

# Using A Behavioral Model to Assess The Barriers And Facilitators to Engaging Local Healthcare Providers In Conducting Interventional Cancer Trials In Nigeria

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## Research article

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# Abstract

**BACKGROUND:** Globalization of cancer clinical trials is now involving low middle income countries such as Nigeria as a rationale for global equity. With this ongoing clinical trial globalization, it is important to engage stakeholders such as local providers at the institutions where these trials are conducted by improving knowledge and perception of local providers concerning clinical trials.

**METHODS:** This is a qualitative focused group study consisting of ten groups conducted at Lagos State University Teaching Hospital between November 2019 and January 2020 using locally developed probe questions to engage local providers according to departments. Transcripts of semi-structured interviews was analyzed using direct content analysis and was mapped against the implementation theory of capability, opportunity and motivation for behavior change(COM-B) to access the challenges and barriers reported by local providers.

**RESULTS:** 239 local providers participated in this study, the challenges identified by providers were low knowledge about clinical trials, poor attitudes and systemic barriers. The opportunities suggested by local providers to improve the conduct of clinical trial in that environ included clinical trial workshops to improve baseline knowledge and perception and team collaboration between providers.

**CONCLUSION:** As cancer clinical trials are being globalized, the local healthcare community should be brought to par with this new intervention and not be left behind. Training about clinical trials should not be limited to providers actively involved in the clinical trials but all the providers in that region should be empowered by improving the baseline knowledge and perception of clinical trials.

## Contributions To The Literature

- We discuss the barriers and facilitators to conducting cancer clinical trials in Nigeria
- We report on the importance of engaging all local healthcare providers in conducting clinical trials in Nigeria to prevent misinformation and disinformation.
- This is the first study to assess behaviors reported by Nigerian healthcare providers that will improve the collaboration with the clinical trial team.
- We discuss on implementation strategies to integrate the local providers in Nigeria with the clinical trial unit so as to improve the knowledge and perception of the healthcare community towards interventional cancer clinical trials

## Background

Global disparity between cancer patients in High Income Countries (HIC) and Low Middle Income Countries(LMIC) continues to widen[1, 2] as such the participation of LMIC in cancer clinical trials is the most proactive route to bringing innovative cancer therapies and functional infrastructure to ensure global cancer equity. Progress in cancer research and improved patient outcome is seen in countries,

communities and institutions where cancer clinical trials are conducted[3, 4]. Over the last decade, cancer clinical trials have been decentralized from the Western world to involve other countries including African Countries[5–7]. The University of Chicago partnered with four academic institutions in Nigeria to improve local ability to conduct ethical biomarker driven cancer clinical trials in the country[8]. To facilitate cancer clinical trials, a well-trained local clinical trial team also known as clinical trial unit which consisted of physicians, nurses, pharmacists, technicians and administrative support was developed within the oncology department of the four institutions. The vision of the equal partnership was to develop and sustain local translational research capacity and clinical skills to address the cancer burden in the country. The success of this partnership has yielded many dividends but the most relevant dividend for this paper is the launching of investigator-initiated multi-institutional biomarker driven clinical trial in early stage breast cancer conducted in four Nigerian institutions[9].

Whilst this initiative is laudable, lessons should be learned from conducting cancer clinical trials in the Western World. These lessons includes the dismal involvement of black patients in clinical trials[10, 11], low clinical trial accrual rate[12], poor engagement of other healthcare providers with the clinical trial teams[13] leading to poor patient participation. In addition to these lessons, the experiences from conducting infectious disease clinical trials in Nigeria where there was poor community involvement points to an urgent need to implement sustainable interventions to ensure local provider participation and community engagement[14, 15]. Therefore with the introduction of translational cancer clinical trials in Nigeria, comes many pertinent questions that need addressing; how will the clinical trial unit be integrated with local providers? How can local healthcare providers who are already overworked and understaffed have the time to be educated or be engaged in cancer clinical trials? How will local healthcare providers perceive clinical trials in an environ where the fates of cancer patients is abysmal? The engagement of all healthcare providers with the clinical trial unit is important because most cancer patients have established relationships and trust with other healthcare providers prior to their cancer diagnosis and may require their guidance towards clinical trial participation as such they play a critical role in the perception of patients towards clinical trial[16, 17]. Patients' primary providers are often the first point of contact that introduces and refers patients to clinical trials making them gatekeepers of patient opportunity to participate in clinical trials. With this, the following are essential; (i) the collaboration of clinical trial unit(CTU) with local providers, (ii) improving the baseline knowledge and perception of all healthcare providers towards clinical trial and (iii) setting up referral system where cancer patients can be referred for clinical trial. To implement an evidenced based intervention (cancer clinical trial) in a Nigerian healthcare system towards improving cancer patients' outcome, it is important to develop a multilevel, multicomponent intervention aimed at actively involving local providers by improving providers' knowledge and perception towards clinical trials and also integrating the clinical trial unit into the healthcare system. The objective of this qualitative study was to understand the barriers and challenges local healthcare providers see with regards to conducting clinical trials in the institution. In order to understand the nature of the behavior to be addressed, we adapted Mickie and Colleagues Behavior Change Wheel Framework, the COM-B model (Capabilities, Opportunities, Motivation and Behavior)[18] to inform on interventions for engaging local providers

## Methods

### Participants

A convenience sample involving healthcare providers was conducted between November 2019 and January 2020 at the Lagos State University Teaching Hospital (LASUTH) which is one of the four sites that partnered with The University of Chicago to conduct biomarker driven clinical trial. We chose LASUTH due to its easy accessibility to the investigators, with the four institutions all located in the Southwestern part of Nigeria, including its similar culture, language and way of life. The study was approved by the Institutional Review Boards (IRB) at LASUTH and the University of Chicago.

Prior to conducting the study, we engaged the Key Opinion Leaders (KOLs) of LASUTH such as the Chief Medical Director, some Head of Departments (HoD) and policy makers to ensure the involvement of the healthcare providers. In LASUTH, grand rounds were planned monthly but these grand rounds were often booked months ahead, with attendance not robust due to work conflicts.

Healthcare providers are overworked and overburdened by clinical and administrative work making the involvement in this study challenging hence the strategic choice of engaging them at the well-attended departmental meetings. A joint decision was made with the KOLs to conduct this study during departmental meetings. We approached other heads of departments or the provider in charge to discuss the purpose of our qualitative study. We approached ten departments namely Surgery, Community medicine, Pharmacy, physiotherapy, family medicine, Ear Nose Throat (ENT), Ophthalmology, Hematology, Obstetrics and Gynecology (O&G) and Nurses. The availability of all departments was during their scheduled weekly departmental meetings lasting between one hour to three hours. During the initial meeting with HOD, we shared a summary of the study with the HOD who in turn shared with other providers in the department through word of mouth or common social media platform. We were allocated maximum of 15 minutes to conduct the qualitative study in all departments.

### Data Collection and Focus Groups

To accommodate the very short time of fifteen minutes allocated to us for the focus group discussion, we developed our probe questions with the KOLs and Nigerian experts in human behavior and policy making. These probe questions were field tested among local providers at LASUTH to ensure uniform comprehension from a local context. In developing the probe questions, we used the data from a quantitative pilot study conducted by our team amongst local providers in Nigeria[19] in addition to literature review on barriers and facilitators of healthcare providers engaging with CTU.

We developed ten open ended probe questions with the goal of learning behaviors that will guide the development of interventions to ensuring the collaboration of healthcare providers with the CTU and improving providers' knowledge and perception to clinical trials which was concise to maximize the time frame allocated (**Table 1**).

# Semi Structured Probe Questions

1. Do you know of any ongoing clinical trials at all?
2. Do you know of any ongoing clinical trial in cancer?
3. How do you want to learn about ongoing clinical trials?
4. What will make you refer patients from your clinic for clinical trial?
5. Will you want to get access to information on current trials conducted in your center?
6. Show of hands, have you referred any patients for clinical trials?
7. How should investigators integrate themselves with your team?
8. How do you think the referral process should be built?
9. What way should the referral process be improved?
10. What are the possible challenges/barriers to referring patients to clinical trials?
11. What are your major concerns?

The ten focus group discussions were conducted during the departmental meetings which were attended by providers at all levels i.e senior, mid-level, junior faculties, house officers, medical officers and residents (Table 2). Depending on the convenience of the department agenda, we were invited to conduct our study either at the beginning, middle or the end of the departmental meetings. After necessary introductions and protocols observed, each of the 10 open-ended questions was projected to generate responses from the groups. The sessions were led by personnel in the clinical trial unit and were audiotaped using 3 different recorders placed at different parts of the room to ensure the discussions were captured clearly. The general response, body language, atmosphere and receptiveness were noted. The audiotapes of the focus groups were transcribed verbatim using a local professional transcriber and formatted as text files. We used a modified template approach to analyze the content to be coded. The coding was guided by an initial code book (Table 3), then iteratively updated and amended during the process of data analysis. To ensure reliability, a team of four coders consistently coded all themes from the transcriptions. Working as dyads, each team of two coders coded across focus group transcripts and met on numerous occasions to discuss assigned codes, and clarify code themes. This team approach ensured that all transcripts were coded by two observers and that all coder combinations were equally represented across transcripts, thus reducing bias due to any individual or team coder differences[20]. The COMB behavioral change wheel although not used in the development of our probe questions was mapped with the questions and the themes for behavioral context and future plans for interventions.

Table 2  
Demographics of Participants according to Departments

<b>Departments (10)</b>	<b>Designations</b>	<b>Number of Participants(239)</b>
<b>Community Medicine</b>	Consultants	4
	Senior registrars	8
	Senior medical officers	2
	Medical officer	1
	Registrars	8
	Admin officers	2
	Nursing officers	4
	Interns	13
	<b>Total</b>	<b>42</b>
<b>ENT</b>	Consultants	2
	Senior registrars	2
	Senior medical officers	1
	Registrars	2
	Nursing officers	5
<b>Total</b>	<b>12</b>	
<b>Ophthalmology</b>	Consultants	2
	Senior registrars	6
	Registrars	9
	<b>Total</b>	<b>17</b>
<b>Hematology</b>	Consultants	1
	Senior registrars	3
	Registrars	3
	Resident	1
	<b>Total</b>	<b>8</b>
<b>Family Medicine</b>	Consultants	3
	Senior registrars	5
	Registrars	7

Departments (10)	Designations	Number of Participants(239)
	<b>Total</b>	<b>18</b>
<b>Physiotherapy</b>	Chief physiotherapists	4
	Senior physiotherapist	3
	Principal physiotherapist	1
	Physiotherapist	11
	Director	1
	Nursing officer	1
	Residents	6
	<b>Total</b>	<b>27</b>
<b>Surgery</b>	Consultants	5
	Senior registrars	7
	Head of Department	2
	Registrars	6
	Medical officer	1
	Residents	29
	<b>Total</b>	<b>50</b>
<b>Nursing</b>	ADNS	1
	PNO	1
	NO1	4
	NO2	8
	CNO	7
	ACNO	5
	<b>Total</b>	<b>26</b>
<b>Gynecology</b>	Consultants	7
	Medical officer	5
	Residents	1
	<b>Total</b>	<b>13</b>
<b>Pharmacy</b>	Director	1



<b>Departments (10)</b>	<b>Designations</b>	<b>Number of Participants(239)</b>
	Deputy director	2
	Chief pharmacist	1
	Pharmacist	1
	Residents	21
	<b>Total</b>	<b>26</b>
<b>All Departments</b>	<b>Grand Total</b>	<b>239</b>

Table 3  
CODE BOOK FOR THEMES

Themes	Codes/Nodes/Labels	
Knowledge/Understanding	General Limited	
	Specific Limited (Lack of awareness)	
	Clinical trial versus marketing /detailing	
	Study design (knowledge of SOC, controls, etc)	
Activation	Interest	
Barriers/Challenges	Internal trust	
	External trust	
	Cultural	
	Eligibility	
	Knowledge	
	Lack of teamwork	
	Logistics barriers (Transportation)	
	Clear patient information	
	Patient protection	Financial barrier
		Safety barrier
		Consent barrier
		Confidentiality
		General Pt Benefit
		Financial coercion
		Continuity of care (ongoing care after trial)
		Doctor patient communication (time constraint)
		Social class disparity
		Power barriers
	Patient denial	
	Patient fatalism (I am just going to die)	
Physician time constraints		
Religious barrier		

Themes	Codes/Nodes/Labels
Training	Onboarding
	Hands on training/workshop
	Continuous training – NIH Clinical Trials website programs
	Incentives
Referral	Activation
	Logistical
	Feedback
	Passive referral (just fill out a form)
Attitudes	
Team Collaboration	Desire for active      Available multi-disciplinary teams to family care
	Continuous involvement
	Point of contact
	Ownership
Information Transfer	Social media
	Emails
	Websites
	Leadership meetings
	Posters                      Continuously updated
	External conferences
	Trial forms
	Multiple formats best
	Internal conferences
	Word of mouth
	Publication
Communication	Active
	Passive
Motivation	Physician

## COM-B Model

The COM-B model (Fig. 1) is a part of a more comprehensive system of behavior called the behavior change wheel (Fig. 2) designed by Michie et al[18]to aid implementation scientists analyze behavioral problems to intervention design using the evidence-base.

The generated themes were matched to the COM-B model to further understand the behaviors of the Health Care Providers which will facilitate the collaboration with CTU, increase their knowledge about clinical trial and improve the likelihood of referring patients for Clinical trial. Michie et al defined capability in the COM-B wheel as “the individual’s psychological and physical capacity to engage in activity. Using the COMB behavioral wheel, we defined the “Capability of the Healthcare Providers (HCP)” as their knowledge and understanding of clinical trials, (2) their interest in learning about clinical trials and 3) attitudes of the providers towards clinical trials. The opportunity as defined by the COMB wheel is the factors that lie outside the providers to prompt this desired behavior. The themes inferring the opportunities were (i) communication about ongoing clinical trials, (ii) Training about clinical trials, (iii) Referral system, (iv)Team collaboration. “Motivation” defined by COMB “are the processes that energize and direct behaviors” The themes matched with behavioral motivation are barriers and challenges identified by providers and incentives by providers (Fig. 3).

## Results

A total of 239 healthcare providers who were present during their weekly scheduled departmental meetings participated in the study. All Healthcare Providers were full time employees of LASUTH and had direct clinical contact with patients. The groups consisted of senior, mid-level, junior faculty and trainees such as senior resident and junior residents (Table 2). Whist the time frame initially allocated for this study was 15 minutes; the focused group lasted between 18–56 minutes with an average of 35 minutes.

## Major Themes

Our thematic analysis found ten major themes, briefly summarized and illustrated with quotes from study participants: 1) Baseline knowledge and understanding of clinical trials, 2) Past involvement with clinical trial team, 3) Attitudes to clinical trials, 4) Training about clinical trials, 5) Referral to Clinical trial, 6) Team collaboration, 7) Information transfer, 8) Communication, 9) Barrier and Challenges toward clinical trials and the clinical trial unit and 10) Motivation (Table 3).

## Capabilities for integrating Cancer Clinical Trial with Nigerian Healthcare providers

### Low baseline Knowledge and Understanding of Clinical Trial

Generally, across all departments, there was a low baseline knowledge and understanding about clinical trials and its role in science. The few providers who were conversant with clinical trials were senior faculty members whose knowledge was described as theoretical i.e more of textbook knowledge than real life

experience. Only few providers were aware of the existence of the ongoing biomarker driven cancer clinical trial in LASUTH. There was poor understanding about conducting cancer clinical trials in Nigeria or study designs and some providers confused clinical trials as drug marketing.

“ Can I say that it will not be totally correct to assume that everybody seated here understands what a clinical trial is?”.

I think I need to clarify something. Maybe you should tell us what you mean by clinical trials We know from our textbooks and reading. We know there are phases of how clinical trials are done but I am not sure we'll have that kind of in-depth knowledge and it will be good to know

## **Past involvement with other Clinical Trials**

Even though ARETTA[21] was the first interventional biomarker driven trial in LASUTH, there have been other interventional trials in other departments. Often times knowledge about the existence of these trials were within the departments and few providers within the departments were aware of these trials with only few senior providers reported to have actively referred patients to these trials. The awareness of such trials and patient accrual to the trials was limited within the departments.

### Attitudes to clinical trials (Capability Physiologica I)

The providers agreed that there was a need to involve patients of African Ancestry in oncology clinical trials by conducting trials in Nigeria. They were concerned about the participation of patients in clinical trials and also the attitudes of workers towards patients on clinical trials.

There are sometimes that the attitude of the people at the clinical trial is very poor so what will you do to make things different so that patients are quickly attended to and the attitude of workers are good towards patients so that they don't feel an extra disadvantage in participating in the trial?

## **Opportunities for involving Nigerian Healthcare providers with Cancer Clinical Trial**

### **Training about clinical trials**

Unanimously, providers strongly expressed interest in learning more about clinical trials and the mode of training suggested were through workshops, conferences, hands on training on clinical trials, continuous training, the use of departmental meeting presentation and were interested to collaborate with the clinical trial unit. The length of training varied across departments, the surgeons wanted the shortest training time i.e 2 hours compared to family medicine where a day workshop was requested.

### **Referral of patients for Clinical Trial**

Due to the use of paper chart and the lack of electronic medical records, the referral system was described as needing room for improvement. The baseline referral system was by writing a letter or using the referral form which most times are hand-delivered by the patient to the receiving provider. The providers re-iterated that this form of referral was inefficient as patients were often confused, lost in the healthcare system and not followed in timely fashion. The providers suggested possible upgrade to the system by suggesting each department having a contact person within the department who would work closely with the Clinical trial Unit for easy referral process. In addition, the contact number and information of the investigators should be readily available and shared with the providers. HCP were prepared to activate referral process if they deemed patients eligible for the trial and were interested to have a summary of eligibility criteria. Feedback concerning the referred patient was important, to know if the patient was enrolled on the trial, and how the patient responded to the trial.

The referral system here is so difficult I think that is one thing. For me I will look at the advantage of clinical trial.

## **Team collaboration between the clinical trial team and other healthcare providers**

The providers raised concerns about collaboration with the Clinical trial team. From some providers past experience, the providers conducting clinical trials could be condescending or dismissive.

“ I referred two patients to him and the next thing I heard from my colleagues is that I don't know what I was doing. So such things...will I ever send somebody for trial again? So perspective wise, doctors should be educated that about it, if I send a patient for your clinical trial it actually favors your practice it is not as if you are doing me a favor”.

The providers wanted team collaboration between the Clinical trial unit and respective units through focal persons.

That is why the focal person is important, (you know) you liaise with them from time to time, and they can tell the focal person their challenges

The providers were not going to abandon their patients after the patient was enrolled on clinical trial, they wanted to get feedbacks about the patient in addition to the outcomes of the trials conducted in the center. Clinical trials was thought to be a trans-departmental programs and not limited to only one department.

clinical trials should be a collaborative thing, it is not just a one department thing depending on what the person is doing trial on

Thing is we don't have a Multi-Disciplinary Team so we don't get to hear. If we do, a lot of us, I think I'll speak for most of us are really interested in clinical trials but there is no MDT team - we don't have interdepartmental interaction. So that would be a concern on how it's going, but we've talked about that before so I am hoping that with all we've said. But that would be my major concern

# Information transfer about clinical trials

To transfer information to providers about newly opened clinical trial and ongoing clinical trial, the use of social media platform such as WhatsApp was suggested overwhelming by all departmental groups. Almost all providers in the hospital are in the WhatsApp platform therefore this serves as a viable use of technology at minimal cost to pass valuable information concerning the clinical trial. According to the providers WhatsApp seemed to be the most reliable source of information transfer compared to the other listed sources.

We can also disseminate information through the hospital WhatsApp platform

No they should create a separate WhatsApp group for clinical trials, so that when you see clinical trial you will be able to open it. If you see other groups you can see wedding, this one, that one so it is better to just say clinical trial... So when you see a notice of clinical trial you open it. But if I see a notice on a group in LASUTH I won't open because you will see all sort of things.

Other sources of information transfer were the use of emails, leadership meetings such as Head of department meetings, the use of posters strategically placed in all clinics and word of mouth.

“ Another thing you can do is if you have like a summary poster of the trial, you can paste it on the departmental board. So as you pass you will see it with emphasis on criteria for recruitment, the inclusion criteria so that as you are passing by, you are always seeing it like the large poster presentation so that any time you see any patient that you think would fit the criteria, you know there will be the contact number for who to meet with if you have any patient like that because it's an ongoing thing and if possible the progress of the clinical trial.”

Communications between the clinical trial team and the healthcare providers.

Passive and Active continuous communication between the clinical trial team and the providers was deemed important to serve as reminders for the providers.

Progress on the trial as it goes, an update at the center there so you put it up. So it serves as a wakeup call sort of for people to easily remember and know what is going on about it and the stage that it is and the part that they still need to play so that everybody knows

## Motivation for Healthcare providers to engage with Clinical trial

Barriers and Challenges towards clinical trials and the clinical trial unit.

The barriers and challenges were extensively expressed by most providers which also included junior faculty. These identified barriers were clear factors which could be a stumbling block towards motivating the providers and could be grouped into (i) trust of clinical trials and the clinical trial team, (ii) patient related barriers and (iii) system barriers.

Trust of clinical trials and the clinical trial team: There was hesitation and distrust of the Clinical trial team by some providers especially in the departments where the knowledge of clinical trials was low. The providers who distrusted clinical trials were more likely to advocate for standard of care even when a clinical trial was available.

“Are you from a private institution or government?” [after introduction by the investigators and well into the focus group discussion, this question was asked again with suspicion]

Before we try something, so who are the team members? Because I don't know who formed them, who are these people?

My own concern is continuity, when you leave because I don't know how long you are going to stay with us. Is there a future plan because when you move now we can forget what happened and start another new one that will also collapse; Is there any future plan for this been taken down...

... training of staffs at your end to be empathetic because considering the condition of the patients and being subjected to a trial should be easy as possible and not cumbersome you know that will also help to reduce the chances of losing patients from attrition

I will rather go for standard of care than for me to say trial

Patient related barriers: The providers were very protective of the patients going on clinical trials. They were concerned about the financial impact, patient safety, benefit to the patient, low patient health literacy, financial coercion, continuity of care after trial ends, religious beliefs, social class disparity as they feared that due to poverty poor patients will disproportionately be on trials. Since they had little knowledge of clinical trials, they were concerned of having discussions about clinical trials with the patients and also concerned about clinical trial given their extensive clinical workload. In almost all departments, there was a notion that the patients were used as guinea pigs or experiments.

Maybe they are being used as guinea pigs or something like that. It can be an issue

...in our environment here, patients tend to waste a lot of time in the hospital, so what will you do to make things different so that patients are quickly attended to and the attitude of workers are good towards patients so that they don't feel an extra disadvantage in participating in the trial?

System related barriers: Due to high physician patient ratio in that region[22], providers are often burdened and overworked raising concern that providers may not have the time to initiate clinical trials with their patients.

I know in LASUTH because of the pressure of work, those are part of the challenges that have hindered us partaking in clinical trial. People are overburdened with the work that to involve them in research becomes a challenge.

...Nobody is going to make out time to say there is a clinical trial, does the patient want to ask question no. So nobody has that time.

Motivation (direct benefit to the providers).



The providers were highly motivated to acquire knowledge about clinical trials, engage with the clinical trial staff and having the opportunity to offer patients other options.

The last management organized a program where they were doing clinical governance training so they spoke to somebody from the US via skype and what he explained is that from that hospital they made millions of dollars from clinical trials because overtime or sometimes they come out with information and for them it is even a source of revenue for the hospital. So for someone involved in that it is even a motivation that I am not just coming to work and seeing my patients are going back home not..... so I think that will be an advantage.

## Discussion

We examined the capabilities, opportunities and motivations for integrating the clinical trial unit with the Nigerian healthcare system. Using the COM-B behavioral model as a guide to interpreting our findings we identified factors such as (i) tailored providers' education and training towards clinical trial, (ii) developing an easy sustainable referral process, (iii) team collaboration between the clinical trial team and other healthcare providers and (iv) information transfer and communication which can lead to successful integration of healthcare providers with clinical trials.

This study reports on the capability of health care providers in relation to baseline knowledge and understanding of clinical trials and the knowledge of ongoing clinical trials which was low across all departments. The engagement of all local healthcare providers is important because patients are more likely to trust their providers due to the paternalistic relationship between providers and patients in that environ[23]. While the clinical trial team is solely made up of local providers, some of these cancer patients already developed a relationship and trust with their providers or may simply seek the opinion of other providers outside of their primary oncologist who may be part of the clinical trial unit. Improving the knowledge and understanding of providers is key in ensuring the enrollment of patients to clinical trials as the providers will be more empowered to initiate, discuss or educate their patients about clinical trials. Their improved knowledge about clinical trials will boost the system's ability to conduct clinical trials in other disciplines.

This study reports on the opportunities to improve the knowledge of healthcare providers about clinical trials. Our findings will aid in developing educational interventions tailored to the departments to their convenience, interest, and patient group. In addition to training of the healthcare providers, this study shows that the clinical trial team will need additional training aimed at interacting with the other healthcare providers and ensuring optimized patient communication and care in the trial.

Other opportunities are to improve teamwork between the clinical trial team and other departments, therefore addressing the siloes noted in this environment when collaborating with researchers in High Income Countries. While this study only explored the team collaboration between the clinical trial team and other departments, this can also serve as a blue print to interdepartmental collaborations such as Multidisciplinary Teams (MDT) focused on improving cancer patients' outcome. We reported on the

referral system which is not optimal given the lack of electronic medical records, while this is a serious limitation within the healthcare system, the providers suggested several ways to optimize the referral system to ensure that the patient gets referred to the clinical trial team in a timely fashion. The use of social media (WhatsApp) is widely known, accessible and preferred by all healthcare providers showing that mobile technology can be used to spread information about clinical trial cheaply and quickly.

The providers were highly motivated by the presence of a biomarker driven clinical trial in the system due to the benefits this may afford the system[8], but this motivation was met by hesitation due to concerns about the impact of clinical trials directly or indirectly to their patients.

Researchers in high income countries should engage researchers in low income countries to jointly discuss barriers and facilitators to implementing an intervention particularly to improving the conduct of cancer clinical trial in Nigeria. We must not wait until there is a catastrophe in relation to conducting clinical trials in Nigeria or other African countries but should learn lessons from other countries and other disciplines. As clinical trials are being globalized, the local healthcare community should be brought up to par with this new intervention and should not be left behind.

## **Conclusion**

Globalization of cancer clinical trial to involve Africa is fast becoming a reality therefore it is important to engage all stakeholders such as local healthcare providers to improve knowledge about clinical trials thereby limiting disinformation or misinformation about clinical trials. Cancer clinical trials or partnerships with academic institutions in High Income Countries is often driven by a few personnel in the low middle income countries as such other local providers may not be aware of ongoing trials or partnerships which may have been beneficial to them. As cancer clinical trials is being extended to African countries, it is important to improve the literacy and engagement of all local healthcare providers as a step towards community engagement.

## **Strengths and Limitation**

This study offers first-hand in-depth insight into perceived challenges and barriers towards clinical trials as reported by local providers. Opportunities to involve providers, improve teamwork collaboration, and behaviors to encourage motivation were developed. The use of implementation theory of capabilities, opportunities and motivation for behavioral change (COM-B) aided in better understanding of the data.

Our study had several limitations: Given the short time frame (15 minutes) allocated to us by key opinion leaders for the semi-structured interviews, we could not use an extensive implementation science framework to guide the development of our probe questions. Secondly, the focus groups consisted of senior, mid-level and junior faculty which caused a power imbalance, affecting group dynamics. To reduce power imbalance issues, junior faculties were purposely engaged more during the focused group discussions.

# Abbreviations

- ARETTA
- Assessing response to neoadjuvant taxotere and subcutaneous trastuzumab in Nigerian women with HER2-positive breast cancer.
- COM-B
- Capabilities, Opportunities, Motivation-Behavioral.
- CTU
- Clinical Trial Unit.
- HIC
- High Income Countries.
- HOD
- Head Of Department.
- KOL
- Key Opinion Leader.
- LASUTH
- Lagos State University Teaching Hospital.
- LMIC
- Low Middle Income Countries.
- MDT
- Multidisciplinary Team.

# Declarations

- Ethics approval and consent to participate: This study was approved by Lagos State University Teaching Hospital Institutional Review Board for written and verbal consents as deemed necessary and all participants in this study were verbally consented.
- Consent for publication: Not applicable.
- Availability of data and material: All data including transcribed data are available when requested from the corresponding author.
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AS: Akinyimika Sowunmi

SO: Stella Odedina

AP: Abiodun Popoola

TC: Toni Cipriano

OOI (Olopade): Olufunmilayo Olopade

OO: Oladimeji Oladepo

BP: Blase Polite

Project conceptualization: AI, OOI,OO, BP

Project planning: AI, MO, AA, AS, SO, AP, OOI, OO, BP

Project execution: AI, MO, AA, AS, SO, AP, OOI, OO

Data collection: AI, AA, AS,SO,AP

Data interpretation: AI, TC, AS, BP

Data coding and analyzing: AI,TC, AS, BP

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## Figures

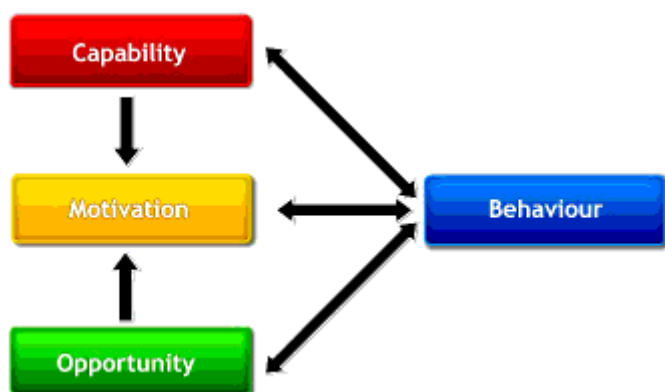


Figure 1

The COM-B model- a framework for understanding behavior. Adapted from Implementation Science (Permission pending)

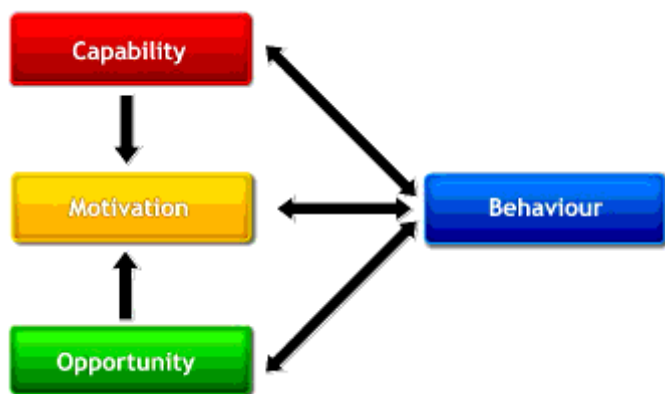
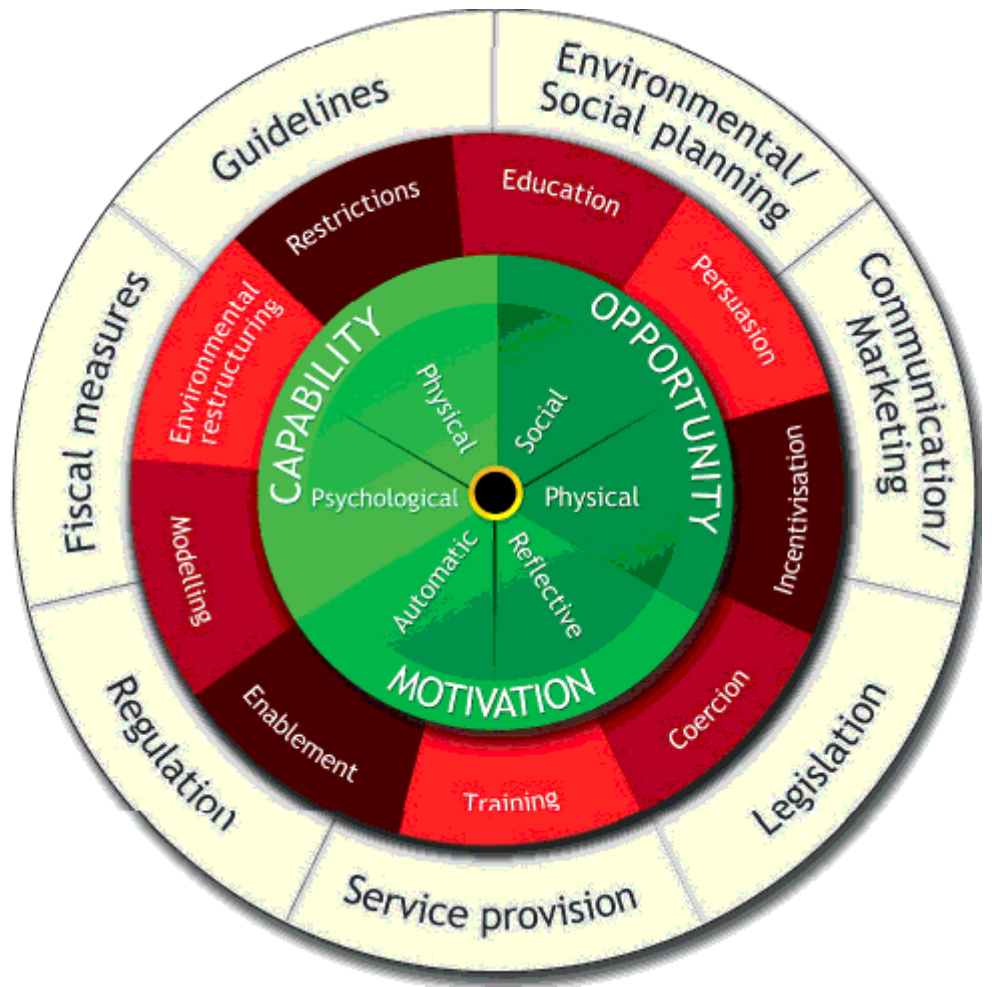


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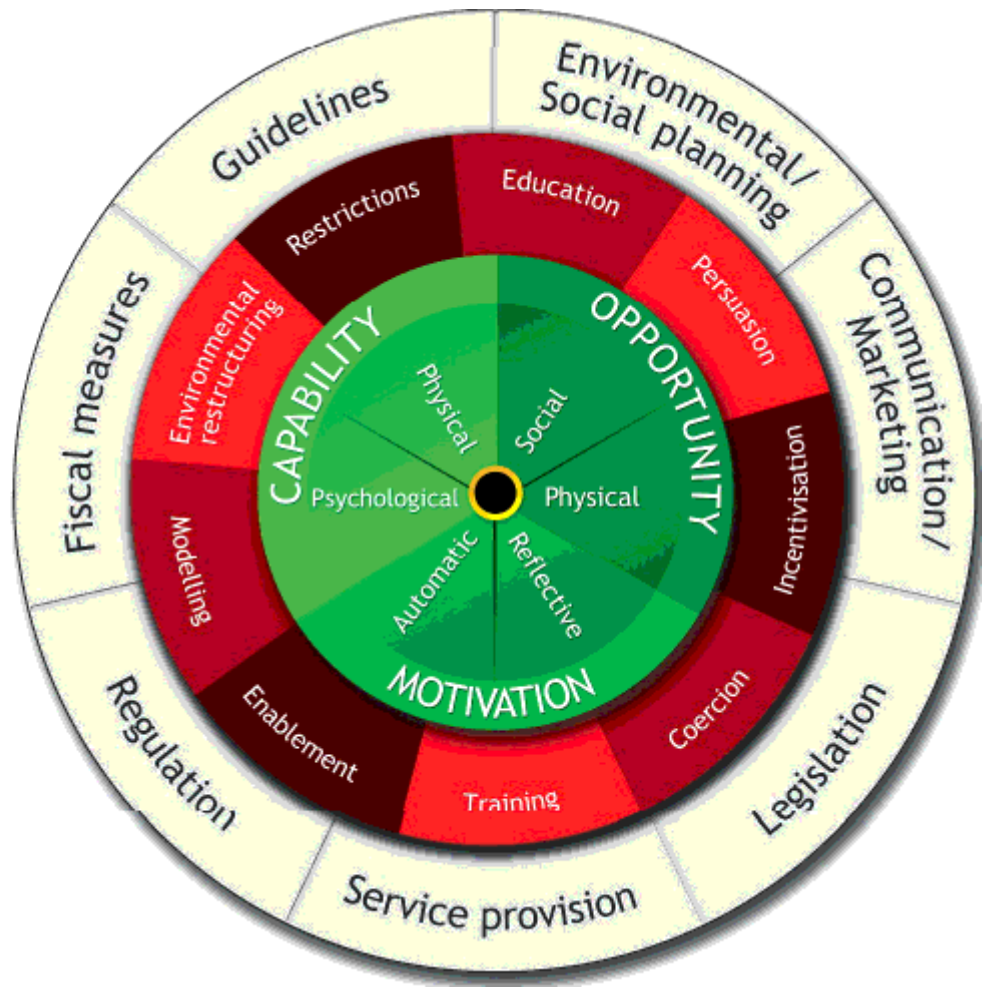
- Sources of behaviour
- Intervention functions
- Policy categories



**Figure 2**

The behavior change wheel used to characterize and design behavior change interventions. Adapted from Implementation science (Permission pending)

-  Sources of behaviour
-  Intervention functions
-  Policy categories



**Figure 2**

The behavior change wheel used to characterize and design behavior change interventions. Adapted from Implementation science (Permission pending)



### **Capability**

- The knowledge and understanding of clinical trials
- Past involvement with other clinical trials
- Attitudes of providers.
- Activation of communication by providers.

### **Opportunity**

- Future training about clinical trials
- Referral system
- Team collaboration
- Information Transfer about clinical trial
- Communication about ongoing clinical trials

### **Motivation**

- Barriers and challenges identified by providers
- Incentives identified by providers.

## Figure 3

Themes matched with the COM-B model

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