International Journal of General Medicine

Dovepress
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ORIGINAL RESEARCH

Knowledge, awareness, and attitudes about research ethics committees and informed consent among resident doctors

This article was published in the following Dove Press journal:
International Journal of General Medicine

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Background: Medical research involving humans is now common all over the world. Medical doctors and residents are increasingly involved in such research. As part of their training requirements, medical residents in many institutions have to be involved, to different degrees, in human research projects.

Methods: In this study, knowledge, awareness, and attitudes of resident doctors toward research ethics committees (REC) and informed consent (IC) processes were evaluated. For that purpose, a sample of 209 medical residents of different years from a major teaching hospital was surveyed.

Results: Results showed that resident doctors had minimal knowledge of major ethical guidelines such as the Declaration of Helsinki and Belmont Report. However, more than half of respondents in this study had general knowledge of REC. Additionally, the majority of participants believed that there is a need for REC in each research conducting institution, and that training is also needed for REC members. Moreover, 82.7% of participants thought that investigators should have some training in research ethics. Finally, the current study showed that 60.3%–88.7% of participants were aware of IC requirements in clinical research.

Conclusion: Although many residents showed good knowledge and positive attitudes regarding certain aspects related to REC and IC, others need improvement.

Keywords: knowledge, awareness, attitudes, research ethical committee, informed consent, resident doctors, Jordan

Introduction

Recently, medical research involving human subjects has increased in many countries to ultimately provide high standard health care. However, such research should be guided by internationally agreed ethical principles to ensure the protection of participants' rights, welfare, and dignity such as the Belmont report and the Helsinki declaration.[1–4] In addition, awareness of research ethics and continuous training on ethical guidelines are essential for medical researchers to facilitate participation in international research projects. Recently, many developing countries have been a target for clinical trials by pharmaceutical companies with the aim of improving health care and to reach out to the global drug market.[2,5]

In 2000, the WHO stated, "The purpose of a Research Ethics Committee (REC) in reviewing health research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants. An important principle of research involving human participants is 'respect for the dignity of persons'."[6]

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DovePress
http://doi.org/10.2147/IJGM.S197511

Furthermore, informed consent (IC) to participate in research is one of the fundamental ethical principles considering respect for the persons, their dignity, and autonomy.[2]

Like in many developing countries, medical research in Jordan has been growing dramatically, with very serious effort to follow the international standard of research ethics. The RECs, also referred to as institutional review boards (IRBs), are available in many health institutions in Jordan where they provide assessment of all ethical research aspects. Currently, resident doctors are more engaged in medical research in an effort to get better fellowship positions or as a requirement of graduation from residency program in some institutions. The aim of this study was to assess the knowledge, awareness, and attitudes of resident doctors toward REC and IC processes.

Methods

This was a cross-sectional study carried out at King Abdullah University Hospital (KAUH), Jordan during the period from January to June 2018. After IRB approval, a convenience sample of 209 resident doctors were recruited from different residency programs/departments at KAUH. Residents were approached after their daily morning report meeting, or during the last 10 minutes of their lunch break. The survey was distributed and collected by a research assistant with a master's degree in clinical pharmacy who had received training on the study protocol. The research assistant was available for questions or clarification during the time the participants scored the survey. All study participants gave their verbal consent, and verbal consent was accepted and approved by the KAUH IRB for the current study protocol. Participation in the study was voluntary, and none of the study participants had any relationship with the study investigators.

A questionnaire was developed in order to assess the knowledge, awareness, and attitude of resident doctors regarding REC and IC. The questionnaire consisted of three main sections. The first section contained demographic information of the participants including age, gender, nationality, specialty, residency year, and whether the resident had participated previously in a research project. The second section of the questionnaire assessed participants' knowledge of the principles of research ethics including REC, IC, Helsinki declaration, and Belmont report. Participants were asked to select"yes", "no", or "don't know" as options. The third section of the questionnaire included statements assessing participants' attitudes toward REC and IC, where a Likert scale ranging from 1–3 ("agree" =1, "disagree" =2, "neutral" =3) was used for scoring.

The questionnaire was developed and distributed in English language because participants were medical doctors who are proficient in English. The questionnaire items were chosen based on opinions of expert researchers and medical consultants who carried out a face validation of the items. The questionnaire was pilot-tested on 20 randomly selected resident doctors at KAUH to estimate its reliability and content validity. Participants highlighted statements that needed further clarification; and necessary revisions were made accordingly. The principles of the Helsinki declaration and the Belmont report were carefully considered during the development process of the questionnaire. Data were described using frequency distribution for categorical variables for positive responses.

Results

Of the 220 questionnaires distributed, 209 responses were received with a 95% response rate. Table 1 shows demographic data of the participants. The mean age of participants was 26.8±2.1 years. There were 48.9% males and 51.1% females. Almost half of the participants (49.3%) were in surgical residency program, whereas 25.6% were in medical residency program, and 25.1% were in other available residency programs. Only 36.2% had prior involvement in clinical research. In this study, most of the participants had no previous knowledge about the Helsinki declaration and Belmont report.

Table 1 Demographic data

Characteristic	Number	% of total
Gender		
Male	98	48.9
Female	111	51.1
Nationality		
Jordanian	193	92.3
Non-Jordanian	16	7.7
Specialty		
Medicine	53	25.6
Surgery	102	49.3
Other	52	25.1
Residency year		
First	80	38.8
Second	46	22.3
Third	33	16
Fourth	35	16.9
Fifth	12	6
Prior involvement in research	75	36.2

Table 2 demonstrates the participants' responses regarding their knowledge of REC and IC. Most of the participants (86.8%) were aware of the role of REC in evaluating human research. Furthermore, when participants were asked about other concepts regarding REC, correct responses ranged between 14.9% and 64.2%. For example, only 14.9% thought that retrospective studies should not be exempted from review by REC.

Regarding IC, 73.3% were aware that it is a voluntary agreement to participate in research, 87.3% were aware that IC should explain the extent of confidentiality protection for the individual, and 88.7% were aware that an IC should explain the risk and benefit of the research. However, a lower level of knowledge was found concerning patients' right to withdraw from clinical research despite signing an IC, as only 60.3% had a correct response.

The responses of attitudes about REC and IC are depicted in Table 3. The majority of the participants (95.5%) believed that researchers must take measures to protect patient data from being exposed by accident. Furthermore, 80.4% agreed that REC members should have training on research ethics and 75.5% agreed on the need for REC in each research conducting institution. About 46% of participants disagreed with the statement that ethical review of research by REC could delay research and make it harder to deliver. The majority of participants (75.1%) supported the idea of postgraduate training on research ethics.

The majority of participants (86.1%) agreed that patients should be informed about compensation policy in case of injury due to protocol and 87.6% agreed that patients should be fully informed with complete information and alternative options. On the other hand, 47% of participants disagreed with vulnerable groups' ability to provide IC, and 49% disagreed with vulnerable groups' inclusion in the absence of surrogates' consent. The majority (81.2%) of the respondents believed in the need for IC from patients in case of the use of their biological samples in research.

Table 2 Knowledge about research ethics committees and informed consent

Number	Item	Yes, n (%)	No, n (%)	Do not know, n (%)
1	Research with human subjects must be evaluated by a research ethics committee	178 (86.8)	4 (2)	23 (11.2)
2	Ethical review of research by a research ethics committee is only necessary for clinical trials	39 (19.2)	112 (55.2)	52 (25.6)
3	Ethical review of research by a research ethics committee is not necessary since there are scientific committees	28 (13.7)	131 (64.2)	45 (22)
4	Research ethics committee is available only in academic settings	25 (12.3)	122 (59.8)	57 (27.9)
5	Retrospective studies should be exempted form review by research ethics committee	90 (44.6)	30 (14.9)	79 (40.5)
6	An informed consent is a voluntary agreement to participate in research	148 (73.3)	30 (14.9)	24 (11.8)
7	A researcher does not need informed consent to get patients' approval to participate in research	22 (10.8)	168 (82.7)	13 (6.5)
8	Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research	174 (85.3)	9 (4.4)	21 (10.3)
9	Informed consent should explain the extent of confidentiality protection for the individual	178 (87.3)	9 (4.4)	17 (8.3)
10	An informed consent should explain the risk and benefit of the research	181 (88.7)	9 (4.4)	14 (6.9)
11	A participant has the right to withdraw from clinical research even if he signed informed consent form	123 (60.3)	36 (17.6)	45 (22.1)

Discussion

This study provides insight into the knowledge, awareness, and attitudes of resident doctors toward REC and IC. In some academic institutions in Jordan, undergraduate and postgraduate medical students are required to conduct research and it has become a mandatory part of the curriculum. In the present study, resident doctors had a low

Table 3 Attitudes toward research ethics committees and informed consent

Number	Item	Agree, n (%)	Disagree, n (%)	Neutral, n (%)
1	Researchers must take measures to protect patient data from being exposed by accident	192 (95.5)	1 (0.5)	8 (4)
2	Patients should be informed about compensation policy in case of injury due to protocol	174 (86.1)	6 (3.5)	21 (10.4)
3	Patients should be informed of the complete information of alternative options	176 (87.6)	11 (5.4)	14 (7)
4	Informed consent from patients is necessary in case of the use of their biological samples in research	160 (81.2)	11 (5.6)	26 (13.2)
5	There is a need for a research ethics committee in each research conducting institution	148 (75.5)	12 (6.1)	36 (18.4)
6	All types of research proposals involving human subjects must be submitted for review to a research ethics committee	149 (74.5)	18 (9)	33 (16.5)
7	The research ethics committee members should have training in research ethics	160 (80.4)	11 (5.5)	28 (14.1)
8	Vulnerable groups such as children, prisoners, and mentally ill patients could provide informed consent	66 (33.3)	93 (47)	39 (19.7)
9	If no surrogate (caregiver) is available to give informed consent for vulnerable groups they could still be included	54 (27)	98 (49)	48 (24)
10	Ethical review of research by a research ethics committee would delay research and make it harder for the researcher	62 (31)	92 (46)	46 (23)
11	Research ethics should be taught as a mandatory postgraduate module	151 (75.1)	15 (7.5)	35 (17.4)

level of knowledge of major ethical guidelines such as Helsinki declaration and Belmont report. Yet, more than half of respondents in this study had general knowledge about REC.

Results of this study showed that 44.6% of participants thought that retrospective studies should be exempted for review by REC. The Declaration of Helsinki requires that all medical research be submitted to and approved by an ethics committee. It states: "The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins".[2] Therefore, studies (with or without a research intervention) require ethics review if they involve interaction with human subjects or the collection of identifiable private information.[2] Mallela et al, in their study, reported that 96.2% of respondents had accurate knowledge about REC.[7] Notably, in his study, the participants were all faculty members from dental collages of North India.

The majority of participants believed that there is a need for REC in each research conducting institution and a need for training for REC members. These results support the role of REC in reviewing studies with human participants to ensure that they conform to internationally and locally accepted ethical guidelines. Although in the current study, there was a general agreement on the need for an REC at each research conducting institution, only 31% of participants believed that review of research by REC would delay research and make it harder. El-Dessouky et al reported that participants believed that REC would delay research and make it more difficult to perform.[8] Unnecessary delay in research may be because of lack of training and poor understanding of functions of REC. Therefore, there is a need for training of REC members, so that they are more familiar with research ethics. In support of that, 82.7% of participants thought that investigators should have some training in research ethics.

Results of the current study showed that 60.3%–88.7% of participants were aware of IC in clinical research. Similar results of high awareness of IC have also been observed in a study conducted in India by Mallela et al.[7] The vast majority of participants were aware of confidentiality of the individuals' data and measures preventing it from being exposed by accident. In addition, 33.3% of participants agreed that children, prisoners, and mentally ill patients could give IC, and 27% of participants believed that in the absence of a surrogate the vulnerable groups could give IC. Mallela et al and El-Dessouky et al reported that 46% and 40% of

participants respectively believed that certain vulnerable groups could provide IC to participate in research.[7,8] The IC requires that patients understand the information provided, but if the patient is a child or if the patient lacks mental capacity to give consent, a surrogate should make decisions which are in the best interest of the patient.[9]

The current study also yielded useful results regarding the attitude of resident doctors toward important ethical issues. The majority of participants (81.2%) agreed that IC is necessary in case of the use of patients' biological samples in research. Kandel et al reported that 30% of Egyptian faculty agreed with performing research on blood samples that were collected for clinical research without obtaining specific IC for such research.[10]

Although the majority of participants had no prior experience in research, most of them agreed that there should be a course in research ethics for resident doctors and members of REC. We believe that all residency programs in Jordan should include research ethics courses as a mandatory part of the residency curriculum for residents require them to be involved in research in different ways. Implementing such courses would increase the quality and integrity of research.

The current study has some strengths, being among the first to comprehensively tackle the issue of knowledge, awareness, and attitudes of resident doctors toward REC and IC. Yet, this study had the limitation of being done in only one center. Additionally, when trying to divide study participants over all the categories within residency years, and different specialties, the generated sample size per each category did not allow for reliable statistical analysis. A future study with a larger sample is probably warranted.

In conclusion, this study explored resident doctors' knowledge, awareness, and attitudes toward REC and IC. While many of the results showed good knowledge and positive attitudes, others need improvement and there is a need to work closely with residents to emphasize fundamental aspects related to REC and IC.

Acknowledgment

Work on this project was supported by grant number 5R25TW010026-02 from the Fogarty International Center of the US National Institutes of Health.

Disclosure

The authors report no conflicts of interest in this work.

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