


Knowledge and Attitude of Medical Residents Towards Cancer Clinical Trials in Jordan

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Background: Clinical trials are an important tool to test the efficacy of new treatment modalities for cancer patients. Physicians, including medical residents, should play a major role in carrying out clinical trials to generate a strong body of evidence to determine the best available treatment for their patients. Carrying out clinical trials demands adequate understanding of the research phases and requirements including ethical standards as well as presenting positive attitudes toward the clinical research. Hence, evaluating the knowledge and attitudes of medical residents toward running clinical trials is essential to assess their preparedness and willingness to participate in future studies.

Methods: This study was a questionnaire-based observational study. It involved medical residents from various specialties who served cancer patients admitted at King Abdullah University Hospital during the period from June 1 to August 15, 2017.

Results: A total number of 83 respondents completed the questionnaire. Of them, 56.7% and 53.0% of the respondents reported either current or previous participation in clinical trials research, respectively. Only 10 residents (12.0%) had previous participation in clinical research where a new investigational cancer treatment was tested. While, 91.6% of respondents believed that physicians should be involved in running clinical cancer research, only 25.3% had previous experience in writing a cancer clinical trial protocol and 28.9% wrote a scientific manuscript on cancer clinical trials for publication. Moreover, 67.5% of residents knew when informed consent should be obtained and 62.7% were aware of the clinical equipoise concept in clinical trials.

Conclusion: Much remains to be done to improve knowledge and attitudes of medical residents toward cancer clinical trials and the main ethical principles that should be followed to assure having an ideal research environment, which will pave the way for the generation of high quality clinical cancer research and reliable evidence-based clinical practice for cancer management.

Keywords: clinical trials, cancer, Jordan, oncology, medical residents

Introduction

Cancer clinical trials are usually done by physicians to test new ways to treat cancer or find a new cancer prevention method, or to test a new diagnostic or screening test for cancer.¹ There are many regulations and standards that were set up to regulate clinical trials worldwide. Thus, it is very important for investigators who are generally involved with this type of research to understand and apply those standards when they run clinical trials among cancer patients.²

A number of oncological diseases have poor prognosis and there is an eminent need for new-targeted therapies that give the oncologist improved methods of cancer treatment with higher efficacy and minimal unwanted adverse drug

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reactions.^{3,4} Clinical research in oncology presents several ethical issues, as efforts are ongoing to better understand mechanisms of cancer progression and metastasis, hence new therapeutic drug targets are available for testing in clinical trials as potential anticancer agents.⁵ One of the major ethical issues encountered in clinical trials that deal with new targeted anticancer therapy is that it is difficult to identify patients that would benefit from the new treatment before the beginning of the trials. This could expose the patients to unwanted health consequences resulting from the new agents without obtaining any recognizable anticancer benefits.^{5,6}

In 1998, the national institute of health (NIH) in United States implemented a number of new policies to encourage carrying out clinical research by young health-care practitioners.⁷ Nowadays, integration of clinical research concepts into training curricula is mandatory by many of the medical residency programs as well as the accreditation council for graduate medical education (ACGME) of the USA and other medical councils worldwide.^{8,10} Clinical research during the residency period could involve a wide range of forms including case reports, cross-sectional studies, writing a meta-analysis or systemic review, or involvement in randomized controlled clinical trials. During research training, medical residents should be able to comprehend successfully all the necessary phases of research involving the preparatory phase, investigation phase and synthesis task.⁹ Finding a research topic and mentors, developing the skills to design a study, and completion of institutional review board requirements and obtaining ethical approval are among the essential steps to be followed by clinical researchers before moving on with further data collection, statistical analysis and writing conference abstracts or full manuscripts.⁹

Previous studies surveyed medical residents about their research experience during their residency training. The majority of the residents showed positive attitudes toward their research projects.^{11,12} In fact, research part experience received a high rating evaluation by residents compared to other components of residency curriculum.¹² Another study revealed that family medicine residents who were involved in research projects showed higher recognition toward practicing the evidence-based medicine and its role in improvement in medical practice.¹³

In Jordan, several hospitals and research centers have been authorized by the Jordan Food and Drug Administration (JFDA) to run various phases of clinical trials ranging from bioequivalence studies to performing clinical

trials on patients.¹⁴ The Pharmaceutical Research Center (PRC) located at the King Abdullah University Hospital (KAUH), Jordan University of Science and Technology is among the leading research centers in Jordan. Since the establishment of the PRC in 2004, more than 45 clinical trials (phase I to phase IV) and 300 bioanalytical studies were carried out by investigators at KAUH and other affiliated institutions such as national pharmaceutical companies and other academic institutions.¹⁵ Medical residents at this hospital and other teaching and research hospitals are expected to demonstrate adequate understanding of clinical research requirements and apply their research outcomes toward improvement of patients' care.

In the current study, both knowledge and attitude of medical residents toward cancer clinical trials and main barriers and ethical issues that lead to an inadequate number of oncological clinical trials involving cancer therapies in Jordan were investigated. Our future aim is providing recommendations to improve the knowledge of health care teams that are involved in or will be involved in clinical trials regarding related ethical challenges.

Ethical Approval

Approval of the study protocol was granted by the Institutional Review Boards of Jordan University of Science and Technology and the KAUH.

Methods

Study Design

This study was a questionnaire-based observational study.

Inclusion Criteria

Medical residents from various medical specialties who served oncology patients at internal medicine, adult oncology, pediatric oncology, and surgical oncology units at KAUH in Jordan were included in the study. A total number of 83 residents were interviewed and asked to complete the questionnaire during the period from (June 1 to August 15, 2017).

Questionnaire

A literature review was performed to determine the core points utilized to assess attitudes and knowledge of medical residents toward clinical trials.^{16,17} The questionnaire items were tailored to suit the purposed study objectives focusing on cancer-related clinical trials. An informed consent statement was included at the beginning of the questionnaire with a brief description of the study purpose

and the questionnaire participants provided their informed consent for their participation. The questionnaire consisted of three major domains including medical residents individualized characteristics such as gender, age, and current medical rotation specialty. The second domain of the questionnaire inquired about medical residents' attitudes toward cancer clinical trials research. Six close-ended questions with either "yes" or "no" answers were used to assess the attitudes domain. Medical residents were asked about their previous and current participation in cancer clinical trials, and whether their previous participation in clinical trials involved using a new investigational drug for cancer patients. In addition, residents were asked if they had received previous training on how to carry out clinical research. Finally, medical residents' attitudes toward prospective participation in running clinical trials were assessed and if it was important for them to be involved in clinical research. The third domain of the questionnaire inquired about medical residents' knowledge toward clinical trials related to oncology. Seven close-ended type questions of which five were "yes" or "no" answers. Medical residents were asked if they had previously written or at least participated in writing a clinical protocol, and if they had ever submitted a research manuscript on clinical cancer research during their residency training. The knowledge domain involved assessment of residents' knowledge about the international ethical standards regulating the clinical trials in general, and more specifically, cancer clinical trials. Moreover, they were asked about their knowledge of the Declaration of Helsinki as well as clinical equipoise concept in clinical trials. Finally, the questionnaire included one open-ended question to explore the resident's opinions about the main ethical issues that might face the administration of clinical trials, especially those connected with cancer therapies in Jordan.

Data Analysis

The Statistical data analyses of averages and standard deviations, frequencies, and percentages were performed using SPSS program version 17.0 (SPSS Inc., Chicago, IL, USA).

Results

A total number of 83 medical residents from different medical fields and specialties responded and completed the study questionnaire. The majority of medical residents were males (N=68, 81.9%). Their average age \pm SD was 30 ± 3.6 years. (Table 1). Among respondents, 47 reported that they have current participation in oncological clinical trials and 44

Table 1 Medical Residents Individualized Characteristics

Variable	Category	N (%)
Gender	Male	68 (81.9)
	Female	15 (18.1)
	Both	83 (100)
Medical specialty	Medical oncology	18 (21.7)
	Surgical oncology	39 (47.0)
	Pediatric oncology	4 (4.8)
	Internal medicine	22 (26.5)

Note: Average age in years \pm SD= 30 ± 3.6 .

reported a previous participation in cancer research (Table 2). Only 10 of them reported previous or current participation in clinical trials that involved using a new therapeutic drug for cancer patients (Table 2). Most of the residents showed a positive attitude toward future participation in cancer clinical trials and almost all of them believed that physicians should be involved in clinical research (Table 2). A total number of 21 of the respondents (25.3%) reported that they have previously helped in writing a research protocol under the supervision of their mentors and only 24 of them reported they have submitted a research manuscript submitted to international journals (Table 3). Only one of the residents reported a full understating of the Declaration of Helsinki, which is a fundamental document on human research and clinical trials ethics (Table 3).

Table 2 Attitude of Medical Residents Toward Cancer Clinical Trials

Item	N (%)
Do you have current participation in cancer clinical trials? Yes	47 (56.7)
Do you have previous participation in cancer clinical trials? Yes	44 (53.0)
Does your previous or current clinical research involve using new investigation drug for cancer patients? (Yes)	10 (12.0)
Prospective participation in cancer clinical trials Yes	55 (66.3)
Have you ever received any training course on how to conduct clinical research? Yes	37 (44.6)
Do you consider it is necessary for physicians to conduct clinical research? Yes	76 (91.6)

Table 3 Knowledge of Medical Residents Toward Cancer Clinical Trials

Item	N (%)
Have you ever helped in writing a cancer clinical trial protocol? Yes	21 (25.3)
Have you submitted for publication a manuscript on cancer clinical trials? Yes	24 (28.9)
Do you know the purpose of the Declaration of Helsinki?	
I know very well	1 (1.2)
I know to some extent	15 (18.1)
I do not know	67 (80.7)
According to the Declaration of Helsinki, the use of placebo is acceptable under that no proven treatment exists. (Yes)	62 (74.7)
Informed consent from the participants should be obtained in:	
All the clinical studies	56 (67.5)
Depends on the purpose of the clinical trial	27 (32.5)
Do you know the meaning of clinical equipoise in clinical trials? (Yes)	52 (62.7%)
Using the new investigational drug to treat resistant cancer without considering patients well-being. (Yes)	37 (44.6)

Fifteen residents knew about the Declaration of Helsinki to some extent, and 67 of them did not know about it (Table 3). Most of the respondents answered that informed consent should be obtained for all clinical studies (Table 3). Fifty-two respondents were aware of the equipoise term clinical trials and general aspects related to it. (Table 3). A total number of 37 residents believed that they could use the new investigational drugs to treat resistant cancers without considering patients' well-being (Table 3). Finally, 84.3% of respondent believed that bias which might accompany clinical trials, limited resources and budget, and cultural beliefs are the main challenges that might be encountered by the clinical trial administration in Jordan (data not shown in tables)

Discussion

In this questionnaire-based study involving medical residents who had served the cancer patients during their residency training. Less than half of the respondents

reported either previous or current participation in clinical trials in general. These findings were presumed by taking into consideration the relatively small number of clinical trials carried out in Jordan.¹⁸ Almost one third of the world's clinical trials are carried out outside the United States, but the contribution toward these trials from the Middle East and North Africa is considered significantly low representing less than 1% of the world's clinical trials.¹⁹ The current study showed that medical residents have a positive attitude toward future participation in clinical studies and thought that such studies could be highly beneficial for patients. Most participants believed that physicians should carry out clinical trials parallel to their regular work. Current findings were in agreement with results from other studies done in other developing countries.^{11,16,17,20} Although a large percentage of medical residents reported that they have taken training courses about clinical research at some point during their clinical training, only a small number of them showed basic knowledge about ethical standards related to patients' privacy and rights protection codes. More than two thirds of respondent residents showed adequate knowledge about informed consent importance and elements as well as when it is mandatory to be taken. Studies from Nepal and India reported that a large percentage of resident doctors and dental faculty were unaware of core ethical documents and codes related to clinical research such as the Declaration of Helsinki and the Nuremberg Code.^{21,22} Similar studies from the USA, Japan, Saudi Arabia, and India showed that physicians involved in cancer clinical trials had little knowledge or experience about clinical trials, yet they had high interest and positive attitude to learn more about the roles they could play in clinical trial research.^{11,16,20,23} These findings suggest the need to provide physicians, especially those planning to run future clinical trials, with the proper training involving the ethical challenges and other obstacles that they might encounter in the future.

During their residency training, medical residents should demonstrate strong knowledge and skills for effective treatments utilizing the best available medical resources and primary literature. Improving the resident's knowledge and attitudes toward clinical trials will certainly improve the health-care service provided to patients. Previous reports demonstrated that enhancing the understanding of clinical trials among primary physicians would help in relieving the patient's confusion and worries about participation in clinical trials. In addition, it will increase

physicians' capacity for patients' referrals to clinical trials.²⁰ Residents with both strong research and clinical experience are generally more recognized when applying for academic positions or highly competitive subspecialty fellowships.^{24,26} Taken altogether, it is clear that early involvement of residents in clinical research will reflect positively on their clinical performance and career advancement.²⁷

The majority of respondent residents attributed the challenges which might be encountered in the oncology clinical trials to many reasons, including lack of funding, proper infrastructure, cultural beliefs, and lack of patients' willingness to participate in clinical trials, and improper understanding of the regulations pertaining clinical trials practice in Jordan. Similar studies attributed the low number of conducted clinical trials in the developing countries to various reasons including the lack of financial and human capacity, ethical and regulatory system obstacles, lack of proper research environment, operational barriers, difficulty in recruiting participant patients in clinical trials, busy schedule for physicians, and lack of time availability to conduct and follow-up for clinical trials.^{28,30}

The current study did have several strengths. To best of our knowledge, this study is the first to evaluate the medical residents' attitudes and knowledge toward cancer related clinical trials in Jordan. This study will be utilized in the future as a basis to draw the attention toward the need of better training for physicians, especially those in their early career regarding aspects and requirements of clinical trials research as per international standards.

The current study had some limitations including the fact that it was conducted in one research center in Jordan, and it did not involve other hospitals or centers where cancer patients are treated. Although the study data were collected three years ago, we believe that our findings are still relevant today as we have observed that clinical trials have not changed much over the past few years. Our next step includes incorporating more hospitals in Jordan to obtain a better understanding of the current situation in Jordan about physician knowledge and attitudes toward clinical research, aiming to maximize the patient's benefits.

Conclusion

The current study suggests that there is a strong need to improve the medical residents' knowledge towards the cancer clinical trials. Current findings indicate that it is necessary to obtain a better understanding of the ethical

challenges and clinical research barriers which may be encountered by medical residents when they are involved in clinical trials. Obtaining an ideal research environment will create a high-quality level of clinical research, and more reliable evidence-based medicine recommendations for future cancer management.

Abbreviations

KAUH, King Abdullah University Hospital; JFDA, Jordan Food and Drug Administration; IRB, Institutional Review Board; ACGME, Accreditation Councils for Graduate Medical Education; NIH, National Institute of Health.

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Disclosure

The authors report no conflicts of interest in this work.

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