

# Knowledge, attitudes, practices and perceptions of clinicians towards conducting clinical trials in an Academic Tertiary Care Center

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## ABSTRACT

**الأهداف:** تهدف هذه الدراسة لتقييم المعارف والممارسات والمواقف والتصورات لدى الأطباء نحو إجراء الأبحاث السريرية.

**الطريقة:** دراسة مقطعية أجريت على الأطباء في مدينة الملك فهد الطبية، الرياض، المملكة العربية السعودية. تم جمع البيانات باستخدام استبيان ينقسم إلى 5 أقسام: القسم الأول يشمل الخصائص الديموغرافية للمشاركين. بينما تشمل الأقسام الأخرى المعرفة والمواقف، والتصورات، والممارسة لدى الأطباء نحو إجراء الأبحاث السريرية.

**النتائج:** عدد المشاركين 316. أظهرت النتائج بأن (56%) من المشاركين لم يكونوا على معرفة بإعلان هلسنكي على الإطلاق. و بين (88.4%) عن اهتمامها بإجراء الأبحاث السريرية و 61.7% من المشاركين وأظهروا استعدادهم لتسهيل إجراء الأبحاث السريرية التي يقوم بها الأطباء الآخرين. وعلاوة على ذلك، 112 (35.9%) من عينة الدراسة شارك في إجراء أبحاث سريرية سابقا. فيما يتعلق بالعيوب في إجراء الأبحاث السريرية، أشار المشاركون بصعوبة الأعمال المكتبية وأعربوا عن اعتقادهم بأنها قد تفقد المرضى من الممارسة السريرية الخاصة بهم بمجرد تعيينهم في الأبحاث السريرية. عدم تخصيص وقت للبحث بالنسبة للأطباء 295 (97.7%)، ونقص المنسقين للبحوث السريرية 293 (97%)، كانت من المشاكل الرئيسية التي أوضحها المشاركون في الدراسة.

**الخاتمة:** على الرغم من أن غالبية المشاركين على مستوى غير مرض من المعرفة والمفاهيم الخاطئة حول الأبحاث السريرية، أظهروا اهتماما ومواقف إيجابية إزاء إجراء الأبحاث السريرية. زيادة معرفة الأطباء بإجراء الأبحاث السريرية قد تحسن تصورهم نحو إجراء التجارب السريرية.

**Objectives:** To investigate the knowledge, attitudes practices and perceptions of clinicians concerning the conducting of clinical trials (CTs).

**Methods:** A cross-sectional study was conducted on clinicians at King Fahad Medical City, Riyadh,

Saudi Arabia. Data were collected using a self-administered questionnaire which divided into 5 sections: Section 1 covered respondents' demographics. The other 4 sections explored respondents' knowledge, attitudes, perceptions and practice towards conducting CTs.

**Results:** A total of 316 clinicians completed the questionnaire. The majority were assistant consultants and consultants 125 (39.5%) and 108 (34.2%), respectively. One hundred sixty-nine (56%) respondents were not aware of the Declaration of Helsinki at all. Two hundred seventy-five (88.4%) respondents expressed interest in conducting CTs and 61.7% and participants showed their willingness to facilitate and assist in CTs conducted by other clinicians. Moreover, 112 (35.9%) respondents participated in CTs previously. Regarding the disadvantages in conducting CTs, participants indicated that the paperwork was complicated and they believed that they might lose patients from their clinical practice once they are recruited in CTs. Lack of research protected time for clinicians 295 (97.7%), and a shortage of clinical research coordinators 293 (97%) were the main problems reported by respondents.

**Conclusions:** Although the majority of participants had an unsatisfactory level of knowledge and misperceptions about CTs, they showed an interest in and positive attitudes about conducting CTs.

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Clinical Trials (CTs) are considered the gold standard for the identification of therapeutic strategies and diagnostic tests<sup>1</sup> and provide the highest level of evidence on which to base decisions about CTs. However, there is limited research involving the perspectives of clinicians towards patient treatment.<sup>2,3</sup> However, many clinicians remain unaware of how to properly conduct a clinical trial (CT) and how their input contributes to the development of novel drugs, devices, and biologics for treatment.<sup>4</sup> Clinicians' compliance is as important as patients' compliance in CTs. It is important that physicians follow the study protocol and its execution with regular follow-up and prompt submission of accurate data. Factors that affect clinicians' willingness to participate in a CT includes anticipated benefits for participation, clinicians' knowledge of their role as investigators, and time and effort required once involved.<sup>5,6</sup> Some clinicians expressed concern that CTs might conflict with the ethical principles of patient beneficence and autonomy.<sup>7</sup> While, others worried about the double role of clinician and researcher.<sup>8</sup> Moreover, many clinicians in CTs are reluctant to do additional tests for their patients, to avoid possibly inducing any further inconvenience to the patients.<sup>9</sup> However, these concerns may reflect misunderstandings amongst clinicians about important aspects of CTs. Clinicians' knowledge, attitudes, perceptions, and practices towards CTs are all integral elements for the trials' success. It is clear that recruitment is difficult when the process depends on clinicians who do not have enough information and interest in research.<sup>6</sup> Moreover, clinicians have known about the research goals, eligibility criteria, CTs design and phases and the study process. Clinicians' knowledge, attitudes towards conducting CTs and perceptions about the benefits of involvement in CTs remain critical factors to be investigated. Several studies have been performed to investigate the views of patients regarding CTs.<sup>10,11</sup> The Kingdom of Saudi Arabia (KSA) is an important country for conducting CTs as the health care system is rapidly developing and many companies sponsoring medical and research teams within KSA. In 2009, the CT administration was created, and its responsible was

to evaluate all CT applications in KSA. The future of conducting CTs in KSA is promising. The Saudi Food and Drug Authority has created a framework that eases the review and approve CTs. Also, the availability of many first-rate medical facilities and increasing numbers of qualified investigators along with a rapidly growing pharmaceutical market and healthcare investments, attributed to improving KSA's ability to conduct more high quality and robust CTs.<sup>12</sup> Moreover, knowledge among Saudi clinicians regarding CTs has become an area of interest due to practitioner adoption of evidence-based practice in clinical settings.<sup>9,13-14</sup> Thus, this study aims to assess the knowledge, attitudes, practices, and perceptions of clinicians towards conducting CTs. Additional studies would be helpful in further clarifying underlying themes regarding perspectives of clinicians towards conducting CTs.

**Methods. Study design.** After obtaining approval from the Institutional Review Board at King Fahad Medical City (KFMC); Riyadh, Kingdom of Saudi Arabia a cross-sectional study was conducted between January and April 2016.

The KFMC is an academic, tertiary-care hospital and there is more research support compared to other national non-academic hospitals, furthermore the training programs such as the National Institutes of Health, and Collaborative Institutional Training Initiative programs and obtaining formal certificates is mandatory as the CTs at KFMC are conducted in compliance with the Good Clinical Practice standards. Also, each trial has a training module that should be completed by the research team in each study, and evidence of this training should be submitted to the IRB before the study is initiated.

**Study population.** Participants were clinicians with academic titles from different specialties at KFMC. Exclusion criteria included medical students who are not authorized per KFMC policy to be a principal investigator or a co-investigator in a CT. Clinicians who met the inclusion criteria were asked to participate; those who agreed to take part in this study provided a written informed consent.

**Recruitment.** We invited 400 clinicians from various clinics of specialized hospitals within KFMC over a four-month period.

**Data collection.** Data collection was accomplished using a self-administered questionnaire based on information obtained from the literature to assess the knowledge, attitudes, perceptions, and practices of clinicians towards conducting CTs.<sup>15-17</sup> The questionnaire was divided into 5 sections. Section 1

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**Table 1** - Independent variables of participants.

Variables	n (%)
Mean age years (SD)	37.83 ( $\pm 7.92$ )
Median age years [Min-Max]	38.00 [24-62]
<b>Gender (%)</b>	
Male	248 (80.0)
Female	62 (20.0)
<b>Department/unit (%)</b>	
Medical	190 (63.1)
Obstetrics/gynecology	30 (10.0)
Hematology/oncology	30 (10.0)
Pediatric	26 (8.6)
Surgical	18 (6.0)
Intensive care	7 (2.3)
<b>Residency (%)</b>	
Saudi Arabia	175 (55.3)
Eastern Europe	57 (18.2)
Arab countries	41 (12.9)
Western Europe	24 (7.6)
Others	19 (6.0)
<b>Job designation (%)</b>	
Consultant	108 (34.2)
Associate consultant	10 (3.2)
Assistant consultant	125 (39.5)
Fellow	21 (6.6)
Resident	52 (16.5)

covered respondent's independent variables including age, gender, department/units, residency and job designation; which included consultants, associate consultants (who is at the beginning of their consulting career and will typically carry out work to support the consultants and senior consultants), assistant consultants (who finished the fellowship program and can work in a variety of healthcare settings under the supervision of a trained doctor), fellows (who is under fellowship training program) and residents. Section 2 explored respondents' knowledge regarding potential benefits of CTs. The participants were also asked whether they recognized the principles of the World Medical Association Declaration of Helsinki through multiple responses and 4 yes-or-no questions. Section 3 assessed participants' attitudes towards their willingness to facilitate CTs conducted by other clinicians and their interest in conducting CTs. Section 4 explored respondents' practices regarding their previous participation in CTs. The questionnaire was modified, and a pilot study was conducted on 38 participants to ensure the clarity and adequacy of the research instrument and to evaluate the reliability. The Cronbach alpha coefficient was  $<0.70$ . Finally, Section

5 explored respondents' perceptions of challenges and obstacles in CTs. A 5-point Likert scale was used for perceptions questions ("strongly agree," "agree," "uncertain", "disagree," and "strongly disagree").

**Statistical analysis.** Data were summarized using mean $\pm$ SD and/or frequencies and percentages, as appropriate. A multiple logistic regression analysis was performed. Odds ratios and *p*-values were reported for each factor alone and for the factors found to be significant from the backward elimination. All statistical analyses were performed using the Statistical Package for the Social Sciences software version 22.0 (IBM Corp, Armonk, NY: IBM Corp).

**Results.** During the study interval, a total of 316 clinicians completed the questionnaire. Table 1 presents the characteristics of respondents. The mean age of respondents was 37.83 ( $\pm 7.92$ ) years. The majority were assistant consultants and consultants 125 (40.8%) and 108 (35.3%) respectively.

**Knowledge of participants towards conducting CTs.** Among all respondents, 17.5% of clinicians stated that they knew about Declaration of Helsinki ethical principles, 7.6% know most of it, 18.9% knew it to some degree, whereas 56% declared not knowing it at all. Moreover, our results indicated that the majority 293 (97.0%) of respondents stated that one of the potential benefits of conducting CTs is to improve medical knowledge, whereas 27(9.6%) indicated that there is no benefit from conducting CTs (Table 2).

**Attitudes of participants towards conducting CTs.** Two hundred seventy-five (88.4%) respondents expressed interest in conducting CTs. When asked about facilitating CTs conducted by other clinicians, 61.7% of participants indicated that they would be willing to facilitate and assist in CTs conducted by other clinicians.

**Practices of participants conducting CTs.** One hundred and twelve (35.9%) respondents had participated in CTs previously, of whom 33.6% had experience as principal investigators and 63.6% as co-investigators. When asked about their sources of information related to CTs, 231(73.1%) participants responded that they use journals related to CTs, while 23 (7.3%) participants responded that they do not have an opportunity to gain information.

Thirty-five (11.2%) physicians reported participation in CTs that were terminated before completing the entire research protocol timeline, mainly due to the complexity of the trials 12 (3.8%) and difficulty in obtaining the informed consent 9 (2.8%).

**Table 2** - Logistic regression analysis for participant's demographic characteristics and previous participation in conducting CTs.

Variables	OR	P-value	95% CI	
			Lower limit	Upper limit
Age (years)	1.00	0.959	1.05	0.738
<b>Gender</b>				
Male	1.19	0.715	0.47	3.00
Female	1*			
<b>Job designation</b>				
Associate consultant	1.20	0.775	0.34	4.29
Assistant consultant	1.94	0.078	0.93	4.04
Resident	5.38	0.009	1.53	18.87
Fellow	1.51	0.579	0.35	6.56
Consultant	1*			
<b>Department/unit</b>				
Obstetrics/gynecology	0.94	0.917	0.28	3.19
Hematology/oncology	0.34	0.037	0.12	0.94
Pediatric	1.49	0.462	0.52	4.27
Surgical	0.80	0.753	0.21	3.11
Intensive care	3.48	0.274	0.37	32.65
Medical	1*			
<b>Do you know the "Declaration of Helsinki Ethical Principles for Research Involving Human Subjects"?</b>				
No	2.37	0.009	1.24	4.51
Yes	1*			
<b>Are you interested in conducting clinical trials?</b>				
No	3.19	0.054	0.98	10.38
Yes	1*			
<b>Obtaining research grants or other rewards.</b>				
No	1.21	0.538	0.65	2.26
Yes	1*			
<b>Enrollment of trial participants</b>				
No	0.12	0.005	0.03	0.53
Yes	1*			

OR - odds ratio, CI - confidence interval

**Perceptions of participants towards conducting CTs.**

The majority 95.8% of participants believed that the main reason to conduct CTs is to aid in developing new treatments, followed by an understanding of the disease pathology and treatment 92.3% and publishing the results (77%). When asked the participants about the reasons to not to conduct CTs, the highest 3 reasons were: lack of awareness of ongoing trials 216 (68.4%), limited familiarity with research methods and procedures 127(40.2%) and lack of interest in the research topic 110 (34.8%). The physicians were then asked on potential problems they faced in conducting CTs; lack of protected research time for clinicians 295 (97.7%), shortage of clinical research coordinators

293 (97.0%), and difficulties in recruiting subjects 277(95.2%) were the most reported problems.

Regarding the disadvantage from conducting CTs, 115 (36.4%) participants indicated that the paperwork is complicated and 102(32.3%) believed that they might lose patients from their clinical practice once they are recruited in CTs.

A statistical significant difference were found between the response variable previous participation to CTs and resident job designation ( $p=0.009$ ), hematology/oncology department ( $p=0.037$ ), Declaration of Helsinki ethical principles for research involving human subjects ( $p=0.009$ ), and enrollment of trial participants ( $p=0.005$ ) (Table 2).

**Discussion.** Our results provide valuable insights regarding the knowledge, attitudes, practices, and perceptions of clinicians towards conducting CTs. The participants showed an unsatisfactory level of knowledge about Declaration of Helsinki ethical principles and 9.6% indicated that they believed there was no benefit to be gained from conducting CTs. "The majority of respondents showed a positive attitude towards adopting and executing CTs, and expressed their willingness to facilitate and assist in CTs conducted by other clinicians. Moreover, regarding the disadvantages of conducting CTs, participants indicated that paperwork was complicated and they believed that they might lose patients from their clinical practice once they are recruited in CTs. Our results showed that lack of research protected time for clinicians and shortage of clinical research coordinators were the greatest problems reported by respondents. Another important finding is that 7.3% of participants stated that do not have an opportunity to gain information about conducting CTs.

Over half the respondents were not aware of the Declaration of Helsinki at all. Additionally, only one-third of physicians answered all the questions related to the declaration correct. One possible reason for such a result may be attributed to the younger age of the respondents who are more focused on their clinical practice and building their career, in comparison to advancing in research. On the other hand, we should not ignore the possibility of a more concerning reason for such a result, which could be the lack of perceiving and retaining research education material provided locally, especially concerning international declarations and regulations as 7.3% of participants stated that do not have an opportunity to gain information.

As mentioned in our results, lack of research protected time to the clinicians is a major obstacle to conduct CTs. This is most probably due to the shortage of doctors

in Kingdom of Saudi Arabia, and a consequently high workload. According to the World Health Organization data of World Health Statistics 2015, the physicians number was 24.9 per 10,000 populations,<sup>18</sup> and these physicians have to cover the great number of hospital in Saudi Arabia. Similar problems were raised by Ito-Ihara<sup>19</sup> (2013) where Japan and South Korea have a comparable density of physicians. Consistently, in a systematic review, Ross et al<sup>20</sup> revealed that lack of time is a major barrier which influenced participation of physicians in CTs for cancer and other illnesses. Another study conducted by Fallowfield et al,<sup>21</sup> on 357 clinicians to identify their attitudes to CTs of cancer therapy recognized restraints imposed by the health care system which negatively affect CT participation, including lack of time. These difficulties can be related to lack of support staff to help in patient recruitment and handle paperwork. Consequently, the workload continues to affect the already time-limited doctors negatively.

Another perceived major obstacle for conducting CTs was a shortage of clinical research coordinators. Personnel support from the hospital is critical for conducting CTs more efficiently, and the establishment of better training programs for running CTs is necessary to increase the number of skilled personnel. The provision of sufficient study personnel or research nurses, who can regularly contact both the participating patients and physicians, might be the most effective intervention in overcoming this barrier. A study conducted by Al-Badr et al,<sup>22</sup> showed that the researcher evaluation of clinical research coordinators performance is pivotal as it provides an insight into the measure to be taken in further enhancing the research conduct and productivity of an institution. Moreover, all participants acknowledged that clinical research coordinators have a positive effect on research conduct and promptness.<sup>22</sup>

In the present study, clinicians believe that the reason to conduct CTs was to provide new treatments to patients. Previous studies reported that the majority of clinicians recognize CTs as a source of high-quality patient care, as well as, the benefit to themselves and society.<sup>23,24</sup>

On the other hand, obtaining research grants or other material rewards, as well as, gaining credits for board certification were much lesser incentives for conducting CTs. This is despite the fact that board certification at KFMC allows doctors to be recognized as consultants in their respective medical specialties. A

study carried out by Ashar et al,<sup>25</sup> in the United States indicated that a considerable number of physicians participated in pharmaceutical industry-sponsored CTs to enhance their incomes, knowledge, and professional reputation.<sup>25</sup>

In CTs, participants' perceptions were found to be variable and might have been related to beneficence and value of participation. This should not conflict with the concepts of conducting high-quality clinical studies and ensuring GCP standards to enhance participation.<sup>26</sup> Recruitment issues have also been found to be an obstacle, commonly resulting in premature termination of CTs. This has to be also studied further to assess barriers and find solutions at various levels.<sup>27,28</sup> Clinicians have a key role in presenting and explaining the CT option to the patients. The choice to participate in a CT rests on the recommendation of the clinician and how it is apparent by the patient. The 2000 Cancer CTs study reported that 59% of the study participants rely on their doctor as the main source of information. Previous studies on physician-patient communication revealed that positive communications about participation in a CT could be a vital factor to motivate patients to participate in a cancer CT.<sup>29-31</sup>

Around 36% of respondents participated in a CT earlier; similarly, previous studies reported a varied range of percentage of clinicians participating in clinical research, which is 13-90%.<sup>32-34</sup>

**Strength and limitation of the study.** The strength of this study was that our sample included participants who had experience with a CT and those who had not. Accordingly, our results are representative of different insights regarding clinicians' knowledge and perspective towards conducting CTs. Whereas, the study limitation was that this study conducted at a single institution, thus the probability for generalizing the findings among all clinicians in Riyadh is limited.

In conclusions, the conducted study revealed the current understanding of Saudi clinicians towards conducting CTs. Although the majority of participants had an unsatisfactory level of knowledge and misperceptions about CTs, they showed positive attitudes and interest in conducting CTs. Increasing clinicians' knowledge, research services and support staff such as clinical research coordinators may enhance the conduction of CTs among clinicians.

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