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Editorial

Ethical and Legal Issues in Suicide

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Introduction
Suicide is one of the few fatal consequences of psychiatric illness and hence is a source of endless disquiet to mental health professional [1]. Among the survivors of a suicide the reaction is often disbelief, shame, anger and shock even for the mental health professional [2]. One of the shortcomings of suicide is that it unnecessarily answers a remediable challenge with a permanent irreversible negative solution [3]. Even though attitudes in our societies have become more tolerant to suicide there are still undercurrents of ambivalence and social condemnation. Judicial attitudes towards suicide have moved away from assessing guilt and enforcing punishment and towards protecting people who are suicidal and towards efforts to provide care and compensation for the surviving victims of suicide deaths [4].

Proposing a Legal Definition of Suicide
An operational definition of suicide must limit the term suicide to acts of committed suicide or efforts or attempts to cause death by suicide. This would allow for differentiation between sublethal acts and suicide as well the difference between self inflicting behavior and suicide. The boundaries between self mutilation, sensation seeking and suicidal behavior are rather cloudy and there is a lack of clarity whether a consciously expressed suicidal desire accompanying the behavior is a must in order to classify a particular behavior as suicidal [5]. An individual that commits a non lethal, self inflicted and suicide like act is said to have committed parasuicide. There is a body of evidence that in general suicide completers make one lethal attempt while most suicide attempters make many low lethality attempts. Thus those that attempt suicide and those that complete suicide are two distinct though overlapping populations. Fine discriminations between suicide, attempted suicide, parasuicide, suicidal gestures, manipulative suicidal acts and so forth are needed from research and heuristic perspectives though from a legal perspective any time a patient uses or threatens to use even superficially suicidal or suicidal like behavior to demonstrate any form of psychological pain it must be regarded as suicide [6].
An essential element of effective risk management and high quality clinical care in a professional psychiatric practice is the possession of the basic knowledge of the legal system and the understanding of the contemporary legal views on the standards of care. Until the 1990s the incidence of legal battles against mental health professionals in India was very low when compared to what courts regarded as other medical specialties. Furthermore whenever there was a legal battle more often it was the doctor that prevailed. In recent years there has been an increase in the number of malpractice actions against mental health professionals worldwide and decisions by courts in favor of patients is also increasing. Suicide is an uncommon cause of litigation in India though in the US it is the cause for the highest number of medical lawsuits and the highest cash settlements [7].

Failure to Properly Diagnose
One of the legal theories brought into play in suicide cases is the failure to properly diagnose. Much of the case law on suicide abroad is based on the claims that allege liability for a misdiagnosis or

lack of prediction of the risk of suicide. Many of the cases are directed against hospitals and institutions for clinical care and involve either inpatients or recently discharged patients [8]. There have been instances that hospital and physicians have been not held liable for a patients suicide more son if they have taken reasonable steps to assess and supervise the patient. On the other hand, liability can be imposed where the hospital should have known or did know about the suicidal and escapist tendencies of the patient but were negligent in placing the patient in a high-risk situation. Hospitals have also been held negligent in releasing a suicidal patient. It may happen that a physician recommends the release of the psychiatric patient even though he has potentially harmful delusions. The physician did not investigate the pervious psychiatric history of the patient, nor did he investigate the patient's delusions or the incident of the previous evening when the patient had to be restrained.

Failure to Take Adequate Protective Measures

The psychiatrist must take adequate precaution against patient suicide consistent with the accepted practices and on the basis of his or her knowledge and assessment of the patient. Psychiatrists are liable when a treatment plan overlooks or neglects the patient's suicidal tendencies. It is also noted that courts do not usually find the psychotherapist or psychiatrist liable when a patient's suicide attempt is not foreseeable [9]. No liability has been found in many cases when a cooperative or apparently contented patient suddenly attempts suicide as or when an aggressive patient fails to reveal any suicidal intent and commits suicide. The failure to take adequate precautions is also liable when a psychiatrist was found liable when a patient committed suicide after being transferred from a suicide watch status to a lower level of precaution without adequate medical notes to explain the rationale of such a critical management decision. Courts are often less stringent on out-patient suicides especially when they are less foreseeable and there is always an increased difficulty in controlling the patient's behavior. In both out-patient and inpatient cases it is necessary that clinicians must use reasonable care in the development and the implementation of treatment plans. A psychiatrist and a mental health foundation were sued because their patients had taken a lethal dose of sleeping pills that had been prescribed to him. The court found that there was no foreseeable suicidal intent and hence the psychiatrist and the foundation were found not guilty but this case warns us on the judicious use of medications in patients that exhibit suicidal tendencies. A case discussed that a psychiatrist's duty to his outpatients is less than his or her responsibilities to his inpatients.

The parents of a patient who died due to an overdose of sleeping pills brought a malpractice litigation against the treating psychiatrist who was treating the patient on an out patient basis. The psychiatrist had recognized the fact that the patient was disposed to suicide and he recorded his conclusions on his written notes. The parents stated that the psychiatrist had not taken adequate measures to protect the patient. He even had failed to warn the relatives about the seriousness of the patient's condition and his suicidality. The court in this case refused a mandate on the duty to warn although the out patient was a dangerous to self and as the patient was not always under the control of the psychiatrist to take adequate protective measures. The court held the view that the nature of precautionary measures taken by the psychiatrist present a factual question to be resolved at the trial on the merits and both sides were given a chance to produce expert medical testimony on the subject. The case would also require the testimony of expert witnesses analyzing the psychiatrist's performance after the fact to determine if negligence had in fact occurred. The imposition of the duty of a psychiatrist to disclose to others vague or even specific manifestations of suicidal tendencies on the part of the patient who is coming as an out patient may inhibit psychiatric treatment at times. The patient therapist dynamics in an office setting are often very subtle and complex. It is important to consider that when an out patient presents with risk duty to warn the relatives is the most important consideration that a psychiatrist must use seriously. This allows a limited breach of confidentiality to guard the patient and help with the treatment when the patient has an imminent danger to himself and when the patient is unable to follow the recommendations for out patient treatment or hospitalization. Of course, hospitalization in these cases shall involve the family members and significant others.

Early Patient Discharge

A psychiatrist may be found liable for the early release of a patient if the release is negligent and not a valid exercise in professional judgement. A court may impose liability when a psychiatry does not inquire into the nature of a patient's symptoms though observations about the same have been stated by relatives, when a psychiatrist fails to inquire about significant past history and past eventful discharges, if there is failure on the part of the psychiatrist to communicate with the nursing staff and the relatives when they are pressing for a discharge. If a psychiatrist makes a reasonable assessment of the danger and believes that the risk no longer exists then he or she is not held liable for the post discharge death of the patient.

Failure to Commit

In making a decision to commit or not to commit to a patient the legal issue one of whether the clinician took the complete history into account, made a thorough examination of the patient and then exercised sound judgement in his or her decision to commit or not to commit to the patient. The greater the suicidal intent the bigger shall be the psychiatrist's liability for the failure to take the elevated risk into account in the treatment plan. A patient had been hospitalized for 9 days and was determined by the psychiatrist to be well enough to be transferred to less secure part of the hospital. The patient then jumped from the window. The only argument was that the psychiatrist was negligent and erred in judgment. This case brought out the fact that physicians cannot be held responsible for errors in judgment when pursuing methods and practices within the standards of care.

Liability of the Hospitals

Psychiatrists must be aware that malpractice actions of inpatient suicides can be directed against the psychiatrist, the hospital or both. An important point here is that malpractice action can be brought against psychiatrists within the hospital setting if they have staff or hospital privileges. The duty of the hospital can be best defined as using the generally accepted standard of care in the treatment of the patient. If the hospital also notices that a patient is suicidal then it is the duty of the hospital to safeguard the patient from self inflicted injury or death. The issue of foreseeability is crucial. The hospital staff must always perform proper evaluations and observation though the patient may be under private care of a psychiatrist. Hospitals have never been held liable when the surveillance was found adequate or proper procedures were followed. The law and psychiatry have today however come to a conclusion that an overly restrictive environment in suicidal cases can be as destructive as an overly permissive one. The psychiatrists must always balance the benefits of treatment against the risk of freedom. The issue of calculated risk has been rejected. The court states that prediction of the future course of mental illness is a professional judgment of high responsibility and in some instance this involves a measure of calculated risk. Liability cannot be based on the disagreement of another physician with the manner in which treatment is provided. It is remarked that hospitalization has its drawbacks though for relatives it is a panacea. There are benefits but there are risks like regression, fostering dependency, loss of time from work and severe stigma [9]. Psychiatrists must demonstrate their best professional judgment in assessing the therapeutic risks for freedom. They must assess decisions regarding suicidal patients, involving discharge, transfer, decision to commit and other actions.

Abandonement

Once a professional relationship has been established the psychiatrist is required to provide treatment till the relationship is properly terminated. Abandonment may be overt or implied i.e. failure to be available or to monitor the patient adequately. If a therapist errs in judgment that treatment is no longer needed he or she may be liable for negligence under malpractice. Usually expert witnesses are needed to decide this fact. If the therapists willfully terminate or withhold treatment knowing that further care is needed or the referral is indicated then they may be liable for intentional abandonment. Patients must be provided a way of contacting the doctor especially between visits, when on vacation, on leave and so forth. This is all the more needed for hospitalized patients.

There is a tremendous legal burden when it comes to suicide because simply stating, we are holding the clinician responsible for someone else's behavior [10-11]. The threat of litigation compounds the burden that a patient's death carries for the clinician. The threat of suicide is always a possibility in psychiatry. The assessment and diminution of suicide potential among psychiatric patients is a task of highest priority for mental health professionals [12]. Researchers have stated that almost all suicides are avoidable if the patient was properly diagnosed, monitored and treated in an appropriate and timely manner. Suicide as discussed is not always preventable and defies predictability although these facts offer little solace in a courtroom [13]. The pivotal element in most cases of malpractice are the twin issues of the ability to foresee and causation. Courts often struggle with these two issues in cases of suicide focusing on whether the clinician should have predicted suicide or in the presence of sufficient evidence of an identifiable risk, did the psychiatrist do enough to protect the patient [14]. Usually, the quality of the clinician's practice has little to do with malpractice litigation. It is bad outcome combined with bad feelings that leads to lawsuits. The issue of what is meant by adequate training in handling suicide is a thorny issue due to the unpredictable nature of suicide itself. One needs to be wary of reduction when it comes to suicide. Suicide is a symptom and not a diagnosis and though the state of being suicidal can be analyzed the act of suicide cannot. This thought reverberates throughout suicide literature [15]. We cannot be afraid of litigation so as to deny our patients their right to learn to live. Clinical decisions are to be made on a case by case basis and must represent the most through the knowledge available. The manageable standards of care will thus be set by us as mental health professionals and presumable then courts shall follow in our reasonableness.

The Ethics of Suicide

Suicide has always been an act having ethical significance one for which moral blame or praise was a proper response. During the Stoic Era of Greece and Rome, suicide was praised as a morally responsible act of a wise man. During the medieval Christian era, it was blamed as the most reprehensible of sins. With the influence of Esquirol and Durkheim at the close of the 19th century the older ethical view of suicide was replaced by a newer scientific one. Contemporary thinkers are suggesting that ethical considerations do apply in some cases of suicide. The ethical theory divides into two major camps – the utilitarians, both classical and contemporary and the Kantians with their deontological descendants, the modern Kantians and the libertarians.

Utilitarians are consequentialists who assess the moral status of an act by inspecting the outcomes it would have. To decide if a certain thing was good we would consider what result it would have if we did it. If it would provide happiness for the self and those affected by the action in a greater manner than any alternative action open to us then it is the right thing to do. It is wrong to commit suicide as per the utilitarian view if it destroys the life that is of benefit to oneself, and shall cause others anguish, sorrow with emotional, social and financial disbenefits due to deprivation and loss. The other group considers that considerations other than consequences are also relevant in fact is central in any moral choice. One ought to honor contracts and promises not just because the outcomes are good but because contracts ought to be honored and promises ought to be kept. In Kantian theory, underlying and justifying this set of moral rules is the general principle requiring respect for other persons and the respect for the human being as a rational being to generate moral law. Ethical abuses are actions that fail to respect the moral worth of people who are the victims.

On one hand we deplore suicide pointing to all its horrible consequences, and the way suicide violates the most fundamental moral rule – do not kill. The phenomenon of suicide may serve as a test par excellence for both types of moral theory.

Philosophers distinguish between two very diverse issues – whether it is wrong to commit suicide and whether it is desirable, advisable and rational to do so. The former is to be seen from the point of view of society in general for forbidding it. This is a more contractarian view. There are many definite obligation that shall be violated when committing suicide and one has obligations to the community strong enough to make suicide immoral. One can hardly claim that suicide is necessarily imprudent or inadvisable. We should generally be disposed to prevent suicides when we can. Naverson argues whether we own ourselves and hence have the right to do what we want with our bodies. He says that we do own ourselves, being free to choose to live, or die on the basis

of the hedonistic judgment on balance that we make predicting the future courses of our lives. If a person judges that on balance his life shall not go well and will mean less pleasure, more pain than he can endure then we must be prepared to help him change his balance before we have the right to interfere. His life is his own to do with as he will [16].

A Kantian moral theory provides an objection to suicide even when it does not affect persons other than the agent himself. There are four kinds of cases – the impulsive suicide, the apathetic suicide, the suicide who abases himself and the suicide as a result of hedonistic calculation. The attitudes expressed by such suicides are described as those of a consumer who looks ahead to count up the pleasures and pains he can expect from the purchase of an additional life or the obituarist that looks back at life to assess all that has been achieved till date. In discussing the modified Kantian ideals it permits some types of suicide like in those that are facing the onset of permanent vegetative states, of patients in irremediable pain and of people that act with strong moral conviction but it does not commend suicides that are out of line of this ideal. Many of the suicides we confront do fall short of this ideal [17].

Both utilitarianism and modern Kantism fail to provide the modern condemnation that they should. They fail as they do not specify what an individual must do with his life and hence they cannot state why a person ought not to end his life. There are a number of cases where suicide is commendable including the soldier that kills himself to protect the secret military information that torturers would otherwise extract from him and the persons in the final stages of a terminal illness. If someone acts in the morally correct way and if he does the right thing by remaining alive then not only does his life have more intrinsic value it will have more good in it and thereby more pleasure in it as well [18]. Moral theory becomes the basis of public policy with regard to suicide prevention. The liberty of an individual is of paramount importance because what gives meaning to life is the freedom to choose one's own life plan and to live as one sees fit. Under this view no one is entitled to be prevented from suicide. If a person attempts suicide then no one else or no group is entitled to save him. If they do so it is a matter of generosity and above and beyond the call of duty. No one can complain that inadequate rescue efforts or no rescue efforts at all were made on the suiciding individual's behalf [19].

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Review Paper

A Woman's Job, A Man's Privilege? Identifying Ethical, Racial, Societal Factors in the Prevailing Gender Disparity in Organ Donation

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ABSTRACT

Background: Women have been major organ donors in the world while men have predominantly played the role of recipients. This, along with various socio-cultural, racial, and economic factors as well as personal attitudes and beliefs, has made it difficult to meet the growing demand of organs for transplantation. The aim of the study was to investigate the prevailing degree of gender disparity in organ donation and to find out factors which contribute to such disparity.
Methodology: Search were performed using the MeSH terms and the related keywords on MEDLINE. A total of 47 out of 60 articles were included. This study analyzed the various reviews on the association between gender and organ transplantation, and the factors that may influence the same.
Results: We found that there exists a gender disparity not only where women donate more but men are the major recipients, and that multiple other factors medical or otherwise either directly or indirectly contribute to the same. Despite males and females having equal likelihood of getting through the required steps to be approved as a donor, females have shown more likelihood to agree to donate their organs, live or otherwise. Men are more likely to donate for their children than for their wives. Male and younger recipients are favored, while females and middle-aged or older donors are preferred.
Conclusion: Gender disparity in organ donation exists throughout the world and there is a need to bridge this gender gap through a concerted and cohesive plan of action.

Keywords: Gender, Bioethics, Transplantation, Organ Donation, Women Health

Introduction

A larger number of live organ transplantations are facilitated by women as donors than men [1]. Out of all transplants, 54.7% women were donors. A striking contrast was observed with only 39.4% of women being recipients [2]. In such progressive times, organs that are crucial for survival remain inequitable. Many studies conducted all around the world have established this trend. In cases of liver transplants women are more likely to die on the waitlist [3]. In the ever-evolving field

of transplant medicine, there exists a gap and to make organ transplantation accessible to all, this gender gap must be bridged. Benevolence does not only pertain to women. Myths must be driven away, and correct education must be imparted to all minority communities, all genders and all age groups to allow the supply of organs to meet the growing demand. This review analyses the injustice women face when transplant is the only treatment option and its by-products like further complications. The education one receives also shows a conspicuous trend [4]. In a study conducted, it was established that women have less knowledge and are less informed about transplant procedures and therapy, and yet have a greater sense of responsibility to undertake the role of a donor [7]. 13.5% more students in the medical fraternity are willing to donate as opposed to that of students majoring in economics [5]. This review assesses the interplay between the emotional, socioeconomic, racial, educational and ethical aspects in the gender disparity in organ donation.

Research objectives

- To scope for and establish the prevailing degree of gender disparity in organ donation.
- To identify and discuss what factors contribute to the variance in the degree of disparity, if any.

Review approach

The research question entailed assessing the relevance of gender in organ transplantation. A search was done by using PubMed to find all original and review articles with original reports, published from the period of January 2000 to February 2020. A combination of keywords with Medical Subject Headings (MeSH) related to gender and organ donation was used. The following MeSH terms were used interchangeably and in combination, so as to find all relevant articles which encompassed disparity in organ donation with respect to gender: 'gender', 'gender disparity', 'organ donation', 'transplant medicine', 'ethics', 'bioethics', 'religion', 'religious beliefs', 'BAME', 'race', 'women', 'donor', 'recipient'.

Inclusion and exclusion criteria

The articles to be analysed were included if they were found using the aforementioned search process for our review, with respect to the above listed databases, MeSH and search terms. All articles having free full text available through PubMed were included in our review. We included studies which spoke about the importance of gender in organ transplantation and did not limit to a specific organ. Case reports, letters to editors and commentaries were excluded in the scope of this review.

Data Review

Table 1: Details and decision to include/exclude the retrieved reviews on the association between gender and organ transplantation.

Sr. No.	PubMed Reference ID	Year	Endpoint (measurement)	Type of Study	Inclusion/Exclusion Criteria	Included or excluded	Journal Published	Article Source
1	3999296	1985	Public attitudes and behaviour about organ donation	Original Article	No inclusion/exclusion criteria as part of the article.	Excluded	JAMA	National Library of Medicine
2	10977785	2000	Gender disparity in living renal transplant donation	Original Article	family members of living donor allograft recipients at a single large center over a 5-year period (n = 144).	Included	American Journal of Kidney Diseases	National Library of Medicine
3	11821739	2002	Gender imbalance in living donor renal transplantation	Original Article	Electronic medical records of all living related and living unrelated kidney transplants performed between 1964 and 2000	Included	Transplantation	Wolters Kluwer

					were reviewed			
4	12741404	2002	Giving until it hurts: prisoners are not the answer to the national organ shortage	Topic for Debate	No inclusion/exclusion criteria as part of the debate.	Excluded	Indiana Law Review	National Library of Medicine
5	15859919	2003	Ethical issues in organ and tissue transplantation	Topic for Debate	No inclusion/exclusion criteria as part of the analysis.	Excluded	Experimental and Clinical Transplantation	National Library of Medicine
6	15501205	2004	The net transfer of transplant organs across race, sex, age, and income	Original Article	Subjects included were all transplant donors in the United States from 1996 to 2001. 6% of subjects who were neither black nor white were excluded.	Included	The American Journal of Medicine	Elsevier
7	15701672	2005	Gender imbalance among donors in living kidney transplantation: the Norwegian experience	Original Article	Patients > 18 years were included and the medical criteria of : Kidney function must be normal with creatinine clearance >80 ml/min and the urine specimen must be normal. Blood pressure should be in the normotensive range (<140/90 mmHg). X-ray of the chest as well as exercise echocardiogram in donors >40 years of age must be normal. Body mass index >30 kg/m2 and elevated fasting blood glucose are exclusion criteria.	Included	Nephrol Dialysis Transplant	Oxford Academic
8	16127268	2005	Kidney transplantation and gender disparity	Original Report	No inclusion/exclusion criteria as part of the study analysis.	Included	American Journal of Nephrol	Karger
9	15696526	2005	Ethics, transplantation, and the changing role of anatomists	Topic for Debate	No inclusion/exclusion criteria as part of the analysis.	Excluded	Clinical Anatomy	National Library of Medicine
10	16181018	2005	Gender-specific issues in liver and kidney failure and transplantation: a review	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Journal of Women's Health	National Library of Medicine
11	17164705	2006	Gender disparities in the live kidney donor evaluation process	Original Article	Potential donors were evaluated for live donor kidney transplantation between January 1, 2000, and January 1, 2004, if they fulfilled the adequate donor criteria.	Included	Transplantation	Wolters Kluwer
12	16857540	2006	Ethnic and gender differences in willingness among high school students to donate organs	Original Article	883 students attending health science class at nine inner-city high schools in Seattle, Washington	Included	Journal of Adolesc Health	Elsevier
13	18089300	2007	Gender bias in renal transplantation: are women alone donating kidneys in India?	Original Article	Retrospective analysis of all LD renal transplantations performed at a single center between 2001 and 2005	Included	Transplant Proceed	Elsevier

14	17524816	2007	Donor gender balance in a living-related kidney transplantation program in Oman	Original Article	Retrospective study of the distribution of female and male donors or recipients among living kidney transplantations performed from 1980 to 2005, namely 198 Omani recipients of living-related kidney transplantations.	Included	Transplant Proceed	Elsevier
15	17366949	2007	Assessing racial and ethnic differences in medical student knowledge, attitudes and behaviours about organ donation	Original Article	500 first- and second-year students attending one of three Ohio medical schools completed the 41-item questionnaire.	Excluded	Journal of the National Medical Assocn	National Library of Medicine
16	18635494	2008	Gender issues in transplantation	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Anaesthes Analgesia	Wolters Kluwer
17	18580010	2008	Gender disparity in kidney transplantation	Original Article	The data of age, gender, nationality, donor type and waiting time before transplantation of 1426 (61.85% male, 38.14% female) recipients who underwent transplantation in Imam Reza Hospital in the northeast of Iran from 1990 to 2003, was analysed.	Included	Saudi Journal of Kidney Diseases and transplantation	National Library of Medicine
18	18190416	2008	Ethics of organ donation and transplantation involving prisoners: the debate extends beyond our borders	Review Article	No inclusion/exclusion criteria as part of the review.	Excluded	Internal medicine journal	Wiley Library
19	19129311	2009	Age and comorbidities are effect modifiers of gender disparities in renal transplantation	Original Article	National cohort study of 563,197 patients with first onset ESRD between 2000 and 2005.	Included	Journal American Society of Nephrol	National Library of Medicine
20	19469039	2009	Attitudes, beliefs and behaviours surrounding organ donation among Hispanic women	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Current Opin Organ Transplant	Wolters Kluwer
21	21265292	2010	Attitudes toward organ donation and donor behaviour: a review of the international literature	Review Article.	members of the public (i.e., not transplant recipients, donor families, or health professionals)	Included	Prog Transplant	National Library of Medicine
22	20879013	2010	Gender disparity in liver transplant waiting-list mortality: the importance of kidney function	Original Article	Organ Procurement and Transplantation Network data for patients with end-stage liver disease (ESLD) on the waiting list who were registered between February 2002 and August 2009. 42,322 patients and 610,762 person-months of waiting-list experience were included in the analysis.	Included	Liver transplantation	Wiley Library

23	20209639	2010	Gender-specific differences associated with living donor liver transplantation: a review study	Review Article	We contacted 89 national and international transplantation registries, single transplant centres, and coordinators. In addition, a sample of 274 articles dealing with LDLT and its outcomes was reviewed and compared with the registry data.	Included	Liver transplantation	Wiley Library
24	21668497	2011	Organ donation from children: time for legal, ethical and cultural change	Review Article	No age restriction as part of the inclusion/exclusion criteria.	Excluded	Acta Paediatr	Wiley Library
25	21426918	2011	Gender disparity and MELD in liver transplantation	Letter to the Editor	No inclusion/exclusion criteria as part of the research.	Excluded	Journal of Hepatol	National Library of Medicine
26	21239479	2011	Incentivizing deceased organ donation: a Swedish priority-setting perspective	Original Article	No inclusion/exclusion criteria as part of the article.	Included	Scand Journal of Public Health	National Library of Medicine
27	23722379	2011	Organ donation after circulatory death: vital partnerships	Case Report	No inclusion/exclusion criteria as part of the case report.	Excluded	The American Journal of Nursing	Wolters Kluwer
28	23008117	2012	Impact of estimated liver volume and liver weight on gender disparity in liver transplantation	Original Article	The final cohort had 28,866 patients who were analysed depending on the Organ Procurement and Transplantation Network Data as of August 2009.	Included	Liver Transplantation	National Library of Medicine
29	22931405	2013	Gender disparity of living donor renal transplantation in East China	Original Article	139 living donor renal transplants performed in our center between 2003 and 2010.	Included	Clinical Transplantation	Wiley Library
30	24064859	2013	Gender issues in solid organ donation and transplantation	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Annals Transplantation	National Library of Medicine
31	24119046	2013	The effect of gender and gender match on mortality in paediatric heart transplantation	Original Article	population of 3630 heart transplant recipients less than 18 years old.	Included	American Journal of Transplantation	Wiley Library
32	25457096	2014	Organ donation by suicides: sex and ethnicity	Original Article	An analysis of 2,034 actual organ donations by suicides for the years 2008-2010	Included	Psychological reports	National Library of Medicine
33	24996438	2014	Impact of gender and professional education on attitudes towards financial incentives for organ donation: results of a survey among 755 students of medicine and economics in Germany	Original Article	Between October 2008 and February 2009, a quantitative survey was conducted among German students of medicine and economics	Included	BMC Medical Ethics	National Library of Medicine
34	26413291	2015	A peer outreach initiative to increase the registration of minorities as organ	Original Article	A peer outreach programme piloted in Harrow (Middlesex) in 2009 and later rolled out to Hounslow, Lewisham and	Included	Clinical Kidney Journal	Oxford Academic

			donors		Lambeth in 2010 (all in London, UK) was taken as the superset.			
35	26465666	2015	Gender in the allocation of organs in kidney transplants: meta-analysis	Review article	Twenty-nine studies involving 765,753 patients were included.	Included	Revista de saude publica	National Library of Medicine
36	25742669	2015	Postpartum Women's Perspectives on the Donation of Placentas for Scientific Research in Campinas, Brazil	Original Article	Postpartum women at CAISM maternity hospital.	Included	Journal of Empirical Research on Human Research Ethics	National Library of Medicine
37	27692353	2016	Does Donor Status, Race, and Biological Sex Predict Organ Donor Registration Barriers?	Original Article	Young adults residing in Illinois between the ages of 18 and 24 completed a telephone survey.	Included	Journal of the National Medical Assocn	Elsevier
38	27471591	2016	Organ transplantation and gender differences: a paradigmatic example of intertwining between biological and sociocultural determinants	Comment ary	No inclusion/exclusion criteria as part of the commentary.	Included	Biology of Sex Differences	National Library of Medicine
39	27015531	2016	Gender Disparity in Living-Donor Kidney Transplant Among Minority Ethnic Groups	Original Article	analysed 713 living-donor kidney transplant procedures that were performed from 1987 to 2014.	Included	Experiment al and Clinical Transplanta tion	National Library of Medicine
40	28288834	2017	Exception Points and Body Size Contribute to Gender Disparity in Liver Transplantation	Original Article	Data from the United Network of Organ Sharing registry of candidates placed on the waitlist from May 10, 2007, through June 17, 2013.	Included	Clinical Gastroenter ology and Hepatol	Elsevier
41	29284769	2017	Few Gender Differences in Attitudes and Experiences after Live Kidney Donation, with Minor Changes Over Time	Original Article	455 live kidney donors between 1974 and 2008 were considered for this study.	Included	Annals of Transplnt	National Library of Medicine
42	27352118	2017	Assessing Transplant Attitudes: Understanding Minority Men's Perspectives on the Multifarious Barriers to Organ Donation	Original Article	A 57 question Health and Wellness survey was designed to assess participants' demographic information, medical history, professional background, and opinions about organ transplantation. Participants were also asked to complete Quality Metric's Short Form-8 (SF-8) survey to assess physical health, mental health, and quality-of-life. Three	Included	Journal of Racial & Ethnic Health Disparities.	National Library of Medicine

					hundred twenty-six surveys were administered to minority men.			
43	28540899	2017	Gender differences in perceptions and attitudes of general population towards organ donation: An Indian perspective	Original Article	A cross-sectional descriptive study was conducted among randomly selected patient relatives (n = 193) at the outpatient department of a tertiary care center.	Included	Saudi journal of kidney diseases and transplantation	National Library of Medicine
44	29309946	2018	Deterrents to Organ Donation: A Multivariate Analysis of 766 Survey Respondents	Original Article	A survey capturing individual attitudes and factual knowledge of organ donation/transplantation was distributed online (Survey Monkey) and in paper format in four healthcare provider waiting rooms in Georgia.	Included	Journal of the American Colony of Surgeons	Elsevier
45	29880964	2018	NASH Leading Cause of Liver Transplant in Women: Updated Analysis of Indications for Liver Transplant and Ethnic and Gender Variances	Original Article	The study included 127,164 adult patients registered for LT	Included	AM J Gastroenterology	Wolters Kluwer
46	30587146	2018	Gender disparity in health-related quality of life and fatigue after living renal donation	Original Article	Two hundred and eleven (211) living renal donors were evaluated (female 62.2%).	Included	BMC Nephrology	National Library of Medicine
47	30062839	2018	Understanding the sex disparity in living kidney donation	Original Article	Living donors of kidney transplantation.	Included	Journal of Evaluation in clinical practice	Wiley Library
48	30051397	2018	Heart Transplantation Survival and Sex-Related Differences	Review article	No inclusion/exclusion criteria as part of the review.	Included	Advances in Experimental medicine and biology	National Library of Medicine
49	30213924	2018	Factors in Organ Donation Coordinators: A Cross-Sectional Study in China	Original Article	From March to May 2017, we administered questionnaire surveys to 320 organ donation coordinators from 32 cities.	Excluded	Annals of transplantation	National Library of Medicine
50	31929292	2019	Women donate, men receive gender disparity among renal donors	Original Article	A single centre, retrospective cohort study on 600 kidney donors between 2013 and November 2018	Included	Saudi journal of kidney diseases and transplantation	Wolters Kluwer
51	30105865	2019	Gender dynamics in the donation field: human tissue donation for research, therapy and feeding	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Sociology of Health and Illness	National Library of Medicine
52	30747857	2019	Equally Interchangeable? How Sex and Gender Affect Transplantation	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Transplantation	Wolters Kluwer
53	30384800	2019	*A care ethics*	Original	No inclusion/exclusion	Included	Nursing	Sage

			approach to the Gender Kidney Donation Gap	Article	criteria as part of the article.		Ethics	
54	31518477	2019	In sickness and in health: Living HIV positive kidney donation from a wife to her husband, with 7 years' post-transplant follow-up	Case Report	No inclusion/exclusion criteria as part of the case report.	Excluded	Transplant Infectious Disease	Wiley Library
55	31461744	2019	Sex and Gender Considerations in Transplant Research: A Scoping Review	Review Article	No inclusion/exclusion criteria as part of the review.	Included	Transplantation	Wolters Kluwer
56	30777567	2019	Gender Disparity and the Relationship Between Living Donors and Recipients in Kidney Transplants in an Organ Transplant Center in Turkey	Original Article	Analysed the hospital records of living kidney donors (1611 cases) and all 1991 kidney recipients who underwent living-donor and deceased-donor kidney transplant procedures in a university hospital between 1985 and 2017.	Included	Experimental and Clinical Transplantation	National Library of Medicine
57	30879523	2019	Attitude Toward Organ Donation in the Population of Cienfuegos, Cuba	Original Article	Population over 15 years old as stratified by age and sex.	Excluded	Transplantation Proceeding	National Library of Medicine
58	31533778	2019	An ethical comparison of living kidney donation and surrogacy: understanding the relational dimension	Review Article	No inclusion/exclusion criteria as part of the review.	Excluded	Philosophy, ethics & humanity in medicine	National Library of Medicine
59	31906885	2020	Impact of the donor-recipient gender matching on the graft survival from live donors	Original Article	1113 kidney transplant recipients were studied in this retrospective cohort study.	Included	BMC Nephrology	BMC
60	11802081	2020	Understanding disparities in donor behaviour: race and gender differences in willingness to donate blood and cadaveric organs	Original Article	Cross-sectional telephone survey of persons aged 18 to 75 living in the Baltimore, Maryland metropolitan area contacted via random digit dialling.	Included	Medical Care	Wolters Kluwer

From the above taken 60 studies via the database, a total of 47 studies met all the inclusion criteria and were selected following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline [6]. A comprehensive outline for the method of selection is as given in Figure 1.

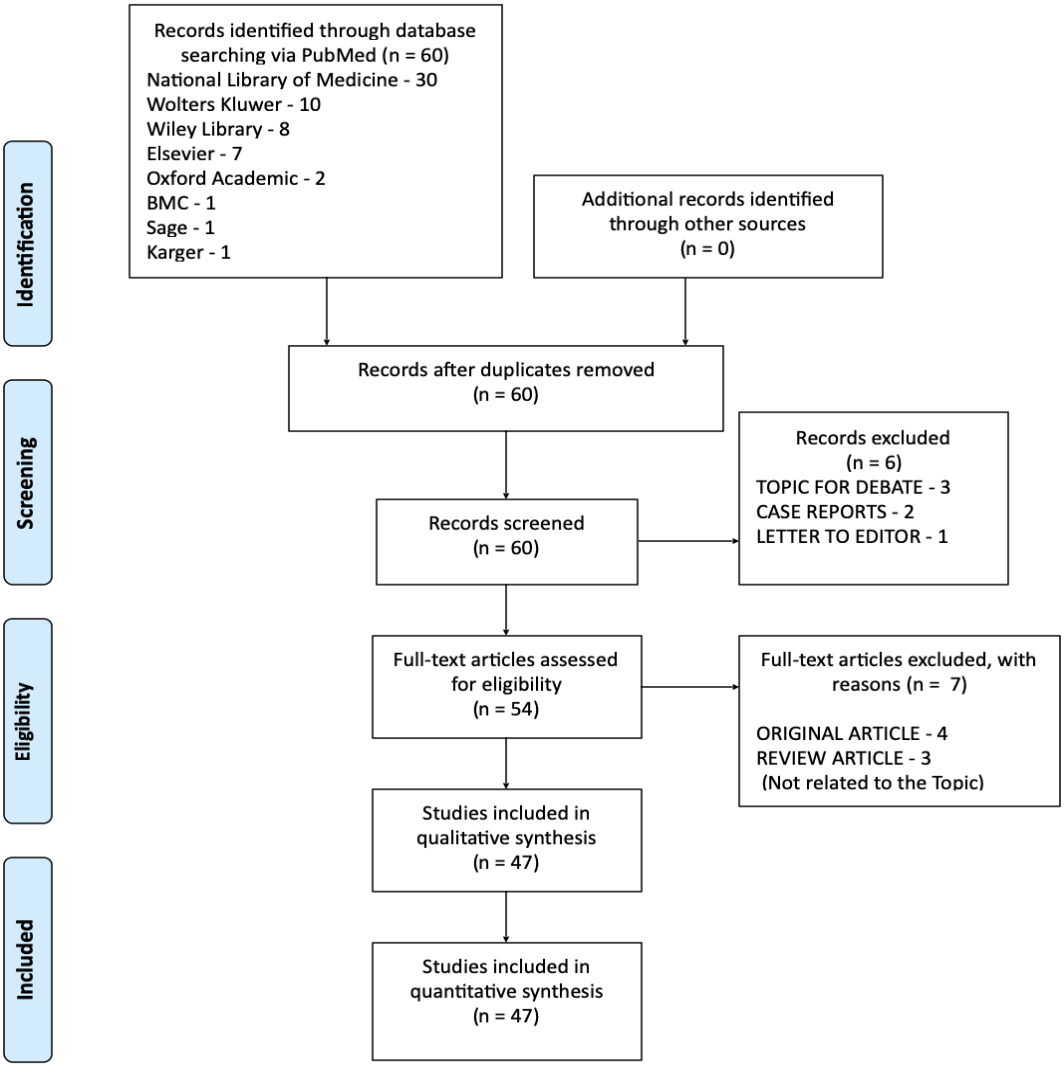

Figure 1: PRISMA Flow Diagram for Selection of Review Material

Results

Through our review, we found that there exists a disparity between men and women in the context of organ donation, which is further substantiated by the fact that not only do women tend to donate more, but also that men are more predominantly the recipients [7-8]. This disparity transcends all relations, in that spousal as well as parental donations are from women to men [9-12]. As for female recipient numbers, they could be 38% vs 62% for males [13], or as skewed as 11% vs 89% for males [14]. Nevertheless, females predominantly donating and males predominantly receiving is a universal trend. This, despite males and females having a level playing field in terms of getting through the required steps to be approved as a donor. However, among approved potential donors, females have shown more likelihood to donate [15] and are also more likely than men to agree to donate their organs, live or otherwise [16].

Organs and organ systems

organ donation patterns have almost universally highlighted a propensity for females to play the role of live donors [17]. This could be as simple as donation of blood [18] or as complex as donation of liver and kidney [19-20]. According to a study done in the United States, women had a 25% lesser chance of receiving a liver transplant, compared to male recipients, in any given month, coming with increasing the likelihood of women dying while waitlisted [21-22]. The same applies for spousal kidney donations; they are more likely to be from wife to husband [19-20].

Role of gender in graft rejection

Female-donated livers come with a higher risk of graft rejection, however it is not known to what degree such findings influence transplantation of other organs like the heart, lung or kidneys [23]. Overall, the findings tend to confirm that genders of the donor and recipient influences the recipient survival, thus exacerbating the already prevalent gender bias in organ transplantation and donation [24]. In one such example, boys in a study of South-Asian study received only the kidneys donated by men [2] despite there being no concrete evidence to support such practice [23], as if pre-emptive measure to reduce the chances of graft rejection on account of the difference in gender between donor and recipient.

Age

There is a palatable disparity in most transplantations of kidney, liver, lung, heart and, in some cases, even hematopoietic transplantations be it in adult or paediatric age-group cases [25]. In a study, we also discovered that in the cases where men agree to be donors, they do so more readily for their children than for their wives [2]. Donations to children have not been as skewed towards males as donations among adults, with women having as much as 11% lesser chance of receiving a transplant, the ratio becoming more skewed in case of specific races or organs [22,26]. Nevertheless, there is a propensity for male and younger recipients to be favoured, while in case of donors, females and middle-aged or older individuals are preferred [27-28]. This suggests that the engulfing by stereotypes and psycho-socio-economic factors, of organ donation and transplantation, occurs nearer to the human "middle age" [26].

Social Relations

It is no secret now that societal factors have been mirrored in the prevalent disparity in organ donation between the two binary genders. With a majority of donations being between those related by blood, it is ever more important to examine exactly how much the prevailing systems burden women [8]. Women themselves are somewhat reluctant to be recipients of an organ [23] but are astonishingly high in number among those who hold a donor card [5]. In a study of South Asian spousal transplants, the majority of the donations were done from wife to the husband, which has been the trend in all the studies reviewed. In the same study, it was found that children were donated to equitably irrespective of their gender. However, boys received only those kidneys that were donated by men [2].

Medical factors

Multiple studies under our review mention the probable iatrogenic factors leading to this disparity in organ donation. Several studies mentioned how, in case of liver transplants, the Model for End-stage Liver Disease (MELD) Score places women at a significant disadvantage as the scores are based on serum creatinine levels, without taking into account that women have physiologically lower serum creatinine levels than their male counterparts [29-30]. In another comparison of men and women on the waitlist for a liver transplant, women were generally less favoured on the grounds of their short stature leading to increased transplantation failure [3]. Besides, the probable and quite accounted for gender bias among medical professionals and their work environment might also be a significant contributor [31].

Race, religion, and culture

It is documented that while women tend to donate more than men overall, White individuals donate more than other races, especially more than Black individuals [32-33] while a study reported that in the United States, Asian-Americans make up the least number of registered donors [34]. In a study of race-gender groups, Black women donated blood the least, while Black men were most reluctant for themselves to be donated as cadavers [35]. This can be attributed to a well-known mistrust of minorities in general and Black communities in particular in the medical system and their perception of the profession, and there is a very strong correlation between race and the unwillingness to donate organs [36]. Concerns also remain among individuals about the acceptance of organ donation in their religion [16], and the desire to be buried intact [37]. As for

certain Asian races, a study conducted in China reported that 34.4% expressed willingness to donate organs, but that the overwhelming majority of respondents showed concerns about appropriate use and legislation, ranging between 61.4% and 88.9% depending on the factors considered, while overwhelming favouring consideration of family opinions [38]. Meanwhile, in India, some religious and linguistic communities are more altruistic than others, as seen in Mumbai, where 85% of eye donations and 95% of skin donations in 2013 and 70% of the cadaver donations recorded in 2016 were from the Jain and Gujarati communities, which have also been known to be leaders in the donation of blood, per Mumbai's Zonal Transplant Coordination Committee [39]. However, misconceptions such as one kidney being insufficient for survival and fear of the operation exist in various Asian communities, preventing the widespread acceptance of such practices [40].

Economic perspective

There is a growing consensus that the shroud of altruism is one of the reasons behind the demand-supply chasm in organ donation, especially of the deceased type, and a lot of organs that could be harvested are missed out on, irrespective of reason [41]. Besides, the idea of altruism and summary bans on commercial transplants have led to factors conducive for monetisation of organ transplantation [42] illegally and exploitatively. Aside from this, certain communities, majorly the Black community, do agree more to subsidies, if not incentives, for deceased organ donors' funeral expenses to be covered, for example [36], especially among men [5]. Even in Chinese communities, 64.5% respondents agreed on compensation for donors, while 74.4% agreed that "Donated organs have not been fairly and appropriately used; the wealthy and celebrities have been favoured [38].

Discussion

There have been professed to be a multitude of factors for the disparity, as described earlier, but the fact remains: women tend to play the role of donors more than they do of recipients, and the problem can only be surmounted through a collective effort by society to carefully analyse and make aware of said factors and commonly tackle them. Women, intrinsically, have been known to hold greater emotional quotient [43] and have an inherently more profound sense of responsibility [7] as their biological role as child bearers and carers. This same sense of responsibility, even in the modern world, leads to their greater self-sacrifice—which might explain their reluctance to undergo transplant surgery[23] and their care not just directed towards the health and longevity of their children, but also of their spouses an idea that has even found place and reasoning in certain religions and prayer. Women have also shown greater application of scientific thought, in that a study found that women hold lesser superstitions and other disgust about organ donation while also not being too keen on the idea of bodies being intact during last rites.[44] This may lead to an inherent bias in women taking on the role of donors, especially of their own volition. Thus, it could be hypothesised that women are inherently more willing to donate organs than men.

However, factors brought in by societal thought and sociocultural relations contribute to an exacerbation of this bias: In another study, it was observed that the transplants most suitable for survival were either male donor to male recipient or male donor to female recipient.[45] This in the light of two observations, one being from the aforementioned study of South-Asians and the other being that women still bear the burden of donating, suggest that the vitality and life and health of males is preferred by society, over females. This is compounded by the universally greater income of men compared to women doing the same work that may place the job of organ donation on women to ensure the breadwinner's health is not compromised. Adding to this, a gender bias among medical professionals [31], that normally extends in a few other fields [46-48], thereby increasing the already inherent gap.

Even in parameters made to assess the need for a transplant, the physiological reasons behind better scores for women remain unaccounted for [21,30,49], thus making them appear healthier and subsequently increasing their time on the waitlist, leading to women dying on the waitlist far more than men [3]. This, coupled with an inequitable access to medical care for women of all ages [25], including but not limited to organ transplantation [25], serves to further widen the gap.

As for racial factors, there remains a deep-rooted historical mistrust in the medical profession [16], of non-white races in general, and Black communities in particular [50-53]. Multiple studies have highlighted the inequitable access of Black women to, for example, pain medications/epidural during delivery [54] as doctors, especially white doctors and medical trainees, tend to wrongly believe that black women have a higher tolerance to pain [55]. As for Black men, the history of their ancestors being used for medical trials without proper information, consent and ancillary care has caused their mistrust in the medical community [56], to a point where they believe "... if doctors know I am an organ donor, they won't try to save my life..." [36]. Nevertheless, here too, women tend to suffer more and as all these factors, along with a perceived inequity on who the organs will go to [36], transcends into organ transplantation and donation, so does the community. However, there was consensus on the willingness to donate a loved one's organs [36] and that no relative should override a deceased donor's wish to donate [57]. Meanwhile, in India, relatives have been known to override a deceased person's wish and express consent to donate, and superstitions about organ donation being sinful, belief in rebirth especially that intact bodies are required for rebirth and acceptance into heaven exist in India. This is known to be one of the major reasons why only 1% of Indians consent to organ donation after death, as compared to 70-80% of Western populations, as per reports from non-governmental organisations (NGOs). It has been widely suggested that religious leaders be roped into popular discourse to dispel a lot of the superstition, as religion has been known to play a key role in influencing followers towards or away from organ donation, be it live or cadaver donations [58].

As for economics, there is no doubt that organ transplant has blossomed into an often-illegal trade, thanks to the principle of altruism that is normally followed, and the lucrative money-making options in the field, leading to people resorting to illegal and unethical means to obtain organs. This may cause poorer girls and women to be forcefully made to donate organs, either by financial conditions or subjugation and suppression by men [1]. However, doubts linger as to whether direct incentivisation should be allowed or indirect benefits [5], for example the coverage of funeral expenses, should be provided. Consensus is split among gender and racial lines [5]. Nevertheless, it is agreed that relying solely on altruism is insufficient to bridge the demand-supply gap and target illegal organ trade [41].

It is therefore abundantly clear that participation will be needed from all levels of society, be it from the individual or from government. The initiative could come from anywhere and in any form, but it shall require a concerted effort from all levels with equal gusto. At the individual level, one could start by scoping for and identifying the various socio-cultural and psychological factors behind the prevailing gender gap in organ transplantation and donation and assimilating them, while also raising awareness among their peers, family and friends and gauging their attitudes and beliefs [59]. The awareness-building could be elevated to a broader level by the efforts of the community, while community organisations can mobilise efforts to assess economic factors as well, to encourage social support organisations especially for women and to encourage "health-seeking behaviours" in women [31] and to provide, per a study, "... Improving the general, physical, and mental health of minorities, coupled with an active educational outreach program.." in case of minorities, as it "...could result in a greater percentage of minorities registering and willing to be organ and tissue donors [60]." As for the medical profession, more needs to be done to repair an often tested relationship with the marginalised and underprivileged, be it in terms of race, financial background or otherwise. The beginning is to revisit the misconceptions plaguing an otherwise scientific profession and coming to terms with our checkered past, for that is the best way to begin to unlearn all falsehoods and through education, community engagement and empathy, can we regain lasting trust of all in the medical fraternity. More theoretically, tests or scores used to assess the need for organs, like the MELD Score, and in general, should account for the biological and physiological differences between the genders. Finally, at the level of government, we need a broad relook at the various legislations governing organ donation in each country and, where necessary, amend existing laws to influence the nations' citizens towards a more informed polity and encourage scientific temper, while also ensuring accountability, transparency and due recourse for any illegalities or immoral transgressions.

It must be acknowledged that no one person, party or platform can effectively bring about lasting reforms unless aided and in cohesion with every element of society, free of bias and personal stake.

Conclusion

Gender disparity in organ donation exists throughout the world. Wives to husbands, mothers to sons and sisters to brothers women have been obeying the gender roles enforced on them for ages. It indeed is a challenge to go beyond the gender gap to make the domain of organ transplant impartial, equitable and just, but it remains the need of the hour if we are to ensure equitable healthcare and healthy living for all, regardless of their gender. Inequitable and immoral practices have personal and ethical implications and need to be eliminated to advance our goals of equality and justice as a basic tenet of respect for every human life and to advance further as a civilised society.

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Review Paper

How To Improve The Ethical Consideration Of Acupuncture Clinical And Basic Research

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ABSTRACT

In this current perspective the aim is the ethical consideration of acupuncture in clinical research. The introduction of acupuncture and its benefit in human health was briefly stated, also gave an overview of the method of carrying out acupuncture clinical research and the choice of control procedure, while the problems faced by researchers regarding the research such as the difficulty of blindness was also put into consideration. Introduced the importance of clinical research in order to prove the medical effect of acupuncture which then makes the acupuncture intervention being more widely accepted in medical treatment. Furthermore, brings up the method to perform ethical research of acupuncture which can be the guidelines in the study of acupuncture clinical research. The seven requirements for ethical research that must be abide were explained in this review. Even though acupuncture had become a common intervention in the medical field, however, more afford was required to solve the acupuncture study-related ethical issues.

Keywords: Ethics, Acupuncture, Clinical research

Introduction

"Acupuncture" is originated from the Latin word 'Acus' means needle, while 'puncture' gives the meaning of dip or punch. Thus, acupuncture gives the meaning of the sense of needle immersion [1]. Acupuncture is known as a therapeutic procedure that stimulates acupoints on the body intending to obtain therapeutic effects. It can be done by using a needle, vacuum, pressure, ultrasound, laser, or electric current [1]. Acupuncture has become a popular Complementary and Alternative Medicine (CAM) in many countries. According to a bibliometric analysis done by Ma et al [2], there are around 13,320 acupuncture-related publications were identified from 1995 to 2014. Besides, there is a striking trend noticed in which the proportion of randomized clinical trials (RCTs) has been increased from 7.4% in 1995 to 20.3 % in 2014. The growth overstepping the 4.5 % proportional growth of RCIs in the field of biomedicine. Acupuncture therapy is endorsed by roughly 25 % of general practitioners (GPs) in the United Kingdom while it is mostly used to cure chronic pains. In 2013, there is reported that acupuncture was utilized in 183 countries according to a survey by the World Federation of Acupuncture-Moxibustion Societies [3].
The authors will discuss the perspective viewpoint available to perform clinical research and the problems that be found in conducting the research. Besides, also pays attention to the ethical issues

that have to be considered in research and the way to conduct ethical research in respective to acupuncture studies.

Carrying Out Acupuncture Clinical Research and the Problem Faced

Randomized controlled trials (RCTs) were regarded as the "gold standard" for demonstrating the effectiveness of healthcare interventions among all of the controlled studies. A standard RCT has three main characteristics: randomization, control, and blind or hidden. Allocation concealment and good randomness ensure the fairness and the comparability between subjects in the experimental group and the control group, as well as to overcome the selection bias problem. Effective controls can control for placebo and/or nonspecific effects and reveal the "real" therapeutic effect. Blindness can ensure the biases caused by the patient's expectations and preferences are minimized. However, due to acupuncture is a complex non-pharmacological intervention, it is "made up of several interrelated components", thus, designing an RCT that maintains the scientific accuracy of the trial design while balancing the nature of acupuncture has been a challenge. Regarding this, the WHO issued the "Guidelines for Clinical Research on Acupuncture" which described the basic elements of clinical investigation on acupuncture and moxibustion, such as patient selection, blinding technique, study site, and control design [4].

The choice of control procedure has become a research question. It depends on the aim of the study. If the study aims to test whether acupuncture shows improvement in the patient than doing nothing for the condition, then the control group does not need to receive anything. The acupuncture could be credible if only the acupuncture be proved to be beneficial than placebo. While, if the research question is testing whether acupuncture provides a better therapeutic effect than the current treatment, then the control group will has to receive the current treatment. For the research test for whether acupuncture has any specific effect, there will be a procedure that is indistinguishable from the real acupuncture intervention. Controlled trials will need the involvement of 'placebo' which can be known as an inert treatment that induces perception in participants that the intervention and placebo is unable to be distinguished from the real treatment. However, placebo control is arguing to be unethical as the patient would not receive the real treatment [5]. Besides, the effect of penetration of needle on the skin might induce treatment effect of acupuncture which implies that the placebo effect not always be regarded as inactive [6-7]. Thus, utilize the term 'sham' acupuncture to bring the meaning of needling to inappropriate points and using minimally acupuncture technique which implies needling superficially [8]. There is non-insertion sham control available which is similar to the actual acupuncture process, but the needles do not penetrate the subject's skin, for example, air guide tubes, toothpicks, semi-blunt needles, and non-penetrating needle devices. This technique aims to control the psychological effects of acupuncture. However, it is impossible to perform on subjects who have acupuncture experience before as they may be able to differentiate the real acupuncture from sham controls. Researchers could recruit subjects with little or no acupuncture experience. The disadvantage of non-inserted sham controls is that the blinding effects may not last long, as subjects may learn real acupuncture experiences through visits to other acupuncturists, or due to the therapeutic effects, they experience in long-term research studies. For example, one study showed that subjects were successfully blinded at week 4, but it failed at week 26 [3].

Besides, appropriate blinding minimizes performance bias, confirmation bias, and detection bias. Acupuncture treatment involves not only the instruments but also the process and techniques of acupuncture, such as needle insertion and manipulation. This makes it impossible for doctors to go blind, thus most acupuncture trials are single-blind, meaning patients are blind. To reduce subject identification bias, interventions should be carefully designed to effectively blind subjects. For example, a blind clip or a screen can be used to block a subject's view while an acupuncturist conducts real or fake acupuncture in the lower extremities of the patient. As the subject's expectations and the subject-acupuncturist relationship may cause potential bias, the acupuncturist is better to communicate with the patient in a neutral/concise manner during research and avoid communication about their trial experience to remain blinding. Results evaluators should keep blind to reduce the test bias, and statisticians also keep blind to ensure the data be analyzed and interpreted without bias.

For the treatment that is proven effective in placebo controlled RCTs, it can be introduced into medical practice. After undergoing further research, if the new treatment is proven to be effective than a standard treatment, it can supplant that standard treatment. However, for treatment that is no better than placebo, will be abandoned as the treatment that proves to be no better than placebo has no clear therapeutic effect that can take precedence over the risks of harm [9].

Ethical Concern of Clinical Research

Historically, doctors have been in a privileged position to conduct research. This caused some researchers to conduct unethical research. The Helsinki Declaration was born to inform biomedical researchers of the principles of clinical research. The Declaration emphasized the principles of good clinical practice, including respect for human dignity and the principle of justice. Research should not take precedence over the health, well-being, and care of the subjects [10].

Ethical concerns take place in the four basic principles of research which are weighting of risk-benefit, respect of human beings, merit and integrity, and justice. These principles lay the foundation for any argument regarding human research ethics. It also can be applied in all research areas as well as acupuncture research and Chinese Herbal Medicine research [11]. Ethical norms act as the goals of research and must be obeyed by researchers. Ethical norms are important to make sure that the aim of the study which is expanding of truth and honest knowledge can be achieved since ethical norms strictly prohibit the behavior of falsifying, fabricating, and misrepresenting the study result. Besides, ethical norms ensure the moral value such as trust, mutual respect, and accountability was carried out by the researchers. This is much more important in the collaboration between the researchers to protect researchers' ideas and experimental results. Ethical norms are crucial to protect intellectual property work and promote the researchers held accountable to the public. Making sure researchers take consideration of human rights, animal welfare, and social responsibilities as it is in the law [12].

In conclusion, the research study that is carried out will be ethical as it can avoid harming human or animal subjects in the sense of knowing which action can be harmful to the research subject.

Ethical Issues of Acupuncture Clinical Research

Even though many types of research have been done in studying the effect and mechanism of the acupuncture, however, a good design of clinical studies is limited by a lack of information and knowledge regarding the ethical consideration in acupuncture research [13].

Moreover, Miller et al reported [14] that participants usually do not be informed that they may accept a sham acupuncture intervention. They are only be told that there are one or more models of acupuncture being contrast in the trial. Such misleading action lacks persuasive methodological sense and it acts against the ethical requirement of obtaining informed consent with full disclosure. Participants need to be informed with accurate and full disclosure about the use of sham acupuncture. A clinical trial conducted in Germany which is to investigate the effect of acupuncture on migraine by using an acupuncture intervention, a sham acupuncture intervention, and no treatment. Participants were being informed about there are different types of acupuncture intervention that will be taken into comparison. One is alike to the acupuncture intervention used in China while the other is a type that does not follow the principles. However, it has related with the positive result in the trials. Besides, another article used the word 'minimal acupuncture' to described sham acupuncture [15]. It is speculated that this absence of accurate disclosure may be due to the worry of full disclosure would affect the recruitment of participants and diminishment of participant blinding. The patient will feel discomfort with the placebo group and think that sham control is physiologically active. Failure to tell the prospective participant that all of them will have an equal chance to receive a sham or placebo acupuncture treatment can be said as deception. This action does not fulfill the requirement of informed consent but also violates the principle of respect for human beings [16].

Furthermore, there are increasing bioethical issues concerning the method of acupuncture study being carried out. Some people argued that it is unethical to conduct any experiment if the concurrent attempt cannot confirm the treatment plan is better than a placebo or withhold

treatment for research purposes. This action will delay the recovery period of the patient, while it might also harm the patient [17].

Besides, it comes to a question where the improvement is incompletely due to the efficacy of healing effect of acupuncture, it might be due to chance, acupuncture consultation, patient expectation toward the benefit of acupuncture, putative consequences of appropriate acupuncture needle stimulation at the right acupoints, general needle insertion's physiological effect, self-limited course of the illness, waxing, and waning of the symptoms. Therefore, it is necessary to apply control groups in acupuncture research to examine to what degree the intervention contributes to the sum of therapeutic effects in the patients.

Ways to Conduct Ethical Research

Although acupuncture treatment has been performed in China for over 3000 years, however, it remains a controversial topic within the medical profession. The rate of production of acupuncture evidence is not satisfactory [18]. Meta-analyses, as well as systematic reviews study about the potential anaesthetic effect of acupuncture treatment haven't been proved to be better than the effect produced by placebo. Many recent systematic reviews have found that the impact of acupuncture on many diseases remains inconclusive. The probable cause, as described in many of the latest Cochrane systematic reviews is due to many clinical trials lacked adequate prescription design and were improperly conducted. Designing high-quality RCTs, scientifically rigorous RCTs of acupuncture remain difficult. This ambiguity generates an ethical dilemma where doctors do not know whether to suggest patients receive acupuncture treatment or other medication because the Good Medical Practice Guidelines (GMC) stated that doctors must perform the most effective treatment according to the best evidence currently available [19].

Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICA) provide guidelines describing details of apparatus, regime, site, and procedure apply in the study of acupuncture. This checklist is related to the reporting of intervention in the clinical research relating to acupuncture. STRICA is useful in promoting the completeness, clarity, and transparency of the acupuncture protocols and the controls or procedure of comparison in the report of research [20].

"Good research has to be well-calibrated, well planned, properly designed, and ethically validated," says Cope. It underscores the basic requirement of researchers to perform research responsibly. To achieve this, research programs should be developed and followed. It must be carefully agreed upon by all contributors and collaborators, and the exact role of each team member should be clarified early on, including issues of authors and publications. Research should aim to answer specific questions, not just collect data.

Moreover, research involving human beings, medical records, and anonymous human tissues must be approved by an Institutional Review Board or an Ethics Committee. The research proposal needs to discuss the potential ethical issues associated with the research. For the placebo-controlled trials, informed consent should be gained with the information that adequately inform the rationale for the placebo and the danger of it [21].

Before the start of a clinical trial, the study protocol and the necessary documents (case report forms, informed consent, advertisements, and posters) must be submitted to the ethics committee for acceptance. Subjects should be provided with a patient information sheet during the recruitment process, it must contain detailing objectives, procedures, potential benefits and harms, and the right to refuse to participate in the study. Subject or guardian consent should be explained and obtained. Works have to be done to ensure the confidentiality of the information provided by the subject. Schemes and documents can be modified by referencing the comments of reviewers. Clinical trials have to be conducted in accordance with the approved protocol. If there are any modifications, the program will require further approval from the Research Review Board. The intervention plan needs to include acupuncture rationale (such as type of acupuncture used, the principle of acupuncture point selection), acupuncture point selection, needle insertion depth, and needle retention needling details (such as needle length, diameter, and brand name), time, electrical stimulation (frequency and intensity). Details of acupuncture techniques need to be considered, for example, manual manipulation (such as lifting and rotation), or *deqi* (needle

sensation). The treatment plan should be clear and specified, such as number of treatments, duration, and frequency of each acupuncture treatment [22]. It should determine the concurrent protocol and use of routine care or ambulance medication during the research. It is important to pay attention to the well-being of the participant. It includes the proper procedure for monitoring of participants which involves precise criteria for early-stage trials termination and standard treatment must be provided [23].

Besides, research needs to be conducted by a qualified acupuncturist. The acupuncturist should have experience in treating the condition being studied. Since acupuncture is 'hands on' type research, thus, the research must be performed by a qualified acupuncturist to avoid the error of practices that might harm the participant. The qualification, clinical experience, and length of training of the acupuncturist must be stated. The effectiveness of acupuncture is influenced by the acupuncturist's experience, for example, the acupuncturist's educational background, years of acupuncture practice, the effectiveness of professional and communication skills. Many adverse events such as cardiac tamponade, organ puncture, and disease transmission are often associated with poorly trained, unlicensed acupuncturists [24].

In the process of planning to publication, researchers are responsible to make sure that research is conducted ethically and responsibly. Researchers should ensure that they are familiar with ethical principles and follow them strictly. Potential ethical issues faced by them in research and publication should be openly discussed within the research team. In case of doubt, it is recommended to consult the expert advice of the relevant Institutional Review Committee (IRB). A clinical researcher must obtain prospective and continuous review by a committee that makes up of members independent of the study to protect the subjects as well as to ensure public liability. Moreover, acupuncture intervention that be compared with biomedical standard care is ethical clinical design as all participant has received treatment. It is best when acupuncture and sham control are compared as adjunctive treatment as all patients can receive standard care. By applying the concept of 'intent to treat', trials that are using an acupuncture group compared with a standard biomedical group or a delayed-treatment group would be expected to be more ethical than the clinical trials using a non-treatment, placebo, or a sham control group [25].

There are seven requirements for ethical research which include social value, fair subject selection, independent review, and respect for the subject, scientific validity, favorable risk-benefit ratio, and informed consent. These requirements put attention on social value. It is important that the clinical research conducted can bring potential clinical significance. If the research lacking value, it is no worth putting the subjects at risk [26]. Moreover, clinical studies need to produce a good risk-benefit ratio that minimizes the risk to the subjects and justifies the risks posed by the potential benefits to the subjects and the value of scientific knowledge gained from the study. Furthermore, the selection of subjects must be consistent with the objectives of the research. The subject should be a competent adult that had been informed about the research details and they must be agreed with it. For incompetent adults and children, the details of the research must be informed to their parents or surrogates and their agreement is required. Besides, researchers have to put consideration to vulnerable groups to avoid ethical violations [27].

Conclusions

Ethical consideration during acupuncture research is quite important. WHO has stated in one of the documents of 'Guidelines for Clinical Research on Acupuncture, where the concern of human rights should be given to different value systems which deal with human rights such as cultural, social and historical matters? It is the responsibility of researchers to put ethical concerns into consideration in conducting clinical research. Human rights cannot be denied during the research as it is unethical to put the patient health and safety in danger. A well-planned protocol can make sure that the research is carried out systematically while at the same time it is a must to emphasize ethical consideration in the planning stage.

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Review Paper

Ethics Dumping and India's Unfortunate History

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ABSTRACT

The practice of researchers in a high-income country exploiting research participants from a low-and-middle-income country (LMIC) due to the relatively less stringent laws and ethical restraints that would otherwise prohibit the same to be carried out in their own home country is referred to as ethics dumping. Historically, there are several instances of ethics dumping internationally, which was a lot more widespread before the Declaration of Helsinki of 1964 and the Universal Declaration of Bioethics and Human Rights. This article aims to look at a few prominent and historic examples of unethical research conducted internationally and critically analyze a few instances of ethics dumping in India. Ethics dumping, unfortunately, persists even after the targeted country or community institutes regulations to prevent exploitation. This can be attributed to a lack of appropriate implementation of the laws, cultural and communication barriers, and a gap in the knowledge amongst the native population and the local researcher or contact persons recruited. The exploitation is oftentimes disguised as health aid from philanthropic organizations contributing to global health which has in many instances resulted in uninformed trials and studies conducted on vulnerable populations, ultimately leading to human rights violations. As future healthcare professionals, it is important that published medical literature recognizes this dark and unfortunate chapter of modern medicine, as only this can help create awareness and mould healthcare students and professionals into proponents of ethical research who will hopefully shape the future of clinical research based on sound ethical principles.

Key words: ethics dumping, unethical, LMIC, human rights, violation.

Introduction

Ethics dumping refers to the unethical practice of independent researchers or organizations in a high-income country exploiting a medium or low-income country to conduct research, harnessing the relatively less stringent laws and ethical restraints that otherwise prohibit the same to be carried out in their own home country. There may be several compelling impetuses for ethics dumping to occur, more often, intentionally, than otherwise. For instance, ethics dumping could be in the form of taking advantage of a country's ambiguous laws and regulations or taking advantage of the lesser required economic resources to conduct research.

In another instance, ethics dumping could be disguised as an altruistic act in the form of providing relief to vulnerable populations who otherwise may not have access to research interventions and in the process, there is a compromise on ethics.

Role of the European Commission

The term 'ethics dumping' was coined by The European Commission in 2013. More recently, the Code of Conduct for Research for Horizon 2020, the research fund of The European Commission, which extends to all research projects funded by the European Union was revised to include clear guidelines to aid researchers in identifying and mitigating the sometimes unintentional and obscure instances of ethics violation. Examples include the necessary employment of translators to ensure valid consent; the maintenance of confidentiality and safety, complying with local and national laws when research on sensitive issues, like the health of homosexual individuals or sex workers, are conducted in countries where it is still illegal [1]. Despite the institution of better guidelines in the European Union, the vast majority of high-income countries are yet to adopt similar policies, which exposes low and middle-income countries, with a large proportion of vulnerable population, to unethical research practices.

International Instances of Ethics Dumping

Ethics dumping is not an entity that has only recently come into existence. Instead, it has only recently been identified and defined with a global consensus to eradicate its prevalence. The infamous Tuskegee trial conducted in the 1900s, where illiterate black men with tertiary syphilis were diagnosed and left untreated, is an excellent example of taking uninformed consent and failing to provide follow-up and standard care, leaving the patients untreated merely for research purposes [2]. Another well-known example, the International Genomics Research trial compared the genome of indigenous San people from Namibia with South African people which was published without prior permission from San leadership. It revealed information claimed as private and discriminatory by San leadership [3]. Another case is that of a study on health-seeking behaviours undertaken by a non-governmental organization (NGO) in an African village pertaining to female genital mutilation. The rural female participants were uninformed about the research as the NGO was primarily involved in providing humanitarian aid. As a result, the study publicly revealed details about illegal female genital mutilation, disregarding safety, socio-cultural norms, and subsequently contributed to stigmatizing their culture [4].

The Indian Cervical Cancer Trial

The World Bank estimates that nearly 75% of the world's population and nearly 62% of the world's poor reside in low-to-middle-income countries (LMICs), like India [5]. India is home to nearly 1.38 billion [6]. A significant majority of India's population lacks access to basic necessities like education and healthcare. More often than not, they are unaware of their basic human rights, especially in the context of receiving healthcare of the highest attainable standard [7]. India has thus inevitably fallen prey to several rather conspicuous attempts of ethics dumping which has cost innocent lives and warranted the institution of new guidelines and re-evaluation of existing protocols and laws surrounding clinical research on human subjects conducted or funded by a foreign body in India.

The Indian Cervical Cancer Screening Trial can be likened to the Tuskegee Trial. This trial, which ran between 1998 and 2015, was a clustered randomized control trial (CRCT) conducted in Mumbai, Osmanabad, and Dindigul in India, to study the sensitivity and specificity of using inexpensive methods of screening like 'direct visual inspection with acetic acid' for detection of precancerous or cancerous cervical lesions [8].

The trials were funded by the National Institution of Health (NIH) of the United States of America and the Bill and Melinda Gates Foundation. A total of 374,000 women were recruited, of which 141,000 women were assigned to the non-screening control arm. While cytology from a Pap smear was and is the gold standard for cervical cancer screening, the participants in the control arm did not receive the established standard of care protocol, i.e., screening by Pap smear, which was possibly because of its limited access. They were only dispensed with health education to identify the signs and symptoms of cervical cancer and information on the available treatment for the same. They were followed up frequently to assess the trial proportion who had developed cervical cancer and subsequently died. These participants did not receive any form of treatment with 254 participants dying from the control arm and 208 from the screening arm [8].

The trials had apparent flaws in their study design with there being alleged deficiencies in the consent form provided in Marathi, the regional language spoken by the majority of the trial participants. It omitted important information on further tests and interventions rendering the consent invalid, as cited by the Office of Human Research Protections (OHRP), United States of America's investigation into one of the three trials. Furthermore, there seemed to be a lack of maintenance of a standard of care throughout the trial. Finally, the trial recruited women from socio-economically disadvantaged backgrounds like homeless women and slum-dwellers who are already at an increased risk for developing pre-cancerous lesions that go undetected and eventually invasive cervical cancer which ultimately bears significant mortality [8]. The participants in the control arm were thus denied basic human rights to avail the highest possible standard of care which was life-saving, as they were left in the dark about not getting any treatment. This trial has since garnered significant criticism, with even an offered refute to the above ethical arguments [9].

The Indian HPV Vaccination Trial

In 2009, The Programme for Appropriate Technology in Health (PATH), an American non-profit, and the Bill and Melinda Gates Foundation funded a 3.6 million HPV vaccination trial, with GlaxoSmithKline and Merck & Co supplying the vaccines in India in order to extend its reach in the Global South. This was to ultimately prove its importance and efficacy to be added to the universal immunization schedule. The trial recruited 24,777 adolescent girls from the states of Andhra Pradesh and Gujarat, predominantly from local tribal communities, the majority of whom were illiterate and their parents/guardians, for the most part, were also incapable of providing consent [10].

The trial was brought to a halt in 2010 when 7 deaths within the trial were reported. Post-mortem examinations were not conducted with trial investigators claiming the cause of most deaths unrelated to the trial (malaria, suicide, etc.). This was met with criticism and later prompted a government inquiry into the nature of the conduct of the trial, the possibility of ethics dumping by exploitation of vulnerable populations, and the relatively lesser stringent laws surrounding clinical trials in India. The Indian Council of Medical Research (ICMR) and the Drug Controller General of India (DCGI) came under heavy scrutiny for their role in the approval and regulation of the trial [11].

This trial not only took advantage of vulnerable minors from rural communities, by failing to obtain valid consent, with a school headmaster consenting on behalf of the study participants in one instance, it also failed to constitute a functional central ethical review board and a system for reporting adverse drug reactions [11]. This resulted in the violation of their basic human rights prohibiting exploitation and allowing dignity and health to all.

Ethical Quandaries of Ethics Dumping, Instituted Guidelines and its Mitigation

It is apparent that the practice of ethics dumping violates all four pillars of bioethics- with participant autonomy compromised and beneficence in question. Such practices are thus maleficent and a gross injustice to unguarded populations.

The 18th World Medical Assembly adopted the Declaration of Helsinki in 1964, which outlines recommendations guiding doctors for clinical research. Since then, with 9 amendments, the latest being 2013, The Declaration has been an authoritative source of reference for ethical principles to be followed in medical research involving human subjects. It was the first document accepted by the medical fraternity wherein they laid out the non-negotiable ethics-appropriate practices, the concepts of freely given informed consent and right to withdraw it anytime, and the explanation of risks and benefits of the proposed intervention. Above all, it stressed that the health of the patient was a physician's utmost responsibility [12].

Today, this Declaration has expanded to state that it is the foremost duty of the researchers to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. It adds that human subject research has to be justified by its potential preventive, diagnostic or therapeutic value, and vulnerable populations must be involved only when it is not possible otherwise and the said people benefit from it, and appropriate compensation and treatment must be provided to participants if they are harmed. Finally, everyone

involved in such research has ethical obligations to register it with national authorities, publicly share the study protocol to allow third-party scrutiny, and publish the findings, whether positive, negative or inconclusive [13].

Ethics Dumping also violates many Articles within the Universal Declaration of Bioethics and Human Rights (UDBHR). With the most pertinent being the exploitation of vulnerable population (Article 10) which is a violation of human rights, and hence human dignity (Article 3), the failure in many instances of ethics dumping to obtain valid consent, thereby undermining autonomy (Article 7&8) and in many cases the breach of confidentiality (Article 11) [14].

To avoid negligence, The Indian Good Clinical Practice Code (GCP), by the Central Drug Standard Control Organisation states guidelines for researchers to ensure the safety and protection of the population's rights, that researchers, individuals or organisations, have to strictly adhere to [15].

The four-value framework proposed by the Global Code of Conduct (GCC) includes Fairness, Respect, Care, and Honesty to be implemented for carrying out research in resource-poor settings. It emphasizes the role of the local ethics committee to reduce exploitation and ensure no harm and equal participatory roles at all the stages of the sanctioned project in case of collaborative research projects [16].

Conclusion

It is thus important that healthcare students, healthcare professionals, and policymakers alike, to sensitize ourselves to the possibilities of overt unethical research practices like ethics dumping. We must educate ourselves and subject future collaborative research proposals and ongoing clinical research to strict scrutiny to warrant upholding the current laws and guidelines to ensure scientifically robust and ethically sound research. It is also our duty to inform potential candidates of clinical research about the objectives, possible benefits and harms of their participation. Furthermore, they need to be made aware of their human rights, and that individuals organizing human subject research have the moral and legal responsibility of upholding those. This may be a possible option of remediation against potential exploitation. The only concrete fail-safe against a repeat of the Tuskegee trials is an investment by ethicists, policymakers and the existing medical fraternity to create an upcoming generation of professionals who have the principles of ethics instilled in them in their formative years of medical education.

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Original Research Paper

A Comparative Analysis of Opinion On Various Bioethical Issues Based On Religiosity: A Pilot Study With Medical Graduates

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ABSTRACT

Background: Religiosity which by definition means people's varying tendencies to commit themselves to religious beliefs is an important aspect in society and especially in bioethics, a field concerned with the moral, legal, political, and social issues raised by medicine, biomedical research, and life sciences technologies. Globally, studies on the impact of religiosity on aspects that are debatable and engrained with ethical issues have been minimally investigated. The current study attempts at understanding the opinion of medical graduates through a structured questionnaire.
Methodology: A total of 207 graduates' volunteers to be a part of the study and majority (72.2%) were females. The most important aspect was that 83.93% expressed that they followed their religion strongly. The data was stratified based on this and subjected to detail analysis to understand the opinion of the graduated based on their degree of religiosity.
Results: A significant difference for questions related to opinion pertaining on embryonic stem cell research is unethical ($p = 0.017$) and to right to end his or her own life when in terminal condition ($p = 0.033$).
Conclusion: As far as the authors are aware of this is the first study that addresses the role of religiosity on opinion to some bioethical aspects with medical graduates from India and the results indicate that religiosity does influence medical practice and opinion on embryonic stem cell research and right to end life in terminal condition.

Key words: Bioethics, medical graduates, religion, religiosity, end of life issues, embryonic stem cell research.

Introduction

Religion is the belief and worship of superhuman being /s (commonly termed as God), following a unique culture, while spirituality refers to adhering to a broad set of principles that transcend all religions and being in right relationship and understanding mutual interdependence of all human beings [1]. Religion and spirituality are the two determining factors in defining the values of life

and is termed as the inner call of the human being to respond to life in the world [2-3]. Religion is a collation of cultural and belief through which the world views humanity and moral values. Many religions have narratives, symbols, traditions and sacred histories that are intended to give meaning to life or to explain the origin of life and the [2-3].

The basic religions in the world are Christianity, Islam, Judaism, Hinduism and Judaism (The big five); the others include Zoroastrianism, Sikhism, Baha'i faith, Shintoism, Taoism, etc [2-3]. The etymology of the word religion itself is a self-explanatory concept (Latin: "religious" – 'to bind together') [2-3]. The followers of a religion mean sharing the same faith, participating in rituals and adhering to the precepts of the community and espousing it when the need arises. Although a religion is considered as "one", at times it has significant diversity in practice among the followers. At times religion also draws others to community and follows a culture rather than the belief itself. Globally, most countries have governments that favour to protect citizens freedom to follow religion of their choice without privileges or penalty. The human rights enshrine this principle and this is considered a 'fundamental freedom'. In lieu of these observations it can be termed as religion is an overwhelming influence in a person's life. The choices an individual makes would inadvertently pursue the tenets of his faith and belief of the followers. Thus, all decisions would invariably be influenced by religion.

On the contrary, ethics concerns recommendation of right attitudes and behaviours is based on adherence to the inherent nature of the attitude and prevailing moral theories. In fact, John Dewey stated that ethics is considered as a function of moral life of the community [4]. Bioethics is a multi-dimensional discipline that has varied inputs. The ontogenesis of ethics is based on for native values, environment and experiences. Surgery, transfusions, organ grafting etc, are anathemas, in most religions. The alteration of the body is considered, blasphemous by the religious orthodox, even at the cost of their own wellbeing. In the recent past there has been a positive association between religious involvement and better health.

Medicine is the applied science or practice of the diagnosis, treatment, and prevention of disease [5-6]. It encompasses a variety of health care practices evolved to maintain and restore health by the prevention and treatment of illness in human beings. Medicine and religion have been closely associated since time immemorial and the belief that science alone cannot cure a disease is widely prevalent [5-7]. Spirituality and religion are known to be inversely related to science and in most religions, diseases are considered by most as 'ire of the gods' or "taboo" to be manipulated [6-10]. Religious beliefs are strongly held in an individual tract, a physician's religious learning could influence practise of medicine [7-9,11]**.** When education and awareness sheds light upon an action that adversely affects some or many, the thought of changing such practices/decisions is necessitated and the remedial or alternate is adopted. Religious beliefs could affect ethical decision making and influence personal choice in health care advancements.

Healthcare professionals have to practise their art within the inhibitory and vacillator spectrum of religious beliefs. The health providers need to be attuned to this fact. Doctors with their own individual religious beliefs and the teachings of medical science are at crossroads. The impact of the doctor's own spirituality and religious attitudes could swerve the practise of medicine. The attitudinal development of a doctor occurs at home in social and educational environment. A study to ascertain the attitudes of the undergraduate and post graduate medical students would give inkling into the practise of medicine and religiousness. Considering this the present study was conducted to ascertain the differences in perspectives of undergraduate and postgraduate medical students on their concepts of religion and whether this impacts their attitudes towards bioethical issues.

Materials and Methods

This study is a single centre study and was conducted under the aegis of the UNESCO Bioethics South India Unit at Father Muller Medical College, Mangalore, India after obtaining the permission of the Institutional Ethics committee. The questionnaire was designed by the investigators and was developed by a local panel of experts in bioethics and researchers. Special attention was given for clarity and the inclusion of the full range of response options. The questionnaire was then pilot tested with 10 students, who were not part of the final sample. The

respondents of the pilot cohort rated the initial questionnaire for clarity and content validity. Emphasis was placed on the opinion for the comprehension and understanding of the meaning of each question. The final instrument underwent only minor grammatical changes and consisted of five demographic questions and twenty subject specific questions.

Study Population and Survey Methods

The study population consisted of MBBS graduates who had registered for postgraduate entrance exam training centres in Mangalore and was carried out in December 2016. The investigators approached the medical graduates individually and briefed about the study purpose. As some questions were dilemmatic the volunteers were also requested not write their names or leave any identification mark on the study questionnaire and requested to return back the filled sheets. Written consent was obtained on separate sheet from all the participants before the administration of the questionnaire.

Statistical analysis

Data was entered in Microsoft excel and answers on the questions were subjected to a quantitative analysis using the Chi-square test and Fisher's exact test using the SPSS software program version 17 from IBM. A p value of < 0.05 was considered significant.

Results

A total of 225 questionnaires were distributed but only 207 responded. The results of the study are presented in Table 1 and Table 2. With regard to gender, the results suggest that majority (72.2%) of the volunteers were female medical graduates (Table 1). With regard to the question on whether students had attended classes in bioethics, 50.99% of the volunteers agreed while 49.01% expressed had not attended the classes (Table 1). The other most important observation was that 88.27% agreed that bioethics has an important role in healthcare curriculum and profession. Majority of the volunteers (67.98%) confessed that they did not read books or articles on bioethics (Table 1). The important aspect was that 83.93% of the volunteers agreed that they followed religion strongly (Table 1).

Table 1: Details of gender, teaching reading and opinion on importance of bioethics and following religion by the medical graduates

Questions	Choice	Total	Percentage
1. Gender	Male	57	27.8
	Female	148	72.2
	Total	205	100
2. Have you attended any classes on bioethics?	Yes	103	50.99
	No	99	49.01
	Total	202	100
3. Do you feel bioethics has important role in healthcare curriculum and profession?	Yes	173	88.27
	No	23	11.73
	Total	196	100
4. Do you read bioethics books or articles on bioethics?	Yes	65	32.02
	No	138	67.98
	Total	203	100
5. Do you follow religion strongly?	Yes	141	83.93
	No	27	16.07
	Total	168	100

For the question," do you think embryonic stem cell research is unethical?", the medical graduates who were religious expressed its unethical nature ($p = 0.017$). With respect to the question, "do you feel you should not tamper god's creation in the name of advancement of science?", the students who were religious opined that tampering of god's creation in the name of advancement

of science, was not acceptable and this was an emerging new trend among the graduates (p = 0.063). For the question, "I try hard to carry my religious beliefs over into all my dealings in life", the medical graduates who were religious carry their beliefs into all their dealings in life (p = 0.003). With regard to the question, "do you feel religious beliefs influence medical professionals" (p = 0.088). Professionals who were religious opined that their religious beliefs have an influence in the delivery of healthcare (Table 2). To the question "do you think a patient has the right to end his or her own life when in terminal condition", students who were religious expressed that patient did not have the right to end his or her own life when in terminal condition (p = 0.033) (Table 2).

Table 2: Opinion expressed by the medical graduates who followed religion strongly as versus to not for the various questions addressing the medical fraternity

Questions	Choice	Religious N (%)	Not religious N (%)
1.Do you think scientific and medical progress is hindered by religion?	Strongly agree	18 (12.9)	5 (18.5)
	Somewhat agree	73 (52.1)	15 (55.6)
	Somewhat disagree	22 (15.7)	4 (14.8)
	Strongly disagree	27 (19.3)	3 (11.1)
	Chi square	1.431	
	P value	0.698	
2.Do you feel religion is over pressing bioethical issue	Strongly agree	16 (11.5)	5 (19.2)
	Somewhat agree	58 (41.7)	15 (57.7)
	Somewhat disagree	42 (30.2)	3 (11.5)
	Strongly disagree	23 (16.5)	3 (11.5)
	Chi square	1.248	
	P value	0.741	
3.Do you feel science must advance at the cost of animal and human experimentation?	Strongly agree	21(15.3)	6(24.0)
	Somewhat agree	53(38.7)	8(32.0)
	Somewhat disagree	36(26.3)	6(24.0)
	Strongly disagree	27(19.7)	5(20.0)
	Chi square	1.248	
	P value	0.741	
4.Should religious healthcare professionals hinder healthcare services?	Strongly agree	12(9.2)	4(15.4)
	Somewhat agree	22(16.9)	3(11.5)
	Somewhat disagree	41(31.5)	5(19.2)
	Strongly disagree	55(42.3)	14(53.8)
	Chi square	2.957	
	P value	0.398	
5.Do you think genetically modified food ie brinjal is harmful?	Strongly agree	17(12.4)	3(12.0)
	Somewhat agree	40(29.2)	6(24.0)
	Somewhat disagree	41(29.9)	5(200)
	Strongly disagree	39(28.5)	11(44.0)
	Chi square	2.590	
	P value	0.459	
6.Do you think genotyping should be done by all patients?	Strongly agree	15(11.2)	2(8.3)
	Somewhat agree	43(32.1)	8(33.3)
	Somewhat disagree	52(38.8)	6(25.0)
	Strongly disagree	24(17.9)	8(33.3)
	Chi square	3.612	
	P value	0.307	

7.Do you think embryonic stem cell research is unethical?	Strongly agree	14(10.3)	0(0.0)
	Somewhat agree	37(27.2)	4(16.7)
	Somewhat disagree	56(41.2)	8(33.3)
	Strongly disagree	29(21.3)	12(50.0)
	Chi square	10.215	
	P value	0.017 Significant	
8. Do you feel you should not tamper god's creation in the name of advancement of science?	Strongly agree	39(28.7)	6(24.0)
	Somewhat agree	52(38.2)	4(16.0)
	Somewhat disagree	28(20.6)	9(36.0)
	Strongly disagree	17(12.5)	6(24.0)
	Chi square	7.305	
	P value	0.063 Trend	
9.Is the influence of religion/spirituality on health generally positive or negative?	Strongly agree	45(36.9)	4(23.5)
	Somewhat agree	58(47.5)	10(58.5)
	Somewhat disagree	16(13.1)	3(17.6)
	Strongly disagree	3(2.5)	0(0.0)
	Chi square	1.786	
	P value	0.618	
10. Religion/spirituality helps patients to cope with and endure illness and suffering?	Strongly agree	85(61.2)	11(45.8)
	Somewhat agree	46(33.1)	10(41.7)
	Somewhat disagree	5(3.6)	2(8.3)
	Strongly disagree	3(2.2)	1(4.2)
	Chi square	2.559	
	P value	0.447	
11. Religion/spirituality gives patients a positive helpful state of mind	Strongly agree	95(68.8)	13(50.0)
	Somewhat agree	39(28.3)	11(42.3)
	Somewhat disagree	3(2.2)	2(7.7)
	Strongly disagree	1(0.7)	2(0.0)
	Chi square	4.96	
	P value	0.416	
12. How often have your patients received emotional or practical support from their	Strongly agree	46(39.0)	7(33.3)
	Somewhat agree	61(51.7)	14(66.7)
	Somewhat disagree	7(5.9)	0(0.0)
	Strongly disagree	4(3.4)	0(0.0)
	Chi square	2.847	
	P value	0.416	
13. Religious/spirituality causes guilt anxiety or other negative emotions that lead to increased patient suffering	Strongly agree	5(3.6)	3(11.5)
	Somewhat agree	40(28.6)	9(34.6)
	Somewhat disagree	43(30.7)	9(34.6)
	Strongly disagree	52(37.1)	5(19.2)
	Chi square	5.315	
	P value	0.150	
14. Religion/spirituality leads patients to refuse delay or stop medically indicated therapy	Strongly agree	18(13.1)	2(7.7)
	Somewhat agree	49(35.8)	16(61.5)
	Somewhat disagree	36(36.3)	3(11.5)
	Strongly disagree	34(34.8)	5(19.2)
	Chi square	6.437	
	P value	0.092	
15. How often have your patients used religious /spirituality as a reason to	Strongly agree	17(14.2)	3(14.3)
	Somewhat agree	49(40.8)	7(33.3)
	Somewhat disagree	29 (24.2)	6(28.6)
	Strongly disagree	25(20.8)	5(23.8)

avoid talking responsibility for their own health?	**Chi square**	0.467	
	P value	0.926	
16. I try hard to carry my religious beliefs over into all my dealings in life?	Strongly agree	29(20.9)	2(7.7)
	Somewhat agree	70(50.4)	8(30.8)
	Somewhat disagree	24(17.3)	6(23.1)
	Strongly disagree	16(11.5)	10(38.5)
	Chi square	14.304	
	P value	0.003 Significant	
17. Do you feel religious beliefs influence medicine?	Strongly agree	36(26.3)	4(16.0)
	Somewhat agree	63(4.0)	15(60.0)
	Somewhat disagree	25(18.2)	1(4.0)
	Strongly disagree	13(9.5)	5(20.0)
	Chi square	6.543	
	P value	0.088 Trend	
18. From ethical point of view does physician or someone else have the responsibility to practice euthanasia when they are asked to do so by a terminally ill patient in a responsible manner?	Strongly agree	19(14.2)	6(26.1)
	Somewhat agree	50(37.3)	9(39.1)
	Somewhat disagree	19(14.2)	2(8.7)
	Strongly disagree	46(34.3)	6(26.1)
	Chi square	2.609	
	P value	0.456	
19. Should human life be defended regardless of its quality?	Strongly agree	36(26.7)	5(20.8)
	Somewhat agree	38(28.1)	7(29.2)
	Somewhat disagree	35(25.9)	8(33.3)
	Strongly disagree	26(19.3)	4(16.7)
	Chi square	0.762	
	P value	0.858	
20. Do you think a patient has the right to end his or her own life when in terminal condition?	Strongly agree	18(12.9)	6(24.0)
	Somewhat agree	32(23.0)	10(40.0)
	Somewhat disagree	18(12.9)	4(16.0)
	Strongly disagree	71(51.1)	5(20.0)
	Chi square	8.717	
	P value	0.033 significant	

Discussion

Our study investigated the impact of religion on attitudes and practise of medicine. It has been known that religion influences the outpouring of attitudes, decision and values. Being a person of science and following a particular religion could be at times contradictory, invoking a turmoil that gets balanced by rationality. As seen in the study the medical students 83.93% of the volunteers were religious. In a study conducted Curlin et al, male physicians and those who are religious will be most likely to express personal objections and least likely to disclose information about the interventions or to refer patients to more accommodating providers [12].

Religion has an important role when it comes to decision taking. Underlying religious beliefs and affiliations strongly affects end of life decision taking [13]. They tend to derive morality, ethics, religious laws or a preferred lifestyle from their ideas about the cosmos and human nature. Religion has a substantial impact on patient care [14]. Patient's recovery and well-being are dependent on their beliefs, spiritual needs and support. Incorporation of spiritual and religious dimension as a part of patient care can help patients cope with their illness [14]. While serving the patients; spirituality can help clinicians to reconnect with their professional roots [15]. Maintenance of hope and stability can be provided by the intervention of spirituality [16]. Greater spirituality is one of the factors for good health among geriatric people [11]. Advanced cancer patients, oncologists and

oncologist nurses value spiritual care [17]. Spiritual development along with professional development is becoming a need as it helps the healthcare individuals to deal with their stress of care giving [15]. Integrating of spiritual needs is also essential along with advanced medical treatment [16]. Making patients understand and coping with medial illness can be achieved by religion [18]. Moral deliberation is substantiated by religious traditions [19].

Limited research data is available on the frequency of spirituality and religion affecting health care professionals [20]. Ethics and informed consent are intertwined which is a central issue on which hangs most of the ethical problems in human experimentation and the options in clinical care [21]. The understanding of interplay of religion and spirituality in health and medicine has increased. There is a renewed interest for its implication on ethicality. Healthcare professionals must acknowledge and address religious issues with regard to disease and health of their patients. In associating with religious issues and needs of the patients the religious and spiritual foundation of the healthcare professional should be sound) [22]. In the study it was observed that 83.93% of the volunteers were religious. Intrinsic religiosity stands for the extent to which a person embraces his or her religion as the "master motive" that guides and gives meaning to his or her life [12].

The incongruity among the various beliefs arises from vague and incorrectly perceived philosophical concepts. Thoughts about the necessity and moral implications of embryonic stem cell research are governed by a variety of religious, ethical and political factors. Some ethicists strive to ascertain what of who is a person by "setting boundaries" [23]. Supporters of embryonic stem cell research assert that to qualify as a person, the individual must fulfil several criteria to be qualified for personhood such as self-awareness, capacity, curiosity, sense of time and neo-cortical function [24-25]. Those defending this theory, argue that human embryo lacks these criteria and therefore cannot be deemed to have a moral status. Scientists affirm that any harm done is outweighed by the potential alleviation of the suffering endured by tremendous number of people with varying diseases [26-27]. As per the deontological approach, "whether a situation is good or bad depends on whether the action that brought it about was right or wrong", and hence the ends do not justify the means. Therefore, this flimsy utilitarian approach deems that stem cell research proceeds at the expense of human life than at the expense of personhood. This argument fails to address the ethical concerns pertaining to the destruction of embryonic life for the possibility of developing certain treatments to eradicate certain diseases [25,28].

Most religions strongly condemn reproductive cloning because of the belief that life is considered to be a gift from god [29]. Religious leaders rarely show the determination to voice their thoughts or take a stand in this matter. The Roman Catholics oppose human cloning and embryonic stem cell lines because it goes against their belief and faith and it is contradictory to the law of god [29]. Hinduism rejects the use of embryonic stem cells and concurs with Christianity [30-31]. Stem cell research propels possible futuristic notions like eternal life and existence beyond human realms, development of ready to use organs which can potentially alter the dynamics of the whole human race [24]. Islam regards research on stem cells as an act of faith and the ultimate will of God and that the intervention can be undertaken with the sole intent for the greater good and improvement of humanity [32-34]. However, Islam expresses concerns with the reproductive cloning procedures and their potential impact on familial and interpersonal relationships [32-33].

The ethicality of stem cell research was agreed by the nonreligious (83%) and the religious (62.5%). Ethical sensitivity and competence is necessary for excellent clinical care and both religion and spirituality aids in development of ethical sensitivity. However, the relationship between science and religion has been complicated. Science has time and again shaken the very foundations of religious beliefs especially the western nations and if it keeps festering, the religious sentiments and hostility can mount leading to stunting of advancements in science [35].

As medical graduates realised the need for creating a universal form of decision without the overwhelming influences of religion to be professional. Volunteers in this study had training to be professional, that belies religious tug-of-war. In a study conducted in 1988 by Cassidy no significant differences were found on perceptions of idealistic and realistic moral behaviours. Comparison based on age of students and their participation in ethics course and seminars was analysed and significant findings were evident. Exposure to bureaucratic environment of

healthcare system and participation in educational offerings have attributed to differences in attitudes [36].

Humanistic desire to end suffering and pain has been sheared from religion and spirituality that could influence decision making amongst doctors [37]. Patients and physicians have an element of disagreement of what a "good death" entails [38]. Every human being has the right to determine what shall be done to his own body. Hence informed consent is the ultimate protection from hazards of research and therapy in medicine. The end result should be a rational decision by the patient based on the information provided to him by the researchers or investigators and patient should have full prognosis [21]. Respect to the individual is inherent to religious beliefs and as manifest as autonomy of the patient [21].

In the conceptual framework of relationship amongst human beings, nature and god, religion, spirituality and medicine have common roots [22]. Recent debates have sparked the need for accessibility to legal treatments when the concerned physicians have trouble about the moral implications of the treatment. Certain countries have formulated laws that shield health providers from refusing medical practises that would violate their consciences [12]. Studies have shown that family physicians beliefs and religious practises are similar to the cross section of the population he practises in [39]. Among the healthcare professionals psychiatrist were found to be less religious than their counter parts and their patients [40]. Moreover, healthcare professionals are the crucial link in augmenting bioethical values in the course of their duty. A study by Bapat et al, in South India, that analysed the awareness, attitudes and beliefs of 123 medical students showed 95% did not believe that organ donation is against religion [41]. The question of religion thus lays a crucial role as it is the belief that prompts the action of the healthcare professional.

Among the ones who follow religion strongly (35.9%) and 64% of the ones who do not follow religion strongly agreed that patient has the right to end his or her own life when terminally ill. Physicians are ultimately the decision makers despite having patient directed modes of end of life care [12]. Patient autonomy and end of life decisions are two factors which lead to a dilemma among the health care individuals as well as the patient party. Views on euthanasia are strongly influenced by religion on health care profession[42].The interesting conclusions drawn by Billow HH, 2012 study, was that the religious were more in favour of treatment and more in favour of life prolongation and less likely to administer active euthanasia than the others. The issue of patient autonomy did not show difference between religious and non-religious [42]. Relief from unbearable pain and suffering, euthanasia was supported majority of the doctors [43]. The factors determining, choice of euthanasia among doctors showed that disappointment was seen in those religious and spiritual [44].This study done earlier on doctors and our study done on medical students showed parallel ideology

Religious and non-religious Medical professionals are in agreement that religion casts a positive influence on health. In fact, Ghadirian has indicated relevance of spirituality in the practise of medicine. In fact there is danger of dehumanisation of medical institutions. Consequently growing number of medical education programs implement integration of spirituality and medicine [45]. Impact of religion on health is primarily a positive one. Thus Religion has an important impact on health [46]. Surprisingly, religion helps to cope in illness was agreed to by the religious (94%) and the non-religious (88%). Within medicine there is an increased focus on the relation between faith and health [46]. It has been shown in a study by Powell LH et al 2003, that religion and spirituality protects against cardiovascular diseases mediated by lifestyle. The depth of religiousness bears on physical health. Religion and spirituality slows progression of cancer or improves recovery from acute illness. The heavy impact of religion and spirituality on patients, disease course could also affect the treating team. Hence the hypothesis was developed [47]. Religion helps to cope with diseases and its consequences which could conflict with physician's recommendations and the patient could face a conflict with physician's recommendation but navigating this issue is an ethical dilemma [48].

Irrespective of religiousness and qualification all agree that religion provides positive attitude and hopeful state of mind of the patients. Highlighting the importance of religion and spirituality among terminally ill patients would mean the meting out of religion and spirituality by health care professionals [49]. Influence due to religious beliefs in practise of medicine was agreed upon by

71.3% of the participants. As physicians are de facto arbiters, especially, in critical situations, despite having appointed surrogates, their decisions would definitely be influenced by personal religious beliefs [38].

Various studies note the influence of religion on the physicians practise but over simplified religious measures limit the veracity of these studies [38]. Ethnicity, geographic region, experience caring for the dying and religious characteristics have an impact on the physician's perspectives on end of life decisions. Frequent exposure to dying patients and the outcome of survival; also have a bearing on physician's attitude on "end of life" issues [38]. The physician's judgements, beliefs, attitudes and obligations could impinge upon their practise [38]. In a study conducted by and co-workers in the United States it was seen that Christian affiliations try to carry their religious beliefs into other dealings in life than Jewish, Hindu and Muslim physicians [39]. Religious leaders themselves are at times inconsistent with their moral standpoint on various ethical issues that prevaricates the stance to be taken by their faithful. Hence further deliberations and discussions are necessary in concluding a debate on new age healthcare advancements. Despite the methodological limitations in this study, the conclusions drawn are contemplative and gives direction to fostering ethical competence amongst healthcare professionals. A true professional unfetters religiosity and other personal biases in ethical decision making.

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Original Research Paper

Awareness of nursing students on legal and ethical issues in day-to-day practice at a teaching hospital in Shillong, northeast India

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ABSTRACT

Background: In the current corona crisis, nurses are likely to face increasing legal and ethical challenges in the path of their industrious career. We have conducted this research to explore the awareness of nursing students on these issues which, we feel, is essential to enable them to deal with practical situations in future
Methods: A total of 162 participants were included in the study. Data was collected with the help of a structured self-administered online questionnaire comprising socio-demographic variables and fifteen items related to the research topic. Analysis was done using SPSS version 11 by descriptive and inferential statistics.
Results: Most of the participants (60.5%) demonstrated fair awareness according to the criteria in the research tool. Around 55.5% were aware of the code of ethics for nurses in India and a majority (92.6%) knew about the concept of patient autonomy in nursing ethics. However, there was no association between level of awareness with age, gender, and duration of clinical exposure.
Conclusion: These findings emphasize the importance of incorporating ethics and law in the curriculum and reinforcement by problem-based learning to better equip students for real life clinical scenarios in a post-pandemic world.

Key Words: nursing students, awareness, ethics, law, curriculum.

Introduction

The field of nursing is perhaps one of the most demanding professionally and personally as the nurse dedicates her time and talents selflessly for the wellbeing of others. During the historic Crimean War (1853-56), the services of Florence Nightingale as a nurse caring for the sick and wounded round the clock earned her the distinction of being called "Lady with the Lamp"- which has become a symbol of good nursing practice to this day. Through the years, nurses have shown compassion and competence in the face of moral, ethical, and legal dilemmas in the path of their industrious career. These challenges are no less today – if at all, they have escalated by leaps and

bounds especially after the corona pandemic of 2020 which has changed our lifestyle and work practices completely. Therefore, those on the road to becoming nurses have to be well prepared mentally and physically to weather the storms of their professional lives.

In the present scenario, nurses are likely to face increasing legal and ethical challenges with respect to triage and treatment of patients, particularly those belonging to vulnerable groups such as children, the elderly, pregnant women, and those with co-morbid conditions. Meanwhile, the conventional principles of consent, confidentiality and autonomy continue to apply at all times. In addition, nurses have to assist doctors in handling cases of accident, trauma and assault which have medico-legal implications.

The legal and ethical aspects of day-to-day practice are taught to nursing students throughout the B.Sc (Nursing) course. The content and quality of training that students receive is thus pivotal in preparing them for their role as healthcare providers of tomorrow. We have conducted this research with a view to exploring the awareness of nursing students on the legal and ethical aspects of routine nursing practice – an essential ingredient of a good and positive holistic health outcome. It is imperative for students to be aware of these issues right from the early stages of their training so that they can deal with them confidently at their designated places of work as they attend to the call of duty in any kind of situation.

Methodology

The present study was performed on four batches of nursing students of the first, second, third and fourth years of the B.Sc. (Nursing) course. As each batch has around 50 students, the target sample size was 200 participants. Data was collected in the form of a structured self-administered online questionnaire comprising socio-demographic variables (age, sex, years of clinical exposure) and 15 (fifteen) items related to the topic of the study over a period of one week, i.e. from 8th to 14th December 2020. This information was entered in MS Office Excel 2007 spreadsheet and analysed using SPSS Version 11 by descriptive and inferential statistics. Responses were evaluated and each correct answer was awarded one mark. There was no negative marking for wrong answers. The total marks secured were computed out of fifteen and percentages calculated for each individual response.

Awareness of nursing students was graded on the basis of scores obtained as follows:-

Good – ≥ 75%

Fair – 50-74%

Poor – <50%

Statistical Analysis: Pearson's Chi Square and Fisher's Exact Tests were employed to find out if there is significant association between level of awareness with age, gender and duration of clinical exposure in the sample population. A p-value of < 0.05 was considered as statistically significant. The reliability of the questionnaire was assessed by tabulating the responses of twenty nursing students and calculating Cronbach's Alpha value which was found to be an acceptable 0.74.

The identity of individual responses was kept anonymous and confidentiality of data maintained by the investigators. Adequate information for participants about details of the study was included in the online form prior to filling out the questionnaire and consent taken for the same. Ethical approval for the project was obtained from the Institutional Ethics Committee (IEC) on 18th September, 2020.

Results

A total of 165 responses were received through the online mode out of which three were incomplete/duplicated and not taken up for analysis. Therefore, the final sample size was 162 (one hundred sixty-two). Results are tabulated in Tables 1-3 and Figure 1.

The majority of respondents were female (93.2%) and only 6.8% were male in the age group ranging from 18-26 years with a mean age of 21.29 years. Among the students, 47.5% had more than 3-4 years of clinical exposure during the course of their practical postings (Table 1).

Table 1: Socio-demographic characteristics of study participants (*n=162*)

Age	Frequency	Percentage (%)
Age range		
18-21 years	96	59.3
≥ 22 years	66	40.7
Gender		
Male	11	6.8
Female	151	93.2
Duration of clinical exposure		
<1 year	42	26
1-2 years	43	26.5
3-4 years	77	47.5
Course of study		
B.Sc (Nursing)	162	100

In the present study, the mean awareness score was 10.27 ± 1.03 with a range of 2-15. Most of the participants (60.5%) demonstrated fair awareness of the legal and ethical aspects of nursing practice according to the criteria in the research tool (Table 2). Around 55.5% were aware of the code of ethics for nurses framed by the Indian Nursing Council and published in the year 2006. More than half of the students (54.3%) knew about recent guidelines from the Ministry of Health and Family Welfare on medico-legal examination of survivors of sexual violence. In relation to consent for minors in the absence of parents, 76.5% were able to pick the correct option that the hostel warden is authorized to give written consent when a 12-year-old boy residing away from home requires immediate surgery.

Table 2: Awareness of study participants (*n=162)*

Item	No. of correct responses	Percentage (%)
Awareness about INC# code of ethics for nurses in India	90	55.5
MoHFW* guidelines on medico-legal examination of survivors of sexual violence	88	54.3
Identifying a medico-legal case in the Emergency Department	116	71.6
Consent for minors in the absence of parents	124	76.5
Recognition of an acid attack	113	69.7
Privileged communication in outbreak of infectious disease	135	83.3
Medico-legal classification of injury	39	24
Manner of injury - whether accidental, self-inflicted, or due to assault	135	83.3
Duty of a nurse in a case of poisoning	103	63.5
Observation and inference on examination of a rape survivor	89	54.9
Sorting and prioritizing injured patients in mass casualties	121	74.7
Medico-legal aspects of road traffic injuries	110	67.9
Principle of confidentiality and professional secrecy	143	88.2
Principle of patient autonomy in nursing ethics	150	92.6
Application of bioethical principles in a clinical scenario	109	67.2

#Indian Nursing Council
*Ministry of Health and Family Welfare

Most of the respondents (69.7%) could recognize an acid attack victim while 83.3% could determine the manner of injury as self-harm based on the clinical presentation in the Emergency

Department. However, only 24% were aware of the medico-legal classification of injury as grievous in the given case study. As regards the first and foremost duty of a nurse in a case of poisoning, 63.5% were able to correctly respond that treatment of the patient with emphasis on supportive care is the priority. Around 54.9% were able to form an inference based on the problem related to examination of a rape survivor. In relation to the medico-legal aspects of road traffic injuries, 67.9% could select the false statement that private hospitals are exempted from attending to medico-legal cases.

In a hypothetical case involving disclosure of a patient's HIV AIDS status to a relative over the phone, 88.2% of respondents answered correctly that they would maintain confidentiality in such a situation. A whopping majority (92.6%) knew about the concept of patient autonomy in nursing ethics while 67.2% were able to apply the principles of bioethics in a clinical scenario. According to the Chi Square Test and Fisher's Exact Test, there was no association between level of awareness with selected variables such as age, gender and duration of clinical exposure (Table 3).

Table 3. Association between level of awareness and socio-demographic variables (*n=162*)

Socio-demographic variables	Level of awareness				
	Good	Fair	Poor	Chi Square Statistics	p-value
Age					
18-21 years	25	59	12	0.9049	0.636056
≥ 22 years	21	39	6		
Gender					
Male	2	6	3	_	0.217581 (Fisher's)
Female	44	92	15		
Duration of clinical exposure					
< 1year	12	25	5	2.0893	0.719338
1-2 years	11	25	7		
3-4 years	23	48	6		

p-value < 0.05

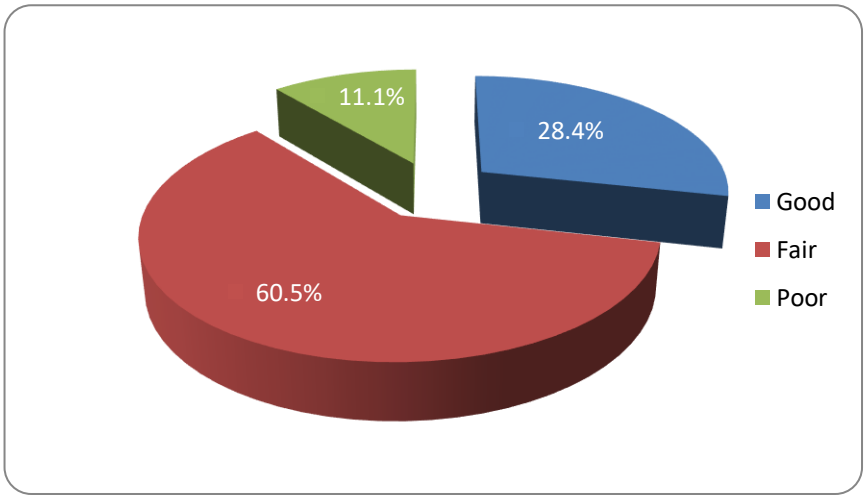

Figure 1: Level of awareness of ethical and legal issues

Discussion

The Indian Nursing Council is instrumental in evolving and administering the Code of Ethics for nurses in India [1]. Accordingly, nurses are obliged to practice within the framework of ethical,

professional, and legal boundaries [2]. An international code of ethics for nurses was first adopted by the International Council for Nurses (ICN) in 1953 [3]. Hafez FE et al stated that nursing ethics had standards to guide the nurse to conduct herself properly, make adequate decisions and carry out actions appropriate and safe for the client and thus protect her from litigation [4].

Although the legal and ethical aspects of practice is covered extensively in the B.Sc (Nursing) curriculum, its relevance may not be understood by students due to theoretical rather than practical case based approach in teaching learning methodology. A study conducted in Malaysia in 2017 concluded that adequate knowledge of healthcare ethics is required for providing holistic care to the patient. The findings of this research comprising 82.8% of females in the sample population (n=128) showed significant association between gender and knowledge of healthcare ethics among nursing students [5]. This varies from our results in that we did not find any statistically significant differences in the performance of male and female students who represented 93.2% of our sample (Table 1). Moreover, there was no relationship between level of knowledge with age and duration of clinical experience which concurs with our study (Table 3).

A study performed on 80 nursing students in Madurai revealed that 48.75% of them had inadequate knowledge on legal and ethical aspects of nursing which differs from our results [6]. Yousefzadeh S et al demonstrated that the majority (77.6%) of midwifery students exhibited moderate knowledge towards observing the ethical and legal aspects of patient rights which is in agreement with the findings in the present study (Fig 1). In addition, the results of the study showed a significant relationship between total knowledge score and studying midwifery ethical codes [7]. In a study conducted on doctors in Manipur, 99% of respondents stated that it was necessary to include the Code of Ethics in the undergraduate curriculum [8].

The findings of research conducted among nurses in Bida, Nigeria revealed that professional qualification, years of experience and rank had statistical significance on some aspects of nursing ethics and law while age and sex did not [9]. Subashini SP suggested that awareness of ethical codes in nursing curriculum and providing continuing education will optimize high quality nursing care, as nursing profession faces legal issues and challenges [10]. Research carried out among 50 staff nurses of both genders in a teaching hospital in Kerala revealed that 78% of participants had inadequate knowledge regarding law and ethics in nursing [11]. The findings of a study in Nepal showed that 58.4% of nurses had inadequate knowledge on medico-legal cases in nursing and 55.4% were not aware of ethical principles in nursing [12]. On the other hand, most of our students had good awareness of the concepts of patient autonomy and confidentiality in nursing ethics. However, awareness of some medico-legal issues such as classification of injury into simple or grievous was found lacking (Table 2).

According to Iglesias MEL et al, nurses are very concerned about situations that create ethical and legal conflicts but do not feel sufficiently trained [13]. Further, research conducted in Barbados, West Indies reveal that nurses commonly encounter legal and ethical issues but are either unaware of their importance or unable to appropriately deal with these issues [14]. Knowledge of the ethical codes and legal issues related to the profession improves the quality of care, which is the ultimate end of the profession of nursing [15]. Osingada CP et al (Uganda) recommend structured Continuing Nursing Ethics Education (CNEE) programs to address basic concepts and their application in clinical practice [16].

Conclusions

In a nutshell, we can conclude that nursing students in our research have a fair awareness of the ethical and legal aspects of day-to-day practice. The importance of knowing the Code of Ethics and Professional Conduct for nurses has to be stressed right from the undergraduate level. Moreover, relevant topics like examination of a rape survivor and medico-legal classification of injury require clarification and emphasis from time to time through seminars and planned teaching activities. There is a need to reinforce learning with a more problem-based approach and introduction of clinical scenarios to help future nurses deal competently with such issues in a post-pandemic world.

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Original Research Paper

Assessment of knowledge and attitudes about responsibility of visitors to health units during a quarantine of COVID 19 in Mongolia

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ABSTRACT

Background: Only a few studies have assessed the knowledge and attitudes about responsibility of visitors to health units during COVID-19 quarantine period. This study aimed to examine the knowledge and attitudes of clients and citizens about their role during visits to health units.
Methodology: We analyzed cross-sectional data collected from 214 participants from the Bayanzurkh, Khan-Uul, and Chingeltei districts in Ulaanbaatar, Mongolia, using descriptive and multivariate logistic regression analysis methods.
Results: Of the total participants, 47.7% (102) of the respondents were men, 52.3% (112) were women, most of them were aged 20-24 (31.3%) and 25-29 (11.7%). The average score was 2.3, the average knowledge level was 39.35%, the average score was 1.85, and the average knowledge level was 19.9%. 54.2% of respondents know, 45.8% did not know and 74.3% did not know the provisions of Article 43.2.3 of the Law on Healthcare "Prevention of the spread of infectious diseases and compliance with the quarantine regime", which is one of the main provisions that must be observed in time of COVID-19 outbreak.
Conclusion: During the outbreak of COVID-19, clients of health care organizations do not have a sufficient level of knowledge (39.3%) about their responsibilities under the law and do not follow the rules and regulations for communicable diseases.

Keywords: COVID-19, responsibility, health care, knowledge, attitude, engagement, public health emergency, COVID-19.

Introduction

According to the World Health Organization (WHO) the worldwide outbreak COVID-19 has already spread to 223 countries, and become a serious public health problem. It is a social

responsibility for everyone to contribute to the well-being of the community while raising human rights issues related to the pandemic [1-2].

The first case of COVID-19 infection in Mongolia was reported in March 2020, as a result of the rapid response, the infection was limited to people arriving from outside the country until November. On November 10, 2020, the first case of domestic infection was registered, and as of July 2021, 147,253 cases and 734 deaths were registered in 21 clusters in Ulaanbaatar and 20 aimags. Over the past month, an average of more than 1,000 cases have been reported per day, and the number of infections is growing rapidly [3-4].

During of the COVID-19 pandemic, health care providers must have the right to access quality health care, as well as a responsibility to protect their own and the public's health. According to the World Health Organization, governments, international agencies, health care organizations have a responsibility to provide health care to all people to the best of their ability, but this may not be possible during a pandemic where health care resources are limited. Awareness of these responsibilities is critical [5]. While the intensive spread of infection is not necessarily caused due to ignorance of Article 43.2.3 of the Law on Health of Mongolia "Prevention of the spread of infectious diseases and observance of quarantine regime" and protection from infectious diseases. The causes may be due to non-compliance with the regime imposed by the authorities, lack of personal discipline and lack of awareness of their responsibilities.[6] Therefore, we determined it is important to assess the legal knowledge and attitudes of health care providers about their responsibilities during the COVID-19 pandemic.

Methodology

Study design

This study adopted a cross-sectional design and the visitor health units located in Bayanzurkh, Khan-Uul and Chingeltei districts of Ulaanbaatar. A quantitative research method was used for data collection.

Study participants

The survey was conducted at the health units located in Bayanzurkh, Khan-Uul and Chingeltei districts of Ulaanbaatar. 214 citizens served by 5 health care providers were randomly selected.

Research ethics

All participants provided their written consent before participating in the study. The study protocol was approved by the Ethics Committee of Mongolian National University of Medical Sciences (MNUMS).

Statistical analyses

All statistical analyses were performed with SPSS version 22.0. The study was designed using descriptive, regression, and and the chi-squared test was used for categorical variables. A multivariate regression model was used to assess whether the knowledge of the health law is affected by the age, sex, ethnicity, education, occupation, family, type of housing, marital status, and number of health care providers. $P<0.05$ was considered statistically significant.

Results

Of the total participants 47.7 percent (102) of the respondents were men, 52.3 percent (112) were women, 87.9 percent were Khalkh, and 22.1 percent were other ethnic groups. In terms of education, 3.3 percent had primary education, 8.9 percent had incomplete secondary education, 36.9 percent had complete secondary education, 6.6 percent had specialized secondary education, and 43.2 percent had higher education. Citizens with 3 or more regular health facilities accounted for 56.1 percent of the respondents.

53.7 percent said they knew the role of a citizen in receiving medical services, and 46.3 percent said they did not know. 30.4 percent said that the Law on Health of Mongolia regulates the

obligations of citizens to receive medical services, while 34.1 percent said that they do not know what legal documents regulate it.

63.1 percent answered that they knew the obligation to follow the internal rules and regulations of the health unit, 19.6 percent said they do not know, and 17.3 percent did not answer. 20.1 percent of respondents receive information about their civil rights and responsibilities from health care providers on TV, the Internet, Facebook, and friends, while 1.45 percent obtain information from newspapers and health information boards.

54.2 percent of respondents indicated they knew of Article 43.2.3 of the Law on Health; "prevention of the spread of infectious diseases and adherence to quarantine" while 45.8 percent indicated they did not know. However, 74.3 percent did not know the specific provisions of Article 43.2.3 of the Law on Health "Prevention of the spread of infectious diseases and adherence to quarantine" which is one of the essential provisions to be followed during an outbreak of COVID-19 infection. 20.6 percent indicated they knew while 5.1 percent indicated they did not know that they have a duty to provide accurate and complete information about their own and their caregivers' physical health to medical professionals.

65 percent knew, 28.5 percent did not know, and 6.5 percent did not respond to the need to inform and explain to the relevant medical professionals if there were any difficulties in strictly following the treatment instructions and regimen.

Assessing the participants' knowledge of their civic responsibilities under the Health Law, 6.1 percent, 71.1 percent, and 13.1 percent did not know the 9 responsibilities of the law. The average score was 2.3 percent and the average level of knowledge was 39.3 percent. was. During the COVID-19 infection, citizens have a legal obligation to protect and prevent their own and their families' health. COVID-19 is a preventable disease, and it is possible to prevent infection if people follow simple routines such as avoiding crowded places, keeping a safe distance from people, wearing masks, and washing your hands regularly. 79.4 percent of the respondents said that they knew that they have a duty to protect and promote their own and their family's health according to the law. However, 42.5 percent did not receive a health check-up, 32.7 percent only did it once, and 14 percent did it twice, from our survey sample more than women have never had a medical inspection. (Table 1)

Table 1. Preventive medical examination in accordance with legal obligations (by gender)

Number of preventive examinations	Male		Female		Total		P value
	n	%	n	%	n	%	
Never	39	38.2	52	46.4	91	42.5	0.291
1 time	39	38.2	31	27.7	70	32.7	
2 time	14	13.7	16	14.3	30	14	
3 time	6	5.9	9	8	15	7	
4 time	4	3.9	4	3.6	8	3.7	

Multivariate regression model was used to assess whether the age, sex, ethnicity, education, occupation, occupation, family, type of housing, marital status, and number of health care providers affected the knowledge of health law.

$$y_i = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2i} + \cdots + \beta_k x_{ki} + e_i \qquad i = 1, n$$

y_i is the knowledge of the model dependent variable or health law, β_i is the parameters of the model, x_{ji} is the explanatory variable or independent variables, and e_i is the expression of the model error.

The analysis of the multivariate regression model was divided into 5 age groups: total sample, under 25 years old, 25 to 40 years old, 40 to 60 years old, and over 60 years old. In order to test the reliability of each model, the heteroskedastic criteria were considered to be heteroskedastic, or the variances of the error expressions were equal, and the Ramsey RESET test concluded that the model was correct and there were no missing variables.

In addition, if the variables are interrelated, regardless of the design optimization, the accuracy of the model evaluation will be lost and the statistical significance of the coefficients will be affected. Therefore, the correlation between the independent variables was examined to see if there was a relationship between the multicollinear or independent variables.(Table 2)
The analysis of the multi-variate regression model was divided into 5 age groups: total sample, under 25 years old, 25 to 40 years old, 40 to 60 years old, and over 60 years old. The results show that the weak interrelationships between the variables do not raise the issue of multi-collinearity in model evaluation. (Table 2)

Table 2. Correlation matrix of independent variables

Indicators	Age	Housing type	Education level	Number of families	Number of visits to health facilities	Employment	Marital status	Ethnicity	Profession	Gender
Age	1.00	-0.07	0.04	-0.10	0.37	-0.05	-0.33	-0.06	-0.07	0.03
Housing type	-0.07	1.00	0.18	-0.07	0.02	-0.18	-0.06	-0.05	0.03	0.10
Education level	0.04	0.18	1.00	-0.05	0.06	-0.29	-0.10	0.08	-0.07	-0.04
Number of families	-0.10	-0.07	-0.05	1.00	-0.10	0.03	0.04	-0.08	0.14	-0.11
Number of visits to health facilities	0.37	0.02	0.06	-0.10	1.00	-0.05	-0.07	0.02	-0.16	-0.04
Employment	-0.05	-0.18	-0.29	0.03	-0.05	1.00	0.06	-0.06	0.25	-0.08
Marital status	-0.33	-0.06	-0.10	0.04	-0.07	0.06	1.00	-0.05	0.04	-0.03
Ethnicity	-0.06	-0.05	0.08	-0.08	0.02	-0.06	-0.05	1.00	-0.10	0.01
Profession	-0.07	0.03	-0.07	0.14	-0.16	0.25	0.04	-0.10	1.00	0.03
Gender	0.03	0.10	-0.04	-0.11	-0.04	-0.08	-0.03	0.01	0.03	1.00

When the sample, which included a total of 214 people, was evaluated, the coefficient of determination of the model was 0.07, indicating that the evaluation of the model was not good. In terms of parameters, all indicators except education were not statistically significant, and education was statistically significant at the 1 percent level. In other words, the higher the level of education of the respondents, the higher their knowledge of the health law.
For the second model, young people under the age of 25, in addition to their level of education, ethnicity is important, and statistically significant at 1 percent. The negative sign indicates that the higher the non-Khalkh ethnicity, the lower the knowledge of the law on health care. A value of the coefficient of determination of 0.17 indicates poor model representation.
The third model, for young people aged 25 to 40, has a coefficient of determination of 0.36, indicating improved representation compared to the previous two models. Also, the largest number of variables considered in the model was statistically significant. Good housing conditions, a high level of education, frequent hospitalizations, and the type of work they do have a positive effect on their legal knowledge.
For the fourth model, the 40- to 60-year-olds, the coefficient of determination is reduced and the model's representation is impaired. It also appears that better housing conditions and occupations have a negative impact on the design, or that better housing conditions and better legal knowledge are less important.
For the fifth model, over the age of 60, although the values of the coefficients of determination of the model were better than in the previous models, none of the parameters were statistically significant. In other words, the factors considered in this model have no effect on the knowledge of civic responsibilities set out in the health law. The main conclusion to be drawn from this is that there are no factors related to improving legal knowledge for retirees. Ethnicity was excluded from the model evaluation. The main reason for this is that everyone in this group indicated they were of Khalkh ethnicity.

Taken together, the five models show that factors such as age, family size, marital status, occupation, and gender have no effect on health law knowledge. (Table 3)

Table 3. Results of the evaluation of the regression model of civic awareness

Indicators	Total	<25	25=<x<40	40<=x<60	60<
C	0.59	1.49	-2.14	5.43	-4.58
Age	0.00	-0.02	-0.04	-0.05	0.16
Housing type	0.06	0.20	0.33***	-0.37*	1.46
Education	0.50***	0.68**	0.60**	0.02	1.20
Number of families	0.03	-0.11	0.06	0.20	-0.68
Number of visits to health facilities	0.01	-0.29	0.53**	-0.09	-0.26
Employment	0.04	0.03	0.32**	-0.33**	-1.77
Marital status	0.27	0.41	0.00	0.60	-0.69
Ethnicity	-0.10	-0.44***	0.24	0.32	-
Profession	0.04	0.03	0.07	0.19	-0.41
Gender	0.39	0.17	0.05	0.61	-0.40
R2	0.07	0.17	0.36	0.24	0.38
Sample size	214	86	60	55	13

Note: *** 1 percent statistically significant, ** 5 percent statistically significant, * 10 percent statistically significant, Dependent variables: Knowledge of civic responsibilities set out in the Health Law

We examined the attitudes of the survey participants on how they fulfill their civic responsibilities when receiving medical care. Of all the participants, 68.7 percent of the respondents did not inform us about the responsibilities of medical professionals when providing services to clients, 65.4 percent did not fulfill their responsibilities and 51.4 percent did not follow the internal rules and regulations of health organizations. However, 65.4 percent of the respondents believe that it is important to respect the rights of others when receiving medical care during this epidemic, and 69.6 percent believe that citizens should be aware of their role in improving health care.

Discussion

The present study found that during the outbreak of COVID-19, clients of health care organizations do not have a sufficient level of knowledge (39.3%) about their responsibilities under the law and do not follow the rules and regulations for communicable diseases. Knowledge levels varied dependent on the age, level of education, living conditions, ethnicity and occupation of the citizens. This COVID-19 study aimed to assess the level of knowledge and attitudes of citizens receiving health care during the pandemic, as defined in the Mongolian Health Law.

To our knowledge, the present study is the first to determine the level of knowledge and attitudes of citizens about their role in communicable diseases during the COVID-19 epidemic in Mongolia. There would also appear to be to inadequate research into this issue in other countries although it is recognized that knowledge and attitudes will vary across different countries dependent on the specific conditions that exist in each country.

One of the issues that must be addressed during the COVID-19 pandemic is the adherence to infection control regimes and the implementation of laws, rules and recommendations aimed at preventing and reducing communicable diseases, recognizing that the rights of one person to another are limited within the social framework of the country. On the other hand, citizens should be aware of their legal responsibilities, implement them, and act responsibly, and understand that working with health organizations to protect their health can stop the chain of infection and reduce its spread [6-9].

Furthermore, the WHO recommends that in order to reduce the spread of the COVID-19 pandemic, citizens should have the health knowledge to perform simple actions such as washing their hands, wearing masks, and keeping a safe distance from other people, and be responsible for adhering to socially responsible standards [10]. Health education and civic awareness are affected by our level of education [4] with 12.5 percent of those with primary education unaware of their civic responsibilities, and 87.5 percent were unaware of one of their civic responsibilities under the health law, consistent with Leena Paakkari's et al [11].

On the other hand, ethics and accountability are important in respecting vulnerable groups in assessing the policies and risks of government and health care in order to reduce and stop the epidemic. This is due to the fact that vulnerable citizens' lack of ethical responsibility reduces risk [12]. In our study, as is important for young people under 25 to have an ethnic background in addition to their level of education.

Knowledge of civic responsibilities was positively influenced by the number of visits to the hospital and the type of employment, and the better the housing conditions for those aged 40-60, the better the legal knowledge of their civic duties. However, there were no factors related to improving legal knowledge for retirees. The influence of age and education and employment on knowledge levels was consistent with the findings of Sulistyawati Sulistyawati and Bates and others [13-14]. This is due to the fact that awareness of the role of citizens in the event of a pandemic varies with age, and the ability of citizens to act in terms of organization, unity and common interests is consistent to the survey conducted in Chile [15-16].

Our survey found that the level of knowledge of citizens about their civic responsibilities under the law is 39.3 percent, which means that they do not fulfill their responsibilities to live a healthy life, receive health education, prevent disease, and promote mental health, especially during quarantine. This result is consistent with Md Mahbub Hossain's et al survey [17]. Therefore, in order to increase the level of knowledge on civic responsibilities set forth in the health law, it is important to educate non-Khalkh ethnic youth about legal issues in terms of education, living conditions, occupation and youth. It is important to coordinate and implement educational training and advocacy activities, as this demonstrates the importance of knowledge. Increasing access to information and intensifying health education in the health sector is important for the prevention of COVID-19 pandemic and the improvement of knowledge and skills about civic responsibilities [18].

According to Bester and others, proper social organization and individual responsibility during a pandemic are critical to a country's security. The results of our study show that the responsibility of citizens is important to protect the well-being of society from the effects of the plague and to improve effective response levels to the epidemic [19]. Furthermore, French Bourgeois and others [20] found that the role of civics and social norms in adhering to public health recommendations for COVID-19 infection. It has been established that civic duty is important to follow health advice and to understand one's responsibilities. While 77 percent of Canadians follow public health guidelines, 54.2 percent in our survey do not. This proves the importance of training and educating citizens in terms of their social responsibilities.

One cross-sectional study reported on some of the important ethical questions that arise in the context of the coronavirus epidemic and highlighted the need for governments to build trust and solidarity with its citizens [21]. In our study, civic awareness and knowledge of personal social responsibilities was poor and has resulted in the rapid spread of COVID-19 infection levels.

Also, according to Gostin Lawrence O et al, without human rights education, human rights becomes a public health issue. This survey emphasized that accountability was more important than human rights in an unprecedented epidemic [22].

An Ethiopian cross-sectional study showed that a lack of education in multi-factor logistic regression analysis and a lack of information sources contribute to poor client prevention practices for COVID-19 infection, and correlation analysis has shown a positive correlation between knowledge and practice [17,23]. In the regression analysis, citizens' knowledge and skills depended on education, living environment, occupation [14,25], and ethnicity (minority), which was similar to the results of a survey in Nepal [24]. Meanwhile, in our study, the level of knowledge of citizens over the age of 60 had no effect on their civic responsibilities, and the level of knowledge of

uneducated people was inadequate, which is consistent with the study of Emily Ying Yang Chan and others [26].

In order to reduce the spread of COVID-19, it is very important to know, observe and be responsible for the civic duties set forth in the laws, rules and regulations of the legal framework.

During the COVID-19 infection, visitors to health facilities have a low level of knowledge about their legal responsibilities, unsatisfactory compliance with communicable disease regulations, and a lack of awareness of their responsibilities. This has led to an increase in the spread of the COVID-19 infection. Therefore, it is necessary to organize trainings and advertisements aimed at reducing the spread of COVID-19 pandemic, taking into account the age, ethnicity, education, living conditions and occupation of citizens, and to promote laws and regulations on the rights and responsibilities of citizens during periods of communicable diseases like COVID-19.

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Position Paper

Physiotherapy Ethical Guidelines Based on UNESCO's Universal Declaration of Bioethics and Human Rights

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The Pandemic of COVID 19 brought to the front many a suffering of mankind and ethical issues at large related to beneficence and harm and equity, equality, justice in terms of resource allocation and patient care. As The entire health care community came together in solidarity to serve to combat and fight the pandemic, Physiotherapist formed an equally important and integral part of the team. The International Leaders of Physiotherapy Community present these guidelines which intend to highlight the ethical dimensions and guide ethical behavior as they apply their knowledge, skills and clinical experience to the care of patients and collaborate with other professional colleagues all over the globe.

These guidelines are based on the principles of the Universal Declaration of Bioethics and Human Rights adopted in United Nations at its 33rd General Assembly in 2005. These principles coupled with the discussions and deliberations held at the international webinar on Bioethics and COVID 19 "Ethical Challenges faced by Physiotherapist around the globe" on 6th and 13th September by Department of Education, UNESCO Chair, HAIFA offers a pragmatic lens to view the global pandemic and guide ethical behavior. Though specific aspects may vary based on socio cultural norms, Regulations and law of the land, the core ethical principles need to be largely adhered to while the physiotherapist strive to uphold the standard of care

The following Core Ethical Principles must be considered:

1. **Nonmaleficence:** "First Do No Harm". Physiotherapists ought to promote and protect decisions and/or actions that will minimize, mitigate, or prevent harm. In absence of a skilled competency as in treating patients the physiotherapist should undergo training to acquire the needed knowledge and skill. 'Do no harm' is the key responsibility of the Physiotherapist in all settings and needs to balance rights and duties to protect those in marginalized positions. They should provide appropriate direction and support for less experienced colleagues and support- staff and incorporate safety and risk management strategies within physiotherapy practice to ensure the safety of patient and staff
2. **Beneficence:** "Do Good Always": It is the intent of striving for net benefit for individual involved. This bond must be founded on professional competency and ethical foundations. The moral choice is what will maximize the chances of effecting the greatest good for the greatest number. Physiotherapist at all times will promote decisions and actions that will help in maximizing the individual's potential towards improved quality of life and good health and minimize disability. Where need be the greater benefit of community needs to be considered over an individual and health needs of the community should be advocated. Physiotherapists should be able to define scope of practice and maintain professional boundaries while administering care to the patient except in life saving situations.
3. **Human Respect and Dignity:** Physiotherapists ought to promote and protect an individual's right to dignity at all times. People have a right to life that they can enjoy in best of health and when ill to be treated with care and compassion by the physiotherapist. They have right to access information regarding their treatment and best practices available and the right to make informed decisions. The privacy and confidentiality of patient ought to be protected at all times. The physiotherapist respects the patient's bodily integrity and mental well being and conducts themselves respectfully towards the patient and family or caregivers
4. **Autonomy:** Intents respect for independence of thought, intention, satisfying the criteria of full disclosure of information, comprehension of the information, and a voluntary decision that is made without undue influence or coercion. Physiotherapist ought to respect and support a person's right to their own decision making process and choices. Upholding the principle of do no harm if the patients decision is leading to harm, a full disclosure with respect to benefit and harm should be done to the level of understanding of the patient or caregiver to make a final choice. Physiotherapist practices with due care and respect to patient beliefs, family values, culture without imposing their own values and beliefs. A respectful partnership for shared decision-making involving assessment, treatment plan and revisiting goals needs to be established. Where the patient is not in the capacity to make decisions, past wishes if any of the patient should be adhered to. Autonomous decision making may be achieved by an individual alone or by an individual with legal guardians, including community members. The patient holds the ultimate decision regarding their willingness to be engaged in therapeutic modality. Notwithstanding that autonomy, public health priorities and goals must be made clear to the patient in order to preserve the health of the community. Furthermore, there may be occasions where the patient is unresponsive and under the supervision of a caregiver.

5. **Justice:** Justice includes issues of appropriate allocation of the resources at the right time to patients who need care, Health inequities needs to be addressed to avoid unjust and unfair health outcomes. Burdens and benefits must be distributed equally and equitably. Physiotherapists need to seek knowledge about how socio-cultural disparities, economic health, racial discrimination can lead to poor health outcomes. They need to identify the factors that can cause social injustice to marginalized and vulnerable population. They need to be aware of the social determinants of health and promote fairness through the equal and/or equitable distribution of health burdens and benefits. There is a need to deploy the right therapist-patient ratio, with the right qualification and experience to protect and promote patient safety. Equality and equity in all aspects from assessments to therapeutics to ensure fairness should be promoted using a coherent, robust and transparent rationale for resource allocation. They should advocate support of the government bodies, policy makers and health care providers for fair allocation, reduce health disparities and inequalities, and improve access to services
6. **Truthfulness or Veracity:** Intents commitment to openness and honesty. Patient care by the physiotherapist should be based on scientific knowledge and must be conveyed to the patient accurate and relevant information truthfully. Each patient nevertheless must be approached individually, and at a level that addresses appropriately his or her needs and interests. If there are any conflict of interest they should be appropriately declared or minimized. They should be open and honest in case any wrong done during care and treatment and take appropriate steps to correct it.
7. **Solidarity:** It is intents working toward a common social objective to keep people healthy and safe. Physiotherapist acts in solidarity with other professionals to promote health of community or society at large. They should advocate patient and public understanding of the role of physiotherapy. They would collaborate in unison for research, production and accessibility of appropriate therapeutic treatments for the good and safety of all. Relevant data, knowledge and findings should be promptly shared with others in order to prevent and/or reduce harm.

A CALL TO ACTION

Members of the global physiotherapy panel had opportunities to participate in International Webinar on Bioethics and COVID 19 through acts of solidarity and cooperation, by coming together as a community of Physiotherapy practice for the webinar series and through ongoing collaborative work to produce a publication. The Panel discussed challenges, including the inequitable allocation of PPE, Safety, economics, mental health ,governance, education and research

The panel of global physiotherapists, which represents 10 individuals and 10 nations around the world, calls on governments, health care organizations, and other stakeholders to renew their commitments to more fully support Physiotherapist and their essential work with multi-disciplinary teams and an inter professional collaboration across diverse health care practice settings.

The Physiotherapist have been recognized as an essential health care provider and key stakeholder in global health, both during crisis and beyond during this coronavirus/COVID-19 pandemic.

This document presents a call to action and proposes international health care ethics guideline recommendations in response to the COVID-19 pandemic from a global Physiotherapy perspective, in the context of UNESCO's Declaration

The panel members recommend the following "Call to Action" to be implemented and to continue in an ongoing basis:

"Call to Action" Areas of Consideration

1. Protect and Promote Physical and Psychological health & Safety of Physiotherapist working in various areas/environments around the world. Assessment, management, and mitigation of risk in various health care settings

requires access to up-to-date, comprehensive, and timely information that is delivered via multiple modalities for communication.

2. Rehabilitation providers in all settings should be ensured personal protective equipment and training to use it effectively. Reasonable expectations for health protection and promotion of the many must be measured against legal and human rights of individuals, and through a lens of equity.
3. Assistance and training in Triaging of various services offered by Physiotherapist involved in different work settings should be encouraged,
4. Respect and recognize physiotherapist as Key stake holders and support Issues with respect to willingness and consent from Physiotherapist to provide their services
5. Support and availability of special allowances for special duty, Compensations, leaves and access to protective equipment as for other medical doctors.
6. Support Leadership opportunities and offer formally designated leadership positions during legislations, public health and health policy development.
7. Help formulate policies at government and non -government organizations to protect the right of physiotherapist and physiotherapy as profession globally, Physiotherapists must be included in all levels of planning and protocol development, including stewardship and allocation of resources with equality in various health care domains
8. Ethical decision making can be promoted and enhanced through activities that support physiotherapist as professionals and their personal moral values as individuals and community members. Ethical issues in practice can be addressed with appropriate knowledge sharing and regularly, engaged dialogue with stakeholders who represent diverse perspectives.
9. National organizations, associations and councils should have an engaged role in supporting research contributions and for the uptake and utilization of evidence-informed findings, engaging all members across all health care sectors to respond in solidarity and cooperation. Such actions recognize and value the importance of global efforts of physiotherapist as community of practice and enhance much needed access to quality information to inform decision making, strengthen human resource skills.
10. Essentiality of Rehabilitation services needs to be recognized for covid 19 and non covid 19 patients to optimize functioning and reduce disability. Remote delivery of care and virtual rehabilitation needs to be optimised with financial, infrastructure, resource and training. The global barriers to telemedicine which include lack of technical knowledge, resistance to change, cost, and a lack of reimbursement for services provided should be addressed.

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Ethical Viewpoint Paper

Failure Of Health Diplomacy To Communicate Covid-19: Political, Ethical, Legal And Medical Perspective

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Health diplomacy (HD) is an arising field that merges foreign affairs to medicine and law, with a focus on negotiations that impact the global policy environment for health [1]. Successful health diplomacy relies on political and diplomatic experience and practice, which must be combined with public health knowledge and evidence-based medicine [2]. It plays a vital role in sharing information which makes a difference to (un)successful communication. The HD core principle relies on the concept of bringing nations together in diplomatic missions to confront public health threats that all countries need to prepare for [3]. The pandemic warning system from political administrations failed when SARS-CoV-2 unexpectedly hit the world, although lessons were to be learned from emergency preparedness and response to HIV and EBOLA [4]. The COVID-19 pandemic has demonstrated the vital importance of global solidarity to confront common public health warnings [5]. Despite the expectations and responsibility of the World Health Organization (W.H.O.) in supporting countries to respond in a coordinated way and to bring together decisions aimed to jointly address the pandemic, it has an enormous global impact and has led to substantial misunderstanding worldwide.

The biggest communication issue from the beginning of the pandemic was the report that there is no presence of human-to-human transmission, which caused a delay in implementation of public health measures like wearing masks, keep social distancing and, taking the situation seriously. The protective measures varied among countries and caused global distrust and protest when wearing the mask became mandatory. Without the United Nation's guidance, countries have imposed quarantine and social distancing measures on their own. That concerns the implications and enforcement of the Universal Declaration of Human Rights [6]. Since then, a reliable source of trustworthy information was very difficult to obtain, as every country's government provided the public with their personal perspectives. Decisions were mostly made by the experts in the department of civil protection, which were presented as national heroes. The points of view divided both, the citizens and the professionals.

For instance, information on the treatment procedure with Hydroxychloroquine (HCQ) as Compassionate Therapy of COVID-19 has shown the rise and fall. Some clinical observational studies have suggested therapeutic benefits of Hydroxychloroquine in COVID-19, whereas other studies have shown mixed results [7]. The study made by Risch et al in 2020 for outpatient treatment efficacy received strong scientific criticism and raised serious concern for openly promoting HCQ without strong clinical trial evidence.

Further, the French authorities warned against the use of ibuprofen in patients with coronavirus disease [8], which was afterward denied. Side by side, as the vaccine developed so did the negotiation process in delivering vaccines started, but without equal distribution globally. The Guardian reported on India's Covid catastrophe by witnessing a crime against humanity and was

seeking help [9]. It should have been thought that the problem could not be solved without considering helping low-income countries.

While awareness of the side effects of vaccines grows, a bigger problem loomed as many millions have been depending on it. It's been one step forward, two back for AstraZeneca's COVID-19 vaccine [10]. A report from the German economic newspaper Handelsblatt's "Setback for vaccine" ran as its top story subtitled, "The AstraZeneca vaccine apparently has an effectiveness of only 8% in the elderly [11]. Just a few days later BBC reported that most adults under the age of 40 will be given an alternative to the Oxford-AstraZeneca vaccine due to its association with rare blood clots [12].

Canada and Germany joined Iceland, Sweden, Finland, and France in recommending against this vaccine's use in younger people, who seem to be at higher risk for developing the clot and are less likely to develop severe COVID-19. The Goethe University from Frankfurt highlighted that the approach makes sense given that other vaccines are available if we do not have just one type of vaccine [13]. The European Medicines Agency (EMA) says it is not yet clear what the risk factors are, and that the benefits of the AstraZeneca vaccine continue to outweigh the very low probability of side effects. Furthermore, there were also reports of side effects after other types of vaccines; Johnson & Johnson, Pfizer and Moderna [14]. Following several cases of individuals incidentally vaccinated with 2 different vaccines, it was presented to the public that all vaccine doses need to be the same to provide an appropriate level of effectiveness. Not long afterward, some countries have adopted an unproven strategy: switching shots midstream believing that it would be extremely likely that mixing vaccines will still produce a strong immune response [15].

Any of this public information has not been officially confirmed or denied by coordinating authority and it leads to a complete vaccine mess and allowed space for the anti-vaxxer movement to flare up. Therefore, each country adopted instructions of safety and implemented an age limit, (under 30, under 40, or 50, etc.) from their evaluation, in the same way as they organized healthcare without common opinion and uniform strategy for hospital management. However, questions have arisen about who is the main coordinating authority as The World Health Organization cannot "overrule" the Center for Disease Control and Prevention (C.D.C.) because they are separate agencies but both make recommendations based on expert advice. The C.D.C. relies on advice from its internal experts while the W.H.O. convenes panels of independent experts from around the world [16].

Now, it is critical to review the shortage of guidelines and protocols sent to the hospitals for disease control for non-COVID patients. Healthcare professionals were not given clear instructions on how to organize healthcare and at the same time, their responsibility was sought, nonetheless without national support. No country, hospital, or clinic can keep its patients safe unless it keeps its health workers safe [17]. The numerous hospital departments were completely empty, while on COVID departments worked doctors from different specialties as physiatrists, ophthalmologists, etc. In the face of incredible efforts to provide full care for patients, putting themselves at risk, it consequently resulted in burnout syndrome of health workers [18].

The growing awareness of ethical and social determinants of health has also made international health negotiations increasingly political, diverse, and multi-sectoral [19].

The introduction of Coronapass or Covid's safe card is an ethical and legal minefield. The bioethical question is the logic behind the coronapass, which excludes people from social life because of their presumed health [20].

Although it has an undoubtedly safety value, the coronapass can be criticized from a legal point of view in that it will inevitably create discrimination [21]. Accordingly, the toughest privacy and security law in the world, the adoption of certain measures taken to govern the COVID-19 emergency generates certain data protection issues. It is important to have a full understanding of what it is to be done under the current General Data Protection Regulation [22]. The outbreak of COVID-19 subsequent measures taken by the government and public authorities raise several challenging issues for employers [23].

The announcement of reopening borders and traveling to and from abroad raises awareness of safe free movement. The information changes from day to day, which particularly affects tourist

countries [24]. The fear of covid restrictions still continues to dominate, especially regarding covid-test on the borders, which shows a failure in communication from politics to clinics [25].
Responding to emergencies, whatever the cause presents a very big challenge for successful world health management. Diplomatic rule of control emergency operation is unique and only when politics admits mistakes could learn from them. As a result, when it comes to planning ahead for positive outcomes, we should be ready to face the new threats and sustain public confidence.

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Ethical Viewpoint Paper

When Providers Become Seekers: The Harsh Ironic Reality

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The importance of mental health has been recognized by World Health Organization (W.H.O.) since its origin and is reflected by the definition of health in the W.H.O. Constitution as "not merely the absence of disease or infirmity", but rather, "a state of complete physical, mental and social well-being" [1]. The fact that healthcare professionals are prone to mental health issues is not a recent finding. Numerous articles on the alarmingly high incidences of stress, anxiety, psychological burn out and depression amongst doctors have been published in the past [2]. The scenario concerning medical students is no different. Medical education has known to impose a significant psychological stress on undergraduate students [3]. Considerable degree and severity of psychological morbidity has been reported among medical students ranging from anxiety, stress, interpersonal problems, depression and suicidal ideation to psychiatric disorder [4-8] and they tend to have greater psychological distress than the general population [9]. The goal of medical education is to graduate knowledgeable, skillful and professional doctors and the current medical school curriculum has been designed accordingly. However, certain aspects of training may have unintended detrimental effects on students' mental health [10]. Previous studies have reported a considerable degree of depression, anxiety and stress among undergraduate medical students and these levels are found to be significantly higher compared to students from other streams [11]. A study conducted in Bangalore, shows that 32.9% of surveyed students suffered from stress, 46.7% from anxiety and 33.7% from depression in varying degrees of severity [12].

While the prevalence of mental disorders was bad amongst undergraduate students, the medical interns fare much worse. Although the compulsory rotational internship does provide one with an all-round exposure, stress and anxiety commonly prevails owing to multiple factors such as long working hours and pressure of preparation for the entrance exams [13]. The to-be-introduced NEXT examination gives a glimmer of hope in this context and its impact remains to be seen [14]. While the causes behind these shockingly high numbers of cases of depression and suicide rates amongst medical students, hostel boarders and localities alike, are well reported, there seems to be a dearth of analysis regarding the inadequate resolution of these issues. So why aren't we able to rectify this worsening trend?

The seeds of this issue are sown right in the early days of our secondary education. The teachers and the ability of the student to identify his/her preferred career choice are the factors that significantly influence the career decision and aspirations of students [15]. However, anyone with a more than average intellect, ability to study long hours and a knack for biology over other subjects is proclaimed by the parents, teachers and colleagues to be destined to enter the profession of medical sciences, or sometimes even the fact that the parents own a private hospital set up, is enough incentive for children to pursue it. Are these criteria enough for a young, naive mind to make such a huge life decision? Can a mere inclination towards biology or dislike for mathematics make one competent enough to understand whether one would prefer a career in healthcare? Shouldn't one be guided regarding career choices by professionals in various fields? If yes, can the

school administration provide for the same in collaboration with the professional institutes in its vicinity? A general observation is that there is a rise in the proportion of students who regret enrolling in M.B.B.S and given a chance again, would rather opt for another stream [16].

The reasons for the worsening trends are plenty, but without any doubt, the lack of awareness and our failure to acknowledge mental health issues just as genuine and concerning as physical problems tops the list. This ignorance has led us to an ironical state of caregivers, who should be the most well informed regarding this issue, being the biggest sufferers. While lectures and symposia are important means of de-stigmatization, the simplest yet most effective measure would be to openly talk about it in our routine lives. As students staying in hostels, our colleagues become our family away from home. Often, the first person to notice stress associated changes in our behaviour is our roommate or a close friend. Hence, sessions must be held, not just to help one acknowledge the disease, but also to identify the signs of depression or anxiety in one's colleagues during the formative years of M.B.B.S. Crossing the first barrier of acceptance, the next hurdle lies in approaching a professional. For a medical student staying in the premises of a hospital, approaching a psychiatrist may seem to be an extremely easy process. Yet, most of the students are reluctant to take that step; and even if they eventually agree to seek professional help, they would prefer to visit a mental health professional outside the institute. I firmly believe that if the students, in their very first year in college, are introduced to the faculty members and residents of department of Psychiatry, such ice-breaking sessions would reduce inhibitions to approach them in the event of mental health issues. Another aspect is that of the students' parents. The awareness regarding mental health problems, although slowly increasing, is abysmally low in people not belonging to the medical profession and hence, just like in cases of substance use disorder or dementia, counselling of caretaker should be an important step in tackling this problem. If this intervention could be done at the start of the course, the parents would be much more vigilant and receptive of their ward's mental health issues.

Prevention is better than cure, and rightfully so, the progression of temporary sadness to depression could be broken with early intervention. M.B.B.S. is perceived by many to be the toughest undergraduate course in India, and while we may not be able to change this fact, suffering in silence is not the way to deal with it. Numerous relaxation techniques such as yoga, sports, excursions, etc should be taken up and students must be encouraged to do so by their peers and teachers. The incorporation of yoga sessions in the recently introduced Competency Based Medical Education curriculum is a good start in this context. While one may argue about the different causes and factors behind the scenario, the fundamental question still remains - "Why are we still not able to do anything – preventive or therapeutic? How many more students would have to lose the battle for us to acknowledge the strength of the enemy?".

Medical students are generally ones with an excellent academic record throughout their schooling. These are students who are habitually used to meticulous planning and having full control over their academics. The same approach during M.B.B.S is neither possible nor necessary. Ups and downs are an inevitable feature of this roller coaster ride where change is the only constant. One must learn to adapt and make oneself comfortable with the unpredictability of this course; the sooner the better. Having a preconceived notion of how the time at college should be, personally, socially or academically will only make us rigid and inflexible, ultimately hampering our capability to adapt and modify our approach according to the circumstances. Unfortunate events and rough patches are bound to befall us, and more often than not, we won't have a say in these instances which break us. Nevertheless, our success lies in the ability to 'NEVER GIVE UP' and the choice between giving up and going; that is completely in our hands.

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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.

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