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# Perceptions and experiences of community-networks that facilitate engagement in health research: Ifakara Health Institute-Bagamoyo case-study

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NM-AIST

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**PERCEPTIONS AND EXPERIENCES OF COMMUNITY-NETWORKS  
THAT FACILITATE ENGAGEMENT IN HEALTH RESEARCH:  
IFAKARA HEALTH INSTITUTE-BAGAMOYO CASE-STUDY**

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**A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of  
Master of Science in Public Health Research of the Nelson Mandela African Institution  
of Science and Technology**

**Arusha, Tanzania**

**May, 2021**

## ABSTRACT

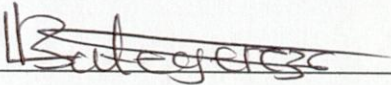
Involvement of communities in the field of health research collectively known as community engagement is considered as ethical conduct of research. At the Ifakara Health Research Institute (IHI) in Bagamoyo, Tanzania, nothing has been documented on how the engagement is being done and what community structures/networks are involved in the facilitation of engagement activities, and what are the systematic functioning of these structures since the formulation of community advisory board (CAB) in 2007. In this study six focus group discussions (FGDs) and 19 in-depth interviews (IDIs) among respondents participated in IHI research for the past five years were performed. Furthermore, focus groups and in-depths interview were audiotaped, transcribed, and analyzed using framework analysis techniques. This study found that; engagement was more likely being influenced by the type of research project and kind of participants needed, different community networks such as village executive officers, community health workers, hamlet leaders, and community advisory boards were the key stakeholders and; community-level public meetings, household visitation and information-giving sessions at the health facilities were the main approaches used during engagement processes. However, it was found that they did not reach most of the target people due to limited levels of interaction with potential participants, there are no central coordination of the engagement activities at the Institute, different research projects at the same Institute have been approaching these structures separately, little engagement, misunderstanding of the research objectives have been reported in contributing to the participants dropout. This study recommends that there is a need of developing a community engagement unit that would work across projects to support engagement with the community.

**Key words:** Community networks/structures, community engagement, health research

## DECLARATION

I, Leah Bategereza, do hereby declare to the Senate of the Nelson Mandela African Institution of Science and Technology that this dissertation is my own original work and that it has neither been submitted nor being concurrently submitted elsewhere for degree award in any other institution.

Leah Bategereza




26 Jul 2021

Name and signature of candidate

Date

The above declaration is confirmed

Dr. Ally Oluto,

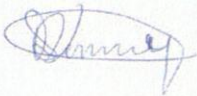


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Name and signature of supervisor 1

Date

Dr. Dorcas Kamuya,



26 JULY 2021

Name and signature of supervisor 2

Date

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## CERTIFICATION

The undersigned have read and certify that, this is the original work of Leah Bategereza and that is fully adequate in scope and quality as a dissertation to be accepted in partial fulfillment of the requirements for the Degree of Master of Science in Public Health Research of the Nelson Mandela African Institution of Science and Technology Arusha, Tanzania.

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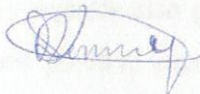


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## **DEDICATION**

This dissertation is dedicated to my lovely children Blessing, Bright and my entire family members for their psychological support, prayers, advice and determination to make me excel in my studies even when times were hard. I pray that the Lord may reward them a lot for their great love, patience, understanding and support.



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## LIST OF ABBREVIATIONS AND SYMBOLS

AIDS	Acquired Immunodeficiency Syndrome
BRTC	Bagamoyo Research and Training Center
CAB	Community Advisory Board
CDC	Center for Disease Control
CERC	Community Engagement Research Core
CES	Community Engagement Studio
CHW	Community Health Workers
CR	Community Respondent
CTSA	Clinical and Translational Science Awards
DED	District Executive Director
FGD	Focus Group Discussion
FW	Field Worker
HIV	Human Immunodeficiency Syndrome
HL	Hamlet Leader
IDI	In-Depth Interview
IHI	Ifakara Health Institute
IRB	Institution Review Board
KEMRI	Kenya Medical Research Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institute of Health
NIMR	National Institutes of Medical Research
PCORI	Patient-Centered Outcome-Research Institute
PI	Principal Investigator
PM	Project Manager
RTS,S	Repeat Region of Plasmodium (P.) falciparum Circumsporozoite, T-cell Epitopes Surface antigen 'S' Protein
SC	Study Coordinator
USA	United States of America
VEO	Village Executive Officer

## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background of the Problem

##### 1.1.1 Community and Community Engagement

Community is referred to as a group of people that interact and support each other, and are bounded by shared experiences or characteristics, a sense of belonging, and often by their physical proximity (Mcheimech *et al.*, 2016), community is also defined as a group of people with shared goals and common interest. Engagement is often described as a spectrum, ranging from information giving, consultations, involvement in research activities, and to higher levels of partnerships where community members are involved in research decision-making e.g. as co-investigators in research activities (Molyneux & Bull, 2013). Community engagement is being defined as a collaborative relationship with a group of people on shared goal or common interest, however, sometimes the definition depends on the level of engagement such as community involvement, community participation, community consultation and community collaboration (Tindana *et al.*, 2007). Most of the engagements are done on research that has been designed and approved by research ethics committee (Tindana *et al.*, 2015). However, some researchers claim that there is no universal definition for community engagement, that the explanation may be based on information sharing and transparency in communities and active consultation is likely to initiate partnership by community members (Molyneux & Bull, 2013). Community engagement have been regarded as one of the important aspect to be considered in National guidelines for clinical research (Sugarman *et al.*, 2015).

Clinical research requires the involvement of the community for successful and attainment of the desired research goals. As collaborative international research increases, involvement of the participants drawn from the population with different background, community engagement becomes very useful for smooth conduction of the research (Nyika *et al.*, 2010b). Studies from different communities and settings illustrate the importance of community collaboration and engagement.

Community engagement is purported to be an important element of ethical research particularly in Sub-Saharan Africa, as it demonstrates respect, can strengthen informed consent processes, the science of the research and can inform on community values that researchers ought to consider (MacQueen *et al.*, 2015). However, community engagement is becoming a common component which is now promoted by number of research institution

and funding bodies, engagement has been allowing marginalized voices and experiences to be represented in the production of scientific knowledge, ensure the relevance of research as well as impactful (Reynolds & Sariola, 2018). Therefore, engagement should be focusing in creating a meaningful partnership between researchers and those that inhabit in the social or physical space where research is being conducted. One definition of community engagement that is highly cited, is researchers and communities working collaboratively. Community engagement have been regarded as one of the important aspect to be considered in National guidelines for clinical research (MacQueen *et al.*, 2015).

### **1.1.2 Community Structures/Networks**

Community structures/networks are explained as relevant groups in a community of which the researchers consult before meeting an individual for informed consent and seeking for permission before approaching members of the community; such groups are community leaders, administrative leaders, religious leaders, ethical committee, community representatives and community advisory board. These structures help the research team in getting insight on the cultural values that may have an implication on the research project (Tindana *et al.*, 2015).

One approach used in health research to engage communities is through community structures. Community structures are described as relevant groups in a community which the researchers consult for research-related activities, including seeking for permission to approach community members to participate in research. They could be engaged using various approaches including consulting to advice on cultural sensitivities of the research and of informed consent information and processes, priority setting of research foci; norms of the community, among others. Thus the community structures could assist the research team in getting insight on the cultural values that may have an implication on the research project (Tindana *et al.*, 2015).

For clinical research, particularly clinical trials, it is imperative that communities are appropriately engaged for the research to be successful. This is because often clinical trials involve consideration of information, unfamiliar process and terminologies that require repeated sessions of information-giving, high retention rates of participants in the research if the power of the research is to be attained. In addition, most clinical trials are often done as part of collaborative international research where the backgrounds, norms, values and understanding of the researchers and the communities might be different; engagement is one way to bridge this diversity (Nyika *et al.*, 2010). For example, a clinical trial that was



conducted in Africa on genomic research, emphasized the importance of community engagement prior to, during and after the conduct of the study (Nyika *et al.*, 2010); including feedback of findings, as an important way to demonstrate respect to communities (Mtove *et al.*, 2018). The researchers on genomic research claimed that the community structure such as community representative and community advisory board can serve as brokers in bringing researchers and local community together (Tindana *et al.*, 2015). Community engagement has been promoted in some countries as an component of health research and regarded as potential approach to strengthen the protection, respect and empowerment of participant communities so as to improve relevance and quality of research (Workshop, 2016). Growing evidence around community engagement also suggests that failure to engage communities appropriately during the conduct of a research can contribute to resistance of the study by the community. For example Johnson *et al.* (2015), Id *et al.* (2020) and Mubyazi *et al.* (2013) documented challenges which were associated with low recruitment, because participants never saw the importance of participating in the research. Therefore, thoroughly engagement about a particular research is an important key to the acceptance of the research project in a particular community.

Funders, researchers and engagement practitioners play an important role in supporting and encouraging community engagement. For all these groups, it is paramount that the aims, objectives and guiding principles for engagement are clear, as sometimes there could be tensions between some of the engagement goals, such as supporting voluntary participation in research (which also includes the right to withdraw from research) and supporting study retention (Aggett, 2018). The importance of community engagement has been well summarized by Wellcome Trust, one of the leading funders of engagement. In their 2017 strategic framework, they recommend that engagement can lead to benefit in improving health of people through three major areas - science, research and engagement with the society (Wellcome Trust, 2017). They make a conceited call to other research funders to pay attention to and investment in engagement, noting that funders focus mostly on investing millions of dollars on product development, clinical training, designing and building of facilities, but have ignored the important part of community engagement (Aggett, 2018).

Engagement with the community for any successful clinical research can be attained by supporting the involvement of the community through creating various forum in which they can openly discuss about the planned research, voice their fears and concerns which are taken up in the design and implementation of the research. Interactions between the community and the research teams can be with the general population or selected members or representatives of those communities. In health research, Community Advisory Board (CAB) a representative

body of community members that might be selected or elected by their communities or appointed by community leaders, is widely documented as one approach of engaging communities (Kamuya *et al.*, 2013). Community representatives can be provided with opportunities to be involved in activities regarding the research such as in development of the research protocol, inform on culturally and socially appropriate consent information and processes. There are also greater aspirational goals for involving CABs in health research including in data collection, reviewing requests for access to research data and samples, and being involved as co-authors in publication of research findings (Kamuya *et al.*, 2013). Community engagement has been highly promoted in health delivery as well. Guidelines in good participatory practice for human immunodeficiency virus (HIV) prevention trial has elaborated importance of community engagement and consenting, it stated that consenting process may be influenced by community engagement activities and these may be regarded as good research practice (Molyneux & Bull, 2013). Thus, community engagement is a process whose activities may aim to inform and strengthen consent process and overcall conduct of the research (Molyneux & Bull, 2013).

### **1.1.3 Ifakara Health Institute-Bagamoyo**

Bagamoyo branch of Ifakara Health Institute (IHI-Bagamoyo) was initiated in 2005 to conduct clinical research. Subsequently, many ground-breaking clinical research studies have been conducted in the Centre, including Coarterm Pediatrics formulation studies, RTSS (malaria vaccine) Phase 3 trial and tuberculosis bacterial (TB) drug trials. All these clinical researches required the participation of many members of the community as participants (Shubis *et al.*, 2009). Since 2006, IHI-Bagamoyo Clinical research site has successfully conducted over 23 trials and only two are currently running. Of the 23 trials conducted so far nine are Malaria Vaccine trials, six Malaria Drugs trials, two TB Vaccine trials, four Projects on TB Drug trials, one Ferrinject (Iron) study, and three Projects of Diagnostics trials.

In 2007, an initial community advisory board (CAB) was established to work alongside Bagamoyo Research and Training Centre (BRTC) on research-related activities involving the community. Their role was to be mediators between the community and the researchers, informing researchers about community concerns with regards to their studies. They were also involved in dissemination of information about the research, and facilitation of interactions between BRTC and the community, ensuring that the community expressed their concerns and these were taken up by researchers. These levels of involvement were said to have enhanced community participation and follow up process during clinical trials, helped in management of rumors and in crisis management. During the formation process it was recognized that

establishment of an effective and reliable CAB within low-income, low-resource environment may present many challenges, including financial support, how to ensure proper training of community members, financial expectation of CAB representatives, and communication of complex scientific concepts to audience who lack basic knowledge in science (Shubis *et al.*, 2009). Partly due to the latter concern, CAB members were thus not expected to play any active role in recruitment activities, in the ethical review of research (i.e. not an additional review board) and in the design of project or trial. However, since the formulation of this CAB nothing have been documented so far on how research are being facilitated in the community, systematic functioning of structures that are involved in engagement activities.

It has also been observed by some of the research scientists of Bagamoyo Research and Training Centre of Ifakara Health Institute that the number of research participants for clinical trials has been dropping compared to previous years amidst on-going rumors about research, how it differs with clinical care, and what happens to samples collected in research. These concerns are not unique to this center, as they are also documented in other settings including in other African settings such as the Gambia, Malawi and Kenya (Id *et al.*, 2018). For this reason, it is especially important to engage the community to increase understanding of research generally and specific studies, and to build relationships supportive of research. This would require researchers to invest in establishing a reliable community structure.

This descriptive qualitative case study, was designed to explore the nature of community structures that could be engaged in health research at the Ifakara Research Centre; the strength and weakness of working with such community structures; and the impact of the structures on research conducted in the centre including in promoting research participation. The study investigated the perceptions that the community structures have with regards to clinical research conducted by Ifakara Health Institute. In this dissertation, community structure refers to community leaders/gatekeepers as earlier described. Engagement includes any form of involvement of these gatekeepers in research activities, including in information sharing about research and consultations to get their inputs in to on-going or/and planned research activities. To understand how community engagement is implemented, it is important to investigate the effectiveness of the different community structures involved in engaging communities with researchers (Macqueen *et al.*, 2015).

## **1.2 Statement of the Problem**

Since the formulation of Community Advisory Boards in 2007 at IHI-Bagamoyo. There has not been any further documentation of the practices of engaging the community at the centre. This is the first research project to be conducted at IHI-Bagamoyo, which will investigate the effectiveness of the different community structures involved in engaging communities with researchers. There is growing literature on community engagement across different research settings. Much of the documented evidence focuses on different approaches of engaging communities including different forms of Community Advisory Board or Groups whose role is to advise researchers on the community they represent (Kamuya *et al.*, 2013). However, there is very little evidence on functionality of the different structures that are involved in community engagement. Anecdotal information at IHI suggests that there has been some form of on-going engagement, but this has been sporadic and confined within specific studies. In addition, there are reports that participation of community members in studies has been dropping over the years, but the reasons for this have not been systematically investigated.

## **1.3 Rationale of the Study**

Clinical research, particularly clinical trials, need appropriate community engagement to be successful. In addition, most clinical trials are often done as part of collaborative international research where the backgrounds, norms, values and understanding of the researchers and the communities might be different; engagement is one way to bridge this diversity (Nyika *et al.*, 2010). For example, a clinical trial that was conducted in Africa on genomic research, emphasized the importance of community engagement prior to, during and after the conduct of the study (Nyika *et al.*, 2010); including feedback of findings, as an important way to demonstrate respect to communities (Mtove *et al.*, 2018). Community engagement is a potential approach to strengthen the protection, respect and empowerment of participant communities so as to improve relevance and quality of research (Workshop, 2016). Growing evidence suggests that failure to engage communities appropriately during the conduct of a research can contribute to resistance of the study by the community. For example Johnson *et al.* (2015), Id *et al.* (2020) and Mubyazi *et al.* (2013) documented challenges which were associated with low recruitment, because participants never saw the importance of participating in the research. Therefore, thoroughly engagement about a particular research is an important key to the acceptance of the research project in a particular community. It has been observed at Bagamoyo Research and Training Centre of Ifakara Health Institute that the number of research participants for clinical trials has been dropping as compared to previous years amidst on-going rumors about research, how it differs with clinical care, and what

happens to samples collected in research. These concerns are not unique to this center, as they are also documented in other settings including in other African settings such as the Gambia, Malawi and Kenya (Id *et al.*, 2018). For this reason, this descriptive qualitative case study, was designed to explore the nature of community structures that could be engaged in health research at the Ifakara Research Centre; the strength and weakness of working with such community structures; and the impact of the structures on research conducted in the centre including in promoting research participation.

## **1.4 Research Objectives**

### **1.4.1 General Objective**

To describe perceptions and experiences of community networks/structures that facilitate community engagement during health research in Bagamoyo district, Tanzania.

### **1.4.2 Specific Objectives**

- (i) To describe the existing community structures and existing community engagement processes used by researchers at Ifakara Health Institute to engage Community during clinical research in Bagamoyo district.
- (ii) To explore perceptions and experiences of community stakeholders with regards to functioning of the community structure in facilitating engagement about clinical research in Bagamoyo district.
- (iii) To explore perceptions and experiences of Ifakara Health Institute -researchers on the functioning of the current community structures in clinical research in Bagamoyo District.

## **1.5 Research Questions**

- (i) What community structure and processes are currently used by researchers to facilitate engagement at Ifakara Health Institute clinical research?
- (ii) What are the perceptions and experiences of the community stakeholders on current community structures in facilitating community engagement?
- (iii) What are perceptions and experiences of the Ifakara Health Institute -researchers on the functionality of the existing community structure in facilitating community engagement?

## **1.6 Significance of the Study**

This study therefore, will feed into, and will have direct relevance, to policies and plans around community engagement in Tanzania and other countries. It will inform strategies by which community structures will be evaluated based on their performance. It will also have wider regional (Sub-Sahara Africa) relevance as document earlier, since the importance of engaging communities in health research is widely acknowledged in this region.

## **1.7 Delineation of the Study**

This descriptive qualitative case study, was designed to explore the nature of community structures that could be engaged in health research at the Ifakara Research Centre; the strength and weakness of working with such community structures; and the impact of the structures on research conducted in the centre including in promoting research participation. The study investigated the perceptions that the community structures have with regards to clinical research conducted by Ifakara Health Institute.

The research findings are not without limitations. The voices of the young people and naïve group in the villages where this research project was conducted are missing, but also the voices from the urban areas of those that participated and not participated in IHI research activities for the past 5 years, were not represented. Therefore, perceptions and experiences from these groups on the systematic functioning of the community network were not captured so as to have comparable data. The data would have helped to have a wide understanding of the perceptions and experiences towards community networks/structures that have been facilitating engagement in health research.

## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 General Information on the Community Engagement

Community engagement is the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people. It is a powerful vehicle for bringing about environmental and behavioral changes that will improve the health of the community and its members. It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices (Ahmed *et al.*, 2018). Researchers describe several ethical goals for engaging communities in health research. These include to protect the community through considering a fair balance of benefits and risks for different types of research; strengthening fair selection of research participants and minimizing risks and burdens in research participation where these might be perceived to be significant (MacQueen *et al.*, 2015). In addition, community engagement can contribute to addressing some of the ethical concerns for conducting research in developing countries including; (a) minimizing potential for exploitation, (c) generating research that has fair benefit, (d) creating awareness and respect of cultural differences between researchers and communities, (e) promoting respect of recruited participants, (f) minimizing community disruption and, (g) minimizing of the health and wealth disparities, inequalities and stigma (evidence of changed norms and behavior around disease related) in the community through community engagement (MacQueen *et al.*, 2015).

#### 2.2 Functions of Community Structures

Empirical research suggests the centrality of working with community structures to nurture mutual respect and trust in research, and to strengthen the science. This was highlighted in a study conducted in Coastal Kenya exploring perceptions and functions of a network of community member's set-up specifically to consult about on-going and planned research activities, and the general understanding of research in the community. The network of community representatives at the Kenya medical research Institute (KEMRI)-Welcome Trust Program is known as KEMRI-Community Representatives (KCR) and acts as a bridge between the community and KEMRI through regularly discussion about community concerns and issues with the Research Program and advising studies on culturally and linguistically appropriateness of study processes and information in consent documents. The KCR members

are expected to consult their communities where they live as part of their daily routine activities. Engaging the community through KCR network was said to have been beneficial to the Research Program. Generally, the knowledge about medical research in the community increased, rumors that had been circulating started being addressed; and there were some policies implemented as a result of feedback from the KCR e.g. employment policies were changed so that fieldworkers and other support staff are employed from within the community where the research activities are conducted (Kamuya *et al.*, 2013). However, there were also documented challenges with the network including KCR members negotiation for their own individual benefits (e.g. employing their own children in the Program), rather than negotiating for community benefits. Some threatened the centre that if their demands were not met, they could fuel false rumors in the community about the research. This seems to suggest that there should be careful consideration of how community structures are set up, that clear mandate and roles are important, as well as ensuring that power and information about research is shared across different forms of community structures, not just concentrated in one.

In another study in Northern Kenya involving a collaborative centre between the Kenya Medical Research Institute and the US Centers for Disease Control (KEMRI/CDC), village reporters were engaged as a means of community structure to consult and be actively involved in research activities (Chantler *et al.*, 2013). Village volunteers started being facilitators of research (i.e assisted in providing study information and in recruiting potential participants into research activities). Their involvement was formalized through the developing of standard operating procedures, which stated their roles and from this point they became village reporters. These village reporters were viewed as the backbone of the community engagement programme at KEMRI/CDC. Their roles involved creating awareness and sensitizing people about current and planned studies; and about specific research activities and procedures. Their strength was based on the interaction and quick access to community they are members of (i.e they were recruited from within their resident community). Being embedded within their community seemed to solidify their ability to create good working relations; exposure gained from KEMRI/CDC in terms of training and meetings strengthened their understanding about research. However, it is reported that the village reporters also faced some challenges. There were many research projects at KEMRI/CDC with different investigators; and each project reimbursed different rates to the village reporters which created tensions between the village reporters and across different study principle investigators (PIs). Another challenge was the increasing expectations and demands from community members to the village reporters, demanding basic needs including clothing, food, health care access, school fees among others. Since village reporters relayed information



about trials within their community, research team found out that the village reporters who felt dissatisfied about involvement in specific trial ended up being passive or influenced different opinions that opposed the trial (Chantler *et al.*, 2013). A study which was done at Vanderbilt University Medical Center in United States of America (USA) on African-American women, was double-blind, randomized, placebo-controlled clinical trial (Johnson *et al.*, 2015); the use of community engagement principles and approaches enhanced clinical trial recruitment and retention. The Community-Engaged Research Core (CERC), a Clinical and Translational Science Awards (CTSA)-supported resource designed to facilitate community involvement in clinical and translational research, was consulted to provide assistance with the implementation of the clinical trial, and specifically to enhance participation of the target population; African American women. The CERC's key recommendations included: (a) Convene a Community Engagement Studio, (b) Redesign the recruitment advertisement, (c) Simplify the language used to explain the scope of the study, and (d) Provide transportation for participants. As a result of these interventions, a comprehensive strategy to recruit, enroll, and retain participants was formulated. After implementation of the plan by the study team, enrollment increased 78% and recruitment goals were met 16 months ahead of schedule. Participant retention and study drug adherence was 100% (Johnson *et al.*, 2015). From the above example show that community engagement is essential to the development of an effective multifaceted plan to improve recruitment of underrepresented groups in clinical trials. In the context of HIV/AIDS research the U.S. National Institutes of Health (NIH) first mandated the use of Community Advisory Boards (CABs) in clinical trials in 1987 in response to AIDS activism in the 1980s. The involvement of CABs is now a requirement for all National Institute of Allergy and Infectious Diseases (NIAID) sponsored programs (Tisherman, 2018) and the mechanisms for forming CABS are an integral component of the ethical review process. The roles that have been documented in the literature for the Community Advisory Board include functioning as a liaison between the researchers and the community, providing information to the community about the study including their rights to consent, generally improving the informed consent process, ensuring human subjects protection, advocacy for fair compensation for trial related injuries, protection of minorities and involvement in disseminating results to communities (Ntseane *et al.*, 2019). Other functions that could be performed by CABs include protocol development and review, identification and referral of potential study participants, and identification of methods to trace lost participant (Barkin *et al.*, 2013). In addition CABs have served to identify community priorities needs and interests; set research priorities; provide input or resources for research activities; identify community members to serve on project steering committees and promote community support for and involvement with research building capacity in the community and developing a culture of human rights were additional roles (Adams & Sherar, 2018). The use of CABs has been associated with a sense of mutual trust and collective ownership when used in studies with long term follow-up. Experiences of Researchers Working with Different Community Structures

Community engagement involving key stakeholders is central to models of translational research regardless of study designs, including clinical research, community-based participatory research, dissemination and implementation research, and public health research (Anderson *et al.*, 2020). The support of community engagement in pragmatic clinical trials was supported by the development of the U.S. Congress to establish Patient-Centered Outcome-Research Institute (PCORI) in 2010. The largest public funder of community-engaged research, recognized and supported.

Research reflecting a continuum of engagement activities from consultation to shared leadership (Patient-Centered Outcomes Research Institute [PCORI], 2020). Collaborator as particularly important to successful pragmatic clinical trials, as pragmatic clinical trials seek to answer questions of interest to patients and care providers (Jeong *et al.*, 2020; Anderson *et al.*, 2020). However, at the end of the study it was found that 80% actualized community engagement via Community Advisory Boards (CABs), using more than one CAB to engage the community. The CABs in health-related research are commonly defined as formalized groups of invested individuals drawn from the community (e.g., patients, community groups), health care providers, practitioners), and academia and government (e.g., researchers, policymakers) that “lend their expertise, advice, and/or approval on important research decisions; some of which the researcher may not have taken into consideration without their input (Barkin *et al.*, 2013). Ideally, CABs advise the researchers regarding every aspect of the research process, from study design, to recruitment, to dissemination and serve as liaisons between the researchers and the communities of interest. In fully realized community-based participatory research studies, CABs are often empowered to identify research questions of interest, adapt or translate evidence-based interventions to more fully align with the cultural resources of the community, share funding resources with investigators, and champion the sustainability of interventions that are translated in their communities (Jull *et al.*, 2017). The widespread use of CABs as well as their composition, roles and responsibilities, has demonstrated the efficient way by which researchers are able to meet research goals.

### **2.3 Stakeholders Perceptions on Community Engagement System**

In a study on community engagement that was conducted in four countries, Thailand, India, South Africa and Canada, challenges encountered by the community stakeholders in facilitating engagement in biomedical HIV prevention trial were explored. Three themes identified from the study were illustrated as essential to community stakeholders. These included: (a) Trial literacy in which the community were educated about some of the key concepts of the trial such as placebo, controls and double-blinding; as communication

challenges and trial-related misconceptions were seen to contribute to low uptake of the trial in the community, (b) Historical mistrust is the one whereby conceptualizations of clinical trials and bio-medicine were described in the context of historical experiences with colonialism. Established community structure were likely to minimize the mistrust in the community since some community members regarded research as forms of colonialism, some claimed that in trial, participants were being injected with diseases such as polio; and there were deep-rooted concerns about study sites, research being perceived as rooted in the historical oppression by the fact that trials were happening only in Africa and the African's were used as guinea pigs, and (c) The importance of early meaningful engagement with community stakeholders was described as important in providing opportunities for community members to participate in the trial planning process, protocol formulation and to determine community perception on the social value of the research. Early engagement was thought to minimize historical mistrust as community stakeholders would feel that they were part of the research activity, and thus identified with some partial ownership and control of the research; they also viewed that community involvement would not end with the trial life, but that it would continue beyond study recruitment and result dissemination only (Newman *et al.*, 2015).

The experience of using Community advisory board was observed in Lusaka Zambia, Zimbabwe, Thailand and South Africa, is based on the use of CAB due to their inside knowledge, understanding of the community and their influence in the community (Mwinga & Moodley, 2015). In the study done in Lusaka Zambia demonstrated the use of community structure in the formation of these CAB members, their selection based on members commitment of the community work and the balance with the understanding given to the nature of the research (Barkin *et al.*, 2013). A gap in understanding between researchers and the CAB members was noted as retention barrier for continuity membership. Perceived important role of CAB was reported to be in dispelling rumours and misconceptions of the study and also reducing stigma related to participation in the study (Adhikari *et al.*, 2020). Enabling factors that were reported to be associated with the functioning of CAB members were reported to be involvement of the community in the selection of the CAB members, advertising for membership as opposed to preselection, using of the former research participants as CAB members, involvement of the community stakeholders at early stage during the study, holding of the regular meeting, the use of the existing structures to form CAB and regular provision of the trainings that increased community understanding of the study (Mwinga & Moodley, 2015). One of the qualitative research project, that was conducted in Hong Kong on family well-being, stakeholders perception on community engagement is

that it offers numerous benefits including increased relevance of the science to local community partners; empowerment of the community's ability to vocalize and address its needs, and the use of the community's strengths and resources to initiate and conduct research. However, community stakeholders highlight the importance of obtaining community feedback on collaborative research in the community.

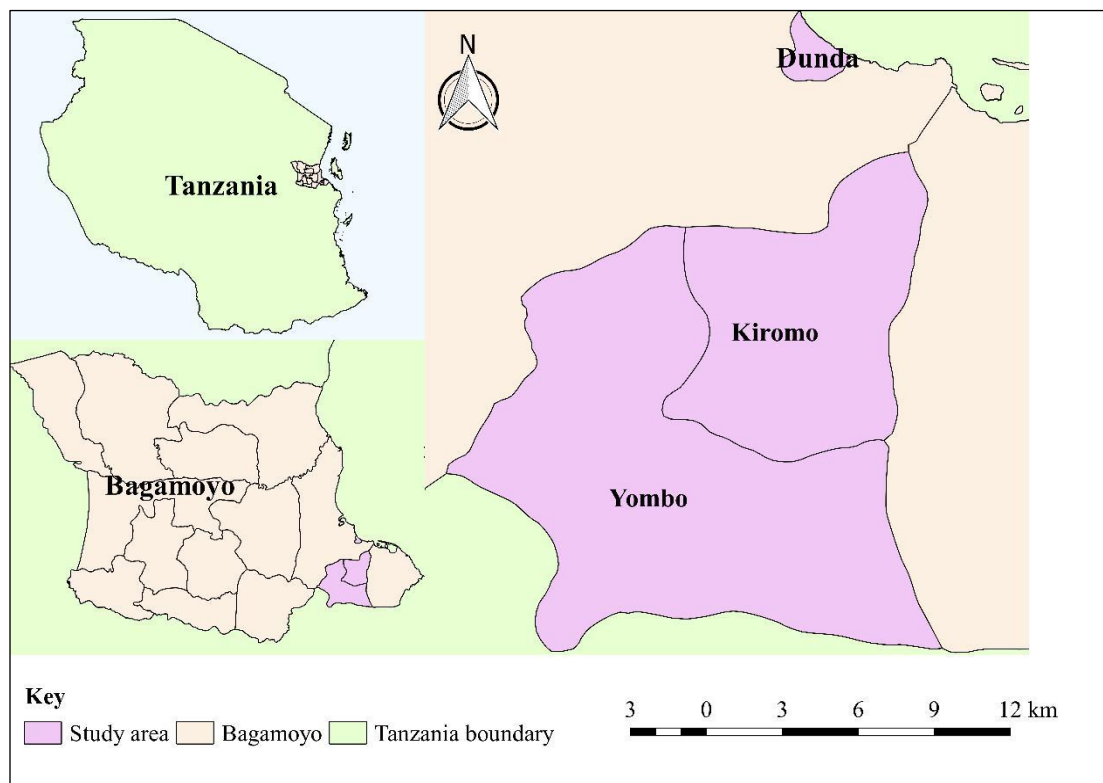
Drawing on these cases of community engagement using community structures, there are different forms of community structures but the common ones include community-recognized leaders/gatekeepers/representatives. These leaders are important in gaining permission from the community for a research to be conducted in an area. The evidence also suggests that community structure often act as bridge between the community members and research team, and that this role is important in strengthening research activities in a community, in promoting social-cultural consideration of communities in research activities, in promoting inclusion of community voices in research activities and can contribute to meeting recruitment and retention targets within time. The evidence also suggests that community structures can wield considerable power gained in the intermediary role they play in research. Such power can be welded positively to promote mutually beneficial conduct of research in the community; and it can also be welded negatively through controlling the information (and promoting misinformation) that gets to their social network especially if the demands of the community structures are not met.

## CHAPTER THREE

### MATERIALS AND METHODS

#### 3.1 Study Area

This study was conducted in Bagamoyo district, Pwani region, in the Republic of Tanzania. Bagamoyo area consists of three Divisions, eight Wards, and 24 village governments; and has a total population of 311 740 people (Census, 2012). Diverse ethnic groups reside in the District including the Zaramo, Kwere, Doe and Zigua; majority of the residents are either subsistence farmers cultivating rice, maize and cassava or/and fisherman working on the Indian Ocean or the Ruvu River and its tributaries. Local Kiswahili, the national language, is spoken widely throughout the study area. The Ifakara Health Institute-Bagamoyo (IHI-Bagamoyo) branch is located on the grounds of the Bagamoyo District Hospital, on the coast of the Indian Ocean. This research focused at IHI-Bagamoyo center (found in Dunda ward) and on the three randomly selected villages (which are Kongo, Buma and Matibwa; Fig.1). These three villages are among the 16 villages which participate or previously participated in clinical research conducted at the IHI-Bagamoyo in the last 5 years (2012-2017).



**Figure 1: Study area**

### **3.2 Study Design**

This was a qualitative case study. This approach was deemed appropriate for this research as it generates rich textual information from interviews with the various stakeholders, and thus draws on individual narration of the lived experiences and perception of the phenomenon under study (Sutton & Austin, 2015). In this study, such an approach allowed us to unpack the range of community structures that are involved in engagement at IHI, the strengths and weaknesses of these structures and recommendations for engagement of IHI with the community hosting its research.

### **3.3 Study Respondents**

Three groups of respondents who had participated in IHI research activities were included in this study. The first group were 36 community members (18 females and 18 males) from the three villages; the second group were community structures which comprised of three village executive officers (VEOs), three Hamlet leaders (HLs) and three Community Health Workers (CHWs); and the third group were researchers which included three Principal investigators (PIs), two study coordinators (SCs), three research project managers (PMs), and two field workers (FWs).

The village leaders of the selected villages were informed about the purpose of the study before the commencement of the data collection. The village leaders contacted the Community Health workers working in the selected villages, and the investigator invited them to participate in the study. The participants who were involved in IHI studies were identified by CHW who were currently living in their village and were invited to participate in the study. Researchers who have been participating in IHI research for the past five years were identified and invited to participate in research by the principal investigator of this research project.

### **3.4 Sample Size Selection**

Purposive sampling was used in selecting the respondents. Purposive sampling was used to allow diversity and depth of views on community structures and thus included the different groups that are described above, to provide perspectives from community members participating in studies, the researchers and the community structures themselves. In the selection of respondents in each category, individuals that participated or are participating in IHI researches for the previous five years, from 2012 to 2017 were considered.

### **3.5 Data Collection**

Two qualitative data collection methods were used. Focus group discussion (FGD) was chosen as it is useful in helping researchers learn about the social norms and perspectives that exist in the community and its subgroups (Natasha, 2005). Furthermore, it can unpack community experiences (among those who participated in research) regarding the community structure that facilitated engagement in clinical research at IHI-Bagamoyo. In-depth interviews (IDIs) were used with the aim of exploring perceptions and personal experiences of the participants about the community structure in facilitating engagement in clinical research conducted by IHI in Bagamoyo.

Prior to data collection, two experienced research assistants were recruited and trained on the interview guides for IDIs and FGDs. The training was done in Kiswahili since data collection and guides were all developed in Kiswahili. The tools were first piloted with 10 respondents from the IHI offices and community members from Chasimba village. Piloting the tools aimed to test the appropriateness of the data collection tools, provide researcher with some early suggestions on the feasibility of the research, and facilitate researcher to obtain experience on data collection (Majid *et al.*, 2017). Importantly, it assisted the researcher to learn critical interviewing skills and how to maintain a flow of conversation (Majid *et al.*, 2017). The pilot phase included four IDIs and one FGD these data were not included in the final analysis.

After piloting the tools, it was observed that some of the questions in the tools had to be adjusted for clarity; for example, in an interview guide for the FGD there were two questions addressing the same information, so one question was dropped. Data were collected in Kiswahili language. Data collection process was flexible enough to allow participants to set the appointment dates, FGDs were held at local government office as well as at village dispensary. Furthermore, IDIs with the community structures (VEOs, CHWs and HLs) and researchers (PIs, PMs, SCs and FWs). The IDI's and FGD's were audio-recorded. The research assistants also took some notes during data collection which were later converted into expanded notes (Azeem & Salfi, 2012).

### **3.6 Data Management and Analysis**

Data were transcribed verbatim independently by three researchers, and translated from local language (Swahili) to English. Quality of the data was checked by the principal investigator through listening of the tape recorder and reading of the expanded notes and debriefing report. The transcribed data from voice recording were read and re-read to gain initial impression of

the data and an in-depth understanding of participants' description. Both inductive approach (ideas emanating from the data itself) and deductive approach (theoretical understanding, literature review and researcher's experience) were used for data analysis (Srivastava & Thomson, 2009). Open coding framework was developed by reading the transcript and these codes were grouped in analytical themes. A framework matrix was developed based on these themes, the themes and matrix were reviewed by another researcher who has back ground in social science. Findings were analyzed by comparing response across different groups in relation to their experiences and verbatm quotes were used to illustrate key themes.

### **3.7 Ethical Consideration**

Ethical clearance was obtained from Institution review board (IRB) of Ifakara Health Institute, with approval number **IHI/IRB/NO: 06-2019**. An information sheet was drawn in Swahili explaining why the study is being carried out, by whom and what it involve. Respondents for IDIs and FGDs read the information sheet and signed it consenting to participate in research, one signed copy was given to the respondent and the second signed copy was taken by the researchers for future references, for those who were unable to read and write, consent was read to them by their colleague and signed by thumb. Confidentiality of all participants were assured. Responsible district authorities in which the study was to be taking place were informed beforehand to ensure support and security.



## CHAPTER FOUR

### RESULTS AND DISCUSSION

#### 4.1 Results

##### 4.1.1 Profile of Research Respondents

Demographic characteristics of participants are displayed in the Table 1 below. Of the total 55 respondents were interviewed, 45 were community members (including community structures) and 10 were researchers. Of the 55 respondents; 47% (n=26) were female while male were 52% (n=29). Most of the respondents reported attaining at most Primary school level of education while two of the community leaders had University first degree, two of the researchers had University first degree, five of the researchers had University second degree and two of the researchers had University third degree. Most of the respondents were between 37 years to 64 years of age; with only two being 25years. One being 27 years and one being 30 years. These included Majority of the respondents were male (M) 52%, most of the males were between 37 years to 64 years in age, whereby female respondents were between 37 to 54 years in age.

**Table 1: Demographic characteristics of respondents**

<b>Characteristic</b>	<b>Community members (n=36)</b>	<b>Community structures (n=9)</b>	<b>Researchers (n=10)</b>	<b>Total (n=55)</b>
<b>Gender</b>				
Male	20	6	7	33(60%)
Female	16	3	3	22(40%)
<b>Age (years)</b>				
≤34	4	2	0	6(11%)
35 - 44	17	0	8	25(45%)
45 - 54	11	6	1	18(33%)
55 - 64	4	1	1	6(11%)
<b>Occupation</b>				
Farmers	6	0	0	6(11%)
Small scale businesses	28	0	0	28(51%)
Not employed	2	0	0	2(4%)
Community health workers	0	3	0	3(5%)
Village Executive Officers	0	3	0	3(5%)
Hamlet Leaders	0	3	0	3(5%)
Principal Investigators	0	0	3	3(5%)
Project Managers	0	0	3	3(5%)
Field Workers	0	0	2	2(4%)
Study coordinators	0	0	2	2(4%)
<b>Education level</b>				
Did not attend school	6	0	0	6(11%)
Primary school	30	7	1	38(69%)
University 1 <sup>st</sup> degree	0	2	2	4(7%)
University 2 <sup>nd</sup> degree	0	0	5	5(9%)
University 3 <sup>rd</sup> degree	0	0	2	2(4%)

#### **4.1.2 Description of the Existing Community Structures and Processes Researchers use for Engagement**

##### **(i) Existing Community Structures Engaged by Researchers**

From the interviews, it appeared that different community structures have been involved by researchers during the implementation of research related activities. One of the male community respondents from Matimbwa village said that any research intended to be done in the community must pass through village office, of which consult community health workers and hamlet leaders:

*Every research before it is done must be reported at the village office, and after that it's the community health worker who makes sure to do sensitization and all leaders know it's her duty together with the hamlet leaders (CR (4), male, FGDs).*

Similar results were reported by one of the principal investigators whereby community structures used for facilitating engagement in health research at IHI-Bagamoyo were Village government which comprises of Ward executive officers, Village Chairmen, Village executive officers and Hamlet leaders, on top of that also reported about community health workers and having heard about community advisory board of which had never had an experience with during research related activities:

*There are different structures or levels which are involved to reach the community, of which researchers must pass through. These are village government, community health workers, there is also a board which I have heard but not having experience with it known as Community Advisory Boards (PI (1), male, IDI).*

These structures were described as being engaged or consulted about research by researchers as they (community structures) are aware of their community and the context where the specific research is happening; have deep knowledge of their community dynamics including their needs and what might appeal to them during research. This insider knowledge is important because it can inform researchers about the important social-cultural issues that they need to take account of in conducting their research.

It also became apparent in the interviews that some of these structures are trusted in the community (e.g. village executive officers, Hamlet leaders and community health workers); thus, it is easier for researchers to enter in particular village/community and access participants for specific projects through village leaders and community health workers. As one of the females from Buma village reported during focus group discussion:

*All researchers who come in our village are escorted by village leaders or CHWs, they convene a meeting with villagers and inform us on research issues going on in*

*our village. This is done through cooperation with the village leaders (CR (3), female, FGDs).*

However, at village Government level there are different social service boards (known as community advisory boards) as reported by one of the project managers during interviews, responsible in advising the villagers on different aspects related to Health, Environment and education. It was said that based on the type of research, the village government leaders can link researchers to a particular board based on their need, which may help in gathering people for public meetings to be informed of the expected study project. For example, since IHI main role is conducting health research, at village Government level, IHI researchers can be linked with community advisory board involved in Health-related activities, of whom community health workers are part of it:

*In the village government there are different boards such as social service board, those related to health, water and education. So if there is any research project, at the village government they connect us with specific board, that board will talk with chairman and gather a village meeting (PM(1), male, IDI).*

It has also been reported that some of the community structures that are often engaged with by IHI researchers are project specific and type of the participants that are required for a particular research project, principal investigator from the Tuberculosis (TB) project, based on the sensitivity of the project they sometimes use community advisory boards, who goes around the community to look for patients with TB and be invited to participate in the projects, but sometimes they use TB district coordinator who work close with nurses and doctors to identify patients with TB to be sensitized to participate in TB research project. These include those at health facilities where research is conducted; patients seeking health care in those facilities may be sensitized about IHI studies by nurses, doctors or people from the research team. Community health workers are involved at the village dispensary level in engaging with community members who happen to visit the dispensary:

*On the side of the hospital, we target patients who come at the Hospital as normal routine for treatment, but also Community health workers who are in the Villages are involved to engage the community at village dispensaries or household (SC (2), male, IDI). Most of the time apart from Community Advisory Boards.....as for me I do research related to Tuberculosis, so I use District Coordinators for Tuberculosis, nurses of the specific area to patients with Tuberculosis (PI (2), male, IDI).*

## (ii) The Process of Forming the Community Structures

Different way of formulating these community networks/structures whose main role is to link researchers with the study participants from the community, however based on the particular type of the research projects and types of the participants required, principal investigator number one through interviews reported that the selection of the community structures that represent community interests is done at the village government meeting; whilst the community health workers are nominated based on their working experience of helping the community on health related matters, whereas hamlet leader are voted at village meeting. Community advisory board (CAB) which was formulated by Ifakara Health Institute during the RTSS project, those members were selected by the community where research was conducted:

*Hamlet leaders and Ward executive officers are kept by the Government, but this CAB was formed by community members themselves where the researchers used to work, so Ifakara initiated formation of that board, the purpose was to be a bridge between researchers and community. It was done on the huge project of Malaria Vaccine known as RTSS (PI (1), Male, IDI). Those community health workers were appointed by the village leaders due to their working experience in health-related issues for a long time. Hamlet leaders were selected through voting at the village meeting (CR (25), Female, FGDs).*

Apart from having different community structures which are used by researchers to engage with the community or participants in research. There are also set up a special community advisory board made of influential people in the community due to sensitivity in the community associated with TB disease. The extra advisory board was influential in ensuring that the patients adhered to the treatment regime of the study. This was reported by the principal investigator of the Tuberculosis projects:

*Community advisory board is the board responsible of advising about research related ideas, so what happen is that the Institute have stakeholders from the community for example for Tuberculosis we call District Medical Officer, District Tuberculosis Coordinators, leaders and influential people in the community these are the ones that give suggestions of who should be board members, those board members are being trained specifically on particular disease or project so that they can be good ambassadors in the community. Most of the time they are the influential people and those who have convincing power in the community (PI (2), Male, IDI).*

### **(iii) Approaches to Engage the Community During Clinical Research Implementations**

From the interviews, mechanisms which researchers have to go through before meeting the expected participants were reported. Using these mechanism/channels was described as showing deep respect for the social-cultural norms of the community. The mechanisms for entering the community included calling on the Government offices that are charged with coordinating and implementing Government policies and directives. Researchers from IHI reported using this system, whereby a drafted letter seeking permission to conduct research in a particular area is first authorized by the District Medical Officer. The researchers use the signed letter to introduce themselves and the studies they intend to conduct to the village government structures such as ward executive officers, village chairman and village dispensary. Afterwards, at village government, village chairman or village executive officer will make announcement and gather public meeting of which researchers use this platform to share their research related activities in that particular community, on top of that hamlet leaders and community health workers make household visitation and share information about a particular research projects, kind of participants required and participant eligibility:

*We normally use writing a letter to District Executive Director which will be channeled to District Medical Officer and then to village government structures (FW (2), Female, IDI). Village chairman or village executive officers, make announcements so as to get audience, hence there after a meeting is done so that the researchers could convey their message. The hamlet leaders and Community Health Workers (CHWs) make household visits so as to inform the people (PM (3), Male, IDI).*

In addition, there are routine health care campaigns in the community to create awareness of the particular diseases such as Tuberculosis day (TB day), Malaria day and HIV day; sometimes researchers use these platforms/campaigns to facilitate engagement around specific research project:

*There are campaign such as TB, Malaria and HIV day, these platform are used to engage the community that today.... In short there are normal routine for patients who goes at the Hospital or dispensaries and awareness of the certain diseases.*

### **4.1.3 Experiences of Community Stakeholders on the Functions of the Community Structures**

In the descriptions of community structures across different respondent groups, it emerged that the perceptions and experiences of community stakeholders on involving the community structures to engage the community about health research were based on several areas that we describe in detail below. These include the perceived knowledge about the activities of IHI by members of the community, their involvement and awareness about IHI activities and the perceived contributions and problems associated with engagement process.

#### **(i) Community Awareness About Ifakara Health Institute**

From the interviews, it emerged that community member respondents often referred to the IHI research institute as “Malaria” or “Mradi wa Malaria” [*malaria project*]. This is because the first projects to be conducted in Bagamoyo by the Institute was a Malaria Vaccine that focused on children and pregnant women. Community members appeared to remember that project and not other projects that have been conducted by the institute since then. The other activities that were associated with IHI Institute were treatment of children and close follow up until recovery for children and people participating in its activities. The community members seemed not aware of other activities that went on at IHI. Similar information of associating the Institute with kind of the project that took place at that time, was reported by all group respondents during focus group discussion:

*Malaria project has helped us a lot, in our families, personally my child had head problem and was assisted in treatment, to the point of taking my child to Muhimbili hospital (CR (23), Female, FGDs). It was Malaria project; they were testing Malaria to the children and those with other problems were treated. They told me this project is for Malaria trial to children, my child was 3 months and had the problem of blood, they took her to Muhimbili hospital for treatment (CR (12), Female, FGDs).*

*As I remember, if a child is having fever and the problem is discovered, the child was provided with the medicines and they make follow up to know how the child is doing, if the child does not recover you call and they come to take him/her to the Dispensary. They used to help us and I use to like their services. If it is possible, they should come back (CR (2), Male, FGDs) deals with research related to human beings and malaria. Their research aims at caring for the citizens (HL (2), Male, IDIs).*

#### **(ii) Participation in IHI Research**

It was reported that community structures/networks were often involved in sensitizing or creating awareness of IHI activities through sharing information on the value of health research generally. It was also explained that some of the village leaders allowed their children to participate in research projects and that this may have contributed to encouraging members of the community to engage in research projects:

*I participated as a parent, my child was involved in research and I also participated as a leader whereby I was involved in sensitization processes” (VEO (2), Male, IDIs). Because we received the research project as stakeholders in the village, I am the one who started to lead by sharing the benefit and disadvantages of the research by passing through households (VEO (3), Male, IDIs).*

Respondents reported to have accrued several benefits, including being visited by the community health workers at home after every 3 months, free medical care, free transport and reimbursement of fares for those who use their own funds to attend study visits at the health facilities. In addition, it was said that those who were part of the research project were given priorities of being provided with food if the child is admitted:

*But for us who were part of the research project, we were proud of our self, when you go with your child if she/he is sick, medicines will be given, he/she will be eating and if admitted every service will be given and your task is just to watch over the child (CR(6), Female, FGDs). Community Health Workers used to visit us at home, they visited children to see how they were doing after every 3 months, good services, we were given medicines, where we live is very far from the dispensary when we go, they return our transport fee (CR (5), Female, FGD).*

### **(iii) Approaches used by Community Structures During Engagement Activities**

Several approaches were reported to be used by the community structures when engaging the community about IHI research projects. The approach used appeared to depend on several factors including the type of research that communities are being engaged about; the study criteria in selection of participants; and the nature of information that will be provided. The approach used include public meetings which were open for everyone to attend for general sharing of information about the general activities of IHI, introduction of a team or research study in the area. Household visits by Hamlet leaders and CHW were used for deeper conversation at the household level about a particular research where potential participants could be recruited from the home. Sensitizing patients who visit certain Health facility be it Dispensary or Hospital was done at the health facility level:



*there is CAB or community service board; they gather a meeting and talk to the community, those CAB members used to go to certain family, communicate general information to the villagers or Hamlet leaders (PM (2), Male, IDI). At the Hospital patients go to seek service, he/she will meet with Health service provider and if diagnosed with Tuberculosis, she/he will be informed of a research project which is going on, when agreed Health provider will inform us, we go and take them or if it is nearby they bring him/her (PI (2), Male, IDI).*

#### **(iv) Reasons for Participants Dropping out of Studies**

Given the interest of the IHI researchers to know why there has been a fall in numbers of recruitment and retention of participants in studies, I sought to explore whether this view is also expressed by other stakeholders and whether there is a role/contribution for engagement in addressing the issue. Community stakeholders reported different aspects which may contribute to participants drop-out from particular research project; that there is little engagement about the research post-enrolment; mobility (people moving to another region); limited awareness of the study objectives, lack of proper feedback of results/findings and false promises associated with unpayment of the community members who happen to assist research in the community, where a particular research is being conducted. The above reasons may also spoil the reputation of the Institute and demotivate other members who may have intention of participating in future health research projects.

*Lack of effective engagement and transparency, thus why participants drop from the project, because they do not understand and have no proper information regarding the research project (CR (8), Female, FGD). Many researchers go outside the agreement, for example they put a trapping material for trapping mosquitoes and say it will stay for one month and it goes up to two months, a person is being told to remove the trap at twelve in the morning and twelve in the evening and is not paid as agreed. At the end of the day will not work effectively (VEO (4), Female, IDI).*

#### **(v) Experiences of the Stakeholders about IHI Research Conducted in their Community**

Interviews with community stakeholders was meant to gather perceptions and experiences related to the research activities that are being/have been conducted in their community. These stakeholders described the importance of having proper system and processes of community engagement which are well known and understood by leaders and community members. It was proposed that having such processes can assist researchers in addressing some of the

challenges they encounter in the community when conducting studies. It was suggested that community leaders should be informed of the challenges encountered during research activities, as they can in handling some of them. Feedback in public meetings of what has been done at a particular area or in a particular research should be considered as it will help in educating the community about research activities; and strengthen trust in the activities of IHI.

*I would like to congratulate them for the great job, they should not be discouraged, they have sacrificed to the community, you cannot do research without challenges, doing research is a very difficult thing, once they encounter challenges should talk to the leadership and they will find a way of helping them (CHW (2), Male, IDI). They may not get good results because of the challenges, where they see there is a need of doing research they should do, but remember to give us feedback in public meeting, it helps in educating the community (VEO (5), Male, IDI).*

#### **4.1.4 Perceptions and Experiences of IHI-Researchers on the Functionality of the Current Community Structures**

##### **(i) Relationship between Community Structures and Researchers**

Researchers reported that the relationship with community structures was through the support given during research activities, such as inform/sensitize community members regarding the study project, acting as gatekeepers of the village by allowing researchers to conduct research in a particular village and communicate with researchers in case of any rumors concerning research:

*The relationship with the Village Government is by them acting as gate keepers of the Village, Village Government give permission to talk to community service board and work in the particular Village, communication with CAB Chairman is done before talking to the Villagers and information on particular research is shared, thereafter go to Villages and deliver information and inform us in case of any rumours, CAB used to be ears for the Institute in the Community, if there are romours they tell us, they tell us if there is a problem then we go early to solve that problem (PM(1), Male, IDI).*

Findings also reveal that the community structures have been acting as the ears for researchers, whereby any information relevant to the research that they learn from the community is channeled to the researchers so as to find a way of solving those problems. Such information includes challenges that the study may be experiencing in the community,

misunderstandings of the work of IHI, rumours, among others. It was also described that the relationship between the researchers and the community structures seemed to be one-way direction; meaning that researchers communicate with the community structures at the time of seeking the support in getting participants from the targeted villages to meet recruitment targets of the study. The relationship is maintained during research activities through having regular communication with the community and conducting quarterly meeting. However, once the study ends there is often no further communication/engagement:

*Our relationship is good and most of the time when we start research project, we call them, we introduce our research project to them, telling them what we want to do, what are objectives of our research, what are their responsibilities and we give them chance of asking questions and we clarify things that are not understood, but we always have quarterly meeting so we can know the challenges, and to ask them to do more emphasis on some areas (PI (2), Male, IDI).*

## **(ii) Advantages of Involving Community Structures in Research**

In interviews with the researchers, it appeared that the advantages of the community structures were linked to the support that the researchers received at the time of initiating their research projects; including support in sharing information of particular research to the community, communicating to researchers of any rumors or problem encountered in the community about the research, and in making sure that research is accepted in the community. The support also included increasing the community trust towards the research team based on positive image about the study; which might have contributed to researchers meeting their research goals on time. Thus, it was suggested that the community structures were most helpful during recruitment phase of the studies, as they helped in solving small conflicts among the community regarding a research project:

*Community structures have been doing very great job specifically during RTSS (Mal 40, Mal 50 and Mal 55) because it was a new vaccine and it had a lot of challenges, but through those structures we did not experience rejection in the Community, and if there were problems in the Community, we were able to solve regarding any rumours for all the years almost 7 years. Village Government cooperated with us effectively (PM (2), Male, IDI).*

*There is big advantage like those I have said, there is simplicity in doing the work, being accepted and get participant. They have helped in getting people and the real results, disadvantages are these community structures work very hard but when it*

*comes on the issue of Community engagement and miss budget for that we will fail and struggle to implement research, but we try a lot for these research to have small budget of Community engagement (PI (2), Male, IDI).*

#### **4.1.5 Views/Opinions on the Community Engagement Activities**

There were different opinions that were reported regarding community engagement processes and activities that have been used to engage the communities about IHI research projects. Community members reported that the involvement of the community structures during engagement activities (which are normally associated with participant recruitment, sensitization and informed consent process), is very important, simply because they have to be informed of what researchers want to do. They suggested that processes of informing the community can be improved to a point of using media such as radio, television, posting announcement so that people can be aware of what is going on around the community. Researchers should also find time to visit areas where community structure have been passing information, so as to emphasis important elements of the information and to and clarify some of the areas that are difficult for community members to understand:

*Other information can be given through media, posting announcement. But going through community structures is the proper way because they have to know any project that comes in the village (CR (12), Male, FGD).*

Researchers also reported that it is important to create questions and answers of the frequently asked questions and find a way of simplifying scientific words in a language that can be understood by people of all levels. This will help in elaborating the different aspects related to research activities:

*On my views there should be close communication, those CAB members, Village Government, researchers should be going often so as to put emphasis on what have been said, there may be difficult information that have been shared differently in more than one village. To generate frequently asked questions and to create answers and be given to those who are very close to the community. For those which have no answers they should make reference from researchers (PM (1), Male, IDI.).*

They also suggested that there should be adequate funds in their budgets allocated to helping CHW with their mobility in the villages during participant recruitment phase. This has been missing in their budgets which makes this activity in engagement difficult to implement:

*It is good for every project to think of community engagement, enough budget should be put aside, for example budget set of going to Kiwangwa, but that person in Kiwangwa what will she/he use in moving around to look for participants, resources should be open and allocated to enable activities of community structure (P(3), Female, IDI).*

The researchers also recommended strengthening the department of community engagement at all branches of IHI, by having reliable and strong community advisory boards. Resources should be allocated in this department for it to work effectively. In addition, relations between researchers and the communities can be facilitated by researchers collaborating in community activities like building of the dispensaries, schools and IHI doctors can also work with district hospitals and help in providing treatment services. This is one way of maintaining regular contact with the communities:

*Sustainable way, I think is to build strong CAB which will strengthen department of community engagement in all IHI branches, and at the level of Institution itself, that department on my views it has not worked effectively, there are still some gaps, I think because resources have not been allocated, these will help to build relationship and establish engagement with the community (PI (1), Male, IDI).*

*It is good to have regular contact with them, if there is anything their doing in the community can collaborate with them, like building of dispensary, schools it gives good relationship, for example IHI doctors can collaborate and involve in treatment activities at the District Hospital, because people are the same and even if we go they recognize us, it help us to be known as Institute to the community (PI (3), Female, IDI).*

## **4.2 Discussion**

From the findings described above, several areas emerge that are related to the role of community structures in facilitating community engagement at IHI; the role that community structures play in engagement and how they are perceived by the researchers and the community; and the recommendations for IHI with regards to community engagement in the research institute. These areas are described as follows:

#### **4.2.1 Role of Community Structures in Facilitating Community Engagement at Ifakara Health Institute**

From the findings, it appears that IHI researchers chose different types of community structures to engage with about research projects depending on, the types of the research, as well as the kind of participants that are needed for specific projects. A range of community networks or structures have been reported being engaged within community engagement at IHI. These include ward executive officers, village executive officers, hamlet leaders, community health workers, community advisory boards, nurses and doctors. Different community engagement approaches have also been described by researchers including the use of signed letter by the District Medical Officer to introduce the study and the researchers at the village levels and to gain entry to the community. From these descriptions, it seems that a form of community engagement has always been going on at IHI. This is important so as to maintain the interest of the community in the work of IHI, even when there are few projects going on, as the research projects depend on the participation of the community members. It is also notable that different community structures are used in the community; and it is not very clear whether there is an overall coordinating body for community engagement at IHI. The use of several structures seems to have worked well, since it appears that the tensions that the use of one structure that were reported in the Kenyan study (Kamuya *et al.*, 2013) seem not to have emerged in this context. In addition, it seems that identifying the community structures through the village government office is one way of recognizing the central role of the local community leadership, and may have demonstrated respect and cultural humility towards the community (Tindana *et al.*, 2015).

#### **4.2.2 Perceptions on the Activities of Ifakara Health Institute and the Role for Community Engagement**

In this study, it also emerged that the community often related the work of IHI to that of specific studies; the Malaria projects, research that involve children, pregnant mothers and trapping mosquito. The name of the Institute was often referred by majority of the community members as “Mradi wa Malaria” or “Malaria”, as the first research projects to be conducted in Bagamoyo by the Institute was Malaria projects, even though other types of research have been conducted since then. Thus, it seemed that the knowledge of the community respondents about the Institute is influenced by the projects that they interacted with regularly or those that they related with, and seemed not to be fully aware of the broader remit of IHI beyond these individual studies. This is not unique to IHI as studies have reported similar findings in the Gambia, Malawi, Kenya, Uganda and other settings (Id *et al.*, 2018). Some of the reasons are

that research is a difficult concept to understand and thus understanding the work of an entire research institute is not easy. In addition, communities often remember aspects of research that seem to address the immediate research need of the participants or that seems to alleviate their health care needs (Marsh *et al.*, 2010). Thus, it is unsurprising that community respondents reported several benefit which were encountered during their participation in research projects such as free transport, free medical care and provision of food to those admitted in the hospitals. However, if such misunderstandings/misinformation are not addressed early, there is potential that they can grow in to rumours (Johnson *et al.*, 2015), particularly when some of their needs that fall outside the mandate of the institute are not addressed. Thus, there is an ethical imperative for IHI to consider the centrality of community engagement strategy that can be rolled out and built-up. Such a strategy can consider the appropriateness of the reported method of engaging the community to participate in research projects included public meeting, household visitation and sensitization of patients at dispensary or hospitals.

#### **4.2.3 Centrality of Community Engagement in Long-term Plans for Ifakara Health Institute**

Different reasons for participants drop out or unwilling to participate in certain health research were reported. These included misunderstanding of the research projects objectives if these were not well communicated to the participants, inadequate feedback of research findings, and little engagement with the communities' post-enrolment. Other factors raised included false promises given to those members that assist researchers in different research activities, which could spoils the reputation of the Institute. These reasons seemed to emphasize a greater responsibility for the research teams to make sure that there is a carefully considered engagement with the community throughout the conduct of the studies, as well as post-end of studies. As similar information has been described in some literature, growing evidence show that lack of appropriate engagement can lead to resistant of some research project in certain community (Mweemba *et al.*, 2019). While community structures described that in their roles, they often emphasize the importance of having proper system for engagement and of giving feedback in the community, it was unclear the extent to which these suggestions were taken up by researchers. This is an area which require careful thinking and consideration on the ethical implications of providing feedback, including potential to compromise participants' privacy and confidentiality. Thus, it was suggested that there is need to establish working procedures and guideline which will address some of the issues that were raised by the community members. Such guidelines can help researchers communicate key information include whether feedback will be provided, when it will be provided and using which

engagement strategies. It can also guide researchers figure out which findings can be fed-back using public meetings, and in ways that it do not compromise the confidentiality of individual participants.

The results of this study also suggest that the respondents felt that relations between researchers and community structures are skewed towards the researchers' interest and needs. Thus, there are closer relations during study sensitization processes, whereby community structures facilitate members of the particular villages to engage in health research. However, once these studies come to an end the relations also seem to wither with no further engagement or communication between researchers and community structures. Given that IHI is likely to be in the community for a long period of time, it is important to re-think how best engagement with the community can be sustained. Individual research projects may not be able to sustain continued engagement with a particular community or community structure beyond the study period due to budget/funding limitations. However, the Institute can make a case to funders for a centralized coordinated engagement that can be funded at programme level, with research budgets supplementing for study-specific types of engagement. This would be one approach to sustain engagement, given the value such engagement seems to have in terms of building appropriate relations with the community participating in research, a relation that can facilitate the research to thrive in this setting.

#### **4.2.4 Improvement of Community Engagement Activities**

Different advantages associated with engagement processes were reported. These were assurance of the safety of the community members about certain research projects, as this helped members of the community to trust researchers and the activities associated with research. Being community gatekeepers, permission of a study by community structures was said to be important in gaining entry to the community and in reassuring communities of the goodwill of the researchers. However, the improvement of the engagement processes were suggested by the community members, which are additional to the previously used method of conducting general public meeting of which most of the community members hardly attended; and the few that attended those meetings, they found it not easy to grasp all the information regarding a certain research. Additional complementary engagement activities suggested include visits at household of the community members to meet head of the house and other family members, use of radios, television, posting announcement at places where people tend to gather for different purposes like in the market places, football play grounds, bars and restaurants. These additional method are likely to emphasize what have been communicated by the other method, and will help community members to understand more when different



method are used to inform them of the certain research project to be initiated in that area (Chantler *et al.*, 2013).

The findings also described the importance of simplifying difficult scientific words in a way that it may be easy to be understood. This goes along with the compiling of questions and answers of the frequently asked questions to ease the communication of the community structures during the engagement activities. This was noted that it is not easy for community structures to share the same information in more than one village without distorting the meaning; and this can contribute to miscommunication of the particular research purpose. This is because often health research involves consideration of information, unfamiliar process and terminologies that require repeated sessions of information-giving (Nyika *et al.*, 2010). In addition, and to support good engagement processes, it was suggested that adequate funds in a budget should be allocated to strengthening the community engagement department. The ethical importance of community engagement is underpinned by its valuing in identifying socially and culturally appropriate consent processes and ethical conduct of different types of studies, and is regarded as good research practice (Molyneux & Bull, 2013). Therefore, having a well-established community engagement system will help researchers know what the needs of the community and how best these can be addressed, and create relations of mutual trust and respect between researchers, community and community structure.

## CHAPTER FIVE

### CONCLUSION AND RECOMMENDATIONS

#### 5.1 Conclusion

This study research was conducted to understand the systematic functioning of the existing community networks/structures in facilitating engagement in health research. The community structures involved in the engagement seemed to have been influenced by the type of research project and kind of participants needed. Challenges identified included low knowledge about the institute and its activities, inconsistency research feedback, insufficient engagement for participants to capture study project objectives and false promises by researchers to community stakeholders. Therefore, there is a need to strengthen community engagement system at IHI which will coordinate research activities so as to address the reported challenges. Proposed ways of strengthening engagement with the community and researchers included use of various media of engagement such as radio, television, posters and regular meetings with the community during the course of a study. Subsequently, this will enhance understanding of the research information by the community members and community structures, as well as help raise some of the issues that could be considered when developing a research protocol. Frequent interactions will also enhance information sharing with the targeted population. This can be done by developing a list of frequently asked questions and answers so to facilitate the understanding of the community stakeholders.

#### 5.2 Recommendations

A system of giving feedback to the community regarding the research work done by the IHI should be considered. Finally, it is important that there is central coordination of the community engagement work at IHI. This requires allocation of enough funds to ensure functioning of the engagement department within the institute. It is especially important to engage the community to increase understanding of research generally and specific studies, and to build relationships supportive of research. This would require researchers to invest in establishing a strong and reliable community engagement system which will help in the coordination of different aspects such as:

- (i) Dissemination of research information to the community, as our findings indicate there has been inconsistency in giving out feedback at the end of research activities, for that

case community engagement system should make sure that all the research findings at the Institute or through institute have been disseminated at community level.

- (ii) Simplification of the complex scientific concepts so as to allow proper and in-depth understanding of a particular research. Researchers reported the importance of simplifying scientific words which are difficult to be understood by the community. Example Before sharing a scientific research protocol to the community, the community engagement system should simplify the language which may be hard to be understood by the community.
- (iii) Exposure of the community structures and study participants to the activities done at IHI center. From the findings it was reported that community respondents have low knowledge regarding the Institute and research activities done by IHI, not aware of the other research projects conducted apart from those participated, for example the study participants can be allowed to visit the laboratory and see how samples are processed and stored, to broaden their understanding as to what extent samples taken from them will be processed and the importance of every specific test.
- (iv) Contact patients or study participants at the end of the project to get their views and opinion about the project they have participated. There has not been proper research system which explore views/opinion of the study participants about the research participated, as this information will assist on the improvement of the research activities for the upcoming research projects.
- (v) Therefore, it is suggested that similar research should be done in urban areas and to the naïve group on research, so as to get variety of view/information that will support along the establishment of the community engagement system.

## REFERENCES

- Adams, E. J., & Sherar, L. B. (2018). Community perceptions of the implementation and impact of an intervention to improve the neighbourhood physical environment to promote walking for transport. *Public Health*, 18(714),1–14. <https://doi.org/10.1186/s12889-018-5619-y>
- Adhikari, B., Pell, C., & Cheah, P. Y. (2020). *Research*. <https://doi.org/10.1080/11287462.2019.1703504>
- Aggett, S. (2018). Turning the gaze: Challenges of involving biomedical researchers in community engagement with research in Patan, Nepal. *Critical Public Health*, 28(3), 306–317. <https://doi.org/10.1080/09581596.2018.1443203>
- Ahmed, S. O., Corbie-smith, G., & Kissack, A. (2018). *Defining and Measuring Community Engagement and Community-Engaged Research: Clinical and Translational Science Institutional Practices*. <https://doi.org/10.1353/cpr.2018.0034>
- Azeem, M., & Salfi, N. A. (2012). Usage of Nvivo Software for Qualitative Data Analysis. *Academic Research International*, 2(1), 262-266.
- Barkin, S., Schlundt, D., & Smith, P. (2013). Community-Engaged Research Perspectives: Then and Now. *Academic Pediatrics*, 13(2), 93–97. <https://doi.org/10.1016/j.acap.2012.12.006>
- Chantler, T., Otewa, F., Onyango, P., Okoth, B. E. N., Odhiambo, F., Parker, M., & Geissler, P. W. (2013). Bioethics ethical challenges that arise at the community interface of health research: Village reporters' experiences in western Kenya. *Developing World Bioethics*, 8731(1), 15–17. <https://doi.org/10.1111/dewb.12023>
- Cobigo, V., Martin, L., & Mcheimech, R. (2016). Understanding Community. *Canadian Journal of Disability Studies*, 5(4),182-203. <https://doi.org/10.15353/cjds.v5i4.318>
- Jeong, N., Kim, S., & Lim, E. (2020). *Pragmatic Clinical Trials for Real-World Evidence: Concept and Implementation*. <https://doi.org/10.36011/cpp.2020.2.e12>
- Johnson, D. A., Joosten, Y. A., Wilkins, C. H., & Shibao, C. A. (2015). Case Study: Community Engagement and Clinical Trial Success: Outreach to African American

Women. *Clinical and Translational Science*, 8(4), 388-90. doi: 10.1111/cts.12264.

Jull, J., Giles, A., & Graham, I. D. (2017). Community-based participatory research and integrated knowledge translation: Advancing the co-creation of knowledge. *Implementation Science*, 12, (150), 1-9. <https://doi.org/10.1186/s13012-017-0696-3>

Kamuya, D. M., Marsh, V., Kombe, F. K., Geissler, P. W., & Molyneux, S. C. (2013). Engaging Communities to Strengthen Research Ethics in Low-Income Settings: Selection and Perceptions of Members of a Network of Representatives in Coastal Kenya. *Developing World Bioethics*, 13(1), 10–20. <https://doi.org/10.1111/dewb.12014>

Keith, A. A., Holly, D. S., Sokha, K., Katherine, M., Laura, N. G., & Joseph, E. G. (2021). The use of community advisory boards in pragmatic clinical trials: The case of the adult day services plus project. *Home Health Care Services Quarterly*, 40(1) 16-26, doi: 10.1080/01621424.2020.1816522

Kohori-Segawa, H., Dorji, C., Dorji, K., Wangdi, U., Dema, C., Dorji, Y., Patou, M. M., Teeranee, T., Sonia, P. S. W., Ryota, S., Masako, O. K., Masahiro, K., & Yuichi, I. (2020). A qualitative study on knowledge, perception, and practice related to non-communicable diseases in relation to happiness among rural and urban residents in Bhutan. *Plos One*, 15(6), 1-15. <https://doi.org/10.1371/journal.pone.0234257>

Macqueen, K. M., Bhan, A., Frohlich, J., Holzer, J., & Sugarman, J. (2015). Evaluating community engagement in global health research: The need for metrics. *Medical Ethics*, 16(44), 1-9. <https://doi.org/10.1186/s12910-015-0033-9>

Majid, M. A. A., Othman, M., Mohamad, S. F., Lim, S. A. H., & Yusof, A. (2017). Piloting for Interviews in Qualitative Research: Operationalization and Lessons Learnt. *International Journal of Academic Research in Business and Social Sciences*, 7(4), 1073–1080. <https://doi.org/10.6007/IJARBSS/v7-i4/2916>

Marsh, V. M., Kamuya, D. M., Mlamba, A. M., Williams, T. N., & Molyneux, S. S. (2010). Experiences with community engagement and informed consent in a genetic cohort study of severe childhood diseases in Kenya. *Medical Ethics*, 15 (11-13), 1-11. doi: 10.1186/1472-6939-11-13.

Molyneux, S., & Bull, S. (2013). Consent and Community Engagement in Diverse Research

Contexts: Reviewing and Developing Research and Practice. *Journal of Empirical Research on Human Research Ethics*, 8(4), 1–18. <https://doi.org/10.1525/jer.2013.8.4.1>

Mtove, G., Kimani, J., Kisinza, W., Makenga, G., Mangesho, P., Duparc, S., Miriam, N., Kamija, S. P., Russell, O., Ricardo, R., & Pol, V. P. (2018). Multiple-level stakeholder engagement in malaria clinical trials: Addressing the challenges of conducting clinical research in resource-limited settings. *Trials*, 19(190), 1-11. <https://doi.org/10.1186/s13063-018-2563-1>

Mubyazi, G. M., Barongo, V. K., Kamugisha, M. L., & Njunwa, K. J. (2013). Public Knowledge, Perceptions and Practices in Relation to Infectious and other Communicable Diseases in Tanzania: Lessons Learnt from Babati District. *Rwanda Journal of Health Sciences*, 2(2),1-12. doi: 10.4314/rjhs.v2i2.1

Mweemba, O., Musuku, J., Mayosi, B. M., Parker, M., Rutakumwa, R., Seeley, J., Tindana, P., & De Vries, J. (2019). Use of broad consent and related procedures in genomics research: Perspectives from research participants in the Genetics of Rheumatic Heart Disease (RHDGen) study in a University Teaching Hospital in Zambia University Teaching Hospital in Zambia. *Global Bioethics*, 1, 1–16. <https://doi.org/10.1080/11287462.2019.1592868>

Mwinga, A., & Moodley, K. (2015). Engaging with Community Advisory Boards (CAB) in Lusaka Zambia: Perspectives from the research team and CAB members. *Medical Ethics*, 1–11. <https://doi.org/10.1186/s12910-015-0031-y>

Natasha, M., Cynthia, W., Kathleen, M. M., Greg, G., & Emily, N. (2005). *Qualitative Research Methods: A Data Collector's Field Guide*. *Family Health International*. <http://www.fhi.org>

Newman, P. A., Rubincam, C., Slack, C., & Essack, Z. (2015). Towards a Science of Community Stakeholder Engagement in Biomedical HIV Prevention Trials: An Embedded Four-Country Case Study. *Plos One*, 10(8), 1–20. <https://doi.org/10.1371/journal.pone.0135937>

Ntseane, D. M., Ali, J., Hallez, K., Mokgweetsi, B., Kasule, M., & Kass, N. E. (2019). The features and qualities of online training modules in research ethics: A case study evaluating their institutional application for the University of Botswana. *Global*

- Nyika, A., Chilengi, R., Ishengoma, D., Mtenga, S., Thera, M., Sissoko, M., Lusingu, J., Tiono, A., Doumbo, O., Sirima, S., Lemnge, M., Kilama, W. (2010). Engaging diverse communities participating in clinical trials: Case examples from across Africa. *Malaria journal*, 9(86),1-9. 10.1186/1475-2875-9-86.
- Nyirenda, D., Gooding, K., Lora, W., Kumwenda, M., McMorrow, M., Everett, D., & Desmond, N. (2018). Complexities and dilemmas in community consultation on the design of a research project logo in Malawi. *Plos One*, 13(10), 1-16. <https://doi.org/10.1371/journal.pone.0205737>.
- Participants in the Community Engagement and Consent Workshop. (2013). Consent and Community Engagement in diverse research contexts: Reviewing and developing research and practice. *Journal of Empirical Research on Human Research Ethics*, 8(4), 1-18. doi:10.1525/jer.2013.8.4.1
- Paulina, T., Jantina, D. V., Megan, C., Katherine, L., Janet, S., Patricia, M., Jennifer, T., Morisola, O., Vincent, P. A., Aminu, Y., & Michael, P. (2015). Community engagement strategies for genomic studies in Africa: A review of the literature. *Medical Ethics*, 16(1), 1–12. <https://doi.org/10.1186/s12910-015-0014-z>
- Reynolds, L., & Sariola, S. (2018). The ethics and politics of community engagement in global health research. *Critical Public Health*, 1596, 1–12. <https://doi.org/10.1080/09581596.2018.1449598>
- Shallcross, L. J., Howard, S. J., Fowler, T., & Davies, S. C. (2015). Tackling the threat of antimicrobial resistance: From policy to sustainable action. *Philosophical Transactions of the Royal Society B: Biological Sciences*, 370(1670), 20140082–20140082. <https://doi.org/10.1098/rstb.2014.0082>
- Shubis, K., Juma, O., Sharifu, R., Burgess, B., & Abdulla, S. (2009). Challenges of establishing a Community Advisory Board (CAB) in a low-income, low-resource setting: Experiences from Bagamoyo, Tanzania. *Health Research Policy and Systems*, 7(16), 1-5. <https://doi.org/10.1186/1478-4505-7-16>

- Srivastava, A., & Thomson, S. B. (2009). Framework Analysis: A Qualitative Methodology for Applied Policy Research. *Journal of Administration and Governance*, 4(2), 72–79. <https://doi.org/10.7748/nr2011.01.18.2.52.c8284>
- Sutton, J., & Austin, Z. (2015). Qualitative Research: Data Collection, Analysis, and Management. *The Canadian journal of hospital pharmacy*, 68(3), 226–231. <https://doi.org/10.4212/cjhp.v68i3.1456>
- Tindana, P. O., Singh, J. A., Tracy, C. S., Upshur, R. E. G., Daar, A. S., Singer, P. A., Janet F., James, V. L. (2007). Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. *Plos Medicine*, 4(9), 1451–1455. <https://doi.org/10.1371/journal.pmed.0040273>
- Tisherman, S. A. (2018). Defining “Community” and “Consultation” for Emergency Research that Requires an Exception from Informed Consent. *Journal of Ethics*, 20(5), 467–474.
- Wellcome Trust. (2017). *Annual report and Financial Statements 2017*. <https://wellcome.org> ›



## APPENDICES

### Appendix 1: Coding book

#### Objective 1: Description of the existing community structures and process used by researchers for engagement

Themes	Definition	Codes & sub codes	Example
Existing community structures	On this section, we wanted to know different structures/networks that are used to engage the community in research related activities conducted by IHI-Bagamoyo.	CHW HL VEO CAB	
Process of forming community structures	On this section, we wanted to know ways by which these community structures are formed or contracted	Selection Voting Nominated	
Approaches/ways of engaging the community	On this section, we wanted to understand mechanism that researchers use to reach the community	Through DMO,WEO,VEO,HL,CHW & awareness campaign	

#### Objective 2: Experience of community stakeholders on the functions of the community structures

Themes	Definition	Codes & subcodes	Example
1.Community awareness about IHI	❖ On this section, we wanted to know what the community understand about Ifakara Health Institute,	❖ Malaria project ❖ Treatment of children ❖ Research on human being & Malaria	

2.Participation in IHI research	❖ On this section, we wanted to know, how community member did came to know about research, who participated in the research, benefits. encountered due to participation	<ul style="list-style-type: none"> <li>❖ Community leaders</li> <li>❖ CHW</li> <li>❖ Free medical care</li> <li>❖ Free transport</li> <li>❖ Provision of food</li> </ul>	
3.Approach used by community structures during engagement activities	❖ On this selection, we wanted to know of different ways used by the community structures to engage community in research related activities/the best approach used of getting participant from the community	<ul style="list-style-type: none"> <li>❖ Public meeting</li> <li>❖ Household visit</li> <li>❖ Patient sensitization at health care facility</li> </ul>	
4.Reason for participants dropping out of studies	❖ On this section, we wanted to know the reason which were associated with fall of recruitment and retention of participants in	<ul style="list-style-type: none"> <li>❖ Little engagement about the research post-enrolment,</li> <li>❖ Mobility,</li> <li>❖ Misunderstandings of the study objectives</li> <li>❖ Lack of proper feedback of results/findings</li> <li>❖ False promises</li> </ul>	
5. Experiences of community structures regarding IHI research.	❖ On this section, we wanted to know of the experience of the community structures on	❖ Research feedback in Public meetings	

	research conducted by IHI,		
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**Objective 3: Perceptions and experience of IHI researchers on the functionality of current community structures**

<b>Themes</b>	<b>Definition</b>	<b>Codes &amp; sub codes</b>	<b>Examples</b>
1. Relationship between community structures and researchers.	On this section, we wanted to know how do researcher relate with the community during research activity in their community	<ul style="list-style-type: none"> <li>❖ Informing community</li> <li>❖ Gatekeepers</li> <li>❖ Ear of researcher</li> <li>❖ One –way direction</li> <li>❖ Quarterly meeting</li> </ul>	
2. Advantages of involving community structures in research.	On this section, we wanted to what are the usefulness of the community structures/advantages in research related activities to the researchers.	<ul style="list-style-type: none"> <li>❖ Support researchers</li> <li>❖ Acceptance of research</li> <li>❖ Trust</li> <li>❖ Recruitment</li> </ul>	

## Appendix 2: Interview Guide Researchers



### IN DEPTH INTERVIEW GUIDE (English version)

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Name of Interviewer \_\_\_\_\_

Date \_\_\_\_\_

Name of Interviewee \_\_\_\_\_

Interviewee position in society/Role \_\_\_\_\_

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**Topic guide:** *This interview is meant to explore perceptions and experience of researchers (principal investigators and field workers) in working with the community structure that facilitate engagement of the community members in various clinical researches conducted by IHI-Bagamoyo.*

#### **This interview will be guided by the following objectives:-**

- i) Explore researcher's experiences and perceptions, in interacting and engaging with community structure in research project.
- ii) To get insight of the advantages and disadvantages encountered when working with the community structures.
- iii) Explore suggestions and recommendation of working with community structure efficiently and sustainably.

#### **About the community structures and community engagement**

1. IHI-Bagamoyo have been doing researches for 12 years! Are you aware of different community structure that are involved in facilitating engagement in clinical researches conducted by IHI-Bagamoyo? (**Probing:** If so, what are they? how are/were they formed of? How do you with them interact during research project?)
2. As researchers what approaches do you use to involve the community structures? (**Probing:** Do you think these approaches are relevant and effective for the community? If yes or no why? Do you know any specific planned activities/strategies that may be used to address the community structures, as well as the communities?)
3. How useful have the community structures been to your research i.e. in what way did they facilitate/hinder your research in the community? What did you do to gain their support? What are the pros and cons of working with the community structures in your research, and for IHI-Bagamoyo?

4. According to you, what are the approaches do the community structures use to engage the community in research related activities? (**Probing:** how effective do you think the community structures are and why do you say so?)
5. What types of concerns have you had or heard regarding the functioning of community structures during clinical researches implementation activities? (**Probing:** based on your own views/opinion what should be done on these functions? Are there benefits to the community and researchers based on these functions?)
6. What are the advantages and disadvantages of working with community structure? (**Probing:** Can you mention them? Do you think they have positive or negative impact to the community and researchers?)
7. What problems are you aware regarding the engagement processes -with the community? (**Probing:** What should be done to minimize those problems?)
8. What do you think about the clinical researches conducted by IHI-Bagamoyo? (**Probing:** Are they beneficial to the Institute and the community? I'd like to know more about what you're thinking on various research activities conducted by IHI-Bagamoyo? )
9. Are there any other information about the community structures or other aspects of the research activities that you think would be useful for me to know? (**Probing:** If so, i may need to probe to gather the information need)
10. What are your suggestions/recommendation on the effective and sustainable strategies to be employed during clinical researches implementation processes? (**Probing:** What should be done to engage the community? What should be done to involve the community structures so as to make sure we meet our research goals?)

## Appendix 3: Interview Guide Community Stakeholders



### IN DEPTH INTERVIEW GUIDE (English version)

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Name of Interviewer \_\_\_\_\_

Date \_\_\_\_\_

Name of Interviewee \_\_\_\_\_

Interviewee position in society/Role \_\_\_\_\_

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**Topic guide:** *This interview is meant to explore perceptions and experiences of community stakeholders (Administrative leaders and village/community leaders) with regards to functioning of the community structure in facilitating engagement of the community members in various clinical researches conducted by IHI-Bagamoyo.*

#### **This topic will be guided by the following objectives:**

- i) To explore perceptions and experiences of community stakeholders on the functions of the community structure in engagement process.
- ii) To explore factors associated with participants drop out, enrolment/recruitment during clinical researches activities.

1. Have you ever been engaged in any clinical researches conducted by IHI-Bagamoyo? **(Probing:** If yes! What was that research about? How did you come to be involved in the engagement activities? What roles were you involved in? For how long were you engaged?
2. What do you think about the clinical researches conducted by IHI-Bagamoyo? **(Probing:** Are they beneficial to the Institute and the community? I'd like to know more about what you're thinking on various research activities conducted by IHI-Bagamoyo?)
3. What problems are you aware regarding the engagement processes -with the community? **(Probing:** What should be done to minimize those problems?)

4. What types of concerns have you had or heard regarding the functioning of community structures during clinical researches implementation activities? (**Probing:** On your own views/opinion what should be done on these functions? Are there benefits to the community and researchers based on these functions?)
  
5. What do you think are the reasons associated with participants drop out and loss of follow up during clinical researches activities? (**Probing:** As community stakeholders, what are your opinion/views that will support participant's retention and recruitment strategies?)
  
6. What are the approaches used by the community structures to engage the community in research related activities? (**Probing:** As researchers/community stakeholder do you find them appropriate or not, if yes or no Why? How do you think the community structures are cooperative enough to make sure that the security of the community is assured and the researchers meet their target goals?)

## Appendix 4: Interview guide community members



### Focus group discussion guide (English version)

#### 1. Information sheet

##### Project rationale

Clinical researches have been conducted by Ifakara Health Institute-Bagamoyo (IHI-Bagamoyo) branch. Since 2006 to date, participation of community members in various research projects have been required, so as to meet project goals. However the participation of community members at different levels have been facilitated with different community structures. Therefore this research project has necessitated the need to explore perceptions, opinions, views, knowledge, attitudes, understanding and experiences of working with community structures in facilitating community engagements in clinical researches.

**Project objective:** The study aim to explore community members perceptions and experiences, with regards to functioning of the community structure in facilitating community engagement in clinical research in Bagamoyo district.

**Potential risks:** No risks are anticipated in this study except minimal interruption in your time to participate in this discussion.

**Potential benefits:** This study will inform on policies and plans around community engagement. As well as strategies by which community structures will be evaluated based on their performance.

**Compensation:** The participation of the community members will be voluntary, refreshment will be provided during the discussion for each member that are going to participate in the discussion.

**Confidentiality:** Confidentiality will not be guaranteed for this discussion. We request you not to mention names during the discussion. Additionally, no names will be attached to the statements and the tapes will be erased as soon as they are transcribed and the project is ended. When we write up the results, we will not use your name and we will write about places in ways that also do not identify where you live.

**Inclusion criteria:** Participants will be men and women who are involved, were involved, have never been involved and have never been involved in Clinical researches that are conducted by Ifakara Health Institute-Bagamoyo branch. The participant must be living in selected villages within Bagamoyo district.



**3. Consent form.**

**Participant's information**

**Village name:** \_\_\_\_\_

**Village leader:** Name \_\_\_\_\_ **Phone**  
No. \_\_\_\_\_

**Study participant: ID** \_\_\_\_\_

I hereby give full approval to the student researchers of the Nelson Mandela African Institution of science and technology in collaboration with Ifakara Health Institute to conduct this study in my community.

I understand the rationale of this research project and I am fully aware of the nature of the research and my role in it.

**Signature or thumbprint of participant:** \_\_\_\_\_ **Date:**  
\_\_\_\_\_

**Signature of witness:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Research team statement

**Name of the research assistant:** \_\_\_\_\_ **Signature:**  
\_\_\_\_\_

**Contact details:** \_\_\_\_\_

I hereby confirm that I have explained the objectives, potential risks, benefits and any compensation of this study to the participants in a language they understand.

**(iii) Introduction Statement**

*This interview guide will be used for the respondents who have been directly engaged with researches conducted by IHI-Bagamoyo. Main objective is to explore community members perceptions, experiences, views, understanding and knowledge on the function of the community structure in facilitating engagement in clinical researches.*

Discussion Topic	Questions Guide
<p><b>Exploring community awareness about IHI_Bagamoyo</b></p>	<p>7. Can anyone of you tell me what you know about IHI_Bagamoyo? (<b>Probing:</b> What are the activities done by IHI-Bagamoyo? How did you come to know of these activities (has anyone of you ever participated in research? or in engagement activities? Could you tell us a little about your involvement? How did you come to be involved in the engagement activities? What roles were you involved in?)</p> <p>8. Is there anyone who has participated in researches conducted by IHI-Bagamoyo? (<b>Probing:</b> If yes, what was the research about? How did you come to know about the research/enrolled/recruited? which year was the research? what used to happen while in the research (probe who were the participants and what procedures used to happen?) and for how long did you participate in the research? What were the advantages/disadvantages of participating in researches? At any point, did anyone in the community (apart from the study team and researchers at IHI) get in touch with you i.e. was there involvement of the community structures in the research activities?)</p> <p>9. How do people in the community get involved in research projects? (<b>Probing:</b> Who gives information regarding the particular research project? How are people being selected?)</p>
<p><b>Exploring understanding of the roles played by the community structure facilitating community engagement in various research projects conducted by IHI_Bagamoyo.</b></p>	<p>10. As you know, this study aims to explore views and experiences of working with community structures. Might you know which community structures interact with IHI on behalf of the community? Give some examples? Have you ever interacted with any of these structures with regards to research at IHI? If you have, could you narrate a little about how you interacted with them i.e. what were they discussing with you? How did you come to know them? do they still do these interactions with communities about IHI research?</p> <p>11. Currently, which structures are involved in facilitating interactions between the community and IHI researchers? (<b>Probing:</b> How does these structures function to facilitate interactions between the community and the IHI research i.e what roles do they perform? What do the community members feel about these structures? Do you think these structures have made a difference in how research is perceived in the community? If so, in what ways? In what ways</p>

have these structures been a) useful b) not useful in research? c) if not useful, how best can they be strengthened? What are the main role played by the community structures to ensure safety and security of the members that participate in research projects?)

12. Recently there have been little engagement of the community in research activities, (**Probing:** can you tell us what could be the reasons? What should be done to ensure sustainability of the community participation?)

13. What are your views/opinion on the ways community structure facilitate engagement of community in clinical research? (**Probing:** What do you think should be done to motivate community participation in various research activities? Do you think the community structures are best means, by which researchers should use to facilitate engagement in the various research projects?)

## RESEARCH OUTPUTS

### (i) Research Articles

Bategereza, L., Olotu, A., & Kamuya, D. (2021). Community-networks that facilitate engagement in health research: Ifakara Health Research Institute-Bagamoyo case study [version 1; peer review: awaiting peer review. *AAS Open Research*, (4)13, 1-12. <https://doi.org/10.12688/aasopenres>

### (ii) Poster Presentation