google meet, WebEx and such social media, portal sites, are easily available during this Pandemic era even with a wider variety. The examination was conducted in a timely and meticulous manner.

#### Methodology

#### What was different in 2019-20 Examination during COVID-19 pandemic?

The model adopted by TSS was a modification of the DeLone and Mclean IS model (Fig 3); the modification being hands on simulation based learning in a seminar/CME format with physical face to face 2-3 times as well.

#### Port-Mapping Tool for Digital Logic Design

Since most education industries are adopting the available digital technologies such as digital video conferencing platforms like Zoom, Microsoft platform and WebEx blackboard and Google classroom, this will be enhancing e-learning globally [12-13].

The Port-Mapping tool was made available for student download from the My E-learning course page. With this resource, students could have taken any data path block diagram and use the step-by-step teaching feature to arrive at the complete VHDL code for the port mapping of any system. A special Buzz4health Zoom webinar portfolio was created for each of 80 students.

## Table 2: Down regulations and advantages in Exam duringCOVID-19 pandemic Down regulations in COVID-19 Exam

- The hands-on workshops, before the exam on simulators were restricted this year due to COVID-19.
- Restricted physical face to face examiner-student viva voce.
- > Student's attention span was less than anticipated.
- Overall Students confidence was weaker this year, as many were doing COVID duty as well and had less time to read for the examination

#### Advantages in COVID-19 Exam

Communication was possible better than before, over Zoom and WhatsApp and the latter was hundred percent.

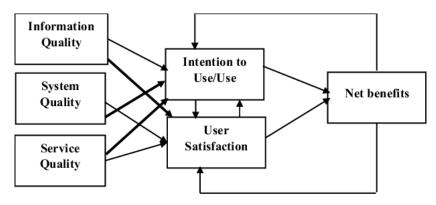


Figure 6: Updated De Lone and McLean IS Success Model (D&MISSM)

#### Male: Female comparison was different this year

Though numbers of females enrolled this year were less than the earlier year, we observed as examiners that the females were more punctual, communicative, and conscientious and more focused on the E-learning portal as compared to the male students. The timeliness, etiquettes and adaptation to the IT platform usage appeared to be better in females than most males. Thus, in the COVID-19 batch of this year, the females scored better! This could be a chance observation.

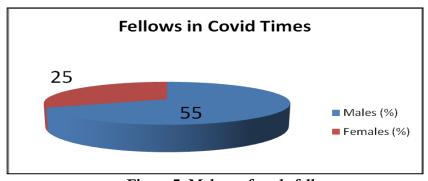


Figure 7: Male vs. female fellows

#### Post-hoc SWOC analysis of the TSS Fellowship this year

It's important for every digital programme, to do a repeated in-house SWOC analysis, of their strength, weakness, opportunities and challenges doing the course. We too, did it this year during the COVID-19 pandemic.

## Introduction to the SWOC (Strengths, Weaknesses, Opportunities and Challenges) Analysis was done by TSS

The objective of conducting a SWOC analysis (in conjunction with other curriculum assessment tools) is to develop key areas of focus for improving the curriculum. The SWOC analysis at TSS was particularly effective when conducted in collaborative group settings at the early stages of the curriculum assessment process (e.g. faculty retreats, student, alumni and/or future employer focus groups) [14].

## Debate style lecturing to engage and enrich resident education virtually What Problems Were Addressed?

The need to create effective virtual educational content and tailor its delivery to the learner is paramount at a time where the corona virus disease 2019 (COVID-19) pandemic has rapidly flipped the traditional educational model on its head.

#### What were the lessons learned?

This online solution was proposed to solve a certification emergency induced by the lockdown. It was challenging to plan assessments with many stakeholders involved. To prevent any setbacks, system tests and 'dry-runs' were conducted many times before the actual examinations. The key to overcoming the multiple challenges was engaging key stakeholders and providing needed support with open communication channels. Importantly, we witnessed a positive change of perspective regarding online examinations during this process. According to the post-examination survey, 96% of examinees and 91% of examiners reported satisfaction with how the examination contents reflected real practice. As a result, SCFHS explored further adaptation to online oral assessment services for activities such as the assessment of ex-patriot practitioners seeking employment in Saudi Arabia prior to their being granted work visas. This service is expected to help reduce the expenses of travelling and accommodation costs commonly associated with certification examinations [15].

 Year
 No of students
 No of Teachers

 2016-17
 55
 6

 2017-18
 160
 13

 2018-19
 221
 8

 2019-20
 84
 4

Table 2: Teachers and student's ratio

#### Feedback from students

Feedback from students indicated that students may have collaborated in the learning of topics. Although the results of students under the teaching strategies appear to be consistent with that of previous years under the traditional techniques. (Figure 6)

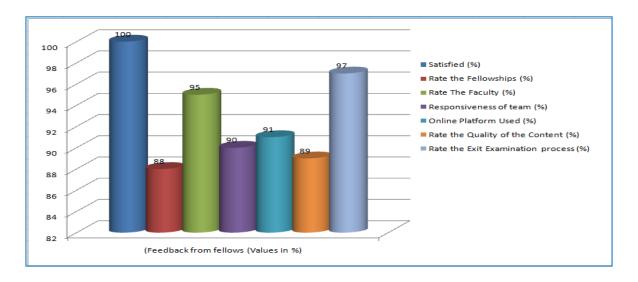


Figure 8: Feedback from fellows as received in COVID-19 TSS fellowships from 59 of 80 students who appeared for digital online examination

#### **IPGMER** pattern

Given the unique scenario of a florid pandemic situation, mandating universal social distancing norms, together with the stringent safety guidelines for conduction of examination issued by the Centre, strategizing a neutral, fair, and effective assessment of students at the end of an academic course was a mammoth challenge. More so, when the task was to assess not only the knowledge, competencies, and skill of the student but also their ability of clinical application.

Under the said circumstance, the state university for health sciences had laid down two options for conducting the practical examination in government Colleges for students appearing for DM/MCh exit exam for the super-specialty subjects, the conventional examination pattern with examiners assessing students face-to-face, following strict safety protocol, or the online examination format which does not mandate examiners to be present physically at the examination center.

Our Department opted to conduct the Practical part of DM cardiac anesthesia exit exam for the outgoing batch of 2017-2020 through the online portal. The format that was followed has been described in the following lines.

As per set guidelines, DM Practical exams have a total allotted mark of 400, with the following marks distribution.

One long case: 100 marks.

Two short cases: 50 marks each.

Viva-voce including spotters ECG, Chest X-ray, Echocardiography video/image, drugs, and instruments: 200 marks.

The two external examiners from outside the state, selected by the university, accepted the formal invitation and consented to participate in the conduction of the online format of practical examination.

We had only a single examinee, though the design of our online format was capable of accommodating a larger number of examinees.

During the process of creation of the skeletal structure of the online examination format, we had ensured the prior arrangement of the following requisites:

- A spacious examination hall, the department seminar room was used for the same.
- A high-speed internet connection as in a Wi-Fi router,
- An optimally functioning laptop with a microphone and web camera for the examinee. This was connected to a projector which projected the laptop screen on the larger display screen of the examination hall.
- A video conference app/platform with proven credentials.

- The two internal examiners used their cell phones with good internet connectivity to access the video conference room of the online practical examination.
- A separate video recorder to record the entire proceedings of the examination day.

A demo was enacted using the same online platform, a day before, to ensure smooth, uninterrupted functioning on the examination day, as well as to acquaint the participants to an alien format and thus ease the anxiety.

On the day, the examination started at 10 am, with the examinee and all four examiners logging into a pre-scheduled video conference link. The examinee was given three clinical case scenarios and an hour to go through the same and write down on the examination sheet to be submitted to the university. The online examination began at 11 am. The examinee, the two internal examiners, and the scrutinizer were seated in the examination hall, maintaining social distancing and other precautionary norms, logging into the video conference room with their respective gadgets. The externals logged in from long distances without actually being physically present. The laptop screen of the examinee was projected onto the bigger projector screen. The entire examination then took place with a virtual face to face interaction between the candidate and examiners on the video conference platform. The entire examination proceedings were recorded by an external video recorder for future reference.

Following this format, the long and short cases viva was carried out by each examiner within a pre-stipulated time limit, which was followed by the viva voce for spotters consisting of ECG, Chest X-Ray, TEE video clips, and stills. The latter was presented in the video conference platform using the incorporated application, for simultaneous viewing by all participants. This was followed by the examiners crossing the candidate on drugs and instruments which they asked the candidate to pick up from a pre-arranged array on display.

After thus completing the examination process, the signatures of all four examiners and the scrutinizer were obtained on the final tabulated assessment sheet through a process of scanning and exchange via email. The final assessment sheet, thus completed with all signatures, was submitted to the university in a sealed envelope.

#### The ISCCM Experience

There are mainly four critical care training courses conducted by the ISCCM (Indian Society of Critical Care Medicine) which include CTCCM (Certificate of Training in Critical Care Medicine), IDCCM (Indian Diploma in Critical Care Medicine), IFCCM (Indian Fellowship in Critical Care Medicine) and IDCCN (Indian Diploma in Critical Care Nursing). Each of the above courses has a theory as well as a clinical exit exam except for the FICCM course which is has only a clinical exit exam. The theory exams consist of multiple-choice questions (MCQs) with a single correct answer model, and the clinical exams consist of case based scenarios (without real patients) followed by various exam stations. The exams are conducted twice a year. The theory exam is conducted in selected centers across a few metro cities in India, and the practical (clinical) exams were in various key hospitals in the different metros. The theory exams (MCQs) for the IDDCM course were conducted as online exams at the Prometric exam centers in the last few years. The candidates reaching the Prometric exam centers are thoroughly frisked with their identity closely verified before permitting them to enter the exam hall equipped with multiple computer systems where each candidate is seated randomly and allowed to log in with their unique ID/password. Potential for cheating at the exam is prevented by preparing the same answers in 2 or 3 different patterns. The exam process is also monitored by invigilators for the entire duration. In view of the ongoing COVID-19 pandemic, the exams had to be modified and converted into a pragmatic online version (except for IDCCN exams which are still conducted regularly). The exams had to restructure in such a way that the candidate could be assessed appropriately & adequately within the shortest time-frame within the given limitations.

ISCCM had collaborated with Prometric testing, a US-based company for the conduct of the above online theory exams with the remote proctoring facility, at candidates' place of convenience. In this model of online exam, each examinee that opts to give the online exam will be issued a unique login and ID details on the exam day just before the start of the exam. Each examinee will be monitored by a distant online human proctor whose job is to closely monitor the examinee and re-

ensure that he/she does not make any unacceptable actions or movements at the exam desk which could facilitate cheating. The remote proctor also reconfirms the identity of the student before the start of the exam by verifying their unique ID cards and hall tickets, soon after their login. One such remote proctor is expected to monitor 10-15 students. The proctoring system is further strengthened by an Artificial Intelligence (AI) system which again could independently micro monitor the candidate's movements and send 'warning signals' or concerns to the proctor (if any). The proctor could take an immediate decision regarding the concerns sent by the AI system either allowing the candidate or stop him/her, to continue the exam. When in doubt, the proctor can immediately contact a designated human 'security agent' who could go through and verify the candidate's entire motion pictures recorded by the system. The security agent can then make the final call on the concerns raised by the proctor or AI. It should be noted that only a few students still opted to give the theory exam at the Prometric exam centers in various cities. This is because the first two Prometric theory exams (for CTCCM and IDCCM where about 260 students were examined) faced significant setbacks with large chunks of students not being able to give the online exam due to technical as well logistic issues. Extreme anxiety and frustration were evident among the student community those who could not log in or complete the exam process. Many students were not able to login or those who logged in were not able to maintain the connectivity due to various reasons. The reasons for this failure could have been due to lack of experience or exposure of candidates to such online exams, failure to fulfill the system requirements, unanticipated power failure, lack of continuous high-speed broadband net connections in various places. "Makeup" exams were allowed twice for the above courses in the coming weeks to enable the students who could not give the exams for reasons beyond their control. The subsequent online Prometric theory exams for the next session fared much better than the first ones though makeup exams had still to be conducted for the smaller number of students who were unable to initiate or complete the online exams due to various technical reasons.

The online practical exams for IDCCM, IFCCM, and CTTCM were conducted successfully in zoom meeting mode with two online examiners attending each student. About 8-12 'digital halls' were created depending on the number of examinees on a particular day with 2 online examiners conducting online examination for 2-3 examinees per hall every day. The examinees were given unique login IDs and passwords to enter the digital hall. The examiners themselves crosschecked the ID /hall ticket of individual students before the commencement of exams. The online exam consisted of case-based scenarios (generally long and/or short cases) followed by consolidated exam stations on PowerPoint presentations. The exams lasted for about 5 days and were conducted smoothly in contrast to the theory exam.

Thus, after addressing the initial glitches in the computer based written examination, the online exams appear to be a promising option during the current pandemic scenario. These glitches did not occur in subsequent exams.

#### **Conclusions**

The suggested online examination system made it possible to evaluate trainees effectively without difficulty compared to the traditional methods. It has the added advantage of reducing the spread of infection during the pandemic. The success of an online examination system depends on proper planning, appropriate information technology resource availability, and the basic knowledge of online platform usage.

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# Original Research Paper

# Awareness, Knowledge and Attitude towards Bioethics among First Year Undergraduate students of a Health Science Institute in Eastern Nepal

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#### **ABSTRACT**

Background: Awareness, knowledge and attitude of the beginner of health science/medical education towards Bioethics and ethical principles will have a great bearing in the future career. We intended to assess the awareness, knowledge and attitude towards Bioethics and bioethical issues in Health Science/Medical students of BPKIHS in the beginning of their medical education. Methodology: This is an academic institute based study carried out among the first year undergraduate (BSc.-Nursing, BSc.- Allied, BDS and MBBS) students of B. P. Koirala Institute of Health Sciences (BPKIHS). We approached all students of the first year of the undergraduate programs of an academic year in BPKIHS. We got the responses from 181 subjects giving written informed consent. The 'semi-structured proforma' and the pretested 'Bioethics Awareness, Knowledge and Attitude' questionnaire were used to collect the responses.

Results: We had 55% female subjects, more from urban settings (65%). Students were from Nepal (76.2%) and India (23.8%). Many students were aware about Bioethics and willing to be a part of Bioethics group. Many students were not aware about the regulatory body giving permission to practice medicine and to conduct clinical trial in Nepal. Majority of the subjects viewed knowledge of ethics very important and wanted to become part of a Bioethics group. More than one fourth participants agreed on the view that health professionals know the best irrespective of patient opinion. Most of the participants believed that patient's wishes should always be adhered to. A few respondent students (4%) also believed that doctors and nurses should refuse to treat violent patients. Majority of the participants had heard of taking informed consent and agreed on entertaining patient's questions during their posting. Almost half of the participants agreed on Bioethics education and research methodology should be a part of UG curriculum.

**Conclusions:** There should be various modes of enhancing the teaching learning opportunities for the medical students to learn about ethics and ethical principles and to enhance their positive view. **Key words:** Awareness, Attitude, Bioethics, Knowledge, Medical students, Nepal

# Introduction

Biomedical ethics or in short, 'Bio-ethics' is the study of moral values and judgments applied to medicine. Conceptually, it is a shared reflective examination of the issues in health-care (service), health science (academics and research) and health policy as right and wrong, with indication of

what to do and what not to [1]. The medical ethics education has been shown to have a positive impact on moral development and on making complete and better doctors [2]. Studies have revealed that most of the knowledge of biomedical ethics is acquired during the undergraduate training [3]. However, most of the students do not receive enough training to sufficiently prepare them for the ethical challenges they face in practice [4]. Medical ethics, a part of bioethics is included and is being taught under Forensic medicine to the medical undergraduates in most medical schools including B. P. Koirala Institute of Health Sciences (BPKIHS).

With the advancing Science and Technologies, there has been great leap by medical and paramedical sectors, so have ethical dilemmas and litigations against health personnel regarding ethical issues. The western societies, working within their own value system, may have been able to develop a 'near consensus' on how to deal with at least some of the thorny bio-ethical questions [5]. However, the Nepalese society, is yet to deliberate upon new bioethical questions in accordance with its own, unique socio-cultural and religious practices. There have been some attempts in the field of Bioethics in Nepal which are largely unorganized. Nepal National Unit of UNESCO Chair on Bioethics joined the UNESCO chair on Bioethics global network in January 23, 2014 and has been constantly working in the field of Bioethics since its establishment [6].

It is important to train, sensitize especially the medical professionals regarding the ethics. With these viewpoints, this research was conducted to assess the awareness, Knowledge and attitude of Bioethics among first year undergraduate students who are just beginning their study in the Health Science fields.

# Methodology

This is an academic institute based descriptive study carried out among the first year undergraduate students from Medical, Dental, Nursing and allied fields (i.e. BSc.- Nursing, BSc.- Allied, BDS and MBBS) of BPKIHS. BPKIHS has a total of 1527 students in various academic programs of Bachelor (MBBS, BDS, BSc.- Nursing, BSc. MIT), Master level (MD, MS, MDS, MSc Basic Sciences, MSc Nursing, MPH and MDHA) and Subspecialty programs in DM (Cardiology, Gastroenterology and Hepatology, Pulmonary, Critical care and Sleep Medicine, Neonatology) and MCH (Urology, GI Surgery) in academic year of 2019/20 in its 4 colleges: Medical, Dental, Nursing and Public Health. Its Teaching Hospital currently has 815 beds and well established major Clinical and Basic Science departments. This WHO Directory recognized health science institute adopts the concept of Teaching District Hospitals; currently serving 10 districts [7].

We approached all of the 210 students enrolled in these academic programs in the academic year of 2016 in BPKIHS [8]. The subjects were approached in person to explain about the study, written informed consent was collected, the 'semi-structured proforma' and the pretested 'Bioethics Awareness, Knowledge and Attitude' questionnaire were used to collect the related responses through face-to-face interview or through self-response. Up to maximum of 3 times, the subjects were contacted if required. Candidates not available during the study period were excluded. We could collect the responses of 181 subjects within the study period. The responses were then analyzed focusing on Knowledge, Awareness and attitude regarding Bioethics.

#### Results

**Table 1: Socio-demographic Information** 

Attribute	Frequency (%)			
Sex				
Male	81 (44.8)			
Female	100 (55.2)			
Nationality				
Indian 43 (23.8)				
Nepalese 138 (76.2)				
Residential Area				
Urban	118 (65.2)			

Semi-Urban	43 (23.8)
Rural	20 (11.0)
]	Religion
Buddhist	2 (1.1)
Christian	3 (1.7)
Hindu	176 (97.2)
Total	181

Table 2: Questions on Awareness of Bioethics with their responses

Questions	Yes	No
Have you heard the term 'Bioethics'?	161 (89%)	20 (11%)
Would you be interested in educating yourself in	162 (89.5%)	19 (10.5%)
Bioethics?		
Are you aware about the bioethics group in your	59 (32.6%)	122 (67.4%)
institute?		
Would you like to become part of bioethics group?	144 (79.6%)	37 (29.4%)
Do you know what an ethical dilemma is?	86 (47.5%)	95 (52.5%)

Table 3: Views on different Bioethical Issues faced by Medical and Paramedical students

Questions	Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree	Total
Health Professionals know the best irrespective of patient opinion.	22 (12.2%)	53 (29.3%)	51 (28.2%)	47 (26%)	8 (4.4%)	181 (100%)
Patient should always be informed of wrong doing by medical personnel.	9 (5%)	6 (3.3%)	22 (12.2%)	97 (53.6%)	47 (26%)	181 (100%)
Patient wishes should always be adhered to.	4 (2.2%)	31 (17.1%)	44 (24.3%)	72 (39.8%)	30 (16.6%)	181 (100%)
Confidentiality can't be maintained in modern care and should be abandoned.	52 (28.9%)	69 (38.1%)	42 (23.2%)	13 (7.2%)	5 (2.8%)	181 (100%)
Certain medical professional charge more from rich patient to compensate for treating the poor.	26 (14.4%)	39 (19.9%)	68 (37.6%)	40 (22.1%)	11 (6.1%)	181 (100%)
Ethical conduct is important only for avoiding legal action.	27 (14.9%)	71 (39.2%)	44 (24.3%)	32 (17.7%)	7 (3.9%)	181 (100%)
Do you think that Bioethics education and research methodology should be a part of UG curriculum?	4 (2.2%)	7 (3.9%)	32 (17.7%)	88 (48.6%)	50 (27.6%)	181 (100%)
Children should never be treated without consent of parent.	8 (0.4%)	24 (13.3%)	33 (18.2%)	82 (45.3%)	34 (18.8%)	181 (100%)
Decision taken in western setup will be applicable in our setup.	10 (5.5%)	60 (33.1%)	74 (40.9%)	32 (17.7%)	5 (2.8%)	181 (100%)
Doctors and Nurses should refuse to treat violent patient.	62 (34.3%)	80 (44.2%)	31 (17.1%)	7 (3.9%)	1 (0.6%)	181 (100%)

#### Discussion

This is a descriptive study which examined the awareness, knowledge and attitude of the undergraduate students in the beginning of their study. To our notice, this study is the first of its kind being done at our institute focusing on the Undergraduate students who are the future of the medical practice in Nepal. The study was carried out under the guidance of the Nepal National Unit of UNESCO Chair in Bioethics.

Majority of our participants (89%) had heard the term 'Bioethics'. This figure is comparable to other study among graduate students and faculty/ researchers of universities in Lahore, Pakistan by Alam and others where 88.9% of the participants were familiar with the term 'Bioethics' [9]. The awareness regarding Bioethics may be due to the sensitization programs carried out by the Bioethics Unit at BPKIHS among the first-year undergraduate students and also the different bioethical issues that they come across in the news and medias.

Only 1.1% of the participants thought that the knowledge of Bioethics to them and their work is not at all important and 89.5% of the participants were interested in educating themselves in Bioethics. This figure is comparable to a study conducted among medical and dental postgraduate in south India by Janakiram and others where 1.8% of the medical postgraduate and none of the dental postgraduate thought that knowledge of medical ethics is not at all important to their work [10].

Thirds of the subjects (67.4%) were not aware about the Bioethics group in their institution although 79.6% of the participants wanted to become part of the Bioethics group in their institution. This shows that although many of the undergraduates wanted to gain knowledge and training about Bioethics, they were not able to do so due to lack of proper place to achieve the training. Many (43.6%) participants acquired their knowledge in Bioethics through lectures and seminar and only 14.9% acquired their knowledge through training. This indicates that Bioethics group in this institute should organize more trainings and seminars and proper publicity of the group and events organized by the group should be done.

In our study, only 21.5% of the participants knew about the ethics committee in the institution. In contrast to the finding of the present study, the study conducted among medical and dental post graduate students in South India by Janakiram and others showed that nearly 98% of the medical participants and 79% of the dental participants knew that their institution had an ethical committee [10]. This difference can be due to the study population. Our study focused on the first year Undergraduate students who were in the beginning of medical career and had less knowledge and experience compared to the post graduate students in the same field.

Many (41.4%) participants didn't know about the content of Hippocratic Oath, 35.9% of the participants didn't know about the regulatory body in Nepal that gives permission for the practice in their respective field and more than half of the participants didn't know about the regulatory body in Nepal that gives permission for clinical trial of new medicine in our country. This shows the need of educating the beginners of the undergraduate Medical, Dental, BSc. Nursing and BSc. MIT students who are the future of the medical field of Nepal. Although the Department of Forensic medicine is teaching students about Medical ethics, Medical Jurisprudence is focused more with not much importance given to other broad aspects of Bioethics. So, more emphasis on Bioethics is needed in curriculum of undergraduate in the medical profession.

Participants had mixed type of attitude towards some bioethical issues. More than one fourth of the participants agreed on the view that health professionals know the best irrespective of patient opinion while more than one fourth disagreed on this view, more one fourth were not sure about this view. This variety in view may be because of the still deep-rooted patriarchal type of medical practice which is slowly fading away with increasing awareness of students on ethics and rising literacy status of the Nepalese population.

More than one third of the participants disagreed and more than one fourth strongly disagreed on the argument that confidentiality can't be maintained in modern care and should be abandoned. This shows the enthusiasm of future medical professionals of Nepal in maintaining the confidentiality and respecting them which is a good indicator in the field of bioethics. On the other hand, almost half of the participants agreed on Bioethics education and research methodology

should be a part of UG curriculum, which portrays the increasing interest and curiosity among students about the bioethics topics.

This study has some limitations. Our study had only first year undergraduates as participants. The results, hence, may not be generalized to the whole undergraduate students. First year students have only little clinical exposure. So, most of the students had not faced ethical dilemma and were most likely unfamiliar about Bioethics. With the findings of current study, we strongly recommend that medical education policy should be revised to include bioethics education to inculcate ethical attitude and behavior in students. There should be proper training in bioethics targeting the undergraduates and post graduates. More similar study needs to be conducted here focusing medical interns and faculties to access their level of attitude and practice as in other parts [11-12].

#### **Conclusions**

Our study brings about the attention to the importance of knowledge, awareness and attitude towards Bioethics in the students of undergraduate level. This study showed that most of the students were aware about Bioethics but not much of them had deep knowledge about its importance in modern day medicine. Variability in the attitude towards different bioethical issues was found but they were more curious to learn about bioethics and wanted bioethics to be the part of their curriculum. If the students are sensitized on various bioethical issues right from the beginning of their carrier, it would be very beneficial in the future and would guide the students to take the more ethical decision as a future medical professional.

#### List of abbreviations

BPKIHS- B. P. Koirala Institute of Health Sciences

#### **Declarations**

# Ethics approval and consent to participate

The study was done after obtaining the approval of Department Research Unit (DRU) of Department of Pediatrics under Institutional Research Committee of BPKIHS (IRC). The IRC is affiliated to Nepal Heal Research council (NHRC). Cases were enrolled after informed written consent from the subject. Strict confidentiality of information was maintained.

**Consent for publication:** Not applicable.

**Competing interests:** The authors declare that they have no competing interests.

**Authors' contributions:** DRS and SS were involved in all steps. RRS, SA and VAC were involved in research designing, assisting data collection and editing. All authors read and approved the final manuscript.

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Conflict of interest: Nil

# Strengthening Quality Research Ethics Review in a Developing Country

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#### **ABSTRACT**

**Background:** The high volume of research proposals increases the workload of Institutional Review Boards (IRBs). Above all, ethical oversight ensures the quality improvement of research. On the other hand, thorough scrutiny of minimal risk proposals including the decisions to waive for informed consent may enhance rapid review cycles. The objective of the study was to determine the nature of ethical review process and assess the opinions of IRB members regarding strengthening the quality of ethics review.

**Methodology:** Using existing IRB records, we analyzed the categories of registered research proposals at the IRB, Department of Medical (DMR), Myanmar (n=703) between January 2016 and December 2019. We assessed the opinions of current IRB members (n=9) of DMR by a self-administered semi-structured questionnaire containing five items on a scale from one to 10 alongside narrative comments.

**Results:** Across the study period, operational research, program evaluation, and community interventions predominated (56%) over biomedical research. In 2019, the proportion of expedited reviews and the frequency of hearing-sessions were higher than the remaining years. Three case studies supported the empirical evidence of relevant decisions for major modifications, minor modifications, and exemption. Furthermore, the IRB members preferred sustained efforts in: capacity building, modification of standard operating procedures, and especially networking (modal rating of 9).

**Conclusions**: This study elucidates the satisfactory progress and achievements in ethical review despite a few challenges. Continuing evaluation of institutional capacity for research ethics might underscore discrepancies that would allow for improvement in quality ethics review. Future research on the development of a framework for feasible and efficient accreditation mechanism with stronger administrative support is critical.

**Keywords:** quality, research, review, ethics.

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#### Introduction

Protecting human research participants is the inherent and vital function of the Institutional Review Boards (IRBs) either in the context of developing or the developed countries [1]. However, the high volume of research proposals increases the workload thereby affecting the timely and quality reviews of IRBs especially in resource-constrained settings [2]. In this connection, sustained ethical oversight and accreditation mechanisms could ensure the quality improvement of research [3]. On the other hand, thorough scrutiny of minimal risk proposals including the decisions to waive for informed consent may enhance rapid review cycles [4-7].

There has been a restructuring process of the ethics review committee (ERC) at the Department of Medical Research (DMR) in terms of its functions following the recognition by the "Strategic Initiative for Developing Capacity in Ethical Review and Forum for Ethical Review Committees in Asia and the Western Pacific" (SIDCER-FERCAP) at the General Assembly in November 2018. The comprehensive steps for accreditation started with the team of independent assessors who thoroughly examined the local ethical guidelines, laws, and regulations, membership of the research ethics committee (REC) and documentation of expertise of both members and the secretarial staff. Also, the extensive review covered the standard operating procedures (SOP), random checks of the submitted research proposals within past three years, evaluation of documentation and archiving at the office of the REC, evaluation of the training curriculum and training records, review of the follow-up policy and procedures after the ethics review process, and examining the agenda and minutes of board meetings. Moreover, the independent evaluators observed and rated the real-time conduct of the board meeting and eventually followed by interviews with REC Chair, members and secretarial staff to clarify about appointment, roles, procedures and suggestions to improve quality reviews. Since its recognition by the SIDCER-FERCAP, there were updates in its SOP inclusive of the submission checklist, the reviewer assessment form, the template for letter of communication to Principal Investigators and in organizing the review meetings [Annual Report to FERCAP, 2019].

In 2019, the Ministry of Health and Sports, Myanmar has reformed and reorganized the structure of ERC (DMR) as the 'Institutional Review Board' (IRB) with 15 members (at least 8 members including one non-affiliated community member to fulfil the quorum) and rejuvenated with young members to work cohesively with senior and experienced members. In the recently reformed IRB (DMR), seven experienced members and three secretariat members of the former ERC (DMR) remained as a Chair and member status together with five new members who have diverse expertise in biomedical, clinical, public health, epidemiology, and social science. A new secretariat team formed in 2019 comprised three permanent members and three rotating researchers every three months. The current version of the revised SOPs and the related sample forms at IRB (DMR) has applied ethical principles stated in the Belmont Report and Helsinki Declaration, complies with existing laws, regulations as well as the National Health Research Policy (2017) and the National Health Plan (2017-2021) in Myanmar, and also followed the good clinical practice guidelines published by the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP) [8]. Among others, the updated manual for SOPs after accreditation mainly covers the following:

- 1. Qualification of IRB members through the experience and expertise;
- 2. The detail description of IRB review policy and procedures to inform IRB members and secretarial staff and researchers and related organizations;
- 3. A comprehensive description of the IRB rules for submission, review, communication, resubmission of amended/revised version, second review, decision and expectations;
- 4. Issuance of additional guidance on SOP for post-approval monitoring as required to facilitate compliance towards ethical guidelines by the research team.

One study from India highlighted the improvements in the performance of IRB concerning the recognition of SIDCER-FERCAP that covered post accreditation and re-accreditation periods [9]. Nevertheless, no studies addressed the performance of IRBs in Myanmar that reflects the effect of the accreditation process. Therefore, this study aimed to self-evaluate the nature of ethical review process at DMR before and a year after SIDCER-FERCAP recognition and to explore the opinions of its IRB members to further strengthen the quality of ethics review.

# Methodology

This cross-sectional evaluation study used the existing IRB records and analyzed the categories of registered research proposals at the IRB (DMR), Myanmar (n=703) between January 2016 and December 2019. Besides, we used three sample case reports purposely selected (title, nature of the research project, justification, study design and study population, sample size and sampling, data collection methods, ethical issues consider before approval) to exemplify the IRB decisions. We assessed the opinions of current IRB members (n=9) of DMR without revealing their identity by a self-administered semi-structured questionnaire containing five items on a scale from one to 10 alongside narrative comments [10-11]. Frequency distributions and statistical averages (modal values) were computed for variables of interest. For the narrative comments, thematic analysis was done manually.

#### Results

Across the study period, operational research, program evaluation research, and community interventions predominated (56%) over biomedical research. In 2019 after accreditation, the number of submitted proposals, the proportion of expedited reviews and the frequency of hearing-sessions (n=190) were higher than the remaining years that ranged from 158-176. The frequency of meetings for both expedited and full board reviews has increased since 2018 compared to previous years.



Figure 1. Distribution of review board meetings at IRB (DMR), Myanmar (2016-2019)

The turn-around time (starting from the date of submission to the date of issuance of approval certificate) varied: 6-12 weeks for the full board review and 2-4 weeks for the expedited review. The approval can get within one week for an exemption. On average, the IRB has reviewed 5-7 proposals per meeting and it usually lasted 5-6 hours for full board. There was an average of seven members in 2016 and 2017, nine in 2018 and 11 in 2019 attended the full board review meeting that surpassed the minimum quorum fulfillment of eight with the presence of at least one non-medical, non-affiliated member. Three case examples extracted from the approval list (2019) as shown in text boxes further supported the empirical evidence of relevant decisions for major modifications and minor modifications of more than minimal risks and minimal risks applications.

# Sample case 1

*Title:* Febrile illness evaluation in broad range of endemicity

*Nature of the research project:* International multi-country collaborative research

*Justification:* The underlying cause of fever is usually misdiagnosed or underdiagnosed due to limitations in the diagnostic facilities. Identifying the common bacterial aetiology of febrile illness will help contributing to better knowledge of epidemiology, will assist in the clinical diagnosis of

individual febrile patients and will ultimately improve patient management, care and disease control priorities.

*Objectives:* To identify the causes of fever and antimicrobial susceptibility of bacterial pathogens causing fever, in low and middle income settings.

*Study design and study population:* Cross-sectional study and included children (10-15 years of age) *Sample size and sampling:* A total of 2,400 eligible children will be enrolled.

**Data collection method:** At the enrolment, study staff will record the basic demographic data, reported history of present illness, and duration of symptoms and will follow by nasopharyngeal swab and urine and venous blood samples according to body weight that is 100ml/kg.

# Ethical issues considered before approval:

- Children as a vulnerable population should be considered to observe coercion and undue influence to parents/guardians/caretakers by the researchers during the recruitment period.
- Data collection through an invasive procedure requires an assent form for children (10-15 years).
- Technically weak research proposal may lead to unnecessary ethical considerations.
- There is a chance for more risks than benefits for the eligible children.
- The Material Transfer Agreement should cover critical issues such as ownership and access to results of materials used.
- Being a multi-country collaborative study, the research team should submit ethics approval from other international study sites.
- Detail procedures for blood samples are to be included.
- It is essential to provide timely feedback of study results to confirm diagnosis and to assist in treatment decisions.

**IRB** decision: Major modifications

#### Sample case 2

*Title:* Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections by a molecular-based point- of-care test using self-collected genital swab specimens obtained from patients attending the STI clinic

*Nature of the research project:* Local collaborative research study between DMR and STD clinic under the Department of Medical Services

*Justification:* Self collected swabs are easy and feasible and will be helpful in development of more consumer-friendly STD screening tests. And also self-collection process could speed up the express visits in a busy STD clinic and identify more infections compared to other methods.

*Objectives:* To detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections from self-collected genital swab specimens using a molecular-based point of care test

*Study design and study population:* A cross-sectional diagnostic accuracy study that will cover patients attending the STD clinic

Sample size and sampling: Altogether 300 patients will be recruited consecutively.

# Ethical issues considered before approval:

- Few technical modifications
- There is a need to revise the recruitment procedure

**IRB** decision: Minor modifications

# Sample case 3

*Title:* HIV testing and ART initiation in people who inject drugs and are placed on methadone in Kachin State, Myanmar

*Nature of the research project:* A collaborative research study between the Department of Public Health, Department of Medical Services and the National Structured Operational Research Training Initiative (SORT-IT) Program

*Justification:* Before 2017, national guidelines specified that HIV-infected persons should start ART if they were in WHO clinical Stage 3 or 4 or if the CD4 count <500 cells/ $\mu$ L. In 2017, the

guidelines were changed to align with those of the WHO, specifying that all HIV-infected persons start ART regardless of WHO clinical stage or CD4 cell count. We wanted to assess whether HIV testing and ART uptake in PWID newly enrolled for MMT and never previously tested for HIV had changed and improved in relation to the new HIV guidelines at the largest government centre. *Objectives:* To compare before (2016) and after (2018) adoption of 'Test and Treat' guidelines for antiretroviral therapy (ART): 1) the demographic profile of PWID, 2) HIV testing uptake and ART initiation in those diagnosed HIV-positive, and 3) time taken for events.

Study design and study population: This was a cohort study using secondary programme data. Ethical issues addressed by IRB:

- To submit the waiver request letter for an informed consent due to the use of secondary programmatic data between 2016 and 2018.
- To revise the data transfer agreement submitted.

IRB decision: Approved with minor modification

# **Opinion ratings**

Among others, the IRB members preferred sustained efforts in: capacity building, modification of standard operating procedures, and especially networking (modal rating of 9) (Table 1).

Table 1. Modal opinion scores of IRB members in strengthening quality ethics review (n=9)

Opinion items	Modal score
Current IRB submission process could satisfy the needs of Principal	6
Investigators	
Current IRB full board reviews could adequately manage the technical and	8
ethical requirements of the submitted research proposals	
Current standard operating procedures of IRB could match with different types	7
of research proposals submitted	
IRB (DMR) needs to synchronize and network with other IRBs in the country	9
IRB (DMR) needs to network with other prominent IRBs in the Asia and the	7
Pacific Region	

Table 2 generated two themes out of narrative comments: IRB submission process and issues on standard operating procedure, capacity building and networking. As for Theme (1), IRB members mainly focused the redundancies during submission process with implications for prolonged duration of turn-around time and workload of the secretariat members. Concerning Theme (2), the respondents highlighted the importance of capacity building of IRB members in support of quality ethics review in addition to regular review and revision of standard operating procedures and the necessity for funding support to IRB so as to enhance networking activities.

Table 2. Narrative comments cited by IRB members

Theme (1): IRB submission process	Theme (2): Standard operating procedures, capacity building and networking		
At the first IRB meeting, PIs usually receive	To attain more benefits through IRB meetings,		
immediate feedback. Many of them need	continuous capacity building of IRB members is		
resubmission after minor modifications and	critical.		
should wait for the ethics approval for a while.			
The way of communication to PIs by the	The SOPs need a review perhaps every year to		
secretariat and their attitude has an impact on	keep abreast with scientific advances, regulations		
satisfaction of PIs.	and statutory laws.		
Introducing the online submission process may	Securing the funding support for sustainable		
satisfy PIs, not only convenient for them but also	networking with prominent IRBs in the Asia-		
reduce the workload of secretariat for preliminary	Pacific region is a challenge.		
checks.			

#### Discussion

There was significant progress of the ethics review process of IRB at DMR, Myanmar, one year after SIDCER-FERCAP recognition [12]. However, there were challenges such as the high volume of submitted proposals, frequency of meetings and lengthy turnaround time. The workload and progress coupled with challenging decisions and opportunities for further improvement of a newly accredited IRB were also highlighted by other REC performance studies in low and middle-income countries [13-15]. Incomplete applications, poorly written research proposals and delay in submission of the amended/revised version of the proposal contributed towards lengthy turnaround time also indicated by other studies [3,9,16-17]. Quorum fulfilment was another challenge for IRB (DMR) but quorum improved dramatically in post-accreditation [9].

Following the submission of the proposals, the IRB has categorized the level of review required: full-board review, expedited review and exemption. Especially for the minimal risks proposals, the IRB has undertaken expedited reviews at the discretion of the Chairperson, by the Chair person and the Member, Secretary and a member with an appropriate expertise thus requiring less knowledge and input to reach the decision. Within the context of IRB submission process, the Principal Investigators received feedback during and after attending the IRB meeting both in form of verbal and written communication in line with the practice of other IRBs in Asia and the Pacific Region [3,14]. A vast majority required resubmission following minor modifications whilst the complex proposals particularly of international multi-centric/multisite collaborative research were most frequently subjected to major modification and substantial revisions, especially for ethical concerns. Their satisfactory revisions may lead eventually to final ethics approval after a certain period of waiting time [15-17]. The way of communication by the secretariat and their attitude might have an impact on the satisfaction of Principal Investigators (PIs) that instigated further research. Introducing the online submission system could satisfy Pls, not only make them easy but also reduce the workload of the secretariat.

Furthermore, the opinions of its IRB members indicated the needs to further strengthen the quality of ethics review. The self-assessment questionnaire informed positive viewpoints, gaps in satisfaction of researchers towards current submission process, capacity-building efforts and pragmatic solutions for quality reviews to handle as next steps [14,18]. Capacity building of IRB members is critical to attaining more benefits through IRB meetings. Some of the SOPs required to be specific and clear. In addition, frequent reviews and revisions of SOPs perhaps every year might pave the way to keep abreast with scientific advances, regulations and statutory laws [15]. Funding support for sustainable networking with prominent IRBs in the Asia-Pacific Region is a challenge. Owing to time constraint and feasibility as a limitation, the satisfaction of principal investigators towards the performance of IRB could not be explored to comprehend the complete picture of the quality ethics review process.

#### Conclusion

This study elucidates the satisfactory progress and achievements in ethical review despite a few challenges. Continuing evaluation of institutional capacity for research ethics might underscore discrepancies that would allow for improvement in quality ethics review. Future research on the development of a framework for feasible and efficient accreditation mechanism with stronger administrative support is critical.

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# Developing Ethical Leadership in Health Care -Experience of Introducing Bioethics in Post Graduate Training

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### **ABSTRACT**

**Background:** Medical ethics is crucial for healthcare delivery. Shalamar Institute of Health sciences (SIHS) is the only institution in Pakistan with mandatory Bioethics training for undergraduate as well as post graduate medical trainees.

**Methodology:** In 2018-19 eight workshops were organized for Post-graduate trainees and feedback was obtained. All the PG trainees who participated in these workshops (n=60) reported it as 'extremely useful'.

**Results:** The 98.3% showed satisfaction from facilitators and considered duration of workshops as adequate. The 88.3% of the PG trainees were of opinion that they would like to attend more sessions on the medical ethics in future. The major themes emerged from the qualitative analysis were: 1) Effects on practices and perspective 2) Improved knowledge about ethical issues 3) Enhanced communication skills. The teaching methodologies like the use of simulated patient, reflection and case discussion were highly appreciated by participants.

**Conclusion:** Bioethics training for PG-trainees will have a long-term effect on sensitizing participants towards moral issues. It provides them the necessary tools to deal with ethical, moral and religious dilemmas faced in every day practice of medicine, making them more compassionate and culturally sensitive. We share our experience with the hope that this initiative would serve as the first step of a long journey towards creating world class medical leaders in the field of ethical professionalism.

**Key words:** Bioethics, Post-graduate training, Ethics education.

#### Introduction

The knowledge and understanding of ethical and moral challenges is imperative for healthcare providers. The 21st century has witnessed rapid development of technology, research and human progress in medical science that gives rise to crucial situations where moral and cultural values collide. The pressing need for familiarity with the ethical dimensions of health care is acknowledged worldwide. United Nations Educational, Scientific and Cultural Organization (UNESCO) made ethics of science and technology one of its five priority areas [1]. However, there remains a huge gap in this area owing to lack of trained professionals as well as formal trainings. Healthcare providers and particularly physicians face many ethical challenges when dealing with patients and their families. Significance of formal ethics trainings for physicians cannot be undermined. It has been observed and reported that physicians are not very well aware of the codes

of ethics and common ethical issues [2]. The onus of responsibility lies not only on the individual colleagues and seniors but also on the institutions to develop and encourage moral discourse (i). The institutions must foster a safe environment where ethical discourse is part of teaching and training.

Shalamar Institute of Health Sciences (SIHS) recognizes the need of structured education of medical ethics among the healthcare professionals and therefore, has taken up the responsibility to educate and train healthcare professionals in Pakistan and specifically in Punjab. The healthcare professionals shall develop skills and knowledge that can be translated into clinical practices, patient care and even health related policy making, all adding up to improve quality of healthcare provided to patients.

The Department of Bioethics was established at Shalamar Medical and Dental College (SMDC) in November 2017. The goal of Bioethics Department is to exemplify compassionate, morally and culturally sensitive environment for healthcare professionals and patients for enhancing experiences of patients and their families at SIHS and beyond.

Several training programs were started by the Department of Bioethics at SMDC and SIHS, in order to achieve the above mentioned goal. One if the most unique program was introduction of a formal Bioethics training program for Post-graduate (PG) trainees at SIHS. The objective of this training program is to disseminate knowledge of Bioethical principles and values among PG trainees and to integrate practical engagement of ethics in research and clinical practices of young physicians [3].

# Methodology

This descriptive study is designed to share the experience of introducing bioethics training as a mandatory part of PG training at SIHS, Lahore and to analyze the feedback given by training participants after these training sessions.

Workshops on six different topics were designed, keeping in mind the teaching methodologies appropriate for discussing ethical issues in clinical practice and research. Teaching methodologies include case-based discussions and simulated patients along with short lectures and reflection. Case based discussions help students to recognize and effectively analyze ethical issues [4].

		Objectives for Participants:	Teaching
	Topics	By the end of the workshop,	Methodologies
	-	participants will be able to:	
1	Confidentiality and Professional	Describe the importance of, and	
	Boundaries	difference between Privacy & Confidentiality	Short Lecture* Reflection
		Analyze ethical issues of confidentiality in clinical practice	
		and research	
		Contemplate professional boundaries in era of social media	
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2	Decision making & breaking bad	Recognize the importance of	
	news	good communication in giving	
		bad information to patients or families	Simulated patients
		Review the factors that can create	
		communication problems	
		Practice skills that can help	
		healthcare providers to improve	
		communication when giving bad	
		news	

4	Conflict of Interest-Physician Pharma Interaction  Informed consent	Describe Conflict of Interest in Healthcare Appreciate ethical aspects of Physician and Pharmaceutical interactions Describe informed consent in healthcare practice and research	Short Lecture* Video Case Studies  Case Studies Short Lecture*
		Identify ethical considerations of informed consent and human dignity Understand and demonstrate skills to analyze ethical dilemmas in clinical practice	Reflection Video
5	End of Life Ethical Issues	Discuss common ethical issues faced at End of Life (EOL) Review strategies to effectively analyze ethical issues at EOL Practice skills that can help healthcare providers to improve communication with patients and families at EOL	Case Studies Short Lecture* Reflection & Narration Video
6	Research Ethics	<ul> <li>Identify ethical issues faced by young &amp; seasoned researchers</li> <li>Analyze ethical issues in research and apply principles of ethics</li> <li>Effectively review a research proposal and provide feedback</li> </ul>	Short Lecture* Video Case Studies

Table 1: Details of Workshops at SIHS

The Department of Bioethics conducted eight workshops in a period of one year (October 2018 to October 2019). These workshops were facilitated by faculty of Bioethics along with other faculty members who narrated their clinical experiences of dealing with ethical issues at work. Two sessions each on topics of 'Confidentiality & Professional Boundaries' and 'Breaking Bad News' were organized for different groups of PG trainees. Workshops on rest of the topics were conducted only once during the year.

The self-reported feedback forms contain the workshop title, date and the name of facilitator. It included closed ended questions about duration of workshop, feedback on facilitator and the topic using a 3 point Likert scale. The feedback form had some open ended questions about participants' expectations from the workshops, how (if) their knowledge was impacted and what would they suggest to the facilitators of the workshops. (see Annexure A)

No identifiable information such as names of the participants or their departments was mentioned on the forms. The questions on the feedback form were analyzed both qualitatively using manual method and quantitatively using SPSS version 20. The data collected was stored in the locked cabinets and password protected computers. Only the researchers were able to access it.

#### Results

The data was collected from 60 participants. All participants reported these workshops extremely useful on Likert scale. The time duration of workshops was found adequate by 98.3% (n=59) participants. The same number of participants reported satisfaction with the facilitation skills. 93.3% (n=56) participants acknowledged that the sessions affected their knowledge and attitudes

<sup>\*</sup>Short Lecture: 10-15 min

towards ethical issues. 4 participants did not answer the question regarding effect on knowledge and attitude. The 88.3% of the PG trainees were of opinion that they would like to attend more sessions on the medical ethics in future while 11.7% of the opinions were missing

The participants were asked if they had ever attended a Bioethics workshop or lecture. Earlier workshop trainings were mostly attended by participants at SIHS.

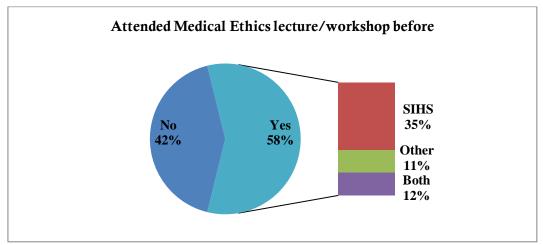


Figure 1: Participants' exposure to Bioethics lectures/trainings, in and outside SIHS

### Expectations from the workshop

The question about expectations of the participants, before attending the workshop, was answered by only 17 participants. However, the responses ranged from 'gaining knowledge' to 'learning communication skills and practical resolution of ethical dilemmas'. Out of 17 responses to this question, about 41% responses were centered on theme of gaining knowledge. About 29% responses were about patient dealing and practical application in clinical practice. One respondent said, "I expected to learn about how to deal with patients in everyday life and how to communicate and transfer information to them". Another one commented, "Participants also anticipated discussion of practically faced ethical issues in clinical practice".

"..it will be helpful in my daily dealing with patients"

# Impact on your existing knowledge and attitudes

The impact on knowledge after attending the workshop was also asked as an open ended question. The cumulative response expressed a positive impact of the trainings. One PG trainee commented, "The workshop helped me sort out ideas and how to deal with challenging situations.... I hope and pray that it turns me into a good physician". The comments suggested that the participants reflected on their own clinical practices: "a take home message: improve your ethical ground at individual level" and, "It helped me enhance my ethical perspective of patient management".

The participants reported a change in behavior and attitude towards patients, after these sessions. "I feel I have become more empathetic after attending the workshop."

# Suggestions by participants

The themes emerging from suggestions of participants included endorsement of such trainings and recommendations to have increased number of 'mandatory' workshops for all junior faculty and trainees.

"These workshops help healthcare professionals by all means....ethics is the most ignored part in our healthcare setup.... therefore such workshops should be conducted more often to help the doctors become more empathetic".

"I personally believe that these kind of workshops should be a part of Continued Professional Development...we all lag behind in ethical aspects of patient management."

"Fruitful exercise...more of such workshops should be conducted..."

<sup>&</sup>quot;..that it will cover clinical experiences related to this topic"

"Such workshops need to be held more often...good platform for learning with real scenarios."

The participants specifically commented on the teaching methodologies used in these workshops. A remark on simulated patients and case discussions said: "it was really beneficial for future interaction with patients". Another participant wrote: "Practice session with simulated patient was helpful... as real life situation"



Figure 2: Words used to describe the workshops

#### Discussion

Bioethics education is an integral part of medical education. Physicians in training, irrespective of their field of training, require basic education of moral principles and their application in their clinical practice. Training programs around the world use various teaching as well as assessment strategies for ethics education [5-6]. Therefore, at SIHS, workshops were designed with various teaching strategies. The topics and teaching strategies were planned so as to cultivate critical thinking and reflective abilities among PG Trainees. The trainees frequently commented positively on interactive and case-based teaching sessions. Problem based teaching has been shown to be an effective strategy for ethical discourse and training [7].

Physician's communication and interpersonal skills help in obtaining the history for accurate diagnosis, explaining the patient about prognosis and giving therapeutic instructions, counseling the patients and establishing a trusting relationship [8]. Particular emphasis on communication skills of PG Trainees was given in all our workshops. The trainees reported a change in perception and understanding of 'end of life' discussions with patients and families. Some trainees regarded experience with simulated patients as meaningful, stating that will help improve their communication with their patients especially when conveying bad news. Similarly, importance of informed consent and value of the process of gaining consent, so that the patient comprehends all the information being relayed, was reported to be appreciated by the trainees. The discussions on informed consent were not limited to clinical practice but also included discussion of practices and procedures in clinical research.

Interactive learning experiences like case-based discussions and interaction with simulated patients have usually been preferred models for teaching and training Bioethics and Professionalism [9]. The participants of our workshops valued the use of videos and interactive case discussions. The cases were mostly real-life experiences of facilitators. Privacy of patients being discussed was respected by using aliases. The workshops on topic of "Confidentiality and Professional boundaries" helped the PG trainees develop understanding of critical and sensitive aspects of patients' rights. Respecting a patient's right to privacy and confidentiality is an important characteristic of medical professionalism. The assurance of maintaining privacy not only helps in building trust of the patients but also reduces risks of stigmatization in a society [10]. Therefore,

this topic is frequently discussed with PG trainees in workshops designed by Department of Bioethics at SMDC.

A physician has a moral obligation to make decisions in the best interests of the patients. Such decisions must be transparent and without any interest of personal gain [11]. Hence, the topic of 'Conflict of Interest' is discussed with PG trainees in our workshops. The undue influence of marketing strategies adapted by pharmaceutical companies may impact practices of physicians. This is phenomenon is prevalent all over the world and has influenced the behaviors of physicians in countries like Pakistan [12]. Discussions on such attitudes versus ethical obligations of physicians are, therefore, discussed with PG trainees at SIHS. As reported by the trainees, these discussions have been helpful to them. They even mentioned in the feedback that their knowledge about such issues improved with the workshops [13].

Deliberation and appreciation of ethical issues faced by physicians cannot be effective without cultural context and social relevance of those issues. Care and health of a person cannot be discussed or described devoid of cultural and social framework [14]. Pakistan has unique and diverse socio-cultural composition. The challenges of healthcare providers and patients are, therefore, also unique to Pakistan. It is imperative that local cultural and social values be considered in ethical discourses. The cases and videos discussed in the workshops, for PG trainees, are derived from real patient experiences. The clinical decision-making in Pakistani culture is often left for physicians. The involvement of extended family, social norms and religious beliefs make 'clinical' decision-making very complex. The ethical issues at the end of life are particularly perplexing [15]. The young physicians, during their trainings have many such encounters. Our workshops aim to enable these young trainees to stride through such challenges. Another way in which these workshops facilitate these physicians is the use of narrative and reflection during the workshops. The workshop facilitators as well as participants shared their personal experiences. This experience sharing and reflective strategies make these workshops relevant to the clinical challenges. Reflection has been established as an effective teaching approach, especially in ethics education [15]. PG trainees of SIHS have emphasized in their feedback that these techniques and experience sharing by senior faculty has been beneficial for them. They would learn from those experiences to improve their dealings with patients and families.

### Limitations

This is a single centered study. The data collected is limited to only those workshops that were conducted at SIHS. Involvement of other institutions and healthcare providers other than physicians should also be studied. That may help in understanding different perspectives about teaching and training ethics to healthcare providers.

The data collected in the study is limited to immediate feedback of the participants. Additional data collection after some time, about these workshops, may be significant. It would be good to find out what the participants think about the workshops after few months. They may be able to reflect on how much were they able to apply this knowledge in their clinical practice and what challenges do they face. Also, validating the feedback form will provide a useful tool.

#### **Conclusions**

Taking care of patients, making difficult decisions with them and sharing worst news of their lives can be very daunting experiences for young physicians. They must be trained to face these challenging tasks, just like they are trained in their clinical skills. Bioethics workshops designed for PG trainees at SIHS are doing that. Ethical discourse with stress on communication skills have been a major component of these trainings. The trainees have expressed their assurance in these workshops and believe that this learning experience shall impact their practices. More frequent sessions with varied teaching methodologies should be conducted for all healthcare providers so as to make them morally sensitive and confident while taking care of their patients. It is inevitable that physicians should learn practical application of their knowledge. Institutions have a great responsibility towards training of ethics and professionalism at undergraduate as well as post-graduate level to healthcare providers.

# ANNEXURE A FEEDBACK FORM

# Department of Bioethics, Shalamar Medical & Dental College, Lahore

Works	shop Title: Date:
Facilit	ator/s:
1.	Did you find this workshop useful?
0	Yes
0	Somewhat
0	Not at all
2.	Is the time duration for the workshop adequate?
0	Yes
0	No it should be increased
0	No it should be decreased
3. 4.	If no, please specify why and how much increase/decrease would you want? Were you satisfied with the facilitation provided by the facilitators?
	O Yes
	O Somewhat
	O Not at all
5.	If you weren't satisfied, please specify how would you want the facilitation to be improved?
6.	What were your expectations from this workshop?
7.	Do you feel that this workshop affected your knowledge of and attitude towards medical ethics?
	O Yes
0	O No
8.	If yes, please elaborate the way that you believe it impacted your existing knowledge and attitudes?
9.	If no, please suggest changes that you want in the future workshops in order to have a
10.	positive impact on your medical ethics knowledge and your attitudes towards it?  . Would you like to attend more workshops on medical ethics in the future?
	O Yes
	O No
11.	. Any other suggestions?
	DEEEDENCES

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# Benefit, Harm and the COVID-19 Pandemic: A Medical Student's Perspective

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#### Introduction

'Benefit and Harm' is Article 4 of the UNESCO Universal Declaration on Bioethics and Human Rights. The basis of this principle is *Primum non nocere*, which means that, above all, do no harm. The bioethical principle of "Benefit and harm" explores all the scientific and medical knowledge to benefit the patients and avoid any damage. COVID-19 pandemic has been arduous for the patients. Lockdown in the initial phase of the COVID-19 pandemic led to the closure of OPDs. Health care facilities were mainly reserved for people suffering from COVID-19, which led to much harm to other patient groups. Now lockdown has been relaxed to some extent, and the governments across the globe are trying to revive the economy. As future healthcare professionals, we need to learn from mistakes and avoid repeating them in the future. Benefit and harm in the context of the COVID-19 pandemic have a vast spectrum of issues. Almost all the bioethical principles are involved in one way or another.

#### **COVAX-** A Global Initiative (Sharing of Benefits)

Across the world, people are responding to the global health crisis caused by the COVID-19 pandemic. Governments, researchers, and scientists are working in unison for the common good. One such global initiative is COVAX. It is co-led by the Coalition for Disease Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO), working in cooperation with developed and developing country vaccine manufacturers. By the end of 2021, the aim is to provide two billion doses of safe, effective vaccines that have received regulatory approval and prequalification from the WHO [1]. These vaccinations will be internationally available to both high-income and low-income countries in an equitable way. Priority to health care staff and then extending to include disadvantaged groups, such as the elderly and those with pre-existing conditions. Further doses will then be made available based on country needs and vulnerability. The COVAX facility will also maintain a buffer of doses for emergency and humanitarian use, including the treatment of severe outbreaks until they escalate out of control.

# Convalescent Plasma Therapy

SARS-CoV-2 has led to the death of millions across the globe. Researchers are incessantly trying to develop methods to combat the deleterious effects of COVID-19 disease on the people. One of the latest developments in treating severe or life-threatening COVID-19 disease is convalescent plasma therapy. The majority of Convalescent donor plasma contains SARS-CoV-2 specific antibodies identified by lateral flow assay tests [2]. The passive antibody administration directly neutralizes the pathogen or through other antibody-mediated pathways and provides short-lived immediate immunization imperative in severe or life-threatening conditions [3]. Initial observational studies advocated for the use of convalescent plasma therapy. Recent studies reveal

that convalescent plasma is not effective in improving mortality or clinical improvement is uncertain in patients with COVID-19 disease [4-6].

### Masks, Sanitizers and PPEs- For the Common Benefit

With the onset of the COVID-19 pandemic, governments' focal point across the globe is to break the transmission chain. The old-age saying of prevention is better than cure holds in this case also. Because of scarce resources and the influx of far too many patients into hospitals, providing healthcare to everyone is difficult. Governments are taking steps to minimize transmission within the community. Taking bold measures will ensure that even if cases increase, the growth rate is slow and prevents sudden spiking in the growth curve. Also, it will help the service providers give quality health care and decrease mortality and morbidity. Studies conducted worldwide reveal that wearing a mask in community settings significantly reduces infection transmission risk and can prevent the COVID-19 outbreak [7-10]. Also, wearing masks is of paramount importance to health care workers. Though the type of masks varies upon the degree of exposure to COVID-19 patients, and there are guidelines issued by CDC and WHO, most evidence supports the use of masks in exposed healthcare workers [11-13]. Nowadays, the limitation concomitant with using the mask is an improper technique, leading to a compromised efficaciousness. We need to provide adequate training and education to individuals and health care workers to overcome the constraints. All around the world, people are using alcohol-based sanitizers to reduce transmission and protect themselves from acquiring the infection. International organizations such as WHO and CDC are advocating the use of alcohol-based hand sanitizers. There are pieces of evidence that buttress the use of alcohol-based hand sanitizers. Gel and foam alcohol-based hand sanitizers available in the market are effective against SARS-CoV-2 when the correct hand hygiene technique is accompanied by other precautionary measures [14-15]. Hand sanitizers can also be harmful as they may cause skin cancer, though it is still not established due to the research gap [16]. If ingested accidentally, alcohol-based sanitizers can lead to acute or chronic toxicity [16-19]. So, we need to be vigilant, especially in the case of the pediatric age group. Healthcare workers are using PPEs to shield themselves and their patients from any further exposure. PPEs are in short supply these days, and everyone is trying to utilize them in the best way possible. PPEs help protect and limit infection spread in hospitals, so professionals use them, especially in the current pandemic scenario [20-23]. The judicious use of PPEs safeguards both healthcare workers and patients.

# Use of Telemedicine in Pandemic- Is it beneficial and accessible to all?

Telemedicine uses technology as a communication channel between doctors and patients to dispense healthcare at a distance. Various facilities are suspended during the pandemic, and emergency services are reserved only for the people with COVID-19 disease leading to a gap between the treatment providers and the patients. For bridging the gap, the alternative of telemedicine was sought. Many studies conducted across the globe suggest telemedicine can help reduce the gap and provide healthcare to patients who need it the most [24-27]. However, telemedicine has its limitations as it is not of much use to people who are inexperienced with technology or have visual and hearing problems [28-29]. Still, telemedicine has a positive impact on many patients who cannot visit clinics or hospitals due to pandemic. Telemedicine minimizes the risk of exposure in patient groups such as diabetics, hypertensive, critically ill, end-stage disease, elderly, and children at higher risk of mortality.

#### Drugs and associated harms and benefits

During the pandemic's initial phase, various drugs were used for prophylaxis and management of patients with COVID-19. In desideratum, everyone rushed to use these without seeking evidence of safety and efficacy. One such category is of anti-malarial drugs, chloroquine, and hydroxychloroquine. These were recommended based on promising preclinical data. Though these drugs have a narrow safety margin and there is limited corroboration from clinical trials to prove their safety and efficacy for prophylaxis and treatment, and usance of these drugs may also create a false sense of security [30-32]. Another category of highly talked about drugs are glucocorticoids. Certain studies support reducing mortality and mechanical ventilation in severe

COVID-19 disease, but there is little evidence from clinical trials to support it [32-33]. Antiretroviral drugs are also being used to treat patients. Again, there is little clinical trial-based evidence to support their use [34-35]. So, before prescribing, associated harms and benefits need to be appraised based on clinical trial evidence.

# Clickbait News and associated harms in pandemic

During the COVID-19 Pandemic, catchy headlines to get clicks and page views are rising. Health professionals or students undergo training regarding cause, transmission, prevention, and treatment of COVID-19. So, they have in-depth knowledge regarding COVID-19 and its recent developments. However, the General Public does not have sound knowledge about the disease process and is vulnerable. This news can be fake and may affect the perception of people towards the disease. False or misleading clickbait information provided through various online platforms can negatively impact public health in general. So, there is a need to address this issue and create awareness among the public to counter it. If we successfully educate the masses regarding ways these clickbait platforms use to get page views, we can curb its negative impact on the people. Clickbait news aims at exploiting the curiosity gap. It forces the person to pursue the information. Abuse of the curiosity gap and treating a person only to gain page views and fulfill personal interests reflects a compromise in human dignity. The definition of health by WHO takes the psychological and social dimensions of people's condition seriously. By exploiting the curiosity gap, clickbait news also causes moral harm. People may realize later that they were tricked, which may lead to psychological harm. We have seen the promotion of various traditional herbs without scientific-based evidence of their actual benefit. Misleading information may lead to harm to the overall health of people. Clickbait news promises to give something that the users desire. People may lose self-control and click these links to pursue their desires, which is an indirect violation of autonomy. Publishers promoting misleading news just for personal gains are not aware of their responsibility to the general public. They are not taking into account the best interests of the general public. Autonomy without responsibility is no autonomy. We often see publishers using the term Chinese virus. Careless use of this term may stigmatize the people of China at the international level. Clickbait news also exploits people's cultural diversity and beliefs for their gains, violating the bioethical principle of Respect for cultural diversity.

# Conclusion

COVID-19 pandemic has presented humans with challenges as never before. With limited resources and knowledge to combat the fewer known variables, we are struggling. The only way to ensure the best outcome is to work together and share scientific and medical knowledge from various research projects conducted across the globe. Sharing of benefits will ensure that all have the best available experience to combat the disease. However, this must not come at the expense of unethical research practices. Any research should involve following standard international protocols and the principle of *Primum non nocere*. Throughout the world, the central area of focus is to break the community transmission chain. We should advocate the use of masks and sanitizers in both community and healthcare settings. The judicious use of PPEs is recommended in healthcare settings. Recent developments in COVID-19 disease treatment include hydroxychloroquine, chloroquine, glucocorticoids, and antiretroviral drugs, but this is without proper evidence from clinical trials. Evidence-based practices should be encouraged; otherwise, there will be adverse and unpredictable outcomes. Respect for cultural diversity, human vulnerability, personal integrity, and bioethical principles of autonomy, equality, equity, and justice is crucial in solving the hurdles we face. This is the time to unite and stand together above all our differences.

#### Abbreviations-

COVID-19: Corona Virus disease 2019; WHO: World Health Organization;

CDC: Centre for Disease Control and Prevention; SARS–CoV-2: Severe acute respiratory syndrome coronavirus 2; PPEs: Personal Protective Equipment; OPDs: Outpatient Departments.

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# 'We are all in this together': Nurses and ethical issues during the COVID-19 pandemic

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#### Introduction

Nurses are at the forefront of health care systems and services world-wide, keeping the health, wellbeing, and safety of patients and families a priority. However, coronavirus disease-19 (COVID-19) has brought pressing issues with unclear guidelines, misinformation, and scarce resources. Nurses are facing dehumanizing situations, stigma and judgment, and many fear for their own lives and the lives of their families. Feeling like the 'last thread of compassion' for patients, nurses have tried to exercise an ethic of commitment and cooperation with other valued members of interdisciplinary health care teams. However, nurses' voices have been barely audible in the rush of pandemic best practices and practically absent in emerging policy work. In an act of solidarity, 14 nurses from 10 countries (see Table 1) recently dialogued about ethical 'brass tacks' over a span of two webinars. The first webinar began 90 minutes after Melbourne, the COVID-19 epicentre of Australia, went into its first night of curfew with a stricter lockdown protocol in place. Summarized here are the common ethical issues that were discussed in the webinars with suggestions for potential next steps forward.

Country (population)	Confirmed	Deaths*	Recovered
	Cases*		Cases*
Australia (approx. 25 million)	26,692	816	23,573
Canada (approx. 38 million)	137,249	9,172	120,724
Hong Kong (approx. 7.5 million)	4,976	101	4,635
India (approx. 1.4 billion)	4,926,914	80,808	3,856,246
Israel (approx. 9 million)	156,596	1,119	115,122
Kenya (approx. 53 million)	36,157	622	23,067
Sultanate of Oman (approx. 5 million)	89,746	780	83,771
United Arab Emirates (approx. 10 million)	80,266	399	69,981
United States of America (approx. 330	6,624,395	197,209	3,578,670
million)			
Wales (approx. 3 million; United Kingdom	371,125 (for	41,637 (for	n/a
[UK], approx. 67 million)	UK)	UK)	
Global (approx. 7.8 billion)	29,114,477	925,596	19,673,071

Table 1- Countries represented and their COVID statistics

https://www.bing.com/search?q=covid+stats&cvid=c1d79aa9f6c64f42a6339d5557e6008e&pglt=43&FORM=ANNTA1&PC=HCTS

With over four hours of discussion about key ethical issues during the COVID-19 pandemic, a dedicated group of committed global nurse leaders identified four general areas of serious concern. One panelist shared a four E's approach with the group: Equip; Engage; Empower; and, Expand (see Figure 1). Upon collating these discussions, panelists' experiences have been combined with this approach and are presented here using that creative context.

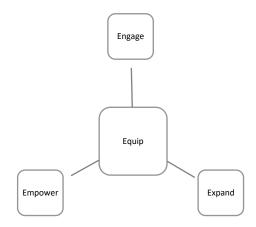


Figure 1-4E's Approach

#### Equip- decision making and resources

Nurses have duties to their profession and to their patients, and also have duties to self-protect. Further, health care organizations have a duty to EQUIP nurses and other health care workers to do their work safely. Nurses have never been strangers to the risks of infectious diseases however COVID-19 has presented high risks to individual nurses, their colleagues, and their loved ones. Struggles to accept these new risks while adequately meeting personal and professional fiduciary duties were noted as ongoing sources of distress among nurses globally.

It is well documented that nurses have been inconsistently included and conspicuously absent in critical (crisis/emergency) decision making and planning during the pandemic [2]. Restrictive family visitation policies at most hospitals have created highly emotional roles for nurses as the

<sup>\*</sup>as of September 14, 2020, from

sole support for patients left alone as a result of pandemic requirements. With concerns about respect for patients' autonomy and informed decision making, nurses are faced with the need to be advocates for goals of care and advanced care planning conversations. Witnessing patients dying alone and knowing that patients are being buried quickly without family presence brings additional issues of grief and bereavement for many nurses and their colleagues.

Even after the outbreak of SARS (2003), the world was caught unaware of the potential of COVID-19. Recent experiences of limited essential resources, namely personal protective equipment (PPE), have brought the ethical principle of justice into reality for nurses. Nurses are left wondering about how scarce resources might be fairly and equitably allocated across organizations, communities, and nations. Also, nurses have reported unjust procedures and processes for decision making regarding which patients should receive care (e.g., upper class or white patients receiving priority status; uninsured or under insured patients being denied care), the type of care patients receive (e.g., futile or non-beneficial care, palliative/end-of-life care, intensive care unit admissions, access to ventilators, etc.), and the use of untested medical therapies.

# Engage- beneficence versus fear

Distress about the lack of resources and rapidly changing decisions with little nursing input, has fueled fears and continues to contribute to the depletion of health and wellbeing among nurses on the frontlines [3]. Health care organizations have a duty to ENGAGE with nurses and other health care professionals to establish common goals, build trust, and address emerging and ongoing fears and concerns. While many countries called nurses out of retirement to assist, some nurses chose to leave nursing all together especially if they were not able to decline circumstances that they perceived to be unsafe. For those who stayed, their duty to care extended into long shifts and overtime contributions. Thus, nurses continue to face the ethical challenges between the benefits of caring versus fears of contamination.

Nurses worried about becoming ill, not being paid while off sick, the potential for losing their job, and of dying of COVID-19 [1]. These are legitimate concerns that are supported by recent research [4]. Some health care organizations reassigned staff away from high risk areas, offered job surety, provided insurance, and/or put hazard pay in place. Many organizations set up surveillance programs [5] to monitor both health care workers and patients, recognizing that asymptomatic carriers may inadvertently add to the burden of disease. Programs that supported free COVID-19 testing of all health care workers at any time served to ease worried minds.

Nurses heard patients' stories firsthand; about being very afraid to come to the hospital to seek care and risk exposure to the virus. In some countries, nurses and other health care workers felt stigmatized by their community members and were perceived to be 'COVID-19 transmitters'. Many nurses wanted to return to their home countries during the pandemic to help their community, but they experienced shunning of themselves and their families.

Real time statistics of health care workers lost to the virus do not accurately reflect the number of nurses who have died. The International Council of Nurses estimates that by June 2020, over 600 nurses across the world have been lost to infection from virus [6]. These experiences of grief and loss are being addressed in some organizations through existing or newly instituted supports (e.g., use of pastoral care and psychologists, hotlines, webinars, call centres with counselling services, ethics rounds, extra paid vacation time, wellness rooms, online church services, etc.).

#### Empower- nurses as heroes

The COVID-19 pandemic has created a space of moral imperative. Health care organizations need to seek to EMPOWER nurses and other health care professionals to perform their full scope of practice. During the pandemic, nurses have been described as reluctant heroes and COVID-19 warriors. Media has shown the public images of the scars of PPE worn for many hours beyond how it was ever intended to be used. The war is being fought on many fronts. Nurses have been isolated from their families and have been left to their own devices to adapt to daily protocol changes. Their ability to be flexible and responsive has often been tapped to its limits.

The saying 'knowledge is power' is true. Power comes from having good and reliable information communicated in a timely manner and then being able to carry out practices that support desired

outcomes. This pandemic has been rife with misinformation, changing information, and, at times, no information. Nurses were told not to routinely wear masks, to use one mask per shift, to bring their own mask from home, to reuse PPE as much as possible, and then to always wear a mask. The rules for acceptable and safe practice appear as a moving target during the pandemic.

In many countries, outpourings of gratitude and acknowledgment for our heroes, health care providers and essential services workers, were a great morale boost to those on the front lines. Donated meals and free hotel accommodations provided much needed sustenance and support. Across the world, messages of hope and solidarity were shared in windows of people's homes, on public billboards, via online cards and messages, and through cheer campaigns (e.g., community handclapping, pot banging, bell ringing, etc.).

### Expand- nurses and resilience

Last but not least is the topic of nurses' responses to the trauma of the COVID-19 pandemic and the need for holistic approaches to support physical, mental, emotional, and spiritual health and wellbeing [7]. Health care organizations need to support and build capacity to EXPAND the resilience of nurses and other health care professionals. During this pandemic, well studied concepts such as compassion fatigue, burnout, moral distress, and moral injury have found new relevance in light of nurses' recent experiences with moral exhaustion in places of moral hazard. Strategies that focus on health promotion, prevention, and early intervention need to be prioritized in the months and years to come. As online programs have been put in place to upskill nurses into critical care positions, upskilling in self-care and holistic health promotion strategies are essential for nurses in all areas of nursing practice to support and enhance resilience and wellbeing.

# Potential next steps forward

Global nurse leaders have expressed a need to get 'back to basics'; for nurses, organizations, and health care systems. The time has come to support a shared decision-making model that includes the voices of nurses at many levels and across health, social, and education systems. Positive changes may include the following:

- Organizational information that flows to and from nurses and is transparently communicated in a timely manner.
- Nurses have a voice and a place 'at the table' in decision making and policy development at every level of health care organizations.
- Nurses routinely advocate on political levels to address ongoing and emerging issues in health and illness care.
- Nursing has a dedicated space in the structure of health care systems with representation across health care sectors.

Further, new and expanded roles for nurses using tele-media, tele-health, and tele-medicine have occurred as a result of the pandemic. Technology is also being used more fully to deliver education and continuing professional development. Once considered essential, didactic nursing training (e.g., traditional classroom lectures) and hands-on clinical experiences have been largely suspended and replaced with online learning and simulation activities for health care professions students including student nurses [8].

However, new roles and responsibilities require ongoing education and training opportunities for nurses in clinical practice and in academia. Nursing curricula will need to be evaluated for the ability to prepare graduates with necessary skills in pandemic management, including psychosocial aspects of patient care and palliative/end-of-life care. Training needs to include, and also extend beyond, disaster nursing, infection control, and managing crisis. There will likely be attention to the development of evidence-based simulation and standardized training tools in these areas.

Further, nursing students who are currently learning while living in a pandemic environment will be evaluated on the additional skills (or lack of) that they must bring to clinical practice areas upon graduation. Dubbed by some as "coronials" [9], the next generation of nurses (those currently in training) will face nursing practice realities that nurses before them did not experience. Perhaps new graduate nurses will present a call to action to health care organizations to fulfill their duties and more fully support the 4E's for nurses and other health care professionals.

#### **Conclusions**

Responsive (versus reactive) planning and the implementation of evidence-informed strategies to address COVID-19 are among the global priorities in the current and foreseeable future. To meet this challenge, the voices of nurses across the world need to be heard. Nurses are at the forefront of health care delivery and they must have a voice in policy and decision making at all levels. Nurses need to be recognized for having advanced knowledge in their profession and for their unique scope of practice; an invaluable vantage point of sage wisdom. As the largest global health care workforce [2,10], nurses are important stakeholders who can identify and problem-solve ethical issues in practice collaboratively with colleagues, patients, families, organizations, communities, and health care systems. With diverse needs and dynamic issues emerging, nurses require ongoing opportunities to dialogue with one another, collaborate with interdisciplinary team members and organizations, and advise the public on how to work toward a 'new normal' within and beyond the COVID-19 pandemic. The entire world is depending on nurses. In the spirit of solidarity we recognize that "we are all in this together!"

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# Warriors without armors: Human Rights violations against healthcare workers in the times of COVID-19

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## Introduction

The United Nations defines Human rights as "rights inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status [1]. Human rights include the right to life and liberty, freedom from slavery and torture, freedom of opinion and expression, the right to work and education, and many more [2]. Everyone is entitled to these rights, without discrimination." On the 10th of December, 1948, in Palais de Chaillot, Paris, the Universal Declaration of Human Rights (UDHR) was adopted by the United Nations [3]. Even though it is not a treaty nor is it legally binding, it has helped shape the concept of universal human beings' rights and freedoms. It is safe to say that the majority of constitutions worldwide embrace most -if not all- of the thirty articles in the UDHR. Among the 30 articles, article 22 addresses the right to social security, article 23 highlights an individual's right to favorable work conditions, article 24 talks about the need for reasonable limitation of work hours, and article 25 discusses an individual's right to well-being and security [3].

December 2019 saw the emergence of the novel Coronavirus Disease 2019 (COVID19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is believed to have originated in Wuhan, China. In less than a year of fighting the pandemic, frontline healthcare workers (HCWs) have faced some unprecedented challenges. As of 27th November, 2020, there have been estimated to be over 61 million cases and 1.3 million deaths due to COVID-19. Out of

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these, healthcare workers (HCWs) comprise over 67,569 of the cases [The median HCW infection percentage among total cases was 10.04% (range 0–24.09%)] [2]. The International Council of Nurses reported in May of 2020 that 90,000 healthcare workers had been infected with COVID-19 [3]. Lack of adequate protective equipment was a major problem early on into the pandemic, the resource-poor countries faced the worst of such shortages. Amnesty International reported a serious shortage of Personal Protective Equipment (PPE) in nearly all of 63 Countries [4].

Possible delay in declaring the pandemic, lack of pandemic preparedness in the public health and healthcare systems in the form of clear cut guidelines and management strategies, lack of adequate training among HCWs in the face of a pandemic, and circulating conflicting evidence on the novel virus and infection were important contributing factors in causing chaos and confusion among HCWs. Across the globe, as millions of people stayed at home to minimize the risk of contracting and transmission of SARS-CoV-2, HCWs prepared to take on the pandemic head on [5]. Although HCWs have repeatedly been portrayed as "warriors in white coats", ironically, they have been expected to expose themselves to hazardous work conditions and risk of infection without being adequately provided with protective equipment. Most countries do not have strict regulations or lack implementation on work hours and workplace conditions for HCWs and lack adequate compensation, either in the form of monetary compensation or as days off to rest and recover. HCWs have been struggling to fulfill what is expected of them while neglecting their own mental and physical well-being.

We have to pause and reflect whether HCWs are able to protect their human rights, we have to question how many of them are enjoying good health themselves. As of 2020, there are 1.2 million physician HCWs in the U.S. alone [6-7]. While some countries like South Korea appeared to have handled the challenges of the pandemic better than other countries, possibly that is after having learned some valuable lessons dealing with the previous SARS and MERS pandemics, countries including the U.S. were woefully unprepared to protect HCWs amidst the rising number of COVID19 patients [8]. In India, opinions varied widely, there has also been speculation of underreporting in some places making it difficult to get a clear picture of the situation in these areas. There has also been worrisome news of the suppression of the voices of HCWs in China by their government. It is saddening to note that the rights of physicians usually overlooked are the ones stated under articles 22-25 of the UDHR, which include the right to work, the right to rest and leisure, and the right to a decent standard of living. These violations clustered together could furthermore constitute the violation of Article 4, which states the right not to be held in slavery or servitude or made to do forced labor.

#### Human Rights and Healthcare workers

The World Health Organization (WHO) divides workplace violence into physical and psychological with the latter including verbal abuse, threats, verbal sexual harassment, and sexual harassment [9]. Workplace violence is one of the primary infringements of human rights faced by HCWs, documented in previous literature. The situation is particularly worse in low resource settings where regulations protecting healthcare workers are sparse [10].

The prevalence of psychological violence in America, Brazil, and South Africa has been reported to be 75%, 39.5%, and 52% respectively [11]. Similar rates can be observed in Asian and European countries. Findings depict that psychological violence was perpetrated by hospital colleagues, supervisors, patients, and relatives causing damaging psychological trauma than external violence [12]. Lack of basic health literacy has been commonly observed to be a precipitating force, exacerbating violence mainly from patients, their relatives, and attendants towards providers in the emergency department in India. Studies also show a high prevalence of violence against HCWs in developed countries [13]. Lack of fundamental rights and institutional discrimination has led to low morale, and subsequent stress, and other health concerns among HCWs. A study indicated that 1 in 5 healthcare workers in India reported experience with physical abuse consistent with prior studies [14]. Inadequate enforcement of rules governing behavior in the hospital has had an overwhelming impact on human rights violations of HCWs, which have been understudied and underreported. In May 2020, an armed attack on a hospital maternity ward in Kabul, Afghanistan,

killed at least 24 civilians, including two infants, which was an example of a tactic of war defying international humanitarian law.

Many HCWs are overworked, underpaid, and are repeatedly exposed to psychological violence. Persistent internal violence is a known cause for depression, anxiety, insomnia, hallucinations, and even suicide [15], an example of which occurred in China [16]. Employees in health care environments are also exposed to a wide range of hazards in their work ranging from exposure to diseases, chemicals, radiation exposure, and ergonomic issues like long working hours, stressful work, and standing for long periods among other issues. The risk of infection (especially with hepatitis C and hepatitis B viruses) among healthcare workers (HCWs) is high as was described in a report published by the WHO, and approximately 100 health care workers die annually from occupational HIV. Almost 80% of healthcare workers remain unimmunized (against Hepatitis B) in many parts of the world. Protection of the health care workers is needed just as much as working in other hazardous environments as miners [17].

We can also find examples of human rights violations against HCWs throughout history. Throughout WW1, hospitals, hospital ships, HCWs, vehicles, and supplies of the Red Cross and Red Crescent were a target of bombing despite the presence of then valid Geneva and La Have Conventions [18]. Similar reports emerged during Israel's attacks on the Gaza strip in 2008-2009, during which 16 HCWs were killed and another 22 were injured while on duty. Fourteen hospitals, 38 primary health care clinics, and 29 ambulances were also destroyed or damaged during the attack [19]. Multiple reports have also emerged out of Syria. A qualitative study involving 29 HCWs in Syria revealed that medical facilities were constantly targeted by bombs and the constant threat to doctors led to mass outward migration. Since there were physician shortages, HCWs had to act beyond their training and in very limited resources, leading to enormous pressure and psychological stress [20]. A study by Abdulaziz and others revealed that an estimated 782 HCWs have been killed during the Syrian conflict and the deliberate targeting of healthcare facilities [21] whereas Michele et al. reported at least 157 medical personnel were executed or tortured to death [22]. A systematic review by Rubenstein et al. reported attacks on medical personnel, transport, and facilities. HCWs were attacked in El Salvador, Philippines, Sierra Leone, Bosnia, Croatia, Rwanda, Colombia, and many other countries. Human rights violations consisted of and were not limited to doctors being killed, tortured, robbed, detained, interrogated, prosecuted, and forced to withhold care to patients [23]. Female HCWs have also been a victim of added sexual harassment. An exploratory study involving 135 female HCWs in 4 different hospitals in India revealed that 77 women had experienced 128 incidents of sexual harassment, consisting of verbal and psychological harassment, sexual gestures and exposure, and unwelcomed physical contact [24].

#### Healthcare Workers and the COVID19 Pandemic

During the past year or so, the issues stated above have been compounded and aggravated by the complex challenges brought about by the COVID19 pandemic. The highly contagious nature of this potentially life-threatening illness mandated unprecedented changes in daily lifestyles. These changes included a compulsory suspension of most of the non-essential businesses and activities, stay-at-home orders, enforcement of social distancing rules, frequent hand-washing, and maskwearing, among many others [25]. Along with the stress and anxiety caused by the onset of an unexpected pandemic, all of these changes were particularly magnified in the lives of frontline healthcare workers, along with an array of others. Many physicians and health care practices reported great financial losses caused by COVID-19 pandemic. In one recent US-based survey, up to 97% of the surveyed medical practices suffered negatively due to the current situation [26]. Drastic decreases in revenues have been recorded in most medical practices. Furloughs, working hours cut short, and salary reductions became a looming threat for healthcare workers and adjunct paramedical personnel [27]. A recent study by the Commonwealth fund demonstrated a more than half decrease in appointments for ambulatory healthcare since the beginning of the pandemic [28] Such sudden and grave financial strain weighs heavily on many doctors' minds. They have families to support, employees and practices to keep open with little to no revenue incoming, and a considerable number of them are struggling with lingering student debt.

Triaging in the emergency department setting was already challenging before COVID-19. Pandemic pathways were created to triage and separate the suspected COVID19 positive cases from ER care, however, there was an enormous exposure risk of HCWs in these departments, due to asymptomatic COVID19 carriers. Excluding trauma, orthopedic and emergent surgical conditions all elective surgeries were stalled or deferred creating a pool and backlog which included on-surgical malignancy surveillance screenings as well specialties with surgeries involving AGP [Aerosol Generating Procedures] like dental, ophthalmology, otorhinolaryngology has been drastically affected and triaged into prioritized cases category and deferred category [29]. There was an observed decline in immunization of young children makes them vulnerable to acquiring infections subsequently [27].

Academicians in the healthcare field faced a particularly difficult situation. The suspension of university courses in the middle of the academic year forced them to immediately adopt distance learning technologies with no prior preparation. The multiple tasks of healthcare educators have been further expanded. From digitizing all the syllabus contents to figuring out how to cope with unfamiliar online teaching methods and media sharing platforms, to devising solutions to compensate the students for the loss of the practical and didactic sessions [25]. Moreover, the research projects and the grants that have been indefinitely suspended has been a frustrating problem to many academics, this has jeopardized their ongoing researches [30]. These factors compound the stresses of overburdened academics [31].

There have been reports of HCWs experiencing extreme stress, anxiety, and depression during outbreaks and subsequently developing somatization and obsessive-compulsive disorder as a result [32]. A systematic review of the effect of COVID-19 infections on mental health concluded that there is a correlation between the SARS-CoV2 infection and worsening of mental well-being. Interestingly, it also revealed that healthcare workers are more severely affected than the lay population [33].

Apart from the risk of contracting COVID19, HCWs have been susceptible to various other health consequences during the pandemic emanating from risk factors such as long working hours, working in high-risk departments such as emergency medicine, lack of proper protection, improper infection control, prolonged PPE usage leading to skin damage, and psychological distress [34]. A recently updated article on Medscape lists about 1800 deaths of HCWs worldwide [35]. Another source listed 278 physicians' death as of April 2020 [36], with the most deaths occurring in Italy, followed by Iran and Philippines. The situations were similar during previous outbreaks such as Ebola (EVD), and MERS (Middle East Respiratory Syndrome) [37]. Nurses in many countries have suffered from various forms of assault, ostracization, and abuse. They have been pelted at, evicted from their homes, and denied access to supermarkets and to public transport [34]. A study of residents in the New York emergency department demonstrated that 97% of the residents suffered from some form of verbal violence. Interestingly, healthcare workers have come to regard psychological violence as part of their daily work [38].

A breach of human rights is seen in the restriction and penalization of free speech in many parts of the world. Doctors and nurses have been asked to remain silent about their working conditions, while there have been reports from several countries, of hospitals and clinics that have threatened HCWs with dismissal if public grievances were made on the lack of PPEs. In India, a criminal complaint was registered against a doctor who spoke on the lack of PPEs [39]. With the lack of proper training of HCWs, biosafety breaches during donning and doffing of PPEs make them vulnerable to acquiring infections.

In some communities, HCWs have experienced violence, harassment and discrimination. This has forced them to either move their homes or be physically attacked [40]. Speaking critically of some governments can bring about harsh punishment. Insecurity Insight, a non-government organization, identified 360 events in 77 countries between March 1 to April 30, 2020, ranging from protests to blocking health-care facilities, to threats and attacks on health workers in the context of COVID-19, possibly as a result of misplaced anger [41]. The World Medical Association has condemned the increasingly reported cases of HCW's being attacked. The situation in India is particularly shocking as their HCW's have been stigmatized, ostracized, discriminated against, and

physically attacked but incidents have been reported across the world, for instance from France, Mexico, Philippines, Turkey, UK, Australia, and the US [42].

Confusion regarding the withdrawal of life-support decisions, triaging of ventilators to the needy (based on incongruent criteria) quality of end-of-life support, disruption of communication between caregiver and family resulting in disappointment with patient's unfavorable outcome, blame for an unshared decision and de-humanization of care can be contributing factors to the possible decline in the doctor-patient relationship.

As the number of COVID19 cases continues to rise, HCWs have an increased risk of exposure to SARS-CoV-2. As patient loads continue to increase, and co-workers become infected with COVID-19 the physical and psychological well-being of HCWs are taking a beating. Adding to concerns for their safety, HCWs are forced to deal with anxiety about passing the infection to their families [5]. The morbidity and mortality of HCWs have warranted interventions to curb the deleterious consequences associated with the abuse and denial of basic fundamental rights. It is pertinent to look into adequate measures and implementation of laws to curb the rising human rights violations meted out on healthcare workers.

### Benefits and limitations of the study

To our knowledge, this study is the first collective work discussing human rights violations against HCWs from different countries both before and during the COVID-19 pandemic. Discussing these issues and taking action to correct them is essential to strengthening our healthcare and public health systems in order to effectively deal with the challenges that the future might have in store for us. We hope that through global co-operation and changes at the grassroots level we can make lasting improvement in these areas. There are some limitations to our study. It was not feasible to include all instances of human rights violations all over the world within the limitations of this paper. Additionally, not all instances of human rights violations against HCWs might be reported, possibly due to the reasons discussed in this paper [42].

### Recommendations

Human rights violations against HCWs is an underestimated global problem that has become evident with crises [43]. The need of the hour is to prioritize the occupational health of health workers and ensure that the workforce is adequately trained and healthy by supporting those on the frontlines, all the equipment needed for their protection should be provided, more social, psychological support [44]. We recommend some ways which can be adopted by the healthcare system and governing bodies to effectively deal with the ongoing pandemic.

### At the Individual level

- 1. Empathy training, bedside manner training, communicating bad news should be incorporated into healthcare education and training settings.
- 2. Healthcare workers need to be encouraged to practice self-care through practices like yoga, meditation among other health and lifestyle practices in order to maintain optimum mental and physical well-being.

# At the Hospital /University/Institution level

- 1. Staff support measures, appropriate psychological support programs, dedicated psychological intervention teams, and availability of helplines, especially to combat the significant psychological impacts of a pandemic and high-stress work environments.
- 2. Establishment of shift systems, online platforms for medical assistance, incentives, provision of adequate breaks and time offs, a place to rest and sleep, and provision of mindfulness activities to support HCWs mental well-being. Additionally, establishing break time will allow for HCWs time to take care of themselves. To decrease workload by incorporating outside registered nurses into the hospital system, re-employing HCWs who recently retired, and adding medical students to the health care system in times of emergencies [7].

- 3. Training and provision on the use of personal protective equipment, strict infection control practices, and national regulatory bodies periodic checks and governmental laws to mitigate contagion and reduce the risk of infection.
- 4. Periodic gender and racism bias checks within a hospital and clinical settings, integrating gender into clinical audits, introducing gender sensitization training, and conventional interpersonal communication training may help reduce gender and race-based discrimination.
- 5. Necessary training should be provided to HCWs and medical training on technologies such as Telemedicine and using online teaching and learning platforms.
- 6. Adequate food and lodging facilities for HCWs in quarantine to avoid the risk of exposing their families to COVID19.
- 7. Adequate compensation for overtime or duty under dangerous working conditions.

### At the National level

- 1. Formulating a Pandemic Preparedness plan based on policeman of policies aimed at increasing the capacity of health systems response (Raising the line strategy), Mitigation strategies, increasing government capacity to respond to the crisis (Strengthening strategy). Dedicated funds and equipment for pandemic and emergency preparedness.
- 2. Establishing surveillance strategies and communication lines between HCWs and governing bodies. HCWs are on the front line and possibly the first to know of the possible emergence of a healthcare emergency or if a health policy is or isn't working [4].
- 3. Establishing an emergency reserve medical supplies program to ensure the adequate provision, based on requirements. Such supplies may include essentials like PPEs, ventilators, masks, sanitizers among others.
- 4. Violence prevention programs and amendment of existing laws with strong legal repercussions for any form of psychological or physical violence on health care workers. In developing emergency care systems, a greater understanding of the surroundings and the community can help establish better practices to curb the assault of HCWs working the emergency departments.
- 5. Framework guidelines for addressing workplace violence in the health sector, jointly developed by WHO, ILO, ICN, and PSI, to support the development of violence prevention policies in non-emergency settings, is a tool that guides through the complexity of issues to be considered when developing anti-violence policies and strategies for all work-settings in the health sector. These can be adapted to meet local and national needs and constraints and must be utilized while creating violence prevention policies.
- 6. Utilization of Bioengineering expertise and modular system inventions which protects HCWs from aerosol contamination thus increasing HCWs personal safety and their confidence, especially in extensive testing in community settings.
- 7. Along with adequate PPE supplies that meet requirements, other practical measures including canceling non-essential events to prioritize resources, provision of food, rest, and family support needs to be considered especially when healthcare systems operate at maximum capacity.
- 8. Establishing grievance redressal systems for if the human rights of HCWs are to be protected from attack, government intimidation, harassment, and arrest as was described in some countries [41].
- 9. Public and Patient health literacy programs and awareness campaigns can help reduce the overwhelming frequency of violence emanating from patient family members and attendants precipitated by unfavorable patient outcomes or death. Studies suggest administrative measures and strong operational directives are optimal ways to control violence in health centers and therefore violence control programs should focus on administrative measures [46].
- 10. Pandemic and emergency preparedness training to be a part of medical training.
- 11. Review and implement systems to ensure implementation and quality control at the grass-root level.

### At the International level

- 1. Encouraging research and development of effective and affordable medicines and vaccines.
- 2. Global Pandemic Preparedness Plan and implementation.
- 3. Establishing a global alarm system for monitoring the possibility of an infectious outbreak that has the potential to become a pandemic and raising the alarm at the earliest such possibility.
- 4. Formulating global health policies as an example for countries to follow.
- 5. Global emergency health funds that could be mobilized in aid of the lower economic countries and in emergency situations. Such funds could also aid in procurement of necessary protective equipment, medicines and vaccines.
- 6. Treaty for global co-operation among countries, especially for emergency situations.

In the post-pandemic period, formulating and implementing a Pandemic Preparedness plan at the national, regional, and local levels would be crucial if we are to be prepared for the next seemingly inevitable one. A multipronged approach incorporating political, public health, and healthcare systems would be necessary. Public education and cooperation would also be vital in the implementation of such policies. The current pandemic has shown that strict implementation of public health measures such as physical distancing, wearing masks, and hand hygiene early in the pandemic is vital to slowing down the spread of infection.

#### Conclusion

Expert opinion has highlighted time and again that we could be expecting another pandemic in the future and such a situation might not be far away. The current pandemic has unearthed some painful deficiencies in the health care systems. A combined approach involving the political, public health, healthcare, and socio-economic systems would be vital if we were to be prepared for the next pandemic. In the post-pandemic period, as countries go about preparing their plans for Pandemic Preparedness it would be a good place to start by addressing the problems faced by their healthcare workers and building a strong foundation for the healthcare system. Healthcare workers are an important foundational pillar of Pandemic Preparedness. It has been clear for a long time that the healthcare systems need an upgrade centering around better working conditions for the health care workers and protection of their human rights. Global cooperation would be paramount if we are to deal with the current pandemic and minimize the potentially devastating effects of a pandemic in the future.

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# Webinar Summary

# **Covid Iatrogenesis**

Webinar by Dr. Harold J. Bursztajn, MD

Prepared by Dr. Sreenivas M., Professor of Forensic Medicine, Maulana Azad Medical College, National Training Faculty, India of UNESCO Bioethics Chair, Haifa.

"The best cure for worry, depression, melancholy, brooding, is to go deliberately forth and try to lift with one's sympathy the gloom of somebody else."

### Arnold Bennett

The Covid-19 pandemic has thrown up many challenges to be tackled by humanity at large; not least of all are the sweeping mental health issues that it brings in its wake; affecting one and in various degrees ranging from overt depression and despair to an insidious undercurrent of anxiety and fear. The webinar was 'performed' by Dr. Harold Bursztajn, who wears the hat of a master 'Psychoanalyst' and very eloquently renders his interpretation of pieces of art (paintings by famous artists). Like a violin virtuoso, he waxed lyrically, elaborating on the theme of 'Art for dealing with Mental health and bioethical issues,' and produced such mellifluous musical musings, which had the capacity to soothe the ears, assuage hurt feelings and heal the heart that has been broken by witnessing human suffering all around.

Opening bar was a definition of Iatrogenesis as the unintended consequences of the treatment that is given. In the context of Covid the question "Is the treatment more dreadful than the disease?" attains ominous proportions.

Man should never give up the quest for beauty, because it is beauty which leads to truth and truth which leads to goodness. All analyses have an unwritten imperative to answer the question- what is true, beautiful and good?

Post-traumatic stress disorder (PTSD) and Extreme personality change after a catastrophic experience (EPCACE) are two commonly occurring mental health issues among patients, their caregivers and health care professionals which need to be addressed appropriately. Unresolved mental issues can manifest as perfectionism, self-righteousness and scapegoating, which in combination lead to a pattern of toxic resilience. We need to be aware of both short-term and long-term consequences of whatever measures we may institute.

Then the performance shifted to the showcased paintings; narratives were drawn from them like strings which connected with and wove around the ongoing existential crisis that people are experiencing in the midst of this Covid pandemic.

Real psycho-mental healing and its gift -- clarity of mind -- do not come about unless the 'unconscious' is brought into the broad daylight of conscious awareness. The paintings and narratives served this important function of reconnecting us with our inner world of existential crisis and led us down a pathway of internal dialogue with our own hopes, aspirations, dreams, fears, despair and desolation.

Each of the pieces of painting was truly evocative, struck at an unseen chord and evinced a clarion call to the heart:

# 1) Coal miner's torch – Henry Moore 1942

### Is the cure worse than the disease?

Where do we need to shine our light? Are we looking in the wrong place for our solutions? Are our strategies misfiring and hence causing more damage? We need to regroup our resources and re-focus, or else we are in danger of running around in circles and ending up in a state of hyperfocus and Acute stress disorder. The question of how we live assumes greater importance than the question of how we die.

# 2) Denial of aging and Entropy – Hyman Bloom 1960s

"Not treating someone with dignity, you lose your own dignity"-HB

# Can we afford to deny aging and entropy?

How are we taking care our of elderly in this Covid crisis? Isolating them and denying them human contact, human dignity and hope...cannot be doing them any good. Demoralising people is only going to reduce their immunity.

### 3) Zwai Schwatzende-Kathe Kollwitz-

# "Teaching and learning is a human reality, not a virtual reality"-HB

To protect children and the elderly, schools have been closed without providing for day care of the children. This not only might lead to a generation that is alienated from itself, but also has the attendant risk of EPCACE in both the parents and the children.

# 4) No one is who they seem to be-Francesco Goya

# "Never worry alone, never grieve alone, be yourself, and always be curious"-HB

Although wearing masks in closed spaces is recommended to prevent spread of infection, mandating use of masks in uncrowded open spaces appears to be unjustified. Social distancing has made an ugly turn to 'social alienation,' further leading to disruption of the very fabric of social life.

# 5) Marsayas – Hyman Bloom 1953

# If you are competing against yourself, you can never win.

Marsayas is a half-human, half-animal character from Greek mythology who was a gifted musician; in his quest for perfection he challenged Apollo. Marsayas lost the competition and, as per the condition set by Apollo, he was flayed alive. We need to give up the ideal of perfectionism (along with self-righteousness, vigilantism, scapegoating, and dehumanization), as it leads to a pattern of toxic resilience which crushes the spirit of people and vitiates respect for human dignity, leaving a swathe of victims in its wake.

# 6) Seascape III – Hyman Bloom

# If we do not acknowledge fear, we humiliate others.

Unless we keep an open mind and acknowledge uncertainty, we are doomed to be lost in the predatory sea. We should not be afraid to change our mind when we reach a better understanding of the current problems being posed on us. Aesthetics, grace and kindness should be our guiding lights in times of crisis. In this sea of uncertainty, a quest for beauty leads on to truth and goodness.

# 7) Keeping Hope alive: Winter -Hyman Bloom 1980

# 8) Keeping Hope alive: Summer -Hyman Bloom 1980

Though it is dark in winter, there is still some light....hope is to be kept alive; the seasons change and eventually summer arrives. This pandemic too will pass, there might be other pandemics in future; we should not react in a kneejerk fashion that will compromise our future stability.

# 9) Photographs showing parents of Dr. Harold (a) in amongst other fekalists (sanitation workers) in the Lodz ghetto during the typhus pandemic 1942; (b) after the Shoah.

### Grieving is important to keep hope alive and hope is what makes us ethical.

The Bursztajns were part of the resistance in the ghetto; they showed remarkable courage and joined forces in the ghetto to fight the typhus which was threatening to wipe out the entire population of the ghetto. The people in the ghetto worked with each other and kept their hope alive by focusing on what they could do to help the situation rather than trying to achieve perfection. The few who survived were able to keep hope alive and memory alive.

### 10) The Rabbi- Hyman Bloom 1960s

Keeping hope alive keeps reason alive

The Rabbi keeps the law of the Torah; even when we are frightened and feel threatened, we cannot let go of the fundamental human values viz respect for human dignity.

# 11) The Owl -Henryk Epstein

Even in a crisis situation we need to hold on to reason and still look for beauty which will lead us to truth and goodness.

The owl is a medieval symbol of the Jew, then often meant disparagingly, but here it represents survival. The painting also has flowers, which epitomise all that is beautiful and inspirational. The recommendation is to go back to our roots and find principles, personalities and creativity from our heritages that will inspire us.

After the narratives were expounded, there was a delightful concerto played by Professor Harold and Professor Mary Matthew as they responded to the attendees' questions, which were more like requests to prolong the performance in order to bask in the luminosity of mood engendered by the articulations and to relish & absorb its finer attainments. Both minds and hearts were again swayed by the lilting music produced.

- 1) Societal response to the virus has been perceived by many to be over the top and has engendered a culture of fear never before seen. In this backdrop what has been articulated has been like a soothing balm, and hence sincere gratitude has been expressed. (Autonomy and individual responsibility)
- 2) The way people are dying and final rites being conducted without allowing people to participate....how does one deal with the despair caused by this denial of grieving. (Article.3. Human Dignity and Human rights)

Asking the question is the beginning; people are not asking enough questions because they are blinded by fear. Questions are not asked due to denial and despair, both of which are deadly in the current pandemic.

The answers perforce will be contextual and vary with different circumstances.

"I have never yet answered a question that I have never been able to ask."

As health care workers we need to be prepared for the next pandemic and have a conceptual road map to deal with the mental health issues.

3) How do we divert from perfectionism and, more importantly, how do we communicate with our leaders about avoiding the pitfalls of perfectionism?

(Article.3. Human Dignity and Human rights & Article 13 Solidarity and cooperation)

Politicians are puffing themselves up as perfectionists at our expense. While they say that they are saving lives, they are not saving human lives, only their own political ambitions. The people need to be heard; they cannot be denied a chance to lead a meaningful life. 'One size fits all' approach is draconian in its conception and diabolical in its implementation. What we need is the realism of our 'human face,' not perfectionism. Individuals have to be supported and empowered in maintaining agency—i.e., to help themselves in a way that is sustainable and upholds their dignity.

For instance, measures taken in developed countries may not suit developing countries. In fact, each country may have to customise strategies, as in the case of Sweden and Norway which adopted different policies though they are geographically, developmentally & economically similar. As it is, the Covid pandemic calls for better strategies for Asian countries in order to save lives and livelihoods.

4) Social isolation occurring in children raises serious concerns about their emotional development. Advent of online virtual classrooms bereft of human presence, eye contact or emotional bonding can be demoralising to the students. How best can one facilitate learning in this setting?

(Article 16. Protecting future generations)

A good approach would be to acknowledge that it is different now and follow it with taking feedback from the students as to how it feels for them. By interacting with them, sharing how we feel as teachers, we create a space wherein the students and teachers can worry together and devise strategies to make the learning experience better. Teachers are best able to use psychoanalysis to unravel conflicts and complexes in the students (Anna Freud). Though not everything is speakable, it is necessary to make them a part of teaching conversations.

## "Teaching and learning is a human reality, not a virtual reality"

The need to see, touch and feel other humans is a big part of our growth and development; the concern with social isolation is that it might beget a generation of fragile 'human robots' without emotional connection. For that reason, we need to go back to traditional in-person teaching as soon as possible.

5) The reported incidence of suicides occurring due to isolation has flagged a serious concern; we may need to modify the way we are quarantining people. (Article 5 Autonomy and individual responsibility & Article 6 Consent)

Stigmatisation is one of the causes of suicides. In one case the person was a patient needing dialysis who was isolated from family and committed suicide out of despair.

One patient died because he was isolated and would not eat food from anyone other than family. In this case PPE could have been provided for the relative. Under circumstances of limited resources, we have to triage with mindfulness of human dignity, otherwise we will end up using triage in automatic-pilot mode; then people will get scapegoated and marginalised with all the trappings of Fascism.

6) Given that not allowing people to grieve leads to loss of hope, what does a doctor do? How do we allow people to grieve...when they are not allowed to attend funerals? (Article 12 Respect for cultural diversity and pluralism)

When a person dies, make his/her memory a blessing, make it heartfelt. Also, accepting one's mortality helps someone who is bereaved and is grieving. Keeping memories alive keeps hope. A person grieving should never be left alone.

7) How to overcome stigmatisation, where does it come from? (Article 11 Non-discrimination and non-stigmatisation)

Stigmatisation comes from a person who is insecure and afraid, who when in pain blames and humiliates another. Fear is nothing to be ashamed of; it is needed for survival. In fact, being fearless is foolhardy.

### "Those who serve others are placed above like candles"

This virus is no respecter of persons; anyone can be infected. Hence, the masses have to be educated.

8) We know now that mandatory lockdown has great economic and health costs, but reopening the economy will lead to greater number of deaths...how do we balance competing costs? (Article 10 Equality, justice and Equity & Article 20 Risk assessment and management)

We need to look at both long-term and short-term consequences. There will be deaths if we reopen the economy, but there will be deaths if we do not reopen the economy. There will be people who drink, people who use drugs, people who will lose hope, their sense of self and dignity, and that also kills. Hence, there has to be a balance in our response.

Psycho-neuro-immunology informs us that immobilisation impairs immunity; if we do not cry after someone dies, IgA gets supressed. Freedom to grieve and to perceive might in fact be saving lives rather than costing lives. Just trying to save lives from Covid leads to a tunnel vision, and we will end up in Hyman Bloom's sea.

9) In India the masses are illiterate, and we need to educate the masses to bring awareness about the pandemic and also to remove the stigmatization. At this time, when people are

hungry there, we need to fill their bellies first. How do we educate the masses in this perilous situation? Internet and television should be used for inculcating good practises and building resilience in children. (Article 8 Respect for human vulnerability and personal integrity)

There has been an overwhelming panic reaction to the pandemic, largely due to the media. At this time, maybe we can educate the religious leaders, head men of villages, who can reach out and sway the masses.

Yes, there is something to fear, but it should not overwhelm us, dominate us; we should not be afraid of fear itself. Courage is reasonable action and acknowledging fear; otherwise fear will lead to panic, which is absolutely deadly.

- 10) Media houses are only showing negative news, which is killing our hope. Is it not their moral responsibility to project positive stories? (Article 14. Social responsibility and health) This is the time that media should be playing a positive role and acting responsibly. Bad news is news; good news is no news.
  - 11) It was such a powerful picture and made us feel so connected and that of teaching that even photographs and real stories could be a medium to create hope that I realise when I listened to his side of the story. (Article 13 Solidarity and cooperation)

The photographers in the Shoah were part of the resistance; the idea was that even if they didn't survive, they had to build hope, and in that hope people worked together. Anything we do to encourage people to build their stories of hope is going to empower them. Even though the media is not doing anything to help the situation, that does not mean that people can't do their positive thinking on their own.

12) For people who cannot appreciate art, is there any other way of engaging them fruitfully? (Article 12 Respect for cultural diversity and pluralism)

Hyman Bloom was a big fan of Indian music and studied with Ravi Shankar. There are many different roads to go up to Mt Olympus or even Mt. Everest; it has to be very individual, has to be very authentic. The best way forward when you are with people is to ask people what's meaningful to them what speaks to their heart.

Expressing your emotions through paintings is so beautiful. I was fortunate to have a very good art teacher who brought out the best in me. Absolutely loved the articulations; they brought the human side of the crisis. At the end of the day it is Hope even more than resilience that is important to our psyche.

The finale to the performance was fittingly a few bars of delightful ethnic Indian music.

### **Epilogue**

In the bible we have: John The Baptist, Mother Mary, Jesus Christ the Messiah who brought grace and twelve apostles who spread the teachings.

This entire performance has allegorical and biblical colourations.

Professor Russell initiated the webinar and introduced Professor Harold, Professor Mary moderated the discussions, and there were twelve participants who interacted and asked questions.

"As above so below"- Matthew 6:10

"Human beings are capable of both far better and far worse than we can imagine" – after reading Freud's Civilization and Its Discontents and On Transience

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# Scope of the Journal & Instructions to the Authors

Global Bioethics Enquiry is a journal of the UNESCO Chair in Bioethics and publishes reviews, original research papers, commentaries and case studies related to all issues in the field of Bioethics. Original viewpoints and narratives as well as poems in the field of bioethics are welcome. The journal also has a student section where articles in the field of bioethics written by undergraduate and post graduate students are considered.

### THE EDITORIAL PROCESS

The manuscripts received shall be peer reviewed for possible publication with the understanding that they are being submitted to only this journal and not simultaneously submitted or accepted for publication elsewhere. The Editors shall review all submitted manuscripts initially. Manuscripts with scientific flaws or vague research designs may often be rejected. The journal will not return any unaccepted manuscripts. The reviewers shall review all papers in a blind review and convey their decision to the Editors. Within a period of 8-12 weeks, the contributors shall receive comments, need for corrections and notice regarding acceptance or rejection of the manuscript. Other journals appropriate for the paper may be suggested in some cases of rejection. Articles accepted would be copy edited for grammar, punctuation, print style, and proofs for correction shall be sent to the author prior to publication. Authors will be asked to sign a copyright form and undertaking for plagiarism in case of accepted manuscripts. Only upon receipt of corrected proofs from the authors and completion of all form required, will a paper be published in the journal.

### TYPES OF ARTICLES

- Original Research Papers or Article: These papers should only include original research findings from planned research studies such as case—control series, surveys with high response rates, randomized controlled trials and treatment based intervention studies. Meta analyses shall be included in this section. The word limit is 6000 words excluding references and an abstract (structured format) of not more than 250 words with 4-6 key words.
- Case Reports: These should contain reports of new, interesting or rare cases of clinical significance or with implications for management. It could also include case reports where novel management methods were used. It has a word count of 1500 words with up to 15 references and an abstract of not more than 150 words.
- Review Papers: These are systematic and critical assessments of the literature which will be invited. Authors wishing to submit a review paper will have to contact the editor and seek permission for submission of the review. Only after permission has been sought will the article be accepted for peer review. The review article has a word limit of 8000 words and must be state of the art in every respect. Only invited reviews will be published. However exceptionally interesting topics even if uninvited when submitted may be considered.
- **Personal Subject Related Viewpoint:** These should be experience-based views and opinions on controversial issues that affect the profession. They could also be part of clinical problems that confront people in routine practice. The author should have sufficient experience or must have some unique personal experience based on the subject being considered. The word limit is 2500 words.
- Announcements: Information regarding conferences, meetings, courses, awards and other items likely to be of interest to readers should be submitted with the name and address of the person from whom additional information can be obtained (up to 200 words).

- **Book or Movie Review:** Exceptionally readable and good books and movies or documentaries which shall be academic and otherwise in the field of mental health shall be considered in this section. The word limit shall be 1500 words.
- **Poems:** Poems related to various themes in bioethics and allied sciences shall be considered based on their merit for this section.
- The journal is in evolution and newer concepts shall be considered from time to time.

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Send soft copy of the manuscript along with a covering letter in Microsoft Word 2007 or 2010. Name and designation of all authors with designation and name of the corresponding author must be mentioned. Copies of any permission(s) to reproduce published material, and to use illustrations or report information about identifiable people must accompany the manuscript.

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