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Original Research Article

Practices of ethics in documentation and awareness about consent among postgraduate resident doctors: A cross-sectional study

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Abstract

Background: Ethical documentation and informed consent are fundamental components of patient-centered care and biomedical research. Postgraduate resident doctors play a pivotal role in implementing these principles; however, gaps in awareness and practice persist.
Objectives: To assess the knowledge, awareness, and practices of ethical documentation and informed consent among postgraduate resident doctors and to determine associations with demographic and professional variables.
Materials and Methods: A cross-sectional study was conducted among 55 postgraduate resident doctors in a tertiary-care teaching hospital. Data were collected using a structured questionnaire based on standard ethical guidelines. Knowledge and practice scores were calculated and categorized. Statistical analysis included descriptive statistics and Chi-square test, with $p<0.05$ considered significant.
Results: The mean knowledge score was 6.5 ± 2.0, with 60% demonstrating good knowledge. The mean practice score was 3.4 ± 1.1, with 76% showing good practice. A statistically significant association was observed between department and knowledge level ($p=0.021$), while research experience was significantly associated with better practice ($p=0.038$).
Conclusion: Although postgraduate residents demonstrate moderate awareness and relatively good practices, important gaps exist in ethical documentation and conceptual understanding of informed consent. Structured ethics training and institutional reinforcement are recommended.

Keywords: Informed consent, Ethical documentation, Postgraduate residents, Bioethics, Medical education

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1. Introduction

Ethical practice in medicine is fundamentally grounded in respect for patient autonomy, beneficence, non-maleficence, and justice. Among these principles, informed consent serves as a critical mechanism through which patient autonomy is operationalized, ensuring that individuals make voluntary and informed decisions regarding their healthcare and participation in research.[1,2] Ethical documentation complements this process by providing a verifiable record of communication, safeguarding both patient rights and medico-legal accountability.[15]

The concept of informed consent gained prominence following historical ethical violations in human experimentation, leading to the development of foundational documents such as the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report.[2-4] These frameworks emphasize voluntary participation, adequate disclosure of risks and benefits, comprehension, and the right to withdraw from research at any stage.[10,11] Contemporary ethical guidelines, including those issued by the Indian Council of Medical Research (ICMR), further elaborate the procedural and documentation aspects of informed consent in clinical and research settings.[5,14]

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International organizations such as the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) have also reinforced the importance of ethical oversight and informed consent in biomedical research.[17,18] Additionally, Good Clinical Practice (GCP) guidelines by the European Medicines Agency emphasize the necessity of proper documentation and participant protection in clinical trials.[15]

In modern healthcare systems, postgraduate resident doctors are often the primary professionals responsible for obtaining informed consent and maintaining clinical documentation. Their role is especially crucial in tertiary-care institutions where complex procedures and research activities are frequently undertaken. Despite the availability of structured guidelines, studies have consistently reported variability in the knowledge, awareness, and practices of informed consent among resident doctors.[6-8]

Previous research has demonstrated that while many resident doctors recognize the importance of informed consent, gaps remain in understanding its components, ethical foundations, and proper documentation practices.[6,7,9] In particular, deficiencies have been noted in areas such as communication in vernacular language, explanation of risks and benefits, and provision of participant information sheets.[12,13] These gaps may compromise the validity of consent and undermine ethical standards in healthcare delivery.

Furthermore, ethical documentation is often reduced to a procedural formality rather than a comprehensive process involving patient engagement and understanding. Advances such as multimedia consent tools have been proposed to improve patient comprehension and participation.[12] This discrepancy between knowledge and practice highlights the need for systematic evaluation and targeted interventions.

This study aims to assess the practices of ethics in documentation and awareness about informed consent among postgraduate resident doctors and to identify gaps that may inform improvements in medical education and institutional policies.

2. Materials and Methods

A cross-sectional observational study was conducted in a tertiary-care teaching hospital. The study included a total of 55 postgraduate resident doctors. Postgraduate residents involved in patient care and willing to provide informed consent were included in the study. Non-consenting participants and residents unavailable during the data collection period were excluded. Data were collected using a structured questionnaire developed based on ICMR Ethical Guidelines (2017), a standard informed consent checklist, and relevant published literature. The questionnaire comprised demographic details, 10 knowledge-based questions, and 5 practice-based questions.

Knowledge scores ranged from 0 to 10, with scores ≥6 considered good. Practice scores ranged from 0 to 5, with scores ≥3 considered good.

Data were analyzed using SPSS software. Continuous variables were expressed as mean and standard deviation, while categorical variables were presented as frequencies and percentages. The Chi-square test was applied to determine associations between variables. A p-value of <0.05 was considered statistically significant. Ethical approval was obtained from the Institutional Ethics Committee. Participation was voluntary, and confidentiality of participants was strictly maintained.

3. Results

3.1. Demographic characteristics

A total of 55 postgraduate resident doctors participated in the study. The mean age of the participants was 28.8 ± 2.9 years. The gender distribution was nearly equal, with 27 (49.1%) males and 28 (50.9%) females. The majority of participants belonged to clinical departments, including medicine and surgery. A total of 22 (40%) participants reported having prior research experience.

Table 1: Demographic details

Variable	Frequency (%)
Age ≤ 28 years	32 (58.2%)
Age > 28 years	23 (41.8%)
Male	27 (49.1%)
Female	28 (50.9%)
Pre/Para-clinical	16 (29.1%)
Medicine	19 (34.5%)
Surgery	20 (36.4%)
Research Experience (Yes)	22 (40%)

4. Knowledge Regarding Informed Consent

The mean knowledge score among participants was 6.5 ± 2.0. Overall, 33 (60%) participants demonstrated good knowledge, whereas 22 (40%) had poor knowledge. Higher awareness was observed in areas such as the mandatory nature of consent (76%) and the need for risk–benefit explanation (84%). However, comparatively lower awareness was noted regarding the components of the informed consent document (31%) and the concept of assent (45%).

Table 2: Knowledge regarding informed consent

Parameter	Correct Responses (%)
Consent is mandatory	76
Ethical principle (Autonomy)	55
Components of ICD	31
Right to withdraw	69
Risk–benefit explanation	84
Local language use	78
Assent knowledge	45

5. Practices of Ethical Documentation

The mean practice score was 3.4 ± 1.1. A total of 42 (76%) participants demonstrated good practices, while 13 (24%) showed poor practices. Most participants reported explaining procedures to patients (90%) and using vernacular language during consent (82%). However, only 56% of participants reported providing a Participant Information Sheet (PIS), indicating gaps in comprehensive documentation practices.

6. Association Analysis

A statistically significant association was observed between the department of the participants and their knowledge level ($\chi^2 = 7.72$, $p = 0.021$), with participants from pre- and para-clinical departments demonstrating higher knowledge levels. Additionally, research experience was significantly associated with better practice scores ($p = 0.038$). No statistically significant association was found between knowledge or practice and variables such as gender or age.

Table 3: Association between knowledge and variables

Variable	Good Knowledge (%)	Poor Knowledge (%)	p-value
Gender	59	41	0.48
Department	72	28	0.021*
Research Experience	68	32	0.09

*Statistically significant

7. Knowledge and Practice Scores (gender comparison)

The comparison of mean knowledge and practice scores between male and female participants revealed no statistically significant difference. Female participants demonstrated slightly higher mean knowledge (6.7 ± 1.9) and practice scores (3.5 ± 1.0) compared to male participants (6.3 ± 2.1 and 3.3 ± 1.2, respectively); however, these differences were not statistically significant ($p > 0.05$). This indicates that gender does not significantly influence the knowledge or practices related to informed consent and ethical documentation among postgraduate residents.

Table 4: Knowledge and practice scores (gender comparison)

Gender	Mean Knowledge Score (Mean ± SD)	Mean Practice Score (Mean ± SD)	p-value
Male (n=27)	6.3 ± 2.1	3.3 ± 1.2	0.62
Female (n=28)	6.7 ± 1.9	3.5 ± 1.0	0.48

8. Comparison of Knowledge and Practice Scores among residents of different departments

A comparison of mean scores across departments demonstrated a statistically significant difference in knowledge scores ($p = 0.03$), with participants from pre- and para-clinical departments showing higher mean knowledge scores (7.2 ± 1.8) compared to those from medicine (6.4 ± 2.0) and surgery (6.0 ± 2.1). This finding suggests that academic exposure and theoretical training may contribute to better conceptual understanding of informed consent among these groups. In contrast, no statistically significant difference was observed in practice scores across departments ($p > 0.05$), although participants from clinical departments, particularly surgery (3.6 ± 1.2), demonstrated slightly higher practice scores. This may reflect greater clinical exposure and routine involvement in consent procedures.

Table 5: Departmental comparison of knowledge and practice scores

Department	Mean Knowledge Score (Mean ± SD)	Mean Practice Score (Mean ± SD)	p-value
Pre/Para-clinical (n=16)	7.2 ± 1.8	3.2 ± 1.1	0.03*
Medicine (n=19)	6.4 ± 2.0	3.5 ± 1.0	0.41
Surgery (n=20)	6.0 ± 2.1	3.6 ± 1.2	0.37

9. Discussion

The present study provides important insights into the knowledge, awareness, and practices of ethical documentation and informed consent among postgraduate resident doctors. The findings reveal a moderate level of knowledge accompanied by relatively better reported practices, yet significant gaps persist in critical areas of ethical understanding and documentation.

The mean knowledge score (6.5 ± 2.0) indicates that although a majority of participants demonstrated acceptable awareness, a substantial proportion lacked comprehensive understanding of key ethical concepts. This finding is consistent with previous studies conducted among resident doctors in India and other regions, which have reported similar levels of moderate knowledge with notable deficiencies in specific domains.[6,7,9] In particular, the limited awareness regarding the components of the informed consent document observed in this study aligns with earlier research highlighting inadequate familiarity with Participant Information Sheets and consent forms.[6,14]

One of the most concerning findings is the inadequate understanding of assent and consent in vulnerable populations. Less than half of the participants correctly identified the concept of assent, reflecting a gap in pediatric and ethical training. Ethical guidelines such as those by ICMR and CIOMS clearly emphasize the need for additional safeguards for vulnerable populations, including minors and individuals lacking decision-making capacity.[5,17] Failure to adhere to these principles may lead to ethical violations and compromise patient rights.

The study also highlights a discrepancy between knowledge and practice. While 76% of participants demonstrated good practices, the depth and quality of these practices remain questionable. Similar observations have been reported in earlier studies, suggesting that healthcare professionals often follow procedural aspects of consent without fully understanding their ethical implications.[7] This phenomenon may be attributed to institutional routines, hierarchical learning environments, and lack of structured ethics training.

Communication plays a central role in informed consent, yet gaps were identified in this domain. Although a majority of participants reported using vernacular language, a significant proportion failed to provide comprehensive information such as the Participant Information Sheet. Effective informed consent requires not only linguistic translation but also simplification of medical information to ensure comprehension.[12,13] Previous studies have demonstrated that patients often fail to fully understand consent forms due to complex terminology and inadequate explanation.[13]

The statistically significant association between department and knowledge level suggests that academic exposure and training influence ethical competence. Participants from pre- and para-clinical departments demonstrated higher knowledge levels, possibly due to greater engagement with research methodology and theoretical ethics training. This finding is consistent with earlier studies highlighting the role of academic exposure in improving ethical awareness.[6,9]

Similarly, the significant association between research experience and better practice highlights the importance of experiential learning. Residents involved in research activities are more likely to be familiar with ethical guidelines, Good Clinical Practice standards, and consent procedures.[15] This supports the integration of research-based training in postgraduate education to strengthen ethical competence.[14]

Another critical issue identified in this study is the incomplete implementation of ethical documentation practices. Proper documentation is essential not only for ethical compliance but also for legal protection and accountability. Regulatory frameworks such as GCP guidelines and WHO recommendations emphasize the importance of maintaining accurate and comprehensive documentation.[15,18] Failure to adequately document informed consent may result in medico-legal consequences and erosion of patient trust.

The findings also underscore the importance of structured ethics education. Despite the inclusion of ethics training in medical curricula through initiatives such as the AETCOM module, implementation remains inconsistent.[16] There is a need for more interactive and competency-based approaches, including workshops, simulations, and Objective Structured Practical Examinations (OSPE), to enhance both knowledge and practical skills.

Furthermore, institutional measures such as regular audits of consent documentation, standardized consent forms, and monitoring by ethics committees can significantly improve compliance.[18,19] Emerging approaches, including multimedia consent tools and digital documentation systems, have also shown promise in improving patient understanding and engagement. International organizations such as the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) have also reinforced the importance of ethical oversight and informed consent in biomedical research.[17,18] Additionally, ethical challenges in the conduct of clinical research, particularly in diverse and resource-limited settings, have been widely discussed in the literature.[20]

Finally, this study reinforces the need for a paradigm shift in the perception of informed consent—from a procedural requirement to a patient-centered ethical process. Ethical practice must go beyond obtaining signatures to ensuring meaningful communication, comprehension, and voluntary participation

10. Conclusion

Postgraduate resident doctors demonstrate moderate awareness and relatively good practices regarding informed consent. However, critical gaps persist in ethical documentation and conceptual understanding. Strengthening ethics education through structured training, workshops, and institutional policies is essential to ensure ethical and patient-centered care.

11. Source of Funding

None.

12. Conflict of Interest

None.

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