**Title: Curriculum development in research ethics for medical postgraduates using Modified Kern’s six step approach**

**Authors and affiliations:**

*Medha Rajappa 1*, Revathy G*1*, Dongre A2, Kadambari D3, Selvarajan S4, Kar SS5, Jayanthi M6, Gladwin V7

1. Department of Biochemistry, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry
2. Department of Preventive and Social Medicine Sri Manakula Vinayagar Medical College and Hospital (SMVMCH), Puducherry.
3. Department of Surgery, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry
4. Department of Clinical Pharmacology, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry
5. Department of Preventive and Social Medicine, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry
6. Department of Pharmacology, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry
7. Department of Anatomy, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Puducherry

**Correspondence to:**

Dr. Medha Rajappa,

Associate Dean (Research) & Additional Professor of Biochemistry,

Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER),

Puducherry-605006

India

Tel No: +91-94863-98875,

Fax No: +91-4132272067,

Email: [linkmedha@gmail.com](mailto:linkmedha@gmail.com)

**Acknowledgement:**

*This research was carried out as an educational innovation project done by Dr. Medha Rajappa* as part of her Foundation for Advancement of International Medical Education and Research (FAIMER) *Fellowship at the PSG-FAIMER Regional Institute, Coimbatore, India from 2017-2019.* The authors wish to acknowledge Dr. Thomas Chacko, Director, PSG-FAIMER Regional Institute, Coimbatore, Dr. Sudha Ramalingam, Co-Director, PSG-FAIMER Regional Institute, Coimbatore and other Faculty Mentors of the PSG FAIMER Regional Institute, Coimbatore for their guidance and support for this educational project. The authors also wish to thank the IEC experts and the second year postgraduates for contributing to this educational project.

**Author contributions:**

MR conceptualized the work and planned the design, did the data acquisition, data analysis, interpretation, drafted the article and approved the final version to be published.

RG made substantial contribution to data acquisition, analysis and interpretation, drafted the article and approved the final version to be published.

AD made substantial contribution to conception and design, contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

KD made substantial contribution to conception and design, contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

SS contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

SSK made substantial contribution to conception and design, contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

JM contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

GV contributed to data analysis and interpretation, revised the article critically for intellectual content and approved the final version to be published.

**Abstract:**

**Introduction:**

Biomedical ethics training is important for the holistic training of a medical student. However, it is largely neglected in the undergraduate curriculum and there is lack in comprehension of the depth of the ethical issues involved in research. In this study, we identified deficiencies in the current understanding and practice of ethical principles and designed a curriculum for ethics training in post-graduate research training program

**Methodology:**

Modified Kern’s six steps approach was used for the above purpose. Needs assessment and core competencies identification was done using focussed group discussion with IEC experts. Educational strategy used was story telling. Evaluation and feedback were done as: Kirkpatrick's Level I: Student feedback; Kirkpatrick's Level II: Pre-test/Post- test using pre-validated MCQs to assess learning.

**Results:**

Needs assessment revealed that postgraduates need training in research ethics due to lack of adequate exposure at undergraduate level. The core competencies identified were autonomy (taking informed consent appropriately), beneficience, non-maleficience (performing the benefit-risk assessment and act appropriately), justice (appropriate selection of participants), responsible authorship and publication of conducted research and rights of participants (right to withdraw, compensation, free treatment, privacy and confidentiality). Feedback revealed that the training was effective and a significant gain in knowledge about ethical practices was also observed after the training session.

**Discussion:**

Needs assessment and core competencies identified were used to develop narrative stories - an innovative delivery vehicle for research ethics training. It was highly effective in improving the comprehension of the ethical aspects of research, as evident from respondent performance and feedback

**Key words:**

Kern’s six step approach, curriculum development, ethics training, teaching learning method, storytelling, workbook

**Introduction:**

Teaching of biomedical ethics has been largely ignored in medical curriculum [1]. However, a doctor is expected to follow certain moral principles in their conduct during patient care. Not just during medical practice, but also medical research involves contact with patients and the need to follow the moral regulations. Biomedical ethics training is important for holistic training of a medical student. Proper ethical training helps in strict adherence to the moral conduct of the medical postgraduates towards the patients resulting in prevention of untoward mental, physical or financial agony of the patients.

Postgraduates are not only involved in patient care services but also in research involving patients. It is essential that a good doctor-patient relationship is required to benefit both the patients and the research that is carried on [2]. A patient needs to be completely appraised of any procedure he is subjected to along with the details of its necessity, benefits and harm in a comprehensive manner and written consent must be taken before the procedure. If the patient is recruited for research, that needs to be clearly explained to the patient and the patient must be made to understand that his participation is purely voluntary and his non-participation will not affect the normal medical care he would receive.

Though there are opportunities where ethics can be taught to the medical postgraduate such as the postgraduate orientation programme, it has been generally observed that they do not fully comprehend the depth of the ethical issues involved in the research [3]. Dissertation is a mandatory requirement for award of degree for medical postgraduates. Ethical documents of postgraduates’ dissertation show incomplete & incorrect entries. The postgraduates can be considered as new learners due to lack of adequate exposure at the undergraduate level. They need to know the basics of research ethics right at the beginning of their PG career, i.e. before undertaking their research. Practice of research ethics should not be a procedural requirement, instead it should be an attitudinal change in them. Advanced level of competency in research ethics is required at a postgraduate level.

Ethical teaching as a didactic lecture doesn’t impress on the postgraduates as well as the small group discussions [4]. Teaching moral principles as such in naïve form also seems less interesting. Hence, design of a novel and interactive teaching learning method in the curriculum in post-graduate research training program with enhanced thrust on ethical practices is required. In this research, story-telling was used as an innovative method for research ethics training in medical postgraduates. Hence, a workbook using narratives for research ethics training was developed as part of this educational innovation.

**Materials and Methods:**

Ethical approval was obtained from the Institute’s Ethics Committee (Human Studies) (JIP/IEC/2017/0325). The study was conducted according to the ethical guidelines of the Declaration of Helsinki [5] and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Second year postgraduate students of JIPMER who had already attended the research methodology training program were recruited in this study to pilot this educational intervention. Written informed consent was obtained from all subjects prior to recruitment.

Modified Kern’s six steps approach in curriculum development was used to develop the workbook [6]. The six steps involved were as follows: (i) Problem identification and general needs assessment, (ii) targeted needs assessment, (iii) goals and objectives, (iv) educational strategies, (v) implementation and (vi) evaluation and feedback, which was done by a mixed methods approach.

Using a qualitative approach, general needs assessment was done by a document review of thirty randomly selected protocols submitted by postgraduates to the JIPMER IEC for approval previously. Targeted needs assessment and objectives were developed using a focussed group discussion with IEC experts. Educational Strategy used was workbook development for research ethics training using story telling method. Core competencies were obtained from focussed group discussion with ethics experts and course material was developed using stories taken from published literature related to biomedical research ethics. Validation was done to check if the historical narratives are illustrative of core-competencies in research ethics.

Workbook was then evaluated for research ethics training to thirty second-year postgraduates. Evaluation and feedback were done using Kirkpatrick’s model of evaluation [7], as follows: Kirkpatrick's Level I: Student feedback and Reflections; Kirkpatrick's Level II: Pre-test/Post- test using pre-validated MCQs to assess the learning – gain in knowledge by a quantitative approach.

**Statistical analysis:**

IBM SPSS statistics version 22 for Windows was used for data analysis. Data were described as mean ± standard deviation and compared by paired Student’s t-test. Analysis was carried out at 5% level of significance and p<0.05 was considered as statistically significant.

**Results:**

Needs assessment revealed that postgraduates need training in research ethics due to lack of adequate exposure at undergraduate level. It revealed that practice of ethics is not a procedural requirement, but involves an attitudinal change in them. They require an advanced level of competency in research ethics at postgraduate level. On document review, about 60% of the protocols had incomplete and incorrect entries. This revealed inadequate knowledge, which required immediate redressal. Core-competencies to be developed during postgraduate training were identified based on a focussed group discussion with IEC experts.

The core competencies identified were as follows:

1. Appreciate the concept of informed consent/ assent (autonomy) and take informed consent in an appropriate manner for research from the research participants/LAR. (Knowledge, Skill and Attitude).
2. Appreciate the concept of benefit-risk assessment (beneficence and non-maleficence) and perform it in an appropriate manner for research. (Knowledge, Skill and Attitude).
3. Understand the concept of selection of participants, (justice), esp. vulnerable groups and take safeguards in such cases in an appropriate manner. (Knowledge, Skill and Attitude).
4. Understand the issues involved in responsible authorship and publication of conducted research and apply the same to his/her research. (Knowledge, Skill and Attitude).
5. Understand the rights of participants including right to withdraw, compensation, free treatment, privacy & confidentiality. (Knowledge, Skill and Attitude)

Implementation and evaluation of the workbook developed was then carried out. The feedback from postgraduates revealed that the training was effective and they wanted such out-of-the-box innovative T-L methods for research ethics training. (Table 1)

**Table 1: Student feedback on intervention - Kirkpatrick level 1 i.e. Reaction/ Satisfaction (N=30)**

|  |  |  |
| --- | --- | --- |
| **Research Ethics Training Using Narrative Workbook** | **Strongly agree** | **Agree** |
| It provoked interest towards conduct of ethical research. | 29 | 1 |
| More motivated and equipped to understand biomedical research ethics principles after the session. | 30 | 0 |
| Promoted reflective learning & stimulated critical thinking towards application of research ethical principles. | 28 | 2 |
| Increased confidence to apply principles of research ethics and informed consent during my dissertation research and in future. | 27 | 3 |
| I recommend this research ethics training to first year PGs in forthcoming years. | 28 | 2 |

Evaluation of the workbook also revealed a significant gain in knowledge in the ethical practices in biomedical research. (Table 2)

**Table 2: Effectiveness of intervention - Kirkpatrick level 2 i.e. Learning**

|  |  |  |
| --- | --- | --- |
| **Pre-test (Mean± SD) N=30** | **Post-test (Mean± SD) N=30** | **P value (Paired t test)** |
| 19.81 ± 1.04 | 25.29 ± 2.34 | 0.004 |

**Discussion:**

In this research, we evaluated story telling as a vehicle for research ethics training in medical postgraduates and we found that indeed it was highly effective in its purpose, as evident from the respondent performance and feedback.

Medical practice is housed with many complex moral and ethical issues. Medical practice and research involve dealing with patients. Without proper practice of the ethical guidelines, the benefit to the patients become elusive and the medical graduates face legal problems [2]. This is largely due to inadequate exposure of medical graduates to the biomedical ethical principles in the undergraduate curriculum [1]. Appropriate training in delineated systematic guidelines in ethical practices in the management of patients will help both the patients and the treating physicians and improve the benefits of current medical practice.

Ethical teaching has been largely undermined in undergraduate teaching [8]. The very few lectures that happen are didactic and boring for the students. Further, there is no evaluation of the biomedical ethical principles as part of undergraduate curriculum [8]. There is no thrust in the importance of practice of biomedical ethics till now. Hence, it has largely been overlooked.

The physician should not take the patients for granted and need to explain to the patient in a comprehensible way the details of the procedure he is subjected to, along with the benefits and possible harm [3]. Any procedure on the patient needs to be undertaken only after an informed consent. Similarly, participation of the patient in a medical research work must be voluntary by the patient after providing him the complete details and obtaining an informed consent. The patient must also not be forced into participation for fear of losing normal patient care services.

In this study, we identified that 60% of protocols of postgraduates’ dissertation showed incomplete & incorrect entries. Further needs assessment and identification of core competencies were done using focussed group discussion with IEC members. Sample stories representing the identified core competencies was taken from published literature and used as an innovative teaching method in this study.

Various teaching and learning methods for medical ethics training has been tried [4]. Didactic lectures were found to be least beneficial and other novel teaching and learning methods with more focus on hands-on approaches and real life experiences are being advised increasingly for this purpose. In this study, story-telling was used as the teaching learning method with a thrust towards practical implication of ethics training. We found that story-telling proved to be an effective vehicle to train medical postgraduates in research ethics.

The literature landscape on use of narratives to teach research ethics to residents is limited [9-10]. Concordant with our findings, Sim et al found that use of narratives could enhance engagement, appreciation of biomedical research ethics and informed consent, and address underlying motivational factors behind learning and understanding of research ethics [9]. Vertrees et al used an experiential case-based didactic program in clinical ethics to engage adult learners and found that it facilitated a comprehensive and clinically relevant educational initiative [10].

In this study, the postgraduates understood the concept of informed consent/ assent (autonomy), benefit-risk assessment (beneficence & non maleficence). They also understood how to select the participants for research and issues involved in responsible authorship and publication. They were able to appreciate the rights of the participants like right to withdraw / compensation / free treatment / privacy & confidentiality. The feedback received from them revealed that the training was effective and helped them in hands on learning. The students felt it as a relief from the mundane lectures and welcomed the out of the box story-based teaching approach and believed it was more hands on and welcomed such sessions. There was a significant gain in knowledge about research ethics.

The module has only been piloted in this educational research. Further implementation and evaluation of the workbook needs its institutionalisation and sustenance in medical ethics training as part of research methodology training program for the postgraduates.

**Conclusion:**

Story telling is an innovative delivery vehicle for research ethics training. The developed narrative workbook was highly effective in its purpose, as evident from the respondent performance and feedback

**References:**

1. Goldie J. Review of ethics curricula in undergraduate medical education. Med. Educ. 2000;34:108–19.
2. Chen DT. Clinical Research and the Physician–Patient Relationship. Ann. Intern. Med. 2003;138:669.
3. Ramana K, Boinpally P, Kandi S. Ethics in medical education, practice, and research: An insight. Ann. Trop. Med. Public Health 2013;6:599.
4. Wajahat Y. Biomedical Ethics Teachings to Postgraduate Doctors. J. Med. Ethics Hist. Med. [Internet] 2009 [cited 2019 Sep 3];2.
5. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310:2191–4.
6. Thomas PA, Kern D, Hughes MT, Chen BY. Curriculum development for medical education: A six-step approach. 2015.
7. Kirkpatrick, D. (1996). Revisiting Kirkpatrick’s four-level-model. Training & Development. 1996; 1: 54-57.
8. Rameshkumar K. Ethics in medical curriculum; Ethics by the teachers for students and society. Indian J. Urol. 2009;25:337.
9. Sim K, Sum MY, Navedo D. Use of narratives to enhance learning of research ethics in residents and researchers. BMC Med Educ. 2015 Mar 10;15:41.
10. Vertrees SM, Shuman AG, Fins JJ. Learning by doing: effectively incorporating ethics education into residency training. J Gen Intern Med. 2013;28: 578-82.