

EFFECT OF AN EDUCATIONAL INTERVENTION ON MEDICAL AND RESEARCH ETHICS OF RESIDENTS OF ZAGAZIG UNIVERSITY HOSPITALS

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ABSTRACT

Medical ethics and research ethics are essential for clinical practice and for achievement of the balance between advancement in science and protection of human subjects' rights. **The aim** of the study is to assess the effects of implementing a short course on medical and research ethics at the Faculty of Medicine, Zagazig University. **Design:** An interventional study was done at Zagazig University Hospitals. **Sample:** The study sample consisted of 108 residents working in Zagazig University Hospitals. **Tools:** Data was collected through an interviewing questionnaire to assess sociodemographic characteristics of the residents, their medical and research ethics knowledge and attitude before and after the intervention course. **Results:** the residents included the study had deficient knowledge and attitude about medical and research ethics. The implementation of educational intervention course was effective in improving their knowledge and attitude toward medical and research ethics. The total satisfactory knowledge and attitude towards medical ethics showed high statistically significant improvements after the intervention (63.9% and 60.2%) respectively compared with (22.2% and 35.1%) respectively before intervention ($p < 0.001$). Also, there were high statistically significant improvements in total knowledge and attitude towards research ethics after the intervention (83.3% and 72.2%) respectively compared with (19.4% and 19.4%) respectively before intervention ($p < 0.001$). **Conclusion and Recommendations:** Knowledge and attitudes of residents towards medical and research ethics found to be inadequate. Educational intervention programs about medical and research ethics are in need to be a priority and repeated medical and research ethics courses should be integrated within the postgraduate curriculum.

Key words: educational intervention, residents, medical ethics, research ethics

INTRODUCTION

Although ethics as applied to medical practice dates back to the ancient civilization by the symbolic adherence to the Hippocratic Oath. Codes of conduct and laws regulating the profession have been updated from time to time to develop students' values, social perspectives and interpersonal skills for the practice of medicine (Kuczewski, 2003). The main goal of Medical ethics is the creation of good doctors who will enhance and promote the health and medical welfare of the people they serve in ways which fairly and justly respect their dignity, autonomy and rights. (Goldie, 2000). Also, medical ethics acts as a "bridge" between theoretical bioethics and the bedside. It improves the quality of patient care by identifying, analyzing, and attempting to resolve the ethical problems that arise in practice". Legal and ethical considerations are inherent and

inseparable parts of good medical practice (Rai et al., 2013).

There is an increased need to conduct medical research in developing countries. Meanwhile, research ethics is needed to achieve the balance between advancement in science and protection of human subjects' rights. In biomedical researches conducted in Egypt, the concerns about the research ethics have been raised recently due to the progressive development in the research centers and processes. Thus a great interest has been developed to explore the Egyptian investigators' awareness, attitudes and practice regarding research ethics (El Shabrawy, 2014).

Previous researches conducted in Egypt suggested that the knowledge of researchers about research ethics is remarkably low so more emphasis on research ethics training is urgently needed. (El Shabrawy, 2014). Many

Studies in different countries were done to explore the knowledge and attitude of physicians on issues relating to medical ethics (Sulmasy et al., 1995; Shiraz et al., 2005 and Walrond et al., 2006).

The aim of this study was to assess the effect of an educational intervention on knowledge and attitude among residents towards medical and research ethics at Zagazig University Hospitals.

SUBJECTS AND METHODS

I- Technical design:

Tools:

1-Questionnaire: Modified standardized questionnaire was used, guided from other survey studies (Hariharan, et al., 2006 and Mohamed et al 2012). The used questionnaire identifying residents characteristics like age, sex and year of residence and including pre and post test for assessment of knowledge and attitude regarding medical ethics and research ethics.

2- Educational message to improve knowledge and attitude of residents regarding medical and research ethics.

The Sample size was calculated using Epi info version 6.04 (Dean et al., 2000); According to the statistical book of Zagazig University, the total number of registered residents at the year 2013 were 870, with expected frequency of lack of awareness regarding medical ethics was 12.9% (Fadare et al., 2012), at confidence interval 95%, with study power was 80%. Accordingly, the total calculated sample size was 108 residents. Residents were selected randomly from different departments including general and specific departments.

Inclusion criteria for participating residents:

Residents in Zagazig University hospitals doing medical research.

Exclusion criteria for participating residents:

Medical staff or any residents not doing medical research.

II-Operational design: An intervention study was carried out during the year (2013/2014). The study passed into 3 stages:

Stage 1:

A-Assessment of resident's knowledge and attitude toward medical ethics through pretest

questionnaire. It included questions about principles of medical ethics, laws pertaining to work, principles of professionalism, resources for medical ethics education, importance of consent and their opinion about importance of teaching medical ethics and attitudes towards Confidentiality, doctor-patient relationship.

B- Assessment of resident's knowledge and attitude toward research ethics through pretest questionnaire. It included questions about ethical concerns regarding keeping patients details, informed consent, ethical consideration regarding the provision of incentives, selection of research participants, right of the research participants to participate in a voluntary way, free from any pressure, scholarly publication, research ethics committee responsibilities. The importance of research ethics and research ethics committee.

Scoring system for the questionnaire:

The right answer take score one and the wrong take score zero. In questions with multiple choices or to calculate total satisfactory scores if number of right answers $\geq 60\%$ from total, it take score one and if right answers less than 60% of total it take score 0.

Stage II (intervention stage):

Eight hours of medical and research ethics were introduced within the bioethics course for postgraduate students at Forensic Medicine and Clinical Toxicology Department of the Faculty of Medicine, Zagazig University and implemented over a period of 4 weeks, i.e. two hours/week. The sessions included lectures, and case discussions. The course included principals of medical and research ethics, role and function of Institutional Review Boards (IRB's). The course was taught by staff of forensic Medicine and Clinical Toxicology Department. This was facilitated by giving the participants booklets covering the important items of medical and research ethics.

Stage III: Evaluate effectiveness of educational course through post test questionnaire after intervention by about 3 months in which results were compared with that of pre test of the same participants.

Ethical issues: Proposal acceptance was obtained from the Institutional Review Board

(IRB) of the Faculty of Medicine; Zagazig University. Moreover, verbal consent was obtained from all participants after explaining the objectives of the study and the confidentiality of the information was assured.

Data management: The collected data were presented, summarized, tabulated & analyzed by using computerized software statistical packages (EPI-info Version 6.04 & SPSS version 19). $P < 0.05$ was considered to be statistically significant. Mac Nemar test: used to determine whether there is statistical

significant difference between pre and posttest or not.

RESULTS

Figure 1 showed the distribution of study participants according to sex and in residency years. A total of 108 respondents belonged to the category of post-graduate medical residents had participated. The sex distribution among participants was 62.0% males and 38.0% females. Forty one (41%) of study participants were in first year of residency, 32% were in the second year and 27% were in the third year of residency.

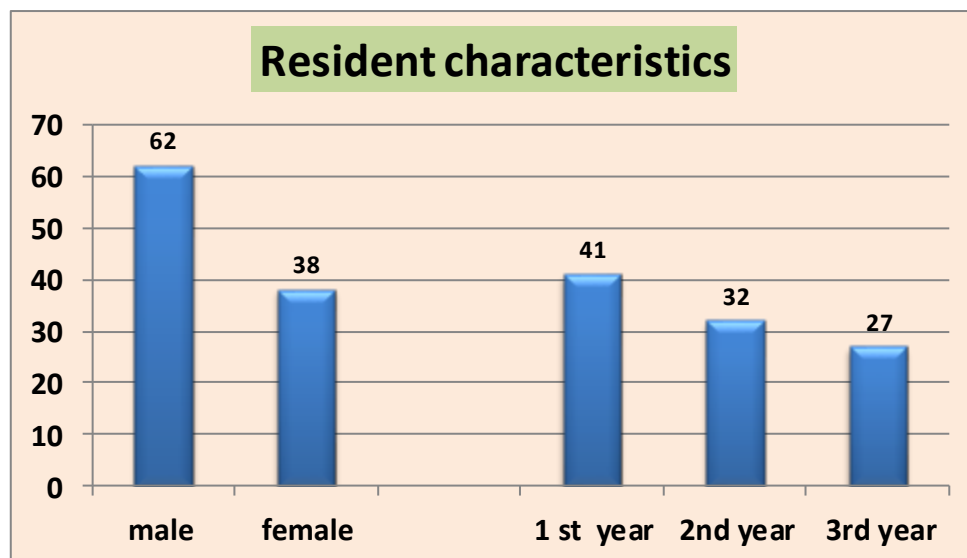


Figure (1): resident characteristics of studied group

Assessment of knowledge and attitude of residents about medical ethics before and after educational intervention (table 1):

Regarding knowledge of the participants about the principles of medical ethics, there was a significant improvement from 25% to 66.5% at the post test $P < 0.001$. On asking the participants whether they know the laws pertaining to their work, only 38.9% said that they know about it and increased to 63.9% at post test $P < 0.001$. Regarding the principles of professionalism, only 27.8% of participants mentioned that they know the principles of professionalism with a significant increase to

70.4 % was observed at post test $P < 0.001$. When we asked them about resource(s) for medical ethics education, only 11.1% of residents said they have a resource. However this percentage increased significantly to 63.1% at post test $P < 0.001$. 70% correctly rejected that consent is indicated only for surgical operation and significantly increased to 99.1% $P < 0.001$. For evaluation of the total satisfactory knowledge ($\geq 60\%$), there was significant improvement in the total knowledge of the residents from 22.2% to 63.9% $P < 0.001$.

Table (1):- Assessment of knowledge of residents towards medical ethics before and after educational intervention by Mcnemar test.

Questions	Pre No.=108		Post No.=108		□ p.value
	No	%	No	%	
Do you know principles of medical ethics	27	25.0	61	66.5	<0.001
Do you know the laws pertaining to work	42	38.9	69	63.9	<0.001
Do you know principles of professionalism	30	27.8	76	70.4	<0.001
Do you have resource(s) for medical ethics education	12	11.1	68	63.1	<0.001
Is consent indicated only for surgeries, not for tests or medicine	75	70	107	99.1	<0.001
Total Satisfactory knowledge ($\geq 60\%$)	24	22.2	69	63.9	<0.001

□ p.value of Mcnemar test, N: number of residents, P <0.0001 highly significant, Pre: pretest questionnaire, Post: post test questionnaire

Assessment of attitude of residents towards medical ethics before and after educational intervention (table 2):

Regarding the importance of teaching medical ethics, 49.1% of the participants agreed that it is important and significantly increased to 86.1% P< 0.001. Only 35.1% consider education of medical ethics important to practice professionally and a significant change was observed at post test to 84.2 % P <0.001. About 41.7% agreed that they want to cover ethical theory and problem-solving skills in more details and increased to 82 % P <0.001. Regarding the doctor-patient relationship, 79.6 % of residents agreed that Doctor is the decision maker and do best for patients regardless of their opinion and this attitude decreased significantly to 60% P = 0.002. Fourteen per

cent 14% of the medical respondents agreed that doctor is contributed as an expert adviser for treatment decisions and this significantly increased to 36.1 % P <0.001. Small percentage 5.6 % reported that the doctor is considered as service provider that decreased to 3.7 % with no statistically significant difference P= 0.517 On exploring confidentiality; the concept "*Confidentiality is an important aspect of treatment*" showed a marked improvement from 42.6% correct responses to 81.5% at post test P <0.001. Also, 75% of residents agreed that Close relatives should always be told about patient condition with non significant change in attitude in post test (70%) P= 0.445. Regarding total Satisfactory attitude, there was marked improvement from 35.1% correct responses to 60.2% P <0.001.

Table (2): Assessment of attitude of residents towards medical ethics before and after educational intervention by Mcnemar test.

Questions	Pre No.=108		Post No.=108		□ p.value
	No	%	No	%	
Is teaching of medical ethics important as compared to clinical teaching?	53	49.1	93	86.1	<0.001
Do you consider education of medical ethics important to help you to practice professionally?	38	35.1	91	84.2	<0.001
Would you liked to cover ethical theory and problem-solving skills in more detailed course?	45	41.7	88	82	<0.001
Attitudes towards doctor–patient relationship:					
a- Doctors are decision makers and do best for patients regardless of their views (paternalistic model)	86	79.6	65	60.2	0.002
b- doctor is an expert adviser for treatment decisions (the sharing model)	15	13.9	39	36.1	<0.001
c-Doctor is considered as service provider (the informational model)	6	5.6	4	3.7	0.517
Confidentiality is an important aspect of treatment	46	42.6	88	81.5	<0.001
Close relatives should be told about patient condition	42	38	52	48.1	0.445
Total satisfactory attitude	38	35.1	65	60.2	<0.001

□ p.value of Mcnemar test, N: number of residents, P <0.0001 highly significant, Pre: pretest questionnaire, Post: post test questionnaire.

Assessment of knowledge and attitude of residents towards research ethics before and after educational intervention (table 3):

Analysis of the results showed that residents' knowledge improved at post-test. Regarding the principals of confidentiality, through the statement "Patient's details must be kept to ensure confidentiality" 26.9% confirmed the statement and this percentage significantly increased to 73.1% at post test P<0.001. At pretest 27.8% agreed that "the informed consent must be written, presented in a manner that is understood by the research participant and include the possible risks and potential benefits of the research" with significant improvement to 90.7 % at post test (P<0.001). Among the participants who reported they positively asked the patients to give written informed consent only 29.4 of them knew the items of informed consent but at post test, the percentage increased significantly to 75.7%

(P<0.001).Regarding provision of incentives,17.6% of participants mentioned they used it in research to encourage participation and the percentage increased significantly to 47% at post test (P<0.001).On evaluation of the principal of justice by The statement "All segments of the population must be fairly selected as participants in any research project" 27.8 % of residents correctly assigning to it with a significant improvement to 85.2 % at the post test (P<0.001). Regarding the principal of autonomy and respect applied to the statement "The capacity and rights of research participants to participate in a voluntary way, free any pressure must be respected by investigators" 39.6% agreed and increased to 63.9% at post test (P<0.001).

The concept of beneficence and nonmalficience as stated "It is the responsibility of researchers to maximize benefits and minimize risks of all persons who take part in a research" showed a marked

improvement from 57.4 % correct responses to 91.2 % (P<0.001).

When we asked the residents about the value of Scholarly publication, only 10.7% answered correctly that increased significantly to 71.5 %.

Regarding knowledge of the participants about the research ethics committee's responsibility, it was increased from 29.6% to

90.7% P<0.001. Only 38% of residents emphasized the importance of teaching of research ethics but increased significantly to 84.3% at post test. Regarding the attitude of residents toward the role of research ethics committee to ensure improvement of research 22.2% mentioned it is important and increased significantly to 75.9% at post test P<0.001

Table (3): Assessment of knowledge and attitude of residents towards research ethics.

Questions	Pre No.=108		Post No.=108		□ p.value
	No.	%	No.	%	
-Knowledge about keeping patients details	29	26.9	79	73.1	<0.001
-Knowledge about asking patients to give written informed and explaining the possible risks and benefits of the research If answer yes what are the items of informed consent?	30 21	27.8 29.4	98 71	90.7 75.7	<0.001 <0.001
-Knowledge about ethical consideration regarding the provision of incentives (compensations)	19	17.6	94	47.0	<0.001
Knowledge about ethics in selection of research participants. "All segments of the population must be fairly selected as participants.	30	27.8	92	85.2	<0.001
Knowledge about right of the research participants to participate in a voluntary way, free from any pressure	32	39.6	69	63.9	<0.001
It is the responsibility of researchers to maximize benefits and minimize risks of all participant	61	56.5	92	85.1	<0.001
Knowledge about the value of scholarly publication	18	10.7	88	71.5	<0.001
Knowledge about research ethics committee responsibilities at the faculty of medicine of Zagazig University.	32	29.6	98	90.7	<0.001
Total Satisfactory knowledge (≥60%)	21	19.4	90	83.3	<0.001
Their opinion about importance of research ethics	41	38.0	91	84.3	<0.001
Their opinion about importance of research ethics committee at the faculty of medicine of Zagazig University.	24	22.2	82	75.9	<0.001
Total satisfactory attitude (≥60%)	21	19.4	78	72.2	<0.001

□ p.value of Mcnemar test, N: number of residents, P<0.0001 highly significant, Pre: pretest questionnaire, Post: post test questionnaire.

DISCUSSION

In the present study, an attempt was made to demonstrate the shortcoming in knowledge and attitudes in medical and research ethics among the residents at the faculty of medicine, Zagazig University and

the fact that education interventions that were made by implementing a short course on medical and research ethics with guiding booklet could increase their knowledge and resulted in changing their attitudes.

The present study revealed that knowledge and attitude of residents towards medical ethics was found to be unsatisfactory at pretest and significantly improved after intervention course. In parallel with this, **Sulmasy and Marx, (1997)** reported that extensive curricular intervention in ethics teaching was effective for raising knowledge of medical students in facing ethical questions. **Chin, et al., (2011)** evaluated the effect of an integrated medical ethics curriculum on first year students with regard to students' opinions on professional conduct and medical law, and reported that the intervention led them to be more receptive to guidance and regulation by codes and regulatory processes of the profession.

Several studies carried out in different parts of the world have shown that there is a need for properly structured medical ethics education to enable medical doctors understand and cope with constantly changing ethical dilemmas in their daily practice (**Fadare, et al., 2012**). In our study, few numbers of the respondents (11.1%) mentioned that they have a resource regarding medical ethics and law and increased to 63.1% which indicate lack of knowledge of the basic principles of medical ethics when compared with other studies. **Hariharan, et al., (2006)** reported that more than half of the respondents answered that they acquired their knowledge of ethics and law from multiple sources. In the study of **Dash (2010)**, most of the respondents said that their main source of knowledge on healthcare ethics was during training, and such experiences should be used to reinforce ethical knowledge and practice. Consent is a basic concept in medical ethics and law. In our study 70% were aware that it should be taken for tests and medication as well as surgeries that markedly increased to 99.1% at post test. These results are in accordance with other studies like **Heywood (2007) and Rai et al., (2013)**.

The results of the present study revealed significant improvement in attitude of the residents towards importance of teaching medical ethics. This was in line with **Levin, et al., (2006)** survey study on bioethics coordinators and chief residents at

University of Toronto about importance of ethics teaching

In a work conducted at New Mexico University by **Lehrmann, et al., (2009)** reported the agreement among medical students on the effect of *medical ethics* education in helping professionals to better recognize ethical issues, improve patient care and clinical decision making. In a similar study in Alexandria university **Mohamed et al., (2012)** reported that All the studied residents felt that there was a great need for improvement of the postgraduate medical education in ethics.

Regarding attitudes towards the doctor-patient relationship the present study showed that the large majority of doctors surveyed were in favor of the partnership model while others respect the decision of their patients to accept or refuse treatment. This was in agreement with **Wandrowski, et al., (2012)** who explained that doctors believe that patients have limited capacity to understand the consequences of therapeutic decisions.

Doctors have been also likely to lean towards revealing a patient's condition to the close relative. In the study by **Hariharan, et al., (2006)** 93% of the respondents considered confidentiality to be important but 37% were in favor of informing relatives about patient's condition. Similar observations have also been made by **Brogen, (2009) and Chopra, et al., (2013)** where their results stated that breach of confidentiality is against ethics but at times, in the larger interest of the public, it may be acceptable to inform the relatives to take care of the patient

Aita and Richer, (2005) reported that research with human subjects gives rise to many ethical questions for healthcare professionals who are in need to expand their knowledge about research ethics. The present study showed that the majority of investigators had a low score for knowledge and attitude towards ethics in medical research that had significantly improved at post test. About 52.3 % of the residents reported that they explain the possible risks and potential benefits of their research to study participants that increased to (70.3) at post test. This was lower than that reported by **Saleh, et al., (2006)** at Ain Shams University

(83%) and by **Abdelhai et al., (2014)** at Cairo university (83% and 90% respectively). Informed consent is an essential document required by the Egyptian National Research Ethical Committee. In the present study, a considerable improvement regarding the conditions for obtaining informed consent was observed. In similar study, **Khalil, (2007)** reported that investigators are not completely aware yet of the necessary conditions for obtaining consent like the extent of the information that should be given, and the method of giving this information to research participants.

Regarding provision of incentives used it in research to encourage participation.

The use of incentives to recruit and retain research subjects is innocuous if the research meets the usual ethical criteria for human subjects' research. But incentives become problematic when conjoined with the following factors, singly or in combination with one another. Where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading and where the participant will only consent if the incentive is relatively large because the participant's aversion to the study is strong (**Grant and Sugarman, 2004**)

The residents participated in the study showed poor information regarding value of Scholarly publication. Publication is the final stage of research and the responsibility for all researchers. Scholarly publications are expected to provide a detailed and permanent record of research. They can affect not only the research community but also, the society at large. So, Researchers have a responsibility to ensure that their publications are honest, accurate, complete and balanced, and should avoid misleading, selective or ambiguous reporting (**Kleinert & Wage, 2011**).

Regarding knowledge of the participants about the research ethics committee's (REC) responsibility 29.6% know the role of REC that increased to 90.7% at post test. Also, their attitudes increased significantly regarding importance of REC to ensure improvement of research. Similar studies at Faculty of Medicine Beni Suef University; **Ahmed and Nicholson, (1996)** in England

and **Dal-re, et al., (1999)** and in Spain stated that the participants mentioned that REC hinde the research due to the time consumed in ethical review. Although the operational guidelines of the World health Organization **WHO, (2007)** showed that the presence of the REC ensured the highest attainable importance of ethics in medical and the protection of ideas of research.

CONCLUSION

Taken as a whole, findings of this study indicated that the implementation of educational intervention course was effective in improving the knowledge and attitude of participating residents toward medical and research ethics. The key strengths of our study were its high response rate that allowed us to gain a better understanding of the issues. We could assess the basic knowledge and attitudes of residents regarding medical and reasearch ethics.

RECOMMENDATIONS

The knowledge of our researchers about research ethics is remarkably low. SO, there is a need to encourage sustained and repeated training courses of ethics to residents. More emphasis on integrating medical and research ethics training is urgently needed.

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أثر التدخل التعليمي على الاخلاقيات الطبية و اخلاقيات البحث العلمى للطباء المقيمين بمستشفيات جامعة الزقازيق

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المقدمة: الاخلاقيات الطبية و اخلاقيات البحث العلمى هما ضروريين للعمل الاكلينيكي و لكي نحقق الاتزان بين التقدم العلمى و حماية حقوق الانسان.

الاهداف: : كان الهدف هو تعيين اثر التدخل التعليمى على المعرفة و المواقف بين الطباء المقيمين تجاه الاخلاقيات الطبية و اخلاقيات البحث العلمى فى مستشفيات جامعة الزقازيق.

الاشخاص و الطرق: تم اجراء دراسة تدخلية على مائة وثمانية نائب من داخل مستشفيات جامعة الزقازيق عن طريق استبيان لتقييم المعرفة و الاتجاهات لدى الاطباء المقيمين نحو الطبية و اخلاقيات البحث العلمى قبل و بعد التدخل التعليمى و الذى كان برنامج يدرس بقسم الطب الشرعى و السموم الاكلينيكية. الاخلاقيات

النتائج: تبين وجود نقص فى المعرفة و الاتجاهات لدى لاطباء المقيمين التى تضمنتهم الدراسة الاخلاقيات الطبية و اخلاقيات البحث العلمى و ان التدخل التعليمى ادى الى تحسن بالغ فى المعرفة و الاتجاهات لدى النواب **الخلاصة:** هناك نقص فى المعرفة و الاتجاهات لدى لاطباء المقيمين التى تضمنتهم الدراسة عن الاخلاقيات الطبية و اخلاقيات البحث العلمى و الذى تحسن بشكل واضح بعد التدخل التعليمى .

التوصيات: توصى هذه الدراسة باستمرار تدريب الاطباء على الاخلاقيات الطبية و اخلاقيات البحث العلمى و دمج هذه البرامج التعليمية بصفة مستمرة و متكررة مع مناهج الدراسات العليا.