



Applying Ethical Guidelines in Clinical Researches among Academic Medical Staff: An Experience from South Egypt

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Authors' contributions

This work was carried out in collaboration between all authors. Author EEIS supervise the work. Author TH give research idea and writing the draft. Author HR design the tool and collection of data. All authors read and approved the final manuscript.

Original Research Article

Received 23rd September 2013
Accepted 2nd January 2014
Published 14th January 2014

ABSTRACT

Background: 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.

Our aim was to assess the knowledge and attitude of researchers in the Faculty of Medicine, Beni Suef University, towards applying ethical guidelines in medical research.

Methodology: This was a descriptive analytical cross sectional study using a self-administered questionnaire.

Results: Around 90% of the study subjects reported previous exposure to bioethics. Only 57.7% of respondents agreed to participate in the study. More than two thirds (67.8%) of participating researchers explained possible risks & potential benefits of their research to the participants. Less than a quarter (22.3%) had published their articles in international publications and among them, only 31% were asked to submit ethical approval. Only 10% of researchers had submitted their research to the Research Ethical Committee (REC) for ethical review.

More than half of investigators did not agree on the role of REC in the protection of human subjects (58.5%).

Only 14.6% (19/130) and 14.7% (11/75) had an acceptable level of knowledge regarding the different codes of ethics and items of the consent form respectively.

Conclusion: The knowledge of our researchers about research ethics was remarkably

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low and more emphasis on research ethics training is urgently needed.

Keywords: Bioethics; knowledge and attitude; consent form; faculty of medicine; Beni Suef University.

1. INTRODUCTION

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 [1].

Medical research involving human participants has increased greatly in many developing countries during the recent decade, which can be explained by the motivation to address the high burden of diseases in these countries [2,3]. The ethical conduct of research specific to developing countries has been the subject of recent discussions and has been addressed in several research ethics guidelines [3-5].

Several qualitative studies have been performed eliciting the views of patients regarding medical research from the United States, Denmark, Australia and Japan. Such results, however, might not be generalizable to developing countries that incorporate different ethnicity, religions and cultures, economic and political backgrounds. Currently, there is limited empirical research involving the perspectives of individuals from developing countries and from countries in the Middle East [6].

In biomedical research conducted in Egypt, concerns about research ethics have been raised recently due to the progressive development in the research centers and processes [7]. Thus a great interest has been developed to explore the Egyptian investigators' awareness, attitudes and practice regarding research ethics [8].

Additional studies would be helpful in further clarifying concerns and underlying themes regarding research participation of individuals from these countries [9]. These important points need also to be studied from the investigators' point of view.

Human research in Egypt is mainly conducted by scientific research institutes related to the different universities scattered all over Egypt. Universities are supervised and related to the Ministry of Higher Education and Scientific Research. There are many other research institutes related to the same Ministry including; the National Academy of Science, Mubarak City for Scientific Research and Technology Applications and other institutes.

In Egypt, the first national committee for reviewing research was developed after a Ministerial decision from the Minister of Higher Education and Scientific Research in 1996. At the same year Al-Azhar (The Islamic University in Egypt) started its Institutional Committee to review the research conducted on humans. The National committee never reviewed research but were mainly trying to put the guidelines for research ethics, while the ethical committee of Al-Azhar university was reviewing only thesis's and projects of Al-Azhar university.

Later on, starting from the year 2002 many ethical committees were identified in Egypt. This was mainly in response of the foreign funding agents requirements of having local IRB to

review researches mainly conducted in the same institute. Now 28 federally approved Institutional Review Boards/Research Ethical Committees "IRBs/RECs" to review researches conducted in Egypt funded by US federal funds. However, no national regulations have been developed for any of these boards to follow [10,11].

Beni Suef Governorate is around 120 Km. south of Cairo. Beni Suef University is one the most junior Governmental Universities in South Egypt and the Faculty of Medicine was established in 1998.

Our aim was to assess the knowledge of ethical guidelines in medical research of staff members in the Faculty of Medicine Beni Suef University, to determine the application rate to the ethical committee and to serve as one of the steps for a situation analysis needed for the establishment of a Research Ethical committee in Faculty of Medicine Beni Suef University "FMBSU".

2. METHODOLOGY

This study was implemented in the Faculty of Medicine Beni Suef University during the period from March 2009 till January 2010. This was an observational analytical cross sectional study. The target population was faculty staff members including assistant lecturers and professors from all clinical and academic departments. Inclusion criteria; All staff members of the Faculty of Medicine, Beni Suef University, who conducted at least one research were included in the study. An anonymous self-administered questionnaire was distributed to all faculty staff members and upon poor response interviews were performed and questionnaires were filled by one of the research team.

2.1 Data analysis and Scoring System

The data were coded and keyed into the Statistical Package for the Social Sciences software version 19 (SPSS Inc., Chicago, IL) used in Windows 7. Descriptive analysis followed by inferential statistics was done. Chi-square test (χ^2) and Fisher's exact test were performed to statistically analyze qualitative data. A P-value of 0.05 was considered

For the questions regarding investigators knowledge concerning ethical guidelines and items of a consent form the responses were coded to values 0 and 1 for wrong and correct answers respectively. Knowledge scores were then transformed to qualitative data as acceptable and un-acceptable level with a cutoff point of 80% of correct answers to be considered as acceptable level of knowledge.

2.2 Ethical Considerations

The study protocol was discussed by the staff members of the Public Health Department, FMBSU and was approved by its council. This constituted the internal review board to guarantee the ethical conformity of the study, followed by having the approval of higher education research board. At the time of conducting this study, there was no formal research Ethical Committee in FMBSU. Waiver of written informed consent was approved based on the nature of the tools used being anonymous, self administered and having no sensitive or private information. A section describing the study and its aim in addition to voluntary participation was present at the beginning of the questionnaire used.

3. RESULTS

The total number of staff members of FMBSU was 220,82 of them were on vacation (maternity, sabbatical or unpaid leave and hence, 138 researchers were available at the time of conducting this study. One hundred and thirty researchers participated in this study with a response rate of (94.2%). Sixty percent were males and 40% were females; 56.2% were professors, 19.2% were assistant (associate) professors, 12.3% were lecturers, 12.3% were assistant lecturers. Around 90% of our study subjects reported previous exposure in bioethics, in the form of training or workshops (71.4%) or only a single lecture or a talk (20.6%). Regarding the need of having a formal training on bioethics, 94.6% reported that they wanted formal training on bioethics. Consent from participants to participate in research was obtained by only 57.7% of participating researchers, among them only 54.7% utilized a written consent form. Only (67.8%) of participating researchers explained possible risks & potential benefits of the research to the participants.

Among this study population, only 22.3% of them had international publications and among these only 31% were asked by editors to submit ethical approval for their internationally published research. Only 10% of researchers had submitted their research to REC for an ethical review. The process of review of the manuscript varied from weeks (28.1%) to months (38.5%). Most of them did not face any difficulties (69.2%). The majority of the investigators were asked at least once to submit the protocol to REC (84.6%), most of investigators were not asked for changes in protocol before approval (76.9).

The majority of researchers; (93.8%) reported that it was important to have a functioning REC in FMBU. Most of the investigators stated that a research ethics committee should review Medical doctorate thesis, Master thesis & any study done by a member in the faculty (78.5%).

The majority of them were convinced that the suitable time for application to ethical committee approval is before the beginning of the study (66.9%), More than half of the investigators did not agree on the role of REC in the protection of human subject (58.5%), while there was no difference between those who agreed or did not agree about the role of REC in the protection of investigators (51.5%/ 48.5%).

When assessing the researchers' level of knowledge regarding different codes and items of a consent form; only 14.6% (19/130) and 14.7 % (11/75) had acceptable levels of knowledge respectively.

Table 1 shows that there were no statistically significant differences between academics and clinical specialists regarding the level of knowledge about ethics and the items of consent forms respectively. However, the majority had below acceptable levels of knowledge regarding both items.

When assessing the relation between level of knowledge and academic degree of investigators, Table 2 shows that higher academic degree (Professors/Assistant professors) had more acceptable level of knowledge than (Lecturers/Assistant Lectures) regarding knowledge about ethics in clinical research ($P < 0.01^*$). This was not the case when comparing the level of knowledge between both groups in relation to items of consent form ($P > 0.05$).

Table 3, shows no association between the level of knowledge of ethics in clinical research and items of the consent form and having published in international journals but noticeably, the majority had below acceptable levels of knowledge for both items.

Number of research studies conducted had no statistically significant associations with the level of knowledge regarding items of consent form ($p= 0.227$), however, the more research studies conducted (>10) the higher the level of knowledge when compared with those who have below 10 published manuscripts (47.4% and 5.3) respectively $p=0.023^*$. Table 4 shows that previous exposure to training on human research protection in any form (lectures, workshop or specific training) had a statistically significant association with the level of knowledge about ethics in clinical research ($p<0.01$), however this was not reflected on the knowledge about consent form.

Table 1. Relation between level of knowledge and specialty of investigators

Level of knowledge about ethics in clinical research	Below acceptable		Acceptable		Total
	No.	%	No	%	
Academic specialty	28	82.4	6	17.6	34
Clinical Specialty	83	86.5	13	13.5	96
Total	111	85.4	19	14.6	130
$X^2= 0.339$ $P=0.578$ $P>0.05$ (NS)					
Level of knowledge about items of consent form	Below acceptable		Acceptable		Total
	No.	%	No	%	
Academic specialty	8	66.7	4	33.3	12
Clinical Specialty	56	88.9	7	11.1	63
Total	64	85.3	11	14.7	75*
$X^2= 3.97$ $P=0.068$ $P>0.05$ (NS)					

* 55 researchers do not have any knowledge about items of consent form

Table 2. Relation between level of knowledge and academic degree of investigators

Level of knowledge about ethics in clinical research	Below acceptable		Acceptable		Total
	No.	%	No	%	
Lectures/Assistant Lectures	89	90.8	9	9.2	96
Professors/Assistant Professors	22	68.8	10	31.3	32
Total	111	85.4	19	14.6	130
$X^2= 9.412$ $P=0.007$ $P<0.01^{**}$					
Level of knowledge about items of consent form	Below acceptable		Acceptable		Total
	No.	%	No	%	
Lectures/ Assistant Lectures	49	89.1	6	10.9	55
Professors / Assistant Professors	15	70	5	25	20
Total	64	85.3	11	14.7	75
$X^2= 2.237$ $P=0.150$ $P>0.05$ (NS)					

Table 3. Relation between level of knowledge and having international publications

Level of knowledge about ethics in clinical research	Below acceptable		Acceptable		Total
	No.	%	No	%	
Had International Publication	24	82.8	5	17.2	29
Did not have International Publications	87	86.1	14	13.9	101
Total	111	85.4	19	14.6	130
X² = 0.206 P=0.766 P>0.05 (NS)					
Level of knowledge about items of consent form	Below acceptable		Acceptable		Total
	No.	%	No	%	
Having International Publication	17	77.3	5	22.7	22
No International Publications	47	88.7	6	11.3	53
Total	64	85.3	11	14.7	75
X² = 1.616 P=0.282 P>0.05 (NS)					

Table 4. Relation between level of knowledge and history of training on human research protection

Level of knowledge about ethics in clinical research	Below acceptable		Acceptable		Total
	No.	%	No	%	
Previous exposure to training	46	41.4	27	89.5	63
No Previous exposure to training	65	58.6	2	10.5	67
Total	111	100	19	100	130
X² = 14.985 P=0.00 P<0.01 **					
Level of knowledge about items of consent form	Below acceptable		Acceptable		Total
	No.	%	No	%	
Previous exposure to training	35	54.7	6	54.5	41
No Previous exposure to training	29	45.3	5	45.5	34
Total	64	100	11	100	75
X² = 0.00 P=0.993 P>0.05 (NS)					

4. DISCUSSION

The present study showed that most investigators knew that ethics was both theoretically and practically useful (93.8%). This was similar to results from Ain Shams University (97%) [20]. Ethics is a cornerstone in medical research [12]?

It is believed that ethical consideration in research should play a decisive role in research planning and execution [13]?

Richer and Aita [14] 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 for providing answers to these questions. Also Nilstun et al. [15] reported that there is growing interest in education in the field of medical ethics within the health care profession. The majority of the studied investigators (94.6%) reported their need to have workshops or training on ethics in medical research. Many of them felt that these workshops or training will benefit them when submitting their research to an ethical committee and international journals for publication. This was similar to Ain Shams Investigators (95%) and Cairo University's investigators (94.8%) [16]. This demand has to be achieved through establishment of ethics programs within the educational courses.

From the previous results, it can be concluded that the overall knowledge of the interviewed investigators about different ethical guidelines and human subject protection was relatively low and incomplete. This might be attributed to the fact that research ethics is a newly introduced topic in the field of medical research in Egypt with only recent concerns arising around it. This would be also due to the lack of teaching and training of medical ethics for postgraduate or undergraduate medical students.

Informed consent is considered as one of the corner stones of research ethics by the federal regulations [17].

All major national or international organizations require that "effective informed consent" or "voluntary informed consent" be obtained before a prospective participant is enrolled in a research study [13]. Informed consent is not only a document, but also a process that continues as long as the study is being conducted. Engaging in informed consent process is one of the best ways that researchers can demonstrate their respect for those they aim to enroll in a study. It also serves as the best means for those who do not wish to participate to protect themselves [18]. Informed consent is an essential document required by the Egyptian National Research Ethical Committee developed by the declaration of Ministry of Health on 2005 in the Egyptian Ministry of health.

Investigators who document the informed consent process were around 57.3%, however those who only obtained verbal consent were representing 45.3%, which is similar in being low as compares with what was reported by Ain Shams University investigators (24%). This is in accordance with what was reported by several studies which reported that investigators in developing countries now recognize that the consent of human subjects is extremely important in medical research. However, 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 study participants [3,5,19].

Almost 70% of investigators claimed to explain the possible risks and potential benefits of their research to study participants. This was lower than that reported at Ain Shams University (83%) [20,21] and Cairo university (83% and 90% respectively) [16,22].

It was noticed that the practicing of ethics in medical research is clearly deficient. Only a very low percentage of investigators showed compliance with ethical principles while conducting medical research. Also, great diversity in practicing research ethics was found; investigators may follow one ethical practice and neglect another. The one which is followed in medical research is usually overlapping that of clinical care like the confidentiality of research participants' data and obtaining verbal consents.

The Helsinki Declaration [23] declared that all types of research involving human subjects which includes research on identifiable human material or identifiable data should be ethically reviewed. Most of the investigators did not know that it is necessary to have an ethical committee approval on research to be published locally or internationally (54.6%). The majority of the investigators (90%) did not submit their research to a REC. This shows to what extent the ethics of research is not really clear in Beni Suf University among researchers performing human subject research. Teaching research ethics and training on human subject protection in medical research could improve the situation.

The present study showed that most investigators perceived the importance of a REC presence in the faculty of medicine (93.8%), compared to Ain Shams university investigators

whose percent was (83%). Although Ahmed and Nicholson [24] in England and Dal-re et al. [25] in Spain showed that REC would hinder the research due to the time consumed in ethical review, yet only (38.5%) of investigators thought the same way, compared to Cairo university investigators' opinions, only about (14.5%) gave the same opinion [16].

In the current study the majority of investigators were convinced that the suitable time for application to ethical committee approval is before the beginning of the study (66.9%), However (23.1%) of investigators were convinced that it was suitable during the study, And only (10%) stated that the suitable time for application to REC is after finishing the study before submitting it for publication.

Although the operational guidelines of the World health Organization [26] showed that the presence of the REC ensured the highest attainable importance of ethics in medical research and the protection of ideas of research, still 1/3 of investigators were unable to see this role.

It was obvious that the included investigators did not reach the acceptable level of knowledge about ethical principles that sound logic to the Egyptian cultural, social background. Also, they were not aware about the ethical principles of clinical care (e.g. informed consent) that they should apply while handling their patients. On the other hand, they were not aware about ethical requirement that cannot be extracted from their norms.

No statistically significant difference was found between different groups of medical investigators, the majority of investigators had a low score for questions on the knowledge for both items of consent form and ethics in medical research. This can be justified by the lack of ethics courses or training for investigators and they did not read about it before. Another factor which could have contributed to this is the absence of a functioning REC in the Faculty of Medicine.

As shown in Table 1, there was no statistically significant difference between academic and clinical researchers for both questions on the knowledge of ethics in medical research and items of consent ($P=0.578$).

Table1 also showed that there was no significant difference between the scores of different degrees of researchers for knowledge questions for items of consent ($P=0.68$). However it was noticed from Table 2 that there was a significant difference between scores of different degrees of investigators for questions of knowledge for ethics in medical research ($P=0.007$) which may be attributed to the experience difference and more exposure to international publications?

As shown from Table 3 there was no significant difference between investigators who have international publication and those who don't have for both knowledge questions for items of consent and ethics in medical research ($P>0.005$). This differs from investigators of Cairo University, as their study showed that there were significant differences between investigators who have international publications and those who did not have any. The investigators who had an international publication had a better score than those without any publications ($P<0,001$) [16]. This can be explained that during the last decade not all of the international Journals asked for ethical clearance.

History of exposure to any source of ethics training affected the knowledge regarding ethical guidelines ($P < 0.01^{**}$) however it has almost no role on the level of knowledge about items needed to be present in the consent form $P = 0.993$ (Table 4).

5. CONCLUSION AND RECOMMENDATION

The knowledge of the studied medical investigators about research ethics was remarkably low and their research ethics practice was deficient and not regulated, in spite of their positive opinions regarding the impact of the application of ethics on medical research. Thus, the inclusion of research ethics in curriculum of under and post graduate courses together with the setting of rules that govern research will lead to conducting more ethical research studies.

A Research Ethics Committee in the FMBSU was established in late 2010 and is still functioning now.

CONSENT

Waiver of documentation of informed consent was approved based on the nature of the tools used being anonymous, self-administered and having no sensitive or private information. A section describing the study and its aim in addition to voluntary participation was present at the beginning of the questionnaire used.

All authors declare that informed consent was obtained from the patient Study participants

ETHICAL APPROVAL

All authors hereby declare that this study have been examined and approved by the Public Health Department, FMBSU and was approved by its council. This constituted the internal review board to guarantee the ethical conformity of the study, followed by having the approval of Higher Education Research Board. Therefore have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Collins FS, Green ED, Guttmacher AE, Guyer MS. A vision for the future of genomics research. *Nature*. 2003;422(6934):835-47.
2. Bhutta ZA. Ethics in international health research: a perspective from the developing world. *BULLETIN-WORLD HEALTH ORGANIZATION*. 2002;80(2):114-20.
3. Khalil SS, Silverman HJ, Raafat M, El-Kamary S, El-Setouhy M. Attitudes, understanding, and concerns regarding medical research amongst Egyptians: A qualitative pilot study. *BMC Medical ethics*. 2007;8(1):9.
4. Shapiro HT, Meslin EM. Ethical issues in the design and conduct of clinical trials in developing countries. *New England Journal of Medicine*. 2001;345(2):139-42.

5. El-Dessouky HF, Abdel-Aziz AM, Ibrahim C, Moni M, Abul Fadl R, Silverman H. Knowledge, awareness, and attitudes about research ethics among dental faculty in the Middle East: A pilot study. *International journal of dentistry*; 2011.
6. Sugarman J, Kass NE, Goodman SN, Perentesis P, Fernandes P, Faden RR. What patients say about medical research. *Irb*. 1998;1-7.
7. Matsoso P, Auton M, Banoo S, Fomundam H, Leng H, Noazin S. How does the regulatory framework affect incentives for research and development. Geneva: CIPRH Study Paper; 2005.
8. Mostafa MM. An Investigation of Egyptian Consumers' Attitudes Toward Ethical Issues in Advertising. *Journal of Promotion Management*. 2011;17(1):42-60.
9. Khalil SS, Silverman HJ, Raafat M, El-Kamary S, El-Setouhy M. Attitudes, understanding, and concerns regarding medical research amongst Egyptians: A qualitative pilot study. *BMC medical ethics*. 2007;8(1):9.
10. Rashad AM, Phipps FMV, Haith-Cooper M. Obtaining informed consent in an Egyptian research study. *Nursing Ethics*. 2004;11(4):394-9.
11. United States Department of health & Heman Services Office of Human Research protection IRB Organization. <http://ohrp.cit.nih.gov/search/SrchMtch.aspx>. 2013 (cited 2013 11 January 2013).
12. Commission NBA. Ethical and policy issues in research involving human participants. Bethesda, MD: National Bioethics Advisory Commission; 2001.
13. Sciences CflOoM. International ethical guidelines for biomedical research involving human subjects. *Bull Med Ethics*. 2002;182.
14. Aita M, Richer MC. Essentials of research ethics for healthcare professionals. *Nursing & health sciences*. 2005;7(2):119-25.
15. Nilstun T, Cuttini M, Saracci R. Teaching medical ethics to experienced staff: participants, teachers and method. *Journal of medical ethics*. 2001;27(6):409-12.
16. Al Baloney N. Human Subject Research: State of Ethical Considerations among Cairo University Medical Researchers. Master Thesis. Faculty of Medicine: Cairo University; 2009.
17. Garfinkel SL. IRBs and security research: myths, facts and mission creep: Defense Technical Information Center; 2008.
18. National Bioethics Advisory Commission. Ethical and policy issues in international research: clinical trials in developing countries; 2001.
19. Arda B. Evaluation of research ethics committees in Turkey. *Journal of medical ethics*. 2000;26(6):459-61.
20. Salah El Dean. Study of the Application of Medical Research Ethics in Ain Shams University. Master Thesis. Faculty of Medicine: Ain Sahms University; 2006.
21. Waleed Salah El-din Ahmed Saleh, Aisha Mohamed Abo-El-Fotouh, Maged Abdel-Karim El-Setouhy, Mohamed Farouk Allam. Study of the Application of Medical Research Ethics in Ain Shams University: Ain Shams University; 2006.
22. National Commission for the Protection of Huamn Subjects of Biomedical Behavioral Research. The Belmont report: Ethical principles and guidelines for the protection of human subjects of research. Department of Health, Education, and Welfare; 1979.
23. World Medical Association. The Helsinki declaration. *Orv Hetil*. 1965;106:1715-6.
24. Ahmed AH, Nicholson KG. Delays and diversity in the practice of local research ethics committees. *Journal of medical ethics*. 1996;22(5):263-6.
25. Dal-Ré R, Espada J, Ortega R. Performance of research ethics committees in Spain. A prospective study of 100 applications for clinical trial protocols on medicines. *Journal of medical ethics*. 1999;25(3):268-73.

26. World Health Organization. Operational guidelines for ethics committees that review biomedical research. WHO Geneva. 2000;7.

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