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Original Article

The Engagement of Physicians in Clinical Trials in Ethiopia

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Abstract

Background: *Physicians have a vital role in the design and conduct of clinical trials. Their involvement promotes evidence-based practice, and improves patient care. However, the degree of their engagement varies across regions and countries. This study aimed to assess the engagement and experience of physicians in the design or conduct of clinical trials in Ethiopia.*

Methods: *A cross-sectional study was conducted in three teaching hospitals where clinical trials are frequently conducted in Ethiopia: Tikur Anbassa Specialized Hospital, University of Gondar Specialized Hospital, and Jimma University Medical Center. The experience of the physicians from the three hospitals was assessed using a self-administered questionnaire. The data were analyzed descriptively.*

Results*: A total of 213 physicians were involved in this study, of whom 40 (19%) reported current or previous engagement in the plan and conduct of clinical trials. Among those who were engaged in clinical trials, 57.5% (23 out of 40) had been involved only in one clinical trial. Of those who were engaged in clinical trials, 80% reported that the clinical trials they were engaged in were registered in clinical trial registry platforms although only half had been an author of any trial-related publications. The physicians noted that obtaining ethics and regulatory approval took too long. While nearly all physicians who participated in the study (98%) expressed an interest in getting involved in future clinical trials, only17% were aware of any ongoing clinical trials within their institutions.*

Conclusion*: The engagement of physicians in clinical trials is low and most appear to have minimal awareness. However, many would like to get more involved. There is fertile ground to engage physicians in clinical trials, though this may necessitate training in clinical trial management and design and greater awareness of clinical research careers.*

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Keywords: *Physician, Clinical trial, Clinical trial involvement, Clinical trial experience, Ethiopia*
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Introduction

Clinical trials play a key role in testing new therapeutics and advancing medical knowledge. They provide the gold standard evidence for policy and clinical decision-making(1, 2). In addition, clinical trials offer opportunities for human and infrastructure capacity building and national economic development(3, 4).

Ethiopia is the 10th most populous country in the world representing about 1.7% of the world's and 9.1% of Africa's population(5). However, only 0.06% of the global (6), and 1.5% of Africa's clinical trials are conducted in Ethiopia(7). Globally, drug development focuses little on diseases that affect the population of Ethiopia or Africa more broadly. For example, only 10 of 1556 new drugs produced from 1975 to 2004 targeted neglected tropical diseases (8). Lack of attention to the clinical challenges affecting Ethiopia leads to limited local evidence to inform policy and practice and lost opportunities to improve quality of care, target diseases that affect the region, and foster employment and economic development opportunities.

Physicians play a crucial role in the design and successful execution of clinical trials, given their involvement in patient care, implementation of trials, safety monitoring, and ethical oversight. Their involvement in clinical trials promotes evidence-based practice, improve patient care and fosters their professional development (9). Without the participation of physicians, the untapped opportunities of clinical trials cannot be fully realized (9, 10). Yet, the number of clinicians engaging in clinical trials is low. A survey conducted by the Association of American Medical Colleges reported that 14% of all physicians and 24% of academically affiliated physicians were involved in research (11). A similarly low number of physicians in Africa are involved in clinical trials (12). In UK, 40% of physicians are involved in clinical research (13) with the majority involved are academically affiliated. Surveys conducted in United States indicated that physicians' engagement in clinical research is declining (11, 14, 15). Several factors such as time constraints, lack of research expertise, lack of confidence, and organizational and operational barriers may limit the engagement of physicians in clinical trials (16). Lack of funding, lack of training and capacity-building opportunities, poor institutional support, and regulatory barriers were reported in developing countries (12). Few clinicians also reported lack of research interest as a reason for not engaging in clinical trials (16).

Despite the relevance of physician engagement in clinical trials, there is limited evidence on the extent of physician engagement in clinical trials in Ethiopia. This cross-sectional survey aimed to assess the engagement and experience of physicians in the design and conduct of clinical trials. The results may inform efforts to strengthen the clinical trial workforce in Ethiopia.

Materials and methods

Study design and setting

This descriptive cross-sectional study was conducted from December 2019 to January 2020, at three university hospitals: Tikur Anbessa Specialized Hospital (TASH), University of Gondar Specialized Hospital, and Jimma University Medical Center. The hospitals were selected based on their engagement in clinical trials, determined by the number of registered clinical trials in two major clinical trials registration databases, such as ClinicalTrials.gov, and the Pan-African Clinical Trials Registry (PACTR).

TASH is the teaching hospital of Addis Ababa University and is the largest public tertiary hospital in Ethiopia, with over 700 beds. The hospital serves approximately 700,000 patients per year and has over 300 medical doctors(17).

The University of Gondar Specialized Hospital is a tertiary healthcare hospital serving about 5 million people in the North-West of Ethiopia, with over 600 beds. The hospital has over 1000 health professionals, including more than 200 physicians (18).

Jimma University Medical Center is a teaching hospital of Jimma University, Ethiopia. The hospital has a bed capacity of 800 and provides services for approximately 16,000 inpatient and 220,000 outpatient attendants annually. The hospital is staffed with over 1000 health professionals, of whom 140 are physicians (19).

Participants and sampling technique

Physicians working in the three university hospitals (TASH, Gondar and Jimma) were selected through a convenience sampling approach. The physicians were recruited in two ways: those who had experience in conducting clinical trials were identified through clinical trial registries and expert recommendations. Those who were not on that list were approached through selected departments. Questionnaires were distributed across institutions without predefined quotas or proportional representation.

Sample size
The sample size was determined using a single population proportion formula. The estimate for the proportion of physicians engaged in clinical trials is not reported from Ethiopia. We, therefore, used the available estimate from the United States: 14.7%(20). With further assumptions of 5% margin of error, 95% confidence limit, and 10% non-response rate, the required sample size was 212 participants. Even though the reference population difference should not be disregarded, we took an overall assumption that

this would be a sufficient sample size for the descriptive objectives of the study. However, due to the higher non-response rate observed during the data collection, we distributed 354 questionnaires (203 in Addis Ababa, 67 in Gondar and 84 in Jimma).

Data collection
A self-administered structured questionnaire was developed for data collection. The questionnaire contained information on demographic and professional profile, engagement in clinical trials, experience obtaining ethics and regulatory approval, trial registration and publication, institutional support to engage in clinical trial, and interest in conducting or continuing to conduct clinical trials.

Data quality assurance
Field supervisors were trained on the contents of the questionnaire before data collection. The supervisors checked the completed questionnaire to ensure completeness and consistency of the filled data.

Data management and analysis
Data were entered into Epi-data version 3.1 and exported to SPSS version 20 for analysis. The data were analyzed descriptively. Percentages, frequency tables, and descriptive figures were used as appropriate. Content analysis was used to summarize the responses of the open-ended questions.

Ethical considerations
Ethical approval was obtained from the institutional review board of the College of Health Sciences, AAU (Ref no. 067/16/Psy) before the start of the survey. The participating institutions were also informed about the study. Informed consent was obtained from the participants after they were informed of the study aims and purpose of the interviews. Only codes were used to secure the anonymity of participants and ensure confidentiality.

Results
Characteristics of participants
A total of 213 participants (112 from TASH, 48 from Gondar, and 53 from Jimma) completed the survey, yielding an overall response rate of 60.2% which varied by setting (55.2% at TASH, 71.6% at Gondar, and 63.1% in Jimma). The overall sample size achieved the calculated minimum sample size required for the study. The demographic and practice characteristics of study participants are summarized in Table 1. Most participants were male (77.4%), and about half of the physicians were specialists (57.3%). More than half of the physicians (58%) had worked as physicians for more than five years.

Table 1: Participants' characteristics at three university hospitals in Ethiopia, 2019/20

Characteristics		Number	Percent
Sex	Male	146	77.4
	Female	48	22.6
Qualification	Specialist	122	57.3
	Sub-specialist	77	36.2
	Others (MSc, PhD)	14	6.5
Year of experience	<5 years	89	42
	5-9 years	55	25.9
	>10 years	68	32.1

Trial engagement
Forty physicians (18.8%) have ever been engaged in clinical trials. Male and female physicians equally participated (19% each). Among those who were engaged in clinical trials, most (80.0%) were engaged only in one or two trials (Fig. 1). Of those who were engaged, about half (52.5%) were engaged in clinical trials at the time of the study (Table 2). Most of the physicians engaged in clinical trials had worked in more than one role: a quarter as Principal investigator (PI) and as trial physician, and about half as co-PIs. Additionally, some participants had roles as co-investigators, monitors, members of the Data Safety Monitoring Board (DSMB), advisors or study managers. One in six physicians is aware of clinical trials being conducted in their institution.

Table 2: Participants' engagement in clinical trials at three university hospitals in Ethiopia, 2019/20

Question		Number	Percent
Awareness about Institutional engagement in Clinical Trials	Aware	36	17
	No awareness	177	83
Engaged in Clinical Trial	Yes	40	18.8
	No	173	81.2
Last time you were involved in a clinical trial	Currently engaged	21	52.5
	One year ago	5	12.5
	Two years ago	4	10
	Three years ago	5	12.5
	Four years ago	0	0
	Before five years	5	12.5
Were the clinical trials registered in clinical trial registration database?	Yes	32	82.1
	No	5	12.8
	Don't Know	2	5.1
Publications from the trials	None	20	50
	One	9	22.5
	More than one	11	27.5

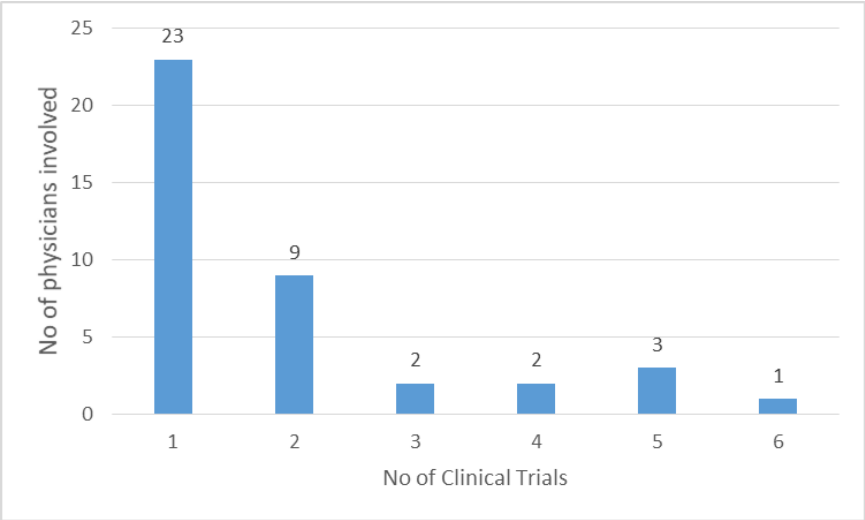

Figure 1. Physicians' engagement in clinical trials at three university hospitals in Ethiopia, 2019/20

Experience in obtaining ethics and regulatory aproval, trial registration, and publication

Physicians who had participated in clinical trials reported that, in addition to the mandatory National Research Ethics Review Board (NRERB) and the Ethiopian Food and Drug Authority (EFDA), one to six additional institutional ethics committees had reviewed and approved the clinical trial protocols. Time to approval from all boards varied from one to 24 months, with an average duration of 12.2 months. The physicians provided different reasons for delay in obtaining

approval. They noted that too many approvals were sought from different unrelated institutions. Respondents noted that delays in the initial review and review of response documents, communication challenges with the ethics committee offices (closed offices or lack of response to phone calls), frequent changes in responsible personnel, and infrequent meetings were barriers. The variable capacity of staff of authorities and institutional ethics committees, the bureaucratic approval process at EFDA and the NRERB, delay in the approval of study drug importation, and delay in customs clearance were additional reasons for the delay. While about 3 in 4 clinical trials were registered in clinical trial registries, only half of the physicians involved had publications from the trials they were involved in.

Institutional support and interest to continue or start being engaged in a clinical trial

Except for one participant, all reported receiving institutional support, including availing the facility, administrative support, mentorship, training, and protected time and funds. Almost all of the physicians (97.7%) expressed interest in beginning or continuing to be engaged in clinical trials. The motivations for their interest were the belief that clinical trials would help generate new knowledge and high quality evidence to improve patient care and treatment outcomes. More broadly, clinical trials were believed to play critical role in healthcare development. The reasons for those who expressed little interest to be engaged in clinical trials were poor readiness of infrastructure, personnel, ethical and legal challenges, and lack of training.

Discussion

This study assessed the engagement and experience of physicians in designing and conducting clinical trials in three teaching university hospitals in Ethiopia. Although most physicians were not engaged in clinical trials and were unaware of ongoing clinical trials in their institutions, encouragingly, those who were engaged reported good institutional support. Almost all expressed interest in getting engaged in future clinical trials. The proportion of female physicians engaged in clinical trials is also encouraging although the overall number of female physicians was relatively small. The findings also suggest that ethics and regulatory approval systems need to be more efficient.

Overall, the proportion of physicians engaged in clinical trials is low, even among a sample that was selected to have higher levels of engagement. Nevertheless, it is comparable to what has been reported in some countries with high clinical trial outputs (11, 15, 20). The major problem was the low intensity of involvement. Among those who were engaged in clinical trials, four in five were involved in just two or fewer trials. With such limited level of involvement, the physicians would not get the opportunity to acquire sufficient expertise. The limited number of clinical trials conducted in Ethiopia might have contributed to this. Lack of training in clinical trials in medical schools, lack of well-defined clinician researcher career pathway and the limited capacity-building opportunities might also contribute to the low engagement.

Virtually all physicians in this study expressed their interest in being engaged in future clinical trials. This finding is consistent with other reports. For example, a survey of 27 African clinical researchers reported that about 93% of the clinicians were interested in being engaged in future clinical studies(12). The motivations mentioned by the respondents, including the importance of clinical trials to generate new knowledge, enhance the quality of care and contribution to personal development were also consistent. Reasons suggested by the respondents for not wanting to be engaged in clinical trials were related to lack of training, experience, ethics and regulatory challenges and poor infrastructure, consistent with reports elsewhere (12, 13, 16, 21, 22). Equally important was the lack of awareness about clinical trials that were being conducted in their institutions. This calls for better awareness creation by their institutions and implementation of dissemination plans of studies set by investigators having active trials

The average reported time to get ethics and regulatory approval for a clinical trial protocol in this study was long. The main reasons given by the respondents for the delays were a lack of skilled staff in the ethics and regulatory bodies, administrative challenges, and the involvement of several ethics boards. A systematic review of studies conducted in developing countries found that delays in approvals as the most common barrier (23). Ethics and regulatory challenges were also mentioned by few physicians in this survey as a factor for low interest to be involved in clinical trials. Therefore, approval processes should be streamlined to attract more clinical trial funding and motivate the engagement of physicians. Some physicians reported shorter approval periods suggesting that the time for approval could be substantially shortened, and lessons may be learned from studies with shorter approval time. The findings showed that although majority of the trials were registered, the publication rate was small. Efforts must be made to ensure clinical trials are registered and results are published.

Given the role of physicians in generating and translating evidences to practice and policy, their engagement in research is crucial(24, 25). Various strategies have been proposed to promote the engagement of physicians in clinical trials. These include integrating training in the medical school curricula, introducing MD-PhD programs, enhancing research funding, offering financial and nonfinancial incentives, offering training, and career mentoring and networking opportunities(9, 24).

Implementation of these strategies has shown promising results in high income countries (9, 26).

The present study has some limitations. The study was carried out in only three university hospitals, which limit the generalizability of the results. Moreover, these university hospitals were selected based on their active engagement in clinical trials and most of the respondents were selected purposively based on their engagement in clinical trial, which might have inflated the proportion participating in clinical trials. The response rate was also much lower than expected, which may introduce non-response bias. To mitigate this, we distributed more questionnaires beyond the initial plan. Factors that affect the participation of physicians on conducting clinical trials were also not explored in this study.

Conclusion

The overall engagement of physicians in clinical trials appears low. However, the primary concern is the low level of engagement. Priority should be given to strategies that attract clinical trials and strengthen physician involvement. The clear barriers described, such as low expertise, low awareness, poor infrastructure, and delayed ethics and regulatory approvals should be tackled through better communication with investigators, strengthening capacity-building programmes, incentivizing clinical trials, and working with industry. Moreover, the mainstreaming of trial approval procedures should be encouraged.

Abbreviations

DSMB: Data Safety Monitoring Board
EFDA: Ethiopian Food and Drug Authority
NRERB: National Research Ethics Review Board
PI: Principal Investigator
TASH: Tikur Anbessa Specialized Hospital

Declarations

Ethics approval and consent to participate:
The study was approved by the Institutional Review Board of the College of Health Sciences, Addis Ababa University. The participating institutions were also informed about the study and assented to the data collection. Prior written informed consent was obtained from the participants. Only codes were used to secure anonymity of participants and ensure confidentiality.

Consent for publication: Not applicable

Availability of data and material: De-identified participant data will be made up on a reasonable request to the corresponding author, AF.

Competing interests: The authors declare that they have no competing interests.

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Author's contribution: AF, EM, AH, YW, TT, SMA, AA, AA, and HG conceptualized the study. MM, MS, HB and MM contributed in the data collection and analysis. RB wrote the first draft of the manuscript under close supervision of AF. All authors reviewed and approved the final version.

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