**Awareness and Adherence with Current National Ethical Guidelines for Biomedical and Health Research among Nurses in North-India**

**Abstract**

**Background:** Bio-medical research involving human participants should focus on patients’ safety and integrity of the information.Nurses’ participation in clinical research has increased with the role advancement in nursing profession and therefore, it is necessary to assess their knowledge and adherence to standard ethical guidelines**. Objectives:** Present study was conducted with an objective to assess the awareness and explore the adherence to the Current National Ethical Guidelines for Biomedical and Health Research among nurses in India. **Methods:** This cross-sectional descriptive survey was carried from 2017-2019 among conveniently selected nursing institutions of North India. A total of 115 nursing faculties/researchers and 280 postgraduate nursing students’ theses were selected using simple random sampling method for participation in study. Data collection on awareness and adherence to ethical guidelines was done with structured knowledge questionnaire and structured observation checklist. **Results:** Out of 280 research thesis, retrospective observation shown that government college nurses were found to be more adhered to the research guidelines as compared to nurses of private colleges on all the six components of ethical consideration. It was found that nursing faculty members were more aware of the informed consent process domain (4.3±0.3) and least aware on ethical conduct in emergency/disaster research (0.8±0.3). **Conclusion:** Private Universities need to be more vigilant on their practices of protocol approval to promote desired ethical practices in research and mandatory regular training on ICMR guidelines are suggested for faculty members to promote good clinical practices.

**Keywords:** Nurse researcher, ethics, good clinical practice, research protocol, adherence, patient safety

**Introduction**

Nursing is considered as a profession that is guided by ethical principles and even routine procedures carried out by nurses in clinical settings bring the challenge of choosing between right or wrong for the client. In the recent years, sudden shift has been observed in the role of nurse from bedside nursing to a clinical researcher. Nurses are efficiently involved in clinical research as a principal investigator and research coordinator and they have to follow three value systems; value of human rights, nursing caring ethics and researchers’ value of scientific inquiry (1). Every research involving human participants has some inherent risks and probabilities of causing harm or inconvenience to participants/communities. Therefore, the four basic ethical principles; autonomy (respecting individual’s decisions), beneficence (doing benefit), non-maleficence (non-harming), and justice (treating equal) should be practiced by researchers while conducting biomedical and health research (2).

Experimental research on human subject has been reported much earlier in history but ethical issues came in limelight after 1947 when cases of research misconduct was observed and one of the popular was Tuskegee Syphilis Study (1923-1972). Research trial on criminals of Nazi war brought the formulation of Nuremberg code (1947) which subsequently led to Helsinki Declaration and many others like Belmont Report and World Medical Association for the protection of human rights (1, 3). International norms require the Research Ethics Committees (RECs) to evaluate the research and promote high ethical standards. In India, the Indian Council of Medical Research (ICMR) establishes the guidelines for providing the required ethical conduct needs to be practiced in all biomedical research (4). Recent ethical guidelines released by ICMR on October 12, 2017 aim to protect the human participants, enhance the outcome quality and establish well organized system for ethical review of the research (5).

Code of ethics in nursing was first formulated by International Council of Nurses (ICN) in 1953. Ethical codes were further stressed by “Nightingale Pledge” (1983), American Nursing Association (1985) and Royal College of Nursing Code (1977). Nurses already follow code of ethics into clinical practice that is governed by regulatory bodies but this is not enough to protect human rights of participants in clinical research (6). Therefore, Good clinical practice (GCP) is mandatory to be followed by every researcher in clinical research. GCP focus on two key components that includes participants’ protection and authenticity of the produced results in research (7).

Although, ethical guidelines are framed a long time ago but Ethical Committees in developing country like ours are still struggling to run efficiently because of inadequate standard operating procedures (SOPs) and no adherence to schedule Y recommendations. As per WHO report, there are 40 ECs in our country which are functioning at their optimum level (8). On the contrary, it was observed in studies from developing countries that most of the ECs are not functioning at optimal level because members are unaware about their roles and responsibilities. ICMR has taken initiative and formulated standard guidelines for functioning of ECs and training of EC members (9-11).

At present several government and private nursing colleges in India are offering nursing education at undergraduate, postgraduate and doctorate level. Furthermore, it is observed that a large number of nursing research studies are conducted without protocol approval of ethical committee and written informed consents which is an indicatory of negligence and unawareness on ethical issues. Although, qualified nurses are expected to know about ethical guidelines for their active participation in research involving human beings (12) but in reality very minimal aspects of traditional nursing training on ethical guidelines to conduct biomedical and health research were given to them as per INC curriculum (2, 13). Moreover, data on nurses’ awareness and adherence to current national ethical guidelines for biomedical and health research are very thin on the ground in India. With regard to the significance of this topic, this study aimed to assess the awareness and explore the adherence to the Current National Ethical Guidelines for Biomedical and Health Research among nurses in India.

**Methodology**

This cross-sectional descriptive survey was carried during the year 2017-2019 among conveniently selected nursing institutions of North India i.e. Rajasthan, Punjab, Haryana, Himachal Pradesh, Delhi/NCR, Uttarakhand, and Uttar Pradesh. Nursing faculty members and dissertations carried out by postgraduate nursing students were approached for data collection.

One government and one private nursing college were selected from each of the selected seven states of north India. Thus, a total of 14 nursing colleges were selected from the target nursing institutes. The nursing faculty who possessed the postgraduate nursing qualification and involved in teaching along with guiding the postgraduate nursing students for more than 3 years were considered eligible for this study. The postgraduate nursing students’ thesis carried out in the last five years period with an available copy in the respective library was included in the study. The participants who were not willing to participate were excluded from the study.

Data collection was done with structured knowledge questionnaire and structured observation checklist. There were two domains in structured knowledge questionnaire exploring detailed information on socio-demographic profile and awareness of current national ethical guidelines for biomedical and health research among nurses involved in research activities. Awareness regarding current ethical guidelines was assessed under twelve different domains and each domain consisted of five items on essential information. To identify nurses’ adherence with current national ethical guidelines, a structured checklist consisting of six items was developed. Validation of research tool was done by experts in the field of nursing, biomedical ethics, epidemiology, and biostatistics and few modifications were made in the statements of the questionnaire. Reliability of the questionnaire was assessed through test-retest methods (0.92) and inter-rater reliability method was used for observation checklist (0.98); tool was found to be highly reliable.

Out of each selected nursing college, a list of nursing faculty was prepared and those who were meeting the inclusion criteria were enrolled using simple random sampling and a desired sample of 10 faculty members from each nursing college were selected. Similarly, 20 thesis of postgraduate nursing students were also selected from each nursing college. A total of 140 nursing faculties/researchers and 280 postgraduate nursing students’ theses were selected using simple random sampling method. After obtaining the informed written consent, self-administered questionnaires were distributed to the nursing faculties. However, 7 nursing faculties were on leave and 3 refused to participate in the study. Out of the given 130 questionnaires, 121 were returned back, out of which six questionnaires were incompletely filled and were excluded from the analysis. Therefore, study population comprised of 115 nursing faculty members, and 280 postgraduate nursing theses which were included in final data analysis.

The study protocol was exempted from review by the Institutional Ethical Committee of AIIMS, Rishikesh. Written informed consent was obtained from the selected nursing faculties before distributing the questionnaires. Additionally, permission from the Principal/ Dean of each selected nursing college was obtained before initiation of data collection. Participation in the study was voluntary and no incentives were provided for participation.Data were analysed using Statistical Package for the Social Sciences (SPSS) version 21. Descriptive statistics was used for data analysis where continuous variables are expressed as Mean ± Standard Deviation; categorical variables are expressed as frequencies and percentages.

**Results**

*Study participants*

The study population consisted of 115 nursing faculty with a response rate of 82% and 280 postgraduate nursing theses. Out of total 115 nursing faculty, higher proportion of the participants 81.8% were females compared to 18.2% males. Around half of the faculty members 58.3% were between the age of 31-40 years and 32.2% were over the age of 40 years. Almost 54% were working in the private nursing institutes and remaining 46% in government hospitals. Majority of the faculty members 86.1% were working at the post of assistant professors/lecturers. It was observed from demographic data that most of the faculty members 93.9% had not participated in any clinical trial and around 83.4% did not receive any ethical training i.e. International Harmonization Conference-Good Clinical Practices (ICH-GCP). **(Table 1)**

*Awareness on current ICMR ethical guidelines*

The awareness of the nursing faculty members on current ICMR ethical guidelines for bio-medical research was assessed with descriptive statistics i.e. mean and standard deviation. Data has shown that nurses were more aware of the informed consent process domain (4.3±0.3) followed by general ethical principles domain (3.8±0.8), IEC committee domain (3.5±1.1), and domain of researchers’ responsible conduct had a score of 3.1±1.1. Furthermore, faculty members had very less awareness on ethical conduct in emergency/disaster research (0.8±0.3) accompanied by ethical conduct in genetic research domain (1.1±0.7). **(Table 2)**

*Nurses’ adherence to ethical guidelines for research*

Nurses’ adherence to ethical research guidelines was explored and presented in frequency and percentage distribution against each component. Government college nurses were found to be more adhered to the research guidelines as compared to nurses of private colleges on all the six components of ethical consideration; research project approval (68.6% vs. 22.1%), informed consent guidelines (74.3% vs. 25%), providing information sheets to patient (55.7% vs. 10%), maintaining confidentiality of information (82.9% vs. 72.1%), maintaining anonymity (76.4% vs. 22.9%), and obtaining custodian permission (97.8 vs. 89.3%). **(Table 3)**

**Discussion**

Ethical principles act as an integral part of every research dealing with human subjects. Present study did not intend to bring new concept on research ethics. Rather, it identifies the knowledge of faculty members on research ethics and adherence to ethical principal while carrying out research. Nurses are supposed to comply the ethical standards in research because participants’ safety is the primary concern. This study was a modest attempt to answer questions like how much knowledge nursing faculty have about research ethics and also to retrospectively observe ethical adherence in research thesis.

Findings of present study have shown that most of the faculty members who participated in this study were female and reason for that could be less number of male into nursing profession. A study conducted in Nigeria reported that those who participated in research did not understood several key elements of informed consent (14). Therefore, nurses who spend more time with patient can judge better that whether patient understood about informed consent and his/ her right to withdraw anytime from study. El-Dessouky HF et.al found that more than 50% of the participants in their study responded correctly about informed consent but majority were not aware about other aspects of ethical guidelines (11). Likewise, faculty members in our study did not know much about other aspects of ICMR ethical guidelines but they were more aware about informed consent that is crucial component while carrying out human research. Similar results of high awareness on informed consent were also reported by other studies from India (15, 16).

Knowledge on one aspect and practice that into real scenario are the two different things and that is why present study also identified adherence of nurse researchers to the ethical guidelines. Helsinki Declaration emphasized on the importance of patient information sheet, volunteer participation and right to withdraw from study to protect patients’ right (3). It is interesting to note that around 49.6% had taken informed consent and only 32.9% focussed on patients’ information sheet. This finding is capable enough to explain that still there is a gap between knowledge and adherence to ethical principles. Maintaining participants’ confidentiality is another major concern in bio-medical research and this is supported by the findings of a study where more than 90% of the study respondents found the need to maintain confidentiality and very few (10%) stated that detailed information should not be given to participants as they may withdraw from research (11). Similarly, confidentiality was maintained in around 77.5% of the thesis which was retrospectively observed. Although, anonymity was only maintained in 48.9% of the thesis (16). On the contrary, a study performed in India found that only 28% participants felt that confidentiality is important in medical research (15).

Ethical dilemmas are the critical aspects in research involving human subjects especially in clinical genetic research including issues of privacy, respect for autonomy and future use of submitted genetic material (17). Appropriate understanding on how to handle ethical issues in such a research is important to prevent potential harm to research participants and researcher as well. Present study revealed that faculty members were less aware about ethical issues in genetic research with a mean score of 1.1±0.7 which is matter of concern as the nurses’ participation has increased in clinical research and lack of awareness can lead to research findings with low methodological quality. In case of vulnerable population, informed consent should be taken from suitable guardian and assent can also be taken for supportive document (1, 3). Present study stated that majority 97.1% thesis had taken custodian into consideration but it was surprisingly noticed that faculty members were not aware about ethical conducts in emergency and disaster research.

Interesting point to note was that thesis from government colleges found to be more adhered to the ethical guidelines as compared to private colleges. Possible argument for this can be the stricter and rigid protocols in government institutes for ethical approval whereas private universities may not follow proper protocols and get waiver off. It has been stated in literature that retrospective studies do not require ethical approval but it is mandatory that researcher justifies reason behind not taking permission from ethical committee (16). Committee on Publication Ethics (COPE) had clearly stated policies for waiver off from ethical permission and submission of project completion report (1). Faculty members were less aware about ethical conduct involved in clinical trials and the probable rationale for this could be minimum participation of nurses in clinical trials which was 6.1% in current study. Similar findings of nurses’ minimum participation i.e. 8.6% in clinical trial was presented by Aksoy HB et.al. Nurses have started working as principal investigator in clinical trial and that is why familiarity with clinical trial is mandatory (18).

Overall awareness score of faculty members on ethical standards in current study was found to be 32.5±10.8 out of 60. Results from another study were in line with current study which stated that knowledge level of nurses in clinical research was 10 out of 19 (18). Although involved in research and had an experience of publications, present study reported that majority of the faculty members 83.4% did not undergo any formal training on research ethics which is strongly recommended as per the Belmont Report. Few studies presented contradictory report stating that participants with previous ethical training felt that ethical approval is time consuming and most of the time delays research (11, 15).

Many reports from research studies mentioned that fabrication and falsification of research data is still done instead of clearly stated ethical guidelines and norms (11, 19). Findings from a meta-analysis concluded that few scientists agreed that they did fabrication of data to make data more presentable (20). Hence, it is important to impart proper training for young researchers in order to enhance knowledge on research ethics and prevent ethical misconduct. It is of vital importance that faculty members in nursing profession remain up to date with the new amendments in ethical standards for clinical research, so that they can inculcate right ethical practices among nursing students that will favour them to become a better researcher. Although, there are many agencies working to preserve patients’ right but still responsibility of maintaining ethical standards lies within the power of seniors in the field by practicing and promoting use of ethical guidelines in research. Educational programmes should be developed and continuous training and sensitization of nursing faculty and students should be done at institutional level.

**Conclusion**

The study findings focussed on the fact that ethical committee of the private universities need to be more careful and should strictly follow the recommended ethical guidelines before approving any research protocol. Regular training on ICMR guidelines are suggested for faculty members to promote good clinical practices. Present study findings emphasized on the fact that more training on ethical standards and involvement of nurses in clinical trials are required to promote quality research projects in nursing. We suggest that further qualitative study can be done to explore problems faced by researchers in carrying out clinical trials so that current guidelines can be updated accordingly.

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**Conflict of Interest**

There is no conflict of interest to disclose.

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**Table 1: Socio-demographic characteristics of nursing faculties/nurse researchers**

**N=115**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Frequency (%)** | **Confidence Interval**  **(CI)** |
| **Age (in years)**  20-30  31-40  > 40 | 11 (09.6)  67 (58.3)  37 (32.2) | (4.9-16.5)  (48.7-67.4)  (23.8-41.5) |
| **Gender**  Male  Female | 21 (18.2)  94 (81.8) | (11.7-26.5)  (73.4-88.3) |
| **Place of Birth**  Urban  Rural | 32 (27.8)  83 (72.2) | (19.9-36.9)  63.0-80.1) |
| **Type of nursing institute**  Government  Private | 53 (46.1)  62 (53.9) | (36.7-55.6)  (44.3-63.2) |
| **Position of nursing faculty**  Professor/ Principal  Associate Professor/ Reader  Assistance Professor/ Lecturer | 07 (06.1)  09 (07.8)  99 (86.1) | (2.5-12.1)  (3.6-14.3)  (78.4-91.8) |
| **Number of publications**  <3  3 – 5  5 – 10  > 10 | 22 (19.1)  53 (46.1)  29 (25.2)  11 (09.6) | (12.4-27.5)  (36.7-55.6)  (17.6-34.1)  (4.9-16.5) |
| **Prior training about ethics ICH-GCP**  Yes  No | 19 (16.5)  96 (83.4) | (10.2-24.6)  75.4-89.7) |
| **Have been part of clinical trails**  Yes  No | 07 (06.1)  108 (93.9) | (2.5-12.1)  (87.9-97.5) |

**Table 2: Nursing Faculty’s awareness on current ICMR ethical guidelines for health research**

**N=115**

|  |  |
| --- | --- |
| **Domains** | **Mean±SD** |
| 1. General ethical principles | 3.8±0.8 |
| 2. General ethical issues and dilemma | 3.1±1.2 |
| 3. IEC Committee | 3.5±1.1 |
| 4. Ethical review process for project | 2.9±0.7 |
| 5. Informed consent process | 4.3±0.3 |
| 6. Responsible conduct of researcher | 3.1±1.1 |
| 7. Ethics on vulnerable participants | 2.8±0.9 |
| 8. Ethical conduct in clinical/ drug trials | 2.2±1.6 |
| 9. Ethical conduct in public health research | 2.4±1.2 |
| 10. Ethical conduct in social and behavioural science research | 2.5±0.9 |
| 11. Ethical conduct in genetic research | 1.1±0.7 |
| 12. Ethical conduct in research during emergencies/ disaster | 0.8±0.3 |
| **Overall awareness score** | **32.5±10.8** |

**Table 3: Nurses’ adherence with ethical guidelines in research**

**N=280**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Areas of ethical considerations in research*** | ***Govt. college***  ***(n=140)***  ***f (%)*** | ***Private college***  ***(n=140)***  ***f (%)*** | ***Total***  ***(N=280)***  ***f (%)*** |
| Research project approved by IEC | 96 (68.6)  CI:60.2-76.1 | 31 (22.1)  CI: 15.6-29.9 | 127 (45.4)  CI: 39.4-51.4 |
| Informed written consent obtained | 104 (74.3)  CI:66.2-81.3 | 35 (25.0)  CI: 18.1-33.0 | 139 (49.6)  CI: 43.6-55.6 |
| Patient information sheet was provided | 78 (55.7)  CI: 47.1-64.1 | 14 (10.0)  CI: 5.6-16.2 | 92 (32.9)  CI: 27.4-38.7 |
| Confidentiality of information was ensured | 116 (82.9)  CI: 75.6-88.7 | 101 (72.1)  CI: 63.9-79.4 | 217 (77.5)  CI: 72.1-82.3 |
| Anonymity of participants was ensured | 107 (76.4)  CI: 68.5-83.1 | 32 (22.9)  CI: 16.2-30.7 | 137 (48.9)  CI: 42.9-54.9 |
| Custodian permission was obtained | 137 (97.8)  CI: 93.9-99.6 | 125 (89.3)  CI: 82.9-93.9 | 262 (97.1)  CI: 90.0-96.1 |

\*CI: Confidence Interval