

Title: Ethical issues encountered at doctor-patient interface in Indian health care setting: A multicentric cross-sectional study

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Abstract:

The ethical issues in the Indian health sector are constantly rising. To investigate the nature, occurrence of ethical dilemmas encountered by physicians and post-graduate (PGs) students in Indian health care setting and to explore the influence of bioethics education on the ethical issues encountered, a cross sectional multicentric survey was conducted using a newly designed validated questionnaire. Out of 205 respondents, 71.7% were PGs and rest were clinicians. Compared to PGs, larger proportion of clinicians encountered ethical issues with more frequency and needed advice to deal with them ($p < 0.001$). 34.5 % of clinicians and 31 % of PGs had some kind of bioethics education. Agreeing to having taken some kind of advice in solving ethical issues weakly correlated with encountering ethical issues and their number. A weak correlation was observed between having undergone some kind of bioethics education and frequency at which ethical issues encountered. The qualitative data on ethical dilemmas encountered generated eight themes namely, 'issues related to patient's autonomy', 'end of life issues', 'issues due to financial constraints', 'beginning of life issues', 'communication issues', 'issues related to privacy and confidentiality', 'issues due to hospital policies and resources' and 'other issues'. Some of the ethical issues faced in Indian context were different from those reported in literature from the West. There is a need to create awareness among clinicians and PGs and train them to deal with these issues.

Introduction:

The ethical issues in the Indian health sector is constantly rising due to the imbalance in the disease burden, limited health care services and rise in the health care costs.^{1, 2} In addition, diversity in cultural practices among Indian patients and other stakeholders of health sector might put health care providers to face ethical dilemmas. This might complicate the process of ethical decision making. However, the fundamental duty of health care professionals will remain same, i.e to keep the patients' interest above all by adhering to the ethical principles including, autonomy, beneficence, non-maleficence and justice.

A study done using medical records of patients admitted to the intensive care unit at Columbia University Medical Center, New York, identified ethical issues faced by consultants as those related to withholding or withdrawing treatment, appropriateness of treatment, goals of care, resuscitation issues, issues related to legal-ethics interface, compromised decision making capacity in patients, psychiatric issues, family conflicts regarding patient's treatment.³ Another study done with physicians, who were selected randomly throughout the United States, identified common ethical dilemmas such as decision making at end-of-life, issues related to patient autonomy and conflict among doctors and patient relatives involved in decision making.⁴ Another study reported, withdrawal of life support system as the main reason for requesting ethics consultation services.⁵ A study done in Bulgaria identified ethical issues related to relationship with patients and relatives and interprofessional issues as major dilemmas that

needed clinical ethics consultation.⁶ As per our knowledge, a systematic study on ethical issues faced by clinicians in India, using phenomenology approach has not been done.

In India, the studies on these aspects are limited to knowledge, attitude and practices (KPA) of clinical ethics.^{7, 8, 9, 10} All these studies had explored KPA with medical education perspective, exploring the need for introducing ethics education in medical curriculum. These studies looked at doctors' knowledge regarding confidentiality, paternalistic behaviour, patient's autonomy, rights of doctor and professionalism.^{7,8,9,10} Though in 1997, Medical Council of India (MCI), the regulatory body for medical education in India, required teaching of ethics in medical education, so far only legal ethics is covered by the Department of Forensic Medicine. No report on standardised medical curriculum for teaching medical ethics with the provision of assessment in undergraduate and postgraduate education is published as yet in India. Recently MCI unsuccessfully tried to make it compulsory from 2017 onwards to include a structured attitude and communication module in medical curriculum (ATCOM module) which emphasises on training attitudinal and communication competencies including ethics. There are certain private Institutions like Manipal Academy of Higher Education, Manipal; Yenepoya (Deemed to be University), Mangalore and PSG Institute of Medical Sciences and Research, Coimbatore have recently developed structured clinical and research ethics Certificate and Diploma courses for faculty, researchers and postgraduate students. In the Government sector the Indian Council for Medical Research (ICMR) and Clinical Development Services Agency (CDSA) have been conducting workshops for researchers, faculty and ethics committees. In addition, Forum for Ethics Review committees in India (FERCI), various ethics committees and Centre for Ethics in various institutions conduct training courses for the ethics committee members. The impact of bioethics education on the management of ethical issues by the clinicians and students in the clinical practice has yet to be explored in-depth.

Objectives of this study were to investigate the nature, occurrence of ethical dilemmas encountered by physicians and post-graduate students in clinical practice and to investigate the influence of bioethics education on the ethical issues encountered.

Methods:

Study design and settings: This was a multicentric, cross sectional survey conducted in the year 2017. The three study sites were from southern part of India in the Karnataka state namely, Kasturba Hospital, Manipal; Dr.TMA Pai Hospital, Udupi and KS Hegde Charitable Hospital, Mangalore. The 4th study site was Shree Krishna Hospital, Karamsad from Gujarat state in India. The study was conducted after obtaining permission from Institutional Ethics Committees of the respective sites. In addition, written informed consents were obtained from all participants.

Kasturba Hospital (KH), Manipal, situated in the Karnataka State is a 2032 bedded tertiary care private hospital with OPD facilities with all clinical disciplines and is fully equipped with departments to facilitate treatment of a wide range of diseases. In addition, 280 bed cancer

hospital is also a part of KH. Majority of patients visiting this hospital are from Karnataka, Goa and Kerala states in India.

Dr.TMA Pai Hospital, Udupi is a secondary Healthcare center, with 200 beds and has General Medicine, Obstetrics & Gynaecology, General Surgery, Paediatrics, Orthopaedics and Dermatology departments. It provides health services to Udupi district in Karnataka and neighbouring localities.

KS Hegde Charitable Hospital is a tertiary care, 1200 bedded hospital caters to the needs of people from Karnataka and Kerala. The hospital has OPD and in patient services in all clinical disciplines and like KH, it has state of art facilities.

Shree Krishna Hospital, Karamsad is a tertiary care 500 bedded hospital which caters to the needs of people from Gujarat state in India. It has OPD and in-patient services in all clinical disciplines.

Participants:

Clinicians and post graduate students from any clinical disciplines, willing to participate, were included in the study. However, researchers stopped seeking participants when informational redundancy was reached.

Data collection method:

The data was collected using a newly designed questionnaire following a literature review.^{3,4,5,6,11} The content validity of the questionnaire was checked by one external and two internal experts in bioethics and among them 2 were clinicians. We asked the participants to list 5 commonly faced ethical issues when accosting patients during their clinical practice. In addition, respondents were requested to mention the strategies adopted by them while solving issues faced by them and describe the role of bioethics education, if they had any, in solving these issues. The responses obtained were anonymous in nature. Questionnaires were left with participants to complete and collected next day. Phenomenological approach¹² was used as the intent for this research was to understand the ethical issues experienced during the personal encounter with the patient in the clinical practice.

Statistical analysis:

Qualitative data was analysed adopting phenomenology approach as the data collected explained lived experiences of study participants. To begin with in horizontalization step, researchers listed the statements providing the understanding of how the participants experienced the ethical dilemmas.³¹ Statement were listed in the decreasing order of frequency of their appearance. In the next step, the researcher developed clusters of meaning from these significant statements into themes. The observed unethical behaviours and practices of colleagues or clinicians were not taken into account. Conflicts due to administrative issues were not considered for analysis.

Chi-square test was used to compare categorical data. Mann-Whitney test was performed to compare ordinal data. The strength of association between variables was analysed using Cramer's V test. A 'p' value of < 0.05 was considered as significant.

RESULTS:

Table 1: Demographic profile of participants

Profile	Clinicians (number and %)	Postgraduate students (number and %)
Number	58 (28 %)	147 (71.7 %)
Sex	Male: 32 (55.2 %) Female: 26 (44.8 %)	Male: 81 (55.1 %) Female: 65 (44.2 %)
Age in years	21-30: 8 (13.8 %) 31-40: 24 (41.4 %) 41-50: 17 (29.3%) 51-60: 9 (15.5 %)	21-30: 138 (93.9 %) 31-40: 8 (5.4 %)
Clinical experiences of participants	1-5 years: 23 (39.7 %) 6- 10 years: 10 (17.2 %) 11-15 years: 5 (8.6 %) 16-20 years: 10 (17.2 %) 21- 25 years : 7 (12.1 %)	1 year: 21 (14.3 %) 2 years: 40 (27.2 %) 3 years : 80 (58.5 %)
Clinical speciality	Medicine:15.5% Obstetrics and gynaecology:25.9% Radiotherapy: 10.3 % Urology: 10.3 % Cardiology: 3.4% Paediatrics: 3.4% Anaesthesiology: 3.4% Surgery: 3.4% Psychiatry: 3.4% Dermatology: 1.7 % ENT: 1.7 % Ophthalmology: 5.7% Orthopaedics: 1.7 %	Medicine:12.9% Obstetrics and gynaecology:7.5 % Radiotherapy: 5.4 % Urology: Nil Cardiology: Nil Paediatrics: 8.1% Anaesthesiology: 13.6% Surgery: 8.8% Psychiatry: 1.3% Dermatology: 2.7 % ENT: 5.4 % Ophthalmology: 5.7% Orthopaedics: 1.3 % Chest and disease: 1.3 %

Table 2: Participants' responses regarding ethical issues

Items	Clinicians (number with %)		Post graduate students (Number with %)		Association and strength of association (Cramer's V)
	Yes	No	Yes	No	
Whether ethical issues encountered	53 (91.4)	5 (8.6)	79 (55.2)	64 (44.8)	$\chi(1)= 23.9$, df=1, $p=<0.001$ Cramer's V= 0.345, $p=<0.001$
Whether needed advice	44 (84.6)	8 (15.4)	67 (56.8)	51 (43.2)	$\chi(1)= 12.341$, df= 1, <0.001 Cramer's V= 0.269, $p= <0.001$
Bioethics education	20 (34.5)	38 (65.5)	31 (23)	104 (77)	$\chi(1)= 2.769$, df=1, $p= 0.096$ Cramer's V= 0.120, $p= 0.096$
Number of Ethical issues encountered Median and IQR	3 (2,5)		2 (1,3)		$p=< 0.001$ Cramer's V= 0.345 , $p= 0.013$
Frequency at which ethical issues encountered	Twice in a month: 4 (7.5 %)		Twice in a month: 3 (3.8 %)		$\chi(1):6.570$, df: 2, $p=0.037$ Cramer's V= 0.223, $p=0.037$
	Once in a month: 23 (43.4 %)		Once in a month: 52 (65.8 %)		
	Once in a week: 26 (49.1%)		Once in a week: 24 (30.4%)		
Frequency at which ethical issues encountered Median and IQR	2 (1,3) 1 : once a month 2: twice a month 3: once a week		1(1,3)		$p = 0.014$
Clinical experience and number of ethical issues encountered (median and IQR)	1-5 years: 23 (39.7 %): 2(1.5,5) 6- 10 years: 10 (17.2 %): 4 (2.5,5) 11-15 years: 5 (8.6 %): 3 (2,5) 16-20 years: 10 (17.2 %): 4 (2.25, 5) 21- 25 years : 7 (12.1 %): 3.5 (2, 4.2) 26-30 years: 3 (5.2 %) : 4(3,5)				

Table 3: Strength of association between variables

	Number of issues encountered	Frequency at which ethical issues encountered	Needed advice	Bioethics education	Age	Gender
Whether encountered	0.873 P=<0.001	0.139 P=0.287	0.431 P=<0.001	0.018 P=0.798	0.287 P=0.001	0.001 P=0.988
Number of issues encountered		0.229 P=0.2	0.440 P=<0.001	0.119 P=0.776	0.354 P=<0.001	0.202 P=0.172
Frequency at which ethical issues encountered			0.104 P=0.499	0.236 P=0.028	0.217 P=0.052	0.220 P=0.041
Needed advice				0.007 P=0.932	0.163 P=0.211	0.188 P=0.015
Bioethics education					0.098 P=0.606	0.021 P=0.767
Age						0.116 P=0.429

p = <0.05 is significant

Table 4: Ethical issues related patient's autonomy

Autonomy as intrinsic value interfering with doctor's duty:	
1. Patients not willing for standard treatment protocols	(22)
2. Noncompliance to treatment protocols	
3. Patient with suicidal attempt wants treatment but does not agree for reporting of information	
4. Patient gives information contrary to relative in case of suicidal attempt	
5. Patients with past history of suicide attempt, requests not to document	
Diminished autonomy of patients:	
1. Relatives not willing for standard treatment protocols	(8)
2. Patients are not able to make decision regarding the treatment	(3)
3. Patient do not take decisions, patient relative takes	(2)
4. Request from caretakers to collude from patients	(2)
5. Disagreement between the patient and first degree relative about the line of treatment	
6. Multiple decision makers	

Value in bracket = frequency of appearance

Table 5: Ethical dilemmas related to end of life (EOL) situations

1. Discontinuation/continuation of ventilator support	(16)
2. Management of terminally ill	(10)
3. Patient's relative does not wish to continue ventilator support	(3)
4. Poor terminally ill patients	

Table 6: Ethical issues due to financial constraints

1. Treatment as per guidelines could not be given because of financial constraints (10)
2. Management of financially poor patients (6)
3. Rejecting treatment for patient due to financial constraints (3)
4. Prescribing expensive medication to poor patients who need it (3)
5. Treatment according to the affordability of the patient
6. Patient needing higher quality/care of treatment but not affordable
7. Insurance issues
8. Covering up patient condition to get insurance coverage (falsification)

Table 7: Beginning of life issues

1. Patients demanding medical termination of pregnancy without genuine indications (4)
2. Patients demanding caesarean (3)
3. Contraception in adolescents (2)
4. Egg donor vs recipient care
5. Invitro fertilization in older women
6. Intravaginal insemination with donor
7. Surrogacy
8. To sacrifice baby to decrease maternal risk
9. Female contraception/sterilization
10. Resuscitation of baby if major malformation present after birth
11. Medical termination of pregnancy for failure of contraception
12. Foetal non-lethal anomalies
13. Intra uterine death
14. Genetic disorders in unborn fetus
15. Refusal of a mother to undergo caesarean section despite foetal bradycardia
16. Consent for breech vaginal delivery
17. Disclosing intrauterine fetal death to mother

Table 8: Communication related issues

1. Dealing with aggressive and arguing patient relatives (5)
2. Explaining death/disease to patient relative (4)
3. To explain poor prognosis to elderly patients
4. To disclose life threatening condition to patient
5. To clearly explain the prognosis of condition
6. To clearly explain the possible complications of treatment

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| <ol style="list-style-type: none"> 7. Explain cost to patient relatives 8. Counselling the patients in cases of hospital acquired injuries, complications and other management 9. Explaining the prognosis in vegetative state |
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Table 9: Issues related to privacy and confidentiality

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| <ol style="list-style-type: none"> 1. Disclosing sensitive/confidential information (7) 2. Disclosing HIV status to patient/spouse/relative (7) 3. When patient's relative/friend request for the details of patient's condition 4. Reporting in cases of rape cases and adolescent abuse cases |
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Table 10: Ethical Issues due to hospital policies and resources

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| <ol style="list-style-type: none"> 1. Triage - need of choosing one patient over the other due to limited resources (3) 2. If we don't have particular investigation/management modality /treatment of patient in our institution, whether we can refer patient to other hospital or should treat as per our hospital facility 3. Rejection /delay in treatment due to non-availability of bed 4. Prescribing costly medicine when patients can get same medicine at cheaper rate outside the hospital 5. Changing treatment protocols for different patients 6. Asking for repeat evaluation in hospital when already evaluated somewhere else 7. Privacy of the consultation is affected in presence of medical students |
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Table 11: Other issues

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| <ol style="list-style-type: none"> 1. Obtaining informed consent (e.g critical conditions/language barrier) (7) 2. Patients with lack of social support (5) 3. Religious bias (2) 4. Covert medications for psychiatric patients 5. Prescribing generic medicines |
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The demographic details of respondents are given in the table 1. Out of 205 respondents 71.7% were post graduate students (PGs) and rest were clinicians. The mean age of PGs was 25 ± 2.2 yr, where as that of clinicians was 35 ± 9.5 yr and men and women were equally represented (Table 1).

Participants' responses regarding ethical issues are given in table 2. Compared to PGs, larger proportion of clinicians encountered ethical issues with more frequency and needed advice to deal with them. Their main source of advice was the head of the Department, followed by senior faculty members, colleagues and internet.

20 % clinicians and 31 % PGs had some kind of bioethics education in the form of workshops, CMEs, conferences or as a part of forensic medicine subject during undergraduate medical studies.

There was weak positive correlation between various variables as shown in table 3. A weak association between age of the participant and agreeing to having encountered ethical dilemmas and the number and frequency at which ethical dilemmas encountered was noted. In addition, agreeing to having taken some kind of advice in solving ethical issues weakly correlated with encountering ethical issues and their number. A weak correlation was observed between having undergone some kind of bioethics education and frequency at which ethical issues encountered.

The qualitative data on ethical dilemmas encountered generated 9 themes. The codes under each theme are provided with their frequency of appearance and the themes are numbered in the descending order of number of codes in them. The themes include, 'issues related to patient's autonomy' (table 4), 'end of life issues' (table 5), 'issues due to financial constraints' (table 6) 'beginning of life issues' (table 7), 'communication issues' (table 8), 'issues related to privacy and confidentiality' (table 9), 'issues due to hospital policies and resources' (table 10) and 'other issues' (table 11).

Discussion:

This multicentre study done in four hospitals in India investigated the nature and occurrence of ethical dilemmas encountered by physicians and post-graduate students and also explored to see whether bioethics education helped in the identification of ethics dilemmas by clinicians and post graduate students.

This is the first survey in India comparing the ethical issues faced by clinicians and post graduate students at patient interface. The response rate was 55% which is similar to previous surveys.^{6,13, 14} From KS Hegde Charitable Hospital, Mangalore, Karnataka, the researchers could collect responses only from post graduate students. Though we had initially planned to categorise ethical issues clinical discipline wise, it could not be carried out due to unsatisfactory response rate (table 1) and researchers stopped seeking participants when informational redundancy was reached.

The median grade of number of ethical dilemmas observed by the clinicians with 0-5 years of experience was lower compared to those with more experience and it was much lesser in postgraduate students (table 2). Clinicians encountered ethical dilemmas more frequently than postgraduate students. In addition, there was strong association between having encountered

ethical issues with their number (table 3). Every encounter in the medical care setting has an ethical dimension. However, a small number of clinicians (8.6%) and 44.8 % of post graduate students reported that they had not encountered any ethical dilemmas. In addition, a weak association between age of the participant and agreeing to having encountered ethical dilemmas with number and frequency at which these were encountered was noted. As shown in table 2, significant number of clinicians and postgraduate students had not received any kind of bioethics education. The most plausible explanation for these findings could be that clinicians would have gained knowledge on clinical ethics while dealing with patients and by attending CMEs, workshops, conference or discussing with colleagues while searching for solutions for the ethical dilemmas encountered. This knowledge and awareness regarding ethical dilemmas made them to recognise more ethical dilemmas during their clinical practice. In a study done in an Indian tertiary care hospital, consultants with long professional career showed better knowledge, attitude and practice of clinical ethics than senior residents.⁸ In other two studies, doctors over 35 years of age showed better knowledge on clinical ethics.^{7, 15} A weak association between bioethics education and frequency at which ethical issues are encountered (table 3) also shows that, education is required to identify ethical issues. Another interesting finding to note that significant larger number of clinicians (84%) needed advice to deal with ethical issues. This shows that, clinical experience and current sources of bioethics information provided an ability to identify issues but not sufficient to solve the ethical issues in contemporary medical practice. Dealing with ethical dilemmas need different set of knowledge and skills among doctors.³ Training clinicians to apply ethical principles and theories to resolve ethical dilemmas or implementation of clinical ethics consultation services in the hospital may be useful.

Literature shows that the most common ethical issue faced in the West was that related to end of life.^{3,4,5} Our study revealed a different set of ethical issues. Dilemmas arising from 'financial constraints' and 'hospital policies and resources' were not reported in the western literature. Patients/relatives refusing to standard treatment protocols and deciding about the end of life issues making it difficult to implement standard treatment guidelines could be related to financial constraints of patients. Understanding these issues create ethical dilemma for the clinician as it is moral obligation of physician to protect families from financial ruin.¹⁶ The treatment guidelines and medical recommendations in India have been developed considering Western published literature. In our study, participants encountered ethical dilemmas as they could not implement such recommendations in the Indian context. To deal with such situations and to promote rational treatment, WHO has recommended teaching medical students the concept of p-treatment.¹⁷ In addition, having a hospital policy might help doctors to deal with issues encountered due to resource constraints.

The concept of autonomy is weak in India.¹⁶ Number of factors affect patient autonomy, including severity of illness, sex, dependence and socio-economic status.¹⁸ Lack of awareness on patients' rights and also the cultural context in India makes spouse/elders/ earning member to be involved in the decision making for the family and patient, further compromising patients' autonomy and rights. The scenario is more complicated when patients are uneducated and less informed about the disease status and importance of treatment. Respecting patient's rights for discharge against medical advice (DAMA), and refusal or non-compliance to treatment may create a set of dilemmas for clinicians as seen in tables 4,5 and 6.

2nd common ethical dilemmas surfaced in our study were related to EOL care. Though a remarkable progress has been made since 2009 with Aruna Shanbuag case on withdrawal of life

support,¹⁹ realistic modifications are still needed for the current legislation²⁰ to enable patient and family centered medical care in addition to providing legal safeguard in such decisions taken by physicians.²¹ Creating awareness in the society on advanced directives and passive euthanasia may help to implement laws at bedside and minimize dilemmas encountered at EOL care and may protect families from financial ruins. This study was conducted before the 2018 Supreme Court Directive about 'living will' for passive euthanasia. Hence it is worth exploring the status of EOL care in the current scenario.

Study also revealed lack of communication skills among participants giving rise to issues. We noted larger number of PGs reporting these issues than clinicians. A sound knowledge regarding ethical issues and way to deal with them added with a good communication skill would be a solution to deal with such issues. The communication skill must become integral part of ethics training.

This was a qualitative study conducted using questionnaire. Though we followed phenomenology methods to get the lived experiences, in depth exploration on each dilemma with larger sample size is needed to understand the factors that give rise to ethical dilemmas in the Indian context. This will help us to in developing policies and guidelines to deal with these issues and also in developing curriculum with the aim of inculcating skill to deal with these issues in the Indian setting.

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