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Research Article

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Commentary on the Challenges of Clinical Trials in Developing Nations: Ethiopian Perspectives

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Abstract

Clinical trials in Ethiopia and other developing nations can generally be considered to be in its embryonic stages. Despite that, motivation of the researchers and efforts to establish clinical trials unit in academic and research institutions is encouraging. This is reflected by increasing clinical trials registered from Ethiopia in trial registration database. Besides, some of the trials conducted in Ethiopia have informed treatment guidelines. However, trained workforce, governmental support, research infrastructure as well as financial support remain weak. Inter-sectoral collaborations, sustainable financial support, training of academic staff to conduct clinical trials and the commitment and engagement of the leadership in research are all important. There is a need for enhanced socio-economic development and translation of research findings into locally relevant evidence. The objective of this commentary is to reflect on the challenges of Clinical trials in developing nations: Ethiopian perspectives to identify the challenges, and use the opportunity to engage in clinical trials for the better health of the poor people.

Keywords: Clinical trial, Developing country, Africa, Ethiopia, Trial registration

Abbreviations

CTI: Clinical Trials Index
NCD: Non-Communicable Diseases
NRERC: National Research Ethics Review Committee
SSA: Sub-Saharan Africa
CT: Clinical Trials
ICTD: International Clinical Trial Day

Background

Ethiopia, with a population of over 104,557,795 million as of Sunday, August 6, 2017, based on the latest United Nations estimates, is the second most populous country in Africa. It has also made substantial gains in reducing maternal mortality and child mortality [1,2]. This reflects that the health system, focused on prevention and primary care, has also shown promising progress. Moreover, the number of medical schools has grown from three to over 30 in just two decades.

The expansions of higher education and research institutions have enormous contribution to the clinical research activities. I strongly believe that decisions on health issues matter, such as the investigation of diseases, treatment of individuals, and design of intervention for research participants need to be evidence-based. The establishment of a state of the art bioequivalence laboratory, only the second in Africa is a big opportunity to conduct clinical trials in this country where marked progress is witnessed in the health sector.

Clinical trials in Ethiopia, and Africa

There is a huge disparity worldwide in the clinical research practice as understood from the share of clinical trials a country or a region has registered in clinical trial registry databases. We have called this the 'clinical trials index' (CTI). For example, the share of studies registered from Africa (in Clinicaltrials.gov) updated as of June 2017 is only 0.025% (about 6280 from a total of 251,206), although the region represents about 15% of the population of the world. Within Africa, most of the clinical trials are conducted in South Africa (37.7%), which makes one of the largest financial investments on health and has a relatively well-developed health system in Africa [3]. Only a limited number of clinical trials are registered from Ethiopia in trial registration sites, representing only 1.5% of all the studies from Africa. These CTI figures are crude reflections of the disparity in clinical research and service capacities within Africa and the world at large.

Understandably, most of the clinical trials conducted in Ethiopia were for infectious diseases (Figures 1 below). However, clinical trials for non-communicable diseases (NCD) are also very important. First, NCDs are becoming increasingly relevant, and given their chronicity, are likely to take a big share of the health investment of any country.

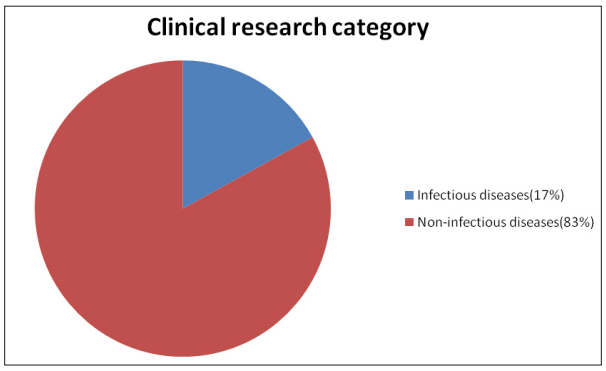

Figure 1: Comparative proportion of trials for non-infectious and infectious diseases in Ethiopia (N = 100). Based on data available at Clinicaltrials.gov (on June 2017).

Ethics Procedures in Ethiopia

Fundamentally, research should be ethically sound and approved by the designated authorities in every country where the research takes place. Ethiopia has relatively advanced ethics procedures and review processes to protect participants in research.

Various ethics committees are established at the level of institutions and there is one national committee. The national-level ethics committee, the National Research Ethics Review Committee (NRERC), handles proposals with complex interventions and those with potentially higher risk to participants [4]. All drug trials are also referred to the NRERC and drug trials are also regulated by the Food Medicine and Healthcare Authority of Ethiopia [5].

Challenges and Opportunities of Conducting Clinical Trials in Ethiopia and Other African Countries

Clinical trials are essential for medical advances as they provide the highest degree of evidence to support new interventions and decisions about disease management. However, the conduct of clinical trials is very complex; people are exposed to potential health risks and vast quantities of data are collected. Professionals working in clinical trials are confronted with numerous regulations, ethical challenges, high workloads and administrative requirements [6].

The challenges of conducting clinical trials in Ethiopia are enormous. The basic problem arises from the country's poor economy that resulted in underdeveloped research infrastructure such as space, supplies and maintenance affecting clinical work, communication, access and the availability of basic refrigerated medicines; added on lack of trained workforce in Clinical research, with concentration on clinical trial which together considerably retard clinical trials.

Besides, there is lower prioritization of research in academic institutions considering research as a luxury; time and money consuming, and this has resulted in the establishment of very few clinical trials units nationwide. There is the lack of equitable incentives for researchers due either to limited sources of funding or very minimal budget allocation to clinical research activities by the government. The regulatory frameworks are also bureaucratic, and this has been discouraging to the few clinical researchers who aspire for efficient and supportive working atmosphere. This has resulted in staff turnover; that is a challenge in health facilities in resource-limited settings as it is associated with increasing workloads, lowering the quality of services, reducing team efficiency and causing a loss of institutional knowledge through brain drain as well.

Other reported challenges include the often poor and/or illiterate study participants and differing cultural values and beliefs, which raise ethical questions and may lead to recruitment, consent and follow up difficulties, which slow down trial progress from my experience in Ethiopia.

Discussion

The way Forward

Developing nations should be committed to clinical trials both to serve its people, its region and the world at large. Clinical trials in sub-Saharan Africa (SSA) are critically important to improving the health of local populations. Guidelines ensure that ethical and scientific quality standards are met in clinical trials (CTs) involving humans. History has shown the need for guidelines to protect the trial participants [7]. Having the appropriate guideline for scientific and procedural rigour in CTs is crucial because of its potential impact on health policy or on new medicines registration.

In Ethiopia, a huge expansion of medical institutions, increasing awareness and readiness of the expertise to conduct clinical trials, and the economic growth of the country are an opportunities to conduct clinical trials. These opportunities, coupled with the strengths to conduct clinical trials including the growing enthusiasm of the health professionals about conducting clinical trials, establishment of independent research directorate office in some teaching hospitals, university wide reforms to improve research infrastructure, and cross-country collaborations are positive signals for improving clinical trial research practice in the near future.

The threats should also be identified urgently and proactive measures taken including tackling brain drain, reforming bureaucratic and lengthy regulatory frameworks, and ensuring self- independence to avoid global financial crisis, and subsequent funding problems

Within Ethiopia, a recommendation was made to establish a clinical trial committee, which would conduct needs assessments, explores opportunities for collaboration, assess priority areas for clinical trials in line with the country's priorities and make recommendations for effective establishment of leading clinical trial centers in the country.

Recommendations on Conducting Clinical Trials in Low Income Settings

Clinical trials immensely benefit patients if they are performed appropriately. I hereby, propose recommendation for institutional engagement of clinical trials in low income countries.

Specific recommendations include:

- Adequate budget should be allocated to provide research training for the health and related professionals in clinical trial to boost their knowledge and skills so that they will practice clinical trials research with confidence, and effectiveness.
- Although the priority of clinical trials in low income countries will be on infectious diseases, it is important to understand that non-infectious diseases are also epidemiologically rising due to a change in the lifestyle of the people, and there need to do clinical trials for interventions in non-communicable disease
- People in low income countries are particularly vulnerable owing to poverty, low education and restrained political empowerment. Therefore, stringent regulatory frameworks are required to

ensure that the principles of non-maleficience and beneficence for the people are upheld.

- Established regulatory frameworks should not be bureaucratic, rather be efficient and inclusive of both national and international collaborators. Full transparency and accountability in relation to registering trial protocols, monitoring and reporting are minimum standards that should be incorporated in the framework.
- All institutions interested in participating in clinical trials should be encouraged to do so. Establishing institutional clinical trial committees may help to support capacity development, collaborations and setting priorities, particularly when in collaboration with International institutions or industries.
- The undergraduate and postgraduate learning curriculum should encompass clinical research training as a major section of learning.

These principles need to be upheld and facilitated by the scholars and government of the developing nations to benefit the lives of the poor people. Inter-continental and international institutional collaborations should be strengthened to work together, and overcome the challenges. International clinical trial conferences should be hosted in developing nations to exchange experiences from likeminded researchers from the developed nations, and this celebration offers an opportunity to inform and motivate academic staff, researchers, students and the leadership about clinical trials being conducted and to discuss the future of clinical trials in their country.

Conclusion

There are some promising signs of progress in clinical research in Africa. For example, there is now the Pan-African Clinical Trials Registry, which is an important resource for clinical trials in Africa. The East African Consortium for Clinical Research, composed of five East African and five European countries, is another initiative that may support clinical trials in Africa. The number of clinical trials and investment in research is increasing [8,9].

However, research in general, and clinical trials in particular lag far behind in Africa. This is demonstrated by the extremely low CTI. Attention should be paid to scaling up clinical trials; not only in infectious conditions, but also in NCDs. Strengthening regulatory frameworks to support researchers and protect participants should be encouraged. Establishing clinical trial units and human capacity development are essential ingredients to scaling up clinical trials in Africa. Researchers work in extremely difficult working environments, with limited support from the system [10].

If clinical trials are to flourish, as they should, researchers have to be supported to focus on the delivery of clinical trials. Hosting CT Conferences and ICTD provides an important platform to create awareness and to advocate on behalf of clinical trials, researchers and patients [10].

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