

Ethics Workshops-Are They Effective in Improving the Competencies of Faculty and Postgraduates?

SUDHA RAMALINGAM¹, S BHUVANESWARI², RAMALINGAM SANKARAN³

ABSTRACT

Introduction: Responsible conduct of research requires a good knowledge about research ethics. With the recent changes in the clinical trial regulations and the proposed introduction of ethics in medical curriculum by the Medical Council of India, there is an urgent need to train the medical faculty and postgraduates in research ethics.

Methodology: We wanted to measure the effectiveness of a one day program which was organized using didactic lectures and case scenarios on the knowledge, attitude and skills on ethics among faculty and postgraduates. This was done using a retropre questionnaire. We performed a Kolmogorov Smirnov

test to measure the normality, Mann Whitney U-test to test the difference in scores between faculty and postgraduates and a Wilcoxin signed rank test to measure the prepost scores.

Results: The faculty showed better scores in knowledge and attitude ($p < 0.05$) when compared to postgraduates both before and after the workshop. The overall scores for both faculty and postgraduates had increased after the workshop ($p < 0.05$).

Conclusion: This re-emphasizes the need for introduction of ethics training during undergraduate course and also the fact that even a short training program in research ethics could be effective.

Keywords: Ethics workshop, Retropre questionnaire, Program evaluation

INTRODUCTION

Increasing biomedical research in developing countries coupled with growing clinical trials scenario [1] mandates the knowledge of human participant protection and following ethical guidelines among medical researchers. Also the National and International standards mandate review of research by Institutional Human Ethics committee [2,3]. Recent regulations by the Medical Council of India require two publications for medical faculty to be considered for promotion. In addition, the Medical Council of India has also recommended introduction of bioethics into the MBBS curriculum. The Vision 2015 document which has recommended changes in the undergraduate and postgraduate curriculum was released by the Medical Council of India on March 29, 2011 [4]. In addition, as per the university regulatory guidelines all post graduate students are expected to carry out a thesis in partial fulfillment of their Masters course which requires a basic knowledge and skill in research ethics.

Presently, in India ethics education is in its nascent stage. The available courses in bioethics in India are few and they are long term (2- 6 weeks) courses. There are practical difficulties for the faculty and postgraduates to attend these courses inspite of the growing need for them to be educated in ethics. There is also a felt need for capacity building programs among faculty and postgraduates in bioethics [5]. A simple strategy to address the need is to organize short continuing education sessions in ethics for postgraduates, faculty and ethics committee members. This strategy has proven to be effective in many countries. A study by Ajuwon et al., has shown a significant improvement in knowledge and attitude towards ethics among investigators after a short workshop [6]. Training in ethics not only increases knowledge in research ethics but also improves problem solving abilities among doctors when faced with an ethical dilemma [7].

A study by Brown and Kalichman [8] among graduate students in experimental sciences also showed that training resulted in improved reports of knowing what to do if faced with an ethical dilemma.

Hence, we proposed that a one-day workshop employing a problem-solving approach using case-scenarios might be suitable. However, we found that evidence for effectiveness of such a course is lacking in the Indian context. We present here results from such a study that we conducted at our Institute of the effectiveness of a course which combined didactic lectures, group exercises involving case scenarios related to real-time experience. We would also like to highlight use of a retro-pre questionnaire as a tool of measurement of program evaluation, in our workshop. We used a retro-pre questionnaire to assess the self perceived effectiveness of the workshop. An accepted method to assess learners' self-reported changes in different domains, retro-pre questionnaires are indeed less time consuming and can overcome response shift bias [9,10]. In this method information is collected only once, at the end of the program.

METHODOLOGY

There were 64 participants who were involved in the study (38 postgraduates and 26 faculties). The workshop was structured to cover all "must know" topics relevant to research ethics. These topics were based on a literature search and also the nature of projects that were received by the Institutional Human Ethics Committee. The workshop was structured to include a mixture of lectures and group work involving case scenarios.

There were didactic lectures on topics such as history and principles of ethics, vulnerable population, composition and roles of ethics committees. Then the participants were divided into groups to and case scenarios were given on confidentiality, stored sample research, conflict of interest and publication ethics. They were asked to reflect and identify the ethical concerns in each scenario. There was active discussion on that topic following a debriefing.

There were eight resource persons and each of them had prior training in research ethics and are members of the research/ethics committee. The same resource persons handled the sessions on both the days.

We chose this method as this is learner centered, interactive and stimulates critical thinking than passive listening. In addition all the scenarios were those which were practically faced by the IHEC and addressed the common mistakes committed by the faculty/postgraduates.

A retro-pre questionnaire is one in which the respondent reflects his/her gain in knowledge or competency before and after an intervention at the same time. This study also involved a retro-pre questionnaire which was developed for self assessment of the competency gained by the participant after the workshop. The knowledge item mainly focused on principles of ethics, roles of ethics committees, different types of review processes, confidentiality, conflict of interest, authorship guidelines and informed consent. The categories of responses for Knowledge domain were 'No idea', 'Have a vague idea' and 'Clear idea'. The score for 'No idea' was 1, 2 for 'Have a vague idea', and 3 for 'Clear idea'. The total items were 20 and the maximum score for this domain was 60. The attitude questions elicited the participant's attitude towards ethics in medical curriculum, requirement for ethics clearance for all research projects, capacity building in research ethics and informed consent requirements. The attitude domain response was in likert scale. The scores were: 5 = strongly agree, 4 = agree, 3 = no opinion, 2 = disagree and 1 = strongly disagree with the statement. The maximum possible score was 30. Five sets of 'Skills' were studied. The skills questions focused on their ability to develop and administer an informed consent to a research participant, analysing risks and benefits of their research project, minimizing conflicts of interest and how to maintain confidentiality. For each skill the following choices were given: 'not confident', 'somewhat confident', 'very confident' in performing the skill and 'will be able to do independently in future'. These were given the scores 1, 2, 3 and 4 respectively. The total skills score was calculated adding the scores of the five skills. The maximum score was 20 for the skills domain.

STATISTICAL ANALYSIS

The total scores of each domain were calculated before and after the workshop. A Kolmogorov- Smirnov test was used to test the normality of the variables. Since most of the variables did not follow a normal distribution a non parametric test was used to find out the statistical significance. Median scores were compared

according to sex and position (Faculty/Postgraduate) before and after the module, using a Mann-Whitney U-test. Median scores before and after the module were compared using the Wilcoxon signed ranks test. A p-value less than 0.05 was taken as statistically significant.

RESULTS

There were 26 faculty members (18 females and 8 males) and 38 postgraduate students (22 females and 16 males).

The retro-pre questionnaire had a maximum score of 60, 40 and 20 for knowledge, attitude and skills domains, respectively. The median (interquartile range) scores for knowledge, attitude and skills before the module were 32(8.5), 31(7) and 8(4) and after the workshop were 58.5(5.75), 36(7), 15(4.75) respectively. The overall median total scores before and after the workshop was 71 and 106.

[Table/Fig-1] shows the "Knowledge", "Attitude" and "Skills" scores at the beginning of the workshop. The median knowledge and attitude scores were significantly higher among the faculty ($p < 0.05$). There were no differences in the scores between males and females in all the three domains.

[Table/Fig-2] shows the "Knowledge" "Attitude" and "Skills" scores after the completion of the workshop. The median scores for the knowledge and attitude continued to be higher for the faculty ($p < 0.05$). The scores were not significantly different among males and females. The overall rise in skill was high in both groups though it was statistically significant among the two groups.

[Table/Fig-3] depicts the median scores of the "Knowledge" "Attitude" and "Skills" before and after the workshop. As shown in the table, the overall scores were significantly higher after the workshop in both the groups.

DISCUSSION

While there are a number of online and other training programs in ethics funded by International organizations, the access to these programs are limited either due to time or money for scientists from developing countries. Short training programs in ethics have been shown effective in various studies at different contexts [6,7,11]. Our findings also support this and found that the short training programs are effective. These types of program evaluations are

| Variables | Mean Knowledge Score (Interquartile range) | Median Attitude Score (Interquartile range) | Median Skills Score (Interquartile range) | Median Total Score |
|-----------------------|--|---|---|--------------------|
| Gender | | | | |
| Male | 31.5(5.75) | 30(7) | 8.5(5.5) | 71.5(13.5) |
| Female | 32(9.75) | 31(7) | 8(4) | 70.5(17.5) |
| p-value | 0.945 | 0.770 | 0.983 | 0.917 |
| Qualifications | | | | |
| Faculty | 33(7) | 33.5(6.25) | 9(2.25) | 76.5(10) |
| Postgraduates | 30(8.75) | 29.5(5.5) | 8(5) | 65.5(12.5) |
| p-value | 0.042 | 0.001 | 0.162 | 0.001 |

[Table/Fig-1]: Knowledge, attitude and skills of the participants before the workshop (comparing sex and qualification of the participants)

| Variables | Mean Knowledge Score (Interquartile range) | Median Attitude Score (Interquartile range) | Median Skills Score (Interquartile range) | Median Total Score |
|-----------------------|--|---|---|--------------------|
| Gender | | | | |
| Male | 59.5(3) | 36(4) | 15(4.5) | 110.5(12) |
| Female | 57(6.75) | 36(7) | 13.5(4) | 105(21) |
| p-value | 0.107 | 0.829 | 0.086 | 0.08 |
| Qualifications | | | | |
| Faculty | 59.5(3) | 37.5(4.25) | 15(5.25) | 112.5(9) |
| Postgraduates | 57(8.5) | 34.5(8.5) | 14.5(5) | 102.5(21.5) |
| p-value | 0.037 | 0.003 | 0.081 | 0.001 |

[Table/Fig-2]: Knowledge, attitude and skills of the participants after the workshop (comparing sex and qualification of the participants)

| Domains | Pre workshop scores (Inter Quartile Range) | Post workshop scores (Inter Quartile Range) | p-value (Inter Quartile Range) |
|-----------|--|---|--------------------------------|
| Knowledge | 32(8.5) | 58.5(5.75) | <0.001 |
| Attitude | 31(7) | 36(7) | <0.001 |
| Skills | 8(4) | 15(4.75) | <0.001 |
| Total | 71 (17) | 106(19) | <0.001 |

[Table/Fig-3]: Median scores at the beginning and end of the research ethics workshop

essential in any Institution as it provides a concrete measure of the effectiveness of the program. This helps in policy making and also for taking corrective actions in future if found necessary.

While our findings on the attitude towards ethics was different among faculty and postgraduates, their scores in skills required in research ethics which included developing and administering informed consent, minimizing conflict of interest, maintaining confidentiality and analysing risk benefit of their research did not differ [Table/Fig-1]. This points to the fact that though faculty have some prior research experience either by doing projects or guiding students their skill levels in the above mentioned areas were deficient. A similar finding was observed in a study by El-Dessouky et al., among faculty in Saudi Arabia [11].

The overall increase in knowledge, attitude and skills domain after the workshop was statistically significant in both the faculty and postgraduates. Similar observations were made by Ajuwon and Kass in Ethiopia in a qualitative research which showed the effectiveness of a research ethics workshop among students and faculty. In this study the investigators organized three rounds of workshop each session lasting 7h using various methods such as group work, case studies and lectures which showed a significant increase in Knowledge, Attitude and Skills towards research ethics among faculty following a workshop [6]. Similar observations were made by Barchi et al., in their randomised control study on two groups of researchers in Botswana in building research capacity showed the effectiveness of short training programs. Their study included two groups which included a two day program and the intervention group which received online cases and discussions [12]. Their study showed that in person seminars were more effective. These observations lead us to arrive at a plausible conclusion that short term in person training in ethics is effective.

LIMITATIONS

Our study has certain limitations. The sample size was small as the number of participants in each workshop was restricted. We also need to examine the long term implications and the improvement of skills in preparing and administering informed consent and managing conflicts of interests.

CONCLUSION

The results of our study supports the notion that short term training programs combined with lectures and case studies on important aspects of research ethics are effective. More such training programs are the need of the hour as we build our capacity in research in India. We have made training in ethics and research methodology mandatory for all postgraduates and also for new faculty who guide or take up research projects. Such initiatives are mandatory for ethical conduct of research.

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PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Community Medicine, PSG Institute of Medical Sciences and Research, Coimbatore, India.
2. Professor, Department of Pharmacology, PSG Institute of Medical Sciences and Research, Coimbatore, India.
3. Professor, Department of Pharmacology, PSG Institute of Medical Sciences and Research, Coimbatore, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Sudha Ramalingam,
G4 PSG Doctors Quarters, Peelamedu, Coimbatore-641004, India.
Phone: 9894429646, E-mail: drsudhapsg@gmail.com

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