Awareness and willingness to participate in clinical trials in Togo

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Abstract

Context: Clinical Trials (CTs) are the key when it comes to informing clinical decision-making processes. There is a very low number of CTs conducted in Togo, and there is no study that assessed the willingness of Togolese to participate in CTs.

Aims: The aim of this study was to assess public awareness and willingness to participate in CTs in Togo. **Subjects and Methods:** We designed a cross-sectional study, using an online survey with Google Form in the general population, carried out from December 2019 to March 2020.

Statistical Analysis Used: An Excel sheet was generated from the Google Form, and we performed a descriptive analysis using IBM SPSS Statistics 21. All variables were presented as frequencies and percentages. **Results:** This study involved 210 participants. The findings of this study are showing that Togolese are reasonably aware about CTs, and they have a positive intention to participate, but they are ignorant of national CTs regulations. Although unawareness and unwillingness may be universally common, one challenge in Togo is the lack of communication.

Conclusions: The findings of this study are encouraging. The National Bioethics Committee for Health needs to be better communicative, and providing training in clinical research is essential.

Keywords: Awareness, clinical trial, Togo, West Africa, willingness

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INTRODUCTION

A clinical trial (CT) is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. [1] CTs provide data with more robust scientific rigor than surveys, clinical case studies, or observational studies. They are increasingly becoming

popular when informing clinical decision-making processes, ^[2] and randomized controlled trials are hailed as representing the "gold standard" for scientific research. ^[3] As medical practice becomes more evidence based, they are considered to be the best way of evaluating new interventions. ^[4] CT participation numbers have seen a decrease in the past 30 years, a decline which is expected to continue in the coming years. ^[5,6] This issue is of great concern, particularly in West Africa. While

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Egypt and South Africa are counting, respectively, 5924 and 5396 CTs, all the 16 countries of West Africa do have only 2032. Among these West African countries, Togo is coming at the 14th rank with only 24 CTs [Table 1].[7] This low level of Togo contribution to international CTs may be related to several factors, including lack of awareness or training, willing investigators, appropriate infrastructure across the health-care system, or incomplete regulatory framework. Togo has a Bioethics Committee for Health Research (Comité de Bioéthique pour la Recherche en Santé, CBRS) that is regulating CTs and other types of medical researches. The Togolese government has launched in Mai 2019, the ERUDIT Program to Enhance Togo's Review and Regulatory Competencies for Health Research, with the support of the European Developing Countries Clinical Trials Partnership.[8] To our knowledge, there is no study that assessed the willingness of Togolese to participate in CTs. The purpose of our study was to evaluate the willingness to participate in CTs of Togolese citizens and to assess the level of awareness of CT.

SUBJECTS AND METHODS

This cross-sectional study was conducted online across the country in the general population and social media using a Google Form. The survey contains eight questions, inquiring about awareness of CTs on three topics:

- 1. Willingness to participate in a CT. Willingness to take an investigational treatment
- 2. Existence of international CT regulation globally and in Togo
- 3. Transparency of these regulations.

The survey had the format of closed questions with three possible answers: Yes, No, and uncertain opinion (Doubt).

Table 1: Distribution of clinical trials in West African countries $^{[7]}$

	Frequency (%)	Rank	
Nigeria	550 (27.1)	1	
Ghana	332 (16.3)	2	
Burkina Faso	222 (10.9)	3	
Mali	192 (9.4)	4	
Gambia	145 (7.1)	5	
Senegal	125 (6.2)	6	
Côte d'ivoire	102 (5.0)	7	
Guinea-Bissau	70 (3.4)	8	
Benin	67 (3.3)	9	
Sierra Leone	63 (3.1)	10	
Guinea	45 (2.2)	11	
Niger	43 (2.1)	12	
Liberia	35 (1.7)	13	
Togo	24 (1.2)	14	
Mauritania	17 (0.8)	15	
Cabo Verde	0 (0.0)	16	
Total	2032 (100.0)		

The survey was carried out from December 2019 to March 2020. One answer was accepted per person, and only Togolese were included whether caregiver or noncaregiver.

Statistical analysis

An Excel sheet was generated from the Google Form, and we performed a descriptive analysis using IBM SPSS Statistics 21 (IBM, Armonk, New York, USA). All variables were presented as frequencies and percentages.

RESULTS

This survey involved 210 participants; Table 2 summarizes the survey's CT awareness and willingness to participate across this sample. The 210 participants are divided into two professional groups: noncaregivers (n = 108) and caregivers (n = 102). Table 3 summarizes the distribution of CT awareness and willingness to participate by the professional group. The global question "Do you know what a CT is?" showed 47.1% awareness about CT for the sample and that more than 70% of the caregivers are aware while it is only 25% for the noncaregivers.

Topic 1: For the overall sample, 52.9% of the polled individuals are willing to participate in CTs. Both of noncaregivers and caregivers groups had, respectively, 58.3% and 47.1% of acceptance to participate. The introduction of the idea of signing a consent form has raised the rates of willingness to 75% and 67.6%, respectively, in the noncaregiver and caregiver groups.

Topic 2: More than 40% of the polled individuals across the sample showed acceptance about taking a new investigational treatment. This was similar to our findings for noncaregivers (41.7%) and caregivers (38.2%). Up to 35.7% of the two categories of individuals were uncertain about to take randomly one of the study treatments.

Topic 3: Across the sample, we found that 55.7% of the individuals do know about international regulations and good clinical practice. This awareness rate was more than 79% for caregivers and only 33.3% for noncaregivers. More than 72% of the polled individuals were unaware about the existence of a Togolese legislation and authority. About 87% across the sample were ignorant about the updated legislation in Togo.

DISCUSSION

The present survey showed that there is a very low number of CTs conducted in West Africa compared to other regions like North Africa (Egypt) or South Africa. Within this framework, Togo is ranking 14th among West

Table 2: Clinical trial awareness and willingness to participate in the 210 survey

	Yes (%)	No (%)	Doubt (%)
Q1: Do you know what CT is?	99 (47.1)	27 (12.9)	84 (40.0)
Q2: Are you willing to participate in a CT?	111 (52.9)	39 (18.6)	60 (28.6)
Q3: Are you willing to sign CT consent form?	150 (71.4)	60 (28.6)	
Q4: Are you willing to take a new investigational treatment?	84 (40.0)	57 (27.1)	69 (32.9)
Q5: Are you willing to take randomly one of the treatments?	66 (31.4)	69 (32.9)	75 (35.7)
Q6: Are you aware of the existence of international CT regulations?	117 (55.7)	93 (44.3)	
Q7: Are you aware of the existence of Togo CT regulation authority?	57 (27.1)	153 (72.9)	
Q8: Are you aware of Togo CT regulation transparency?	27 (12.9)	183 (87.1)	

CT=Clinical trial

Table 3: Distribution of clinical trials awareness and willingness to participate by professional group

	Noncaregivers (n=108)			Caregivers (n=102)		
	Yes (%)	No (%)	Doubt (%)	Yes (%)	No (%)	Doubt (%)
Q1: Do you know what CT is?	27 (25.0)	27 (25.0)	54 (50.0)	72 (70.6)	0 (0.0)	30 (29.4)
Q2: Are you willing to participate in a CT?	63 (58.3)	18 (16.7)	27 (25.0)	48 (47.1)	21 (20.6)	33 (32.4)
Q3: Are you willing to sign a CT consent form?	81 (75.0)	27 (25.0)		69 (67.6)	33 (32.4)	
Q4: Are you willing to take a new investigational treatment?	45 (41.7)	36 (33.3)	27 (25.0)	39 (38.2)	21 (20.6)	42 (41.2)
Q5: Are you willing to take randomly one of the treatments?	27 (25.0)	36 (33.3)	45 (41.7)	39 (38.2)	33 (32.4)	30 (29.4)
Q6: Are you aware of the existence of international clinical trial regulations?	36 (33.3)	72 (66.7)		81 (79.4)	21 (20.6)	
Q7: Are you aware of the existence of Togo CT regulation authority? Q8: Are you aware of Togo CT regulation transparency?	9 (8.3) 0 (0.0)	99 (91.7) 108 (100)		48 (47.1) 27 (26.5)	54 (52.9) 75 (73.5)	

CT=Clinical trial

African countries with only 24 CTs.[7] Despite this lack of studies, Togolese citizens had a relatively reasonable awareness about CTs. Comparatively, a Tunisian survey conducted in 2018 showed awareness in more than 69% of 260 individuals polled in the general population despite the fact that there is a low number of CTs conducted in this country.^[9] The low number of CTs in Togo may be explained by the fact that there are only four pharmaceutical generic manufacturers in the country and the oldest was established recently in 1998. In this study, we found that 52.9% of the polled individuals are willing to participate in CTs and more than 70% are ready to sign a consent form. A similar result was found in a study conducted in Saudi Arabia in 2018; out of 653 respondents, 470 (71.5%) reported their interest in accepting enrollment in a future CT phase I.[10] Despite this rate of willingness to participate in CTs in Togo, only 40% of the polled individuals across the sample showed acceptance about taking a new investigational treatment and up to 35.7% were uncertain about to take randomly one of the study treatments. In Saudi Arabia, people's concerns toward participation were above average (58.3%). Comparing these findings with those in the literature revealed that people in different countries had varying attitudes, ranging from 39.3% to 63.9%, toward participation in CT research.[10] Across our sample of 210 individuals, we found that 55.7% do know about international regulations and good clinical practice, but more than 72% were unaware about the existence of a Togolese legislation and authority. About 87% across the sample were ignorant about the updated legislation in Togo. This means that in Togo, there is an encouraging awareness of international CT regulations contrasting with a huge unawareness and ignorance of national regulations and authority updates. The Tunisian study showed a lack of knowledge concerning international regulations, more than 50% of the polled individuals were unaware about the existence of a Tunisian legislation, and about half of the individuals were ignorant about the updated legislation in Tunisia. ^[9] Our data suggested that, although unawareness and unwillingness may be universally common, one major gap in Togo and Tunisia is the lack of communication about CTs, their benefits, and the transparency of the national regulatory framework. There is a need of training about CTs for caregivers and the implementation of ethical research culture.

CONCLUSIONS

The findings of this study are encouraging. Carried out at the early stages of the COVID-19 pandemic, we found that Togolese are reasonably aware about CTs and they have a positive intention to participate. The Bioethics Committee for Health Research (CBRS) needs to be better communicative to all stakeholders. The challenges of the lack of pharmaceutical manufacturers and the needs of training of caregivers regarding CTs should be more addressed. It may be the implementation of an easy systematic registration of all researches at the National Bioethics Committee for Health Research including thesis and other papers in health sciences educational institutions.

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Conflicts of interest

There are no conflicts of interest.

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