**Development and validation of questionnaire to assess health care professionals’ perspective on ethical dilemmas in clinical situations**

**Abstract**

Viewpoints of the Health care professionals (HCPs) in various ethically challenging clinical situations are important, yet lacks research. We aimed to develop a scale to assess the HCPs viewpoints in this regard and to validate it by an online survey. The developed scale comprised of 11 items, measuring six different ethical areas: health-care resource constrains, involvement of family members in decision making, rights of the patients, medical responsibility of the health care provider, consent, and confidentiality. 122 HCPs participated in the validation phase (online survey). Males scored higher than females for ‘resource constrain’ domain (U=1642.50, p=0.003\*); reverse was true for ‘rights of the patients’ domain (U=1110.50, p=0.018\*). Responses of participants differed for ‘resource constrain’ domain (surgeons scored (S) higher than other clinicians (OC) (S Vs OC: χ2 (3) = 31.37, p=0.001\*). Future studies from different settings and involving larger sample size are warranted to validate these findings.

Key words: Ethics, ethical dilemma, health care professionals, health care, scale.

# **Introduction**

The patient-doctor professional relationship is built on the edifice of mutual trust and respect. Health care providers are expected to serve their patients (clients) following the four basic principles of medical bioethics: autonomy, beneficence, non-malfeasance, and justice.[1] Respecting the rights of autonomy of the clients facilitates building a therapeutic alliance, which have been found to be associated with a better treatment outcome.[2] Health care professionals (HCPs) are often confronted with various ethical and legal issues while delivering services to their clients, especially in terms of revealing sensitive information of their clients’ to other people/authority (e.g. suicidal ideations, intention to harm others, terminal illness diagnosis etc.), inter-personal issues with significant others of the client, and information pertaining to intimate sexual and substance use related issues.[3] However, most of the professional ethical bodies suggest that confidentiality cannot be absolute and breaching confidentiality requires a careful balancing between conflicting interests of clients, their caregivers, society and at times the consulting HCPs themselves.[4,5] Further, violation of such code of the conduct can predispose a HCP to civil/criminal penalties in some cases.[6] Thus, striking a balance between clients’ need for autonomy/ confidentiality and at the same time collaborating with their family members or significant others during the treatment process can be a difficult task for HCPs.[7] The available literature on this theme has shown that there are differing opinions even among the HCPs themselves about what is ethically correct in a given ethically challenging situation with regards to respecting the autonomy of patient in deciding their clinical care and also in terms of revelation of sensitive information i.e. how much information to disclose and to whom.[7–9].

A study from United States based on ethical dilemma situations like ‘family member being the surrogate decision maker for a client’, ‘family’s expectation about the recovery of the patient’, ‘conflict among the decision makers and among the treatment providers’, ‘patient’s advanced wish regarding mode of treatment’, ‘moral distress faced by HCPs while dealing with conflicting treatment approach among the health care team’, and ‘futility of treatment’; emphasized that ethical committees and hospital should have a standardised approach and should streamline their resources to aid in resolution of such ethical dilemma situations.[10] Further, previous research has emphasized that the expectations of clients and the HCPs should be aligned, in the absence of which, clients will continue to be offended by, and possibly seek avenues for redress following information disclosures which treating practitioners consider to be innocuous or merely routine.[11] The available studies in this regard lacked use of a standardized instrument for comprehensive assessment of different ethical concerns faced by HCPs while delivering clinical care in various situations, especially in assessing the viewpoint of HCPs regarding the right course of action during ethically challenging situation.

Healthcare professionals are bound by the code of ethics to maintain their client’s autonomy and confidentiality in various situations, which may be practically challenging at times in clinical practice. In the Eastern or Asian countries like India where the client’s family is often an important party in the entire treatment process, HCPs are likely to face various unique ethical dilemmas unlike their Western counterparts. In the absence of any clear-cut guidelines about the right course of action in such ethically challenging situations, when confronted with them HCPs end up in dilemma. There is a lack of standardized instruments available globally, that could assess the viewpoints of HCPs on how to proceed in different clinical ethical situations, especially with regards to developing and/or oriental setting or population. Thus, this study aimed to study aimed to develop a questionnaire (using Delphi-method) to assess the health care professional’s perspective on various ethical dilemma clinical situations faced by them and to assess its validity through an online survey at a tertiary care hospital in India.

# **Methods**

## ***Design***

This study followed a mixed methods design. The initial qualitative study for the questionnaire preparation was supplemented with a cross-sectional online survey among HCPs for validity assessment. To elaborate, the study comprised of two parts: (1) Generation of a questionnaire pertaining to various ethical dilemma clinical situations through inputs from various experts using Delphi-method, and (2) Validity assessment of the newly developed instrument by conducting an online survey among health care practitioners.

## ***Setting***

The study was conducted among health care professionals at a public funded tertiary care hospital and academic institute from North-India.

### *Participants and procedure of the study*

*Phase-1: Development of questionnaire using Delphi-method*

A total of 15 key informants/experts (trained senior resident doctors and consultants) from various medical and surgical disciplines were selected following purposive sampling for questionnaire development using Delphi method. This approach was chosen, considering the utility of Delphi method to study areas which are otherwise doubtful, controversial, under-researched, or lacks clarity. In this method, the study usually includes various experts and stakeholders of the area under consideration for research. It usually begins with the key informant interview which usually proceeds in a free floating, open ended discussion format to encourage bringing about the new and diverse ideas about the topic under study which is known as the ‘idea generation stage’. However, if required, a lead can be provided by the mediator/researcher to facilitate the interview. The subsequent stages of the Delphi method try to form a consensus among the key informants through various rounds of response seeking and providing feedback to the participants with the overall group’s response. This is the ‘evaluation stage’. The participants have a flexibility to reconsider their responses, in case they feel like, by considering the group’s response. This method has advantage over the other methods of consensus building such as panel discussion or focused group discussion in the sense that: 1) the discussion ensures equal participation and is not unduly influenced by the dominant participant(s) of a group, 2) the participants have the opportunity to get the feedback in form of the group’s response and can reconsider their response, if any, at any stage of the Delphi-method, and 3) it maintains the anonymity of the participants. The use of Delphi method is a well-established technique employed for consensus building among a group of experts/participants. [12,13]

In the current study, in the first stage of Delphi method, a researcher conducted 15 separate face-to-face key informant interviews with experts from various disciplines: medicine (general medicine, medical oncology, paediatrics, gastroenterology, infectious disease, geriatric medicine), surgery (general surgery, surgical oncology, neurosurgery, Oto-rhino-laryngology), other clinical (psychiatry, radiology, radiation oncology, anaesthesia), and non-clinical disciplines (forensic medicine). Each interview lasted for about 45minutes. After an initial non-restrictive, free-flow of information part of the interview, probes (as mentioned in the Appendix 1) were used to explore more information as a list of potential ethical dilemma clinical situations, if needed. The information obtained was noted down in informant’s verbatim and in detail.

*Thematic analysis:*

A total of 53 different responses were obtained after completion of key informant interviews. On thematic analysis, eleven different ethically challenging themes and 22 different sub-themes (number of sub-themes have been spelled out in the parentheses) were obtained as follows: (1) confidentiality (two) , (2) patient’s rights (three) , (3) consent (two) , (4) medical responsibility by a health professional: act of commission or omission (four) , (5) resource constraints (five) , (6) palliative care or end of life (two), (7) doctor-patient relationship (one) , (8) organ donation or medico-legal autopsy (one) , (9) preferential treatment to a patient (one) , and (10) Obtaining incentives from the private sector (one) related ethical issues. Different sub-themes obtained after thematic analysis have been listed out in the additional file (supplementary file).

In the second stage of Delphi-method, the key informants were provided with (through online form) the feedback in form of a questionnaire, highlighting aforementioned ethical themes and sub-themes, to build consensus. At this stage, their opinions were also sought regarding: the maximum number of the questions the final questionnaire (for online survey) should comprise of, the optimal time duration (in minutes) in which the proposed questionnaire should be completed during the online survey, and the preferred format of the questionnaire (case vignette pattern with yes/no response, case vignette pattern with response in Likert-scale, case-vignette pattern with numerical scoring from 1 to 10, descriptive responses, and mixed format comprising of any two of the aforementioned pattern).

A total of 12 key informants responded at this stage (response rate 80%). The most recommended themes for inclusion in the questionnaire in the decreasing order of frequency included: confidentiality; rights of the patients; resource constrain; preferential treatment provided to certain patients; consent, medico-legal and autopsy related issues, medical responsibility by a health professional: act of commission or omission, palliative care/end of life related, doctor-patient relationship; and receiving incentives from the commercial sector. The details of the sub-theme analysis have been provided in the supplementary file.

The majority of the key informants recommended that the final questionnaire should have a maximum of 15 questions (n=8, 66.7%); items should be case-vignette based with Likert-scoring (n=6, 50%); and respondents should be able to complete the on-line survey preferably within five minutes (n=6, 50%).

Hence at this stage, three themes with the least recommendations/endorsements were dropped out, which included: organ donation and medico-legal autopsy, doctor-patient relationship, and health professionals receiving incentives from the commercial sector related. Thus, a questionnaire comprising of 32 questions was constructed (with Likert rating) covering the various ethical dilemma clinical situations.

In the third stage of Delphi-method, the questionnaire so formed was mailed to all the 12 key informants, highlighting the most recommended themes/subthemes by the group. At this point, opinions of the key informants were also sought regarding the suitability of each question to be the part of the final questionnaire (yes/no responses), and its clinical relevance (numerical response from one to ten).

A total of 10 key informants responded at this stage (response rate 83.3%). Eight questions were considered non-suitable (operationalized if more than ≥50% of the key informants would consider the question as non-suitable) to be asked to a health care professional by key informants, hence they were removed from the final questionnaire. A total of 15 questions, based upon the highest mean scores (based on clinical relevance) of the responses obtained from the key informants, were included in the final questionnaire. Further, an online survey using this questionnaire was conducted to assess the validity of the questionnaire developed using the Delphi method.

*Phase-2: Validation of questionnaire developed using Delphi-method*

### Online survey

#### Setting of the study

All resident doctors and consultants of the institute under study. The questionnaire used for the online survey can be obtained from the corresponding author upon request.

#### Sample size

A total of 1775 resident doctors and junior consultants of the institute were invited through an email to participate in the online survey. A reminder mail was sent after one week of initial invitation.

## **Statistical analysis**

For the present study, the socio-demographic characteristics of the key informants and the participants of on-line survey were represented using frequencies, percentages, means and standard deviations. Factor analysis was performed to categorize the questionnaire items into various domains. Internal consistency of the questionnaire was assessed calculating correlation co-efficient and represented in terms of the Cronbach’s alpha. The relationship between the duration of clinical experience of HCPs with their response scores for the questionnaire (mean score) was analysed using Spearman’s correlation test. The relationship between the gender and clinical discipline of the participants with the response scores to various items of the questionnaire were analysed using the Mann-Witney U test and the Kruskal-Wallis test coupled with appropriate post-hoc analysis respectively, if needed. Subsequently, the results have been represented in terms of chi-square value. A two-tailed p-value of less than 0.05 was considered significant for all statistical tests. The data was analysed using SPSS software (IBM corp., U.S.A). [14]

## ***Ethical approval***

The study protocol was approved by the institute’s ethical committee prior to the commencement of study.

# **Results**

## ***Response rate*:**

## One hundred twenty individuals responded to the online survey out of 1775, to whom invitation for participation in the survey was sent. Thus, the response rate was 6.8%.

## ***Socio-demographic- and occupational profiles of the participants***

The mean age of the participants was 30.51 (Standard deviation of 5.43) years. About three-fourth (n=87, 71.3%) of them were males, while about one-fourth were females (n=35, 28.7%). The median duration of clinical experience of participants (after completing their medical under-graduation) was 5.00 (Inter quartile range; 2.00, 8.25) years. About 36% (44/122) of the participants belonged to medical disciplines, 28% (34/122) from surgical disciplines, 26% (32/122) from other medical disciplines, and 8.2% (10/122) were from non-clinical disciplines.

## ***Findings of the Factor analysis and internal reliability of the questionnaire***

Factor analysis of the items of questionnaire showed that the questionnaire (15-items) could be factored into six different domains, measuring different aspects of ethical issues, which in turn accounted for 60% of the total variance in the questionnaire. A value (factor loading) of >0.5 was considered to be significant enough for fitting into the same factor. The six different factors represented ethical issues arising out of: (1) resource constrain, (2) Addressing family concerns during treatment or in decision making, (3) right of the patients, (4) medical responsibility of health care provider, (5) consent, and (6) confidentiality. Item number 2, 3, 4, 11, and 13 had negative value in factor analysis, hence their responses were reversed while calculating the total scores for individual domains.

Three questions were left out as it did not figure in any of the factors which included: Revealing the grave investigation’s finding to a patient if family member are not willing, empirically treating patient (e.g. starting anti-tubercular medications) due to logistic reasons, and Restraining (physically/chemically) an aggressive patient (e.g. delirious patient) by the nursing staff without obtaining explicit instructions from doctor (details of the factor analysis shown in table 1). To study the internal consistency of the questionnaire, Cronbach’s alpha was calculated, which had a value of 0.43. On removal of item no 12 (Obtaining consent for performing a medical procedure (e.g. pleural tap) without adequately counselling the patient/caregiver about the possible risks related to the procedure in a busy set-up or when it appears that they would get unduly apprehensive about the procedure), the Cronbach’s alpha increased to 0.54, hence the final questionnaire comprised of only 11 items.

## **Relationship between duration of clinical experience-, gender-, and clinical discipline of participant and response to various items of the questionnaire**

Spearman’s correlation analysis (used since the dependent variables were non-parametric) found that the duration of clinical experience was not significantly related to responses of the participants to any of the items in the questionnaire.

Mann-Witney U test showed significant gender differences, with males (M) having higher mean scores as compared to females (F) for ethical issues related to resource constrain (factor 1) (M vs. F:3.86 [0.86] vs. 3.39 [0.76], U=1642.50, p=0.003\*), whereas the reverse was the case for domain related to the rights of the patients (factor 4) (M vs. F:1.94 [0.82] vs. 2.38 [0.97], U=1110.50, p=0.018\*).

The Kruskal-Wallis test showed a significant difference among participants from various clinical discipline with regard to the ethical issues arising due to ‘resource constrain’ (χ2 (3) = 14.38, p=0.002\*). Post-hoc analysis showed a higher mean score (agreement) for surgical discipline (4.12 [0.67]) as compared to their non-clinical counterparts (3.34 [0.89]) at a statistically significant level (χ2 (3) = 31.37, p=0.001\*).

# **Discussion**

The present study attempted to develop a questionnaire to assess the viewpoints of the health care professionals for various ethical dilemma clinical situations faced by them during their routine clinical practice at a tertiary care hospital in India. The study initially employed Delphi-method to develop the questionnaire. The final questionnaire comprised of 11 items (questions) related to ethical dilemma clinical situations; which were factored under six different domains, measure different aspects of the ethical issues arising during health care delivery by HCPs. The various domains include ethical issues related to: resource constrain, addressing family concerns during treatment or in decision making, rights of the patients, medical responsibility of a health professional: act of commission or omission, consent, and confidentiality. We found that male gender was related to higher scores (higher agreement) on domain of ethical issues related to resource constrain while female gender was related to higher scores on domain of rights of the patients. HCPs from surgical disciplines had higher scores (higher agreement) on ethical issues related to resource constrain than their counterparts from other clinical discipline. However, no relationship was observed between the participants’ years of clinical experience and their responses to any of the domains in the questionnaire.

This work developed a questionnaire to assess the various ethical issues faced by HCPs during health care delivery. To the best of our knowledge, only one study has used any standardized instrument to comprehensively assess various ethically challenging clinical situations[15], however, the questionnaire lacked in assessing real life case-wise ethical dilemma clinical situations rather tried to explore various pattern of ethical practices (paternalistic, deliberationist, and autonomist) in various situations. Moreover, the available instrument has not been validated in Indian context.

The key informants for the Delphi process represented experts from diverse disciplines including experts from core-medicine-, surgical-, other clinical- and non-clinical-disciplines, hence they could provide a wider and diverse range of viewpoints. Although in the present study there was some attrition of key informants during various stages of the Delphi-method, we could still maintain an overall retention rate of 75% (87.5%, n=12 in the second stage; 83.3%, n=10 in the third stage) till the development of the questionnaire, which is within the prescribed (70%) norms. [16]

By using Delphi-method based on the consensus among the experts, we could construct a questionnaire which covered diverse and pertinent domains (six different) of ethically challenging clinical issues, usually faced by the HCPs in routine clinical practice such as resource constrain, confidentiality, consent related etc. The Delphi-method also helped to develop a questionnaire, which was less time consuming (could be filled within five minutes) and easy to administer, hence could have better participant’s acceptance. The internal consistency of the questionnaire was 0.54, which was in the acceptable range as per the literature. [17] The value of internal consistency should be seen light of the questionnaire being relatively short comprising of only 11 items and assessing various domains of the ethical principles. Literature suggests that the key point in developing an instrument is the interpretable result and the ease of its application rather than simply a higher alpha value with too many items in the questionnaire[18,19].

We did not find any relationship between duration of clinical experience with the responses to the various domains in the questionnaire. This finding is inconsistent to a previous study from Norway that has observed an increased paternalists attitude (higher score on paternalism and lower score on autonomy) by older physician (in their thirties-sixties) than their younger counterparts (in their twenties), who tend to be more autonomist (higher score on patient’s autonomy and lower score on paternalism)[15]. The difference of our finding could be attributed in light of an overall younger mean (30.5years [SD:5.43]) age of the participants rather than a wide age range of the participating physicians. It can be speculated from our result that the course of action in any ethically dilemmatic clinical situation is framed at a very early period of academic career of a physician, that might be governed by the cultural or medical practices of that health care setting, and that persists even with gain in clinical experience. However, this finding warrants further study for substantiation.

We found that the male HCPs were more frequently in agreement with referring a patient to another health-care facility in case of health resource constrain or refuse to perform routine surgery (e.g. benign cyst removal) in a tertiary centre that can be performed at the primary or secondary level health-care centre. Our finding is consistent with some of the available literature on nursing care that suggest that female nurse follows ‘principle of care’- receptivity and response to needs of others- than their male counterparts [20,21]. Our finding highlights that the female health professional were more in agreement of respecting the rights of the patient to receive treatment in whatever way it is available or wished by the patient, whereas male HCPs were more considerate for the resource constrain and quality of service. However, such overarching inferences with regard to HCPs should be considered with caution; and more studies are required in this regard.

We also found that the female HCPs were more frequently in agreement of not interviewing a family member with psychotic illness, even when clinically indicated, against the wish of the patient than their male counterparts. This finding highlights that female health professionals more frequently endorse the notion of protecting the rights/autonomy of the patient. Our finding is consistent with the previous studies which have suggested that female health professionals were more considerate to right based autonomy approach to patient care while male counterparts might have followed a more paternalistic guided approach to clinical care, [15,22–24] who might consider that psychotic patient has limited decisional capacity to act in the best interest of himself/herself thereby not involving family members in the treatment process.

We also found that health professionals from surgical disciplines (when compared to their other medical counterparts) more frequently endorsed for referring a patient to another centre for investigation or treatment and refusing to perform a routine surgery (e.g. benign cyst removal) in tertiary centre that can be performed at the primary or secondary health-care centre. A similar comparative finding has been reported from Norway[25]. It could be understood in the light of surgeons often have to deal with patients with complications mandating urgent surgery/intervention, which compel them to prioritize their patients more rigorously and utilize the limited available resources more judiciously. However, further qualitative and quantitative research, that too in other settings, are required in this.

The findings of this study should be interpreted while keeping in mind its limitations. Firstly, the questionnaire was developed at a tertiary care public funded hospital therefore its validity in private setting and primary care setting could not be commented upon. Secondly, the setting for the on-line survey also being a tertiary care centre, hence the findings may not be generalizable in other settings. Thirdly, the online-survey results being quantitative, might not have been able to fully capture the qualitative nuances of the HCPs response to various ethically challenging clinical situations. Fourthly, the response rate for the online survey was quite low. Thus, the generalizability to non-responders could not be ascertained. Lastly, in the absence of the available literature, our findings should not be considered conclusive, and more research is required to better characterize the study findings.

**Conclusion**

The study developed a questionnaire to assess health care professional’s perspective towards various ethically challenging clinically situations. The questionnaire covered ethical issues related to six different domains namely health-care resource constrains, involvement of family members in decision making, rights of the patients, medical responsibility of the health care provider, consent, and confidentiality. The questionnaire developed had a moderate internal consistency. The present study did not observe any relationship between the responses of the physicians and their years of clinical experience. The gender of the participants was related to ethical concerns due to resource constrain, and rights of the patients and responsibility of the health care professionals. The clinical discipline of the participants was also related to ethical concerns due to resource constrain. Future studies are warranted in this area from different settings and a higher sample size to better characterize the findings of the present study.

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