5 The role of research in an institution, using the iCARE training to support research staff

Good health research in low income settings is important to understanding health problems and developing appropriate and practical solutions to health challenges in complex social, cultural and economic contexts. To be able to carry out such research in an institution, there needs to be a team of researchers who collaborate with health providers to collect information and to recruit and manage study participants. The team members need good skills in communication and management of emotions, and thus the course described in this manual is relevant for research teams as well.

An example: In Kilifi, a research project aimed to understand new-born care practices and mothers' experiences with sick babies hospitalized in new-born care units. Research managers observed that researchers working in these units experienced many emotional challenges, including seeing many babies dying, making it even more of a challenge to talk with the mothers. The researchers interviewing the mothers experienced difficulties in carrying out the interviews, both in relation to managing their own emotions, and in responding appropriately to the emotions the mothers showed.

Our team planned and conducted a training course for this group, and the group responded very well – they found it really helpful to learn how to recognise and manage their own emotions as well as the emotions of others, and to learn how to communicate well in challenging situations:

> *"Looking back, I appreciate the efforts I have put in this. For me it has been an eye opener and a great journey of being aware of my emotions and the effects it has on me and my colleagues/ study participants/family. I have learnt that before I react to something I need to try and understand why it happened that way, and that way I would avoid hurting others and much more – not be judgmental every time."* *Research staff, Kilifi*

The Kilifi team has conducted several iCARE-Haaland model training courses for researchers, and also presented these ideas and concepts in international conferences. There is a growing recognition in the research community about the need for researchers to become more self-aware and to learn better skills on interpersonal communication, and on managing emotions – especially related to conducting research on sensitive issues. These skills will have an influence on the quality of research data the interviewers are able to collect, as well as on the researchers' wellbeing.

A course participant in Kilifi commented in an evaluation of the course:

- *"The most valuable learning I have had is the importance of active listening. As I have been doing in-depth interviews I realised that I wasn't doing much active listening to participants. Sometimes I would repeat a question already answered and the response from the participants would be, "I have already told you that!".* *Research Staff, Kilifi*

The role of research in an institution

Health research learning can be beneficial to a range of players in a number of ways:

- **Research participants, and other patients**, can gain from any clinical benefits built into the study design and ancillary care plans, and the patient population as a whole can gain in the long run benefit from the outcomes of what is learned.
- **Wards and health institutions** can benefit from research-related funding, training and other resources, including access to additional professionals

- **Researchers** can develop a deeper understanding about what the main health problems facing people in the area are and contribute to finding shorter and longer term solutions to major health problems.

Each research project should always be carefully checked for science and ethics before it begins through competent local and national review processes. All team members, including any health providers involved, should receive training on technical and ethical aspects of their particular approved research projects. For research staff interacting with patients as research participants, this training is ideally in addition to general communication and EI skills described in this manual. Communicating well with patients, respecting their concerns, questions and emotions and explaining complex processes in a simple way is as much a challenge when dealing with issues related to participating in research as it is in daily clinical care.

Providers involved in research projects need to be able to use their communication skills to –

- ***Screen patients*** to establish if they are eligible for inclusion in studies and make relevant recommendations;
- ***Explain the purpose of the research*** and ***request consent*** for participation by patients or parents/relatives of patients in the various projects, when they are emotionally stable enough to make such a decision;
- ***Ensure all study patients are aware of their rights*** and have signed consent forms;
- *Explain clearly the difference between research and treatment*;
- ***Continuously advise and inform*** patients or parents of the patient's illness, their participations in the studies, and their progress and treatment throughout the hospital stay.

Health research is common across many health institutions in resource poor settings. We therefore assume that a number of the users of this manual will be in contact with research projects during their working life. We thus provide here a brief global look at why we need research in resource-poor countries. We also provide an overview of the process we use to lead our participants through to strengthen their skills specifically related to research.These are added on to the skills participants are trained in throughout the course process. Readers are also referred to research modules in the basic course and in the follow-up course.

Where possible, the Principal Investigators who lead the research projects should be involved in some of the learning processes on research communication with the participants. Frequently, there may be a communication gap with this group, many of whom are used to speaking mainly to scientific communities. Many PIs may have a lot to gain from facilitated communication with the providers, to learn more about their concerns about the research, and to break down some of the status and power gaps that often prevent providers raising (often very important and pertinent) questions with the PIs. This can be important because research hierarchies often have similar power inequities and imbalances to health systems which can make raising issues 'up the system' particularly challenging and demanding. Nevertheless it is important to be able to do so, because the power to change study plans and designs is often held at that level.

A brief global look: Why do we need research in resource-poor countries?

Health research is aimed at producing new health related knowledge, and ultimately health. There are a diverse range of studies conducted globally, ranging from interview-based research, through observational studies, through to many different kinds of trials, e.g trials to develop new products, compare different treatment options, or assess different mechanisms to improve patient adherence to therapy). Although developing countries have far higher morbidity and mortality rates than developed countries, and therefore greater potential to benefit from research, these parts of the world are hugely under-represented in the proportion of total health research budgets

and levels of research activity (Lang et al., 2011). Recognition of this gap, and of the urgent need to evaluate available and affordable interventions in developing countries, has contributed to efforts to strengthen capacity in developing countries to lead and conduct research.
Numerous policies and guidelines have been formulated to help identify and deal with ethical issues and dilemmas that arise from involving people in research[1]. Many issues and recommendations can be broadly grouped under meeting key principles of conducting research, including: : 1) treatment of individuals and communities with respect; 2) ensuring that any risks of being involved in the research are minimised and that the benefits of the research outweigh the disadvantages; and 3) ensuring fairness in who is involved and who gains from in research.

Frontline staff include those who explain studies, administer consent processes, conduct research and clinical care procedures, and feedback test and study findings. These staff are essential to how studies are actually administered and unfold over time, and therefore are key to scientific quality and ethical practice. Frontline staff face many practical, technical and emotional challenges in their day to day research activities, many of which require significant communication skills. Many fundamental concepts of health research (eg randomisation, equipoise) are challenging to explain and understand in any setting, but further complicated in clinical settings by the stress of illness and being away from home, and by health providers often wearing 'two hats': both a research roles and a clinical care role. There is potential for patients to think that research activities being proposed are primarily for their own therapeutic benefit as opposed to for learning at a population level ('therapeutic (mis)conceptions').

Health workers may also feel that principles of research come into conflict with or have to be balanced with their own personal or professional ethics. The need to share experiences and strategies to cope with challenges and conflicts has been highlighted in our setting for fieldworkers. It is also clearly a need for health workers involved with research, or who have questions about research conducted by their colleagues and researchers on 'their patients' or in 'their' health facilities and wards.

5.1.1 An example from the process of learning about research in Kilifi:

Part 1: An "open day" on research for health providers

Participants in the communication training courses who were directly involved in research activities in the hospital expressed a need to learn more about these activities to strengthen their understanding and enable them to communicate research issues better to patients. However, the needs raised by participants were way above what the communication training team could accommodate within the time available in the workshops (half a day in each workshop on specific research topics, and connection to research from almost all the modules).

Thus, the training team came up with the idea of organizing an open day for the participants to learn more about research activities currently going on at the hospital as an added activity to the main training modules. The open day on research took place during the first three months of the learning process.

The open day was organized in collaboration with the community liaison group and the hospital administration. The community liaison group has the mandate to strengthen relationship between researchers and communities within Kilifi. The open day is meant to be used as a forum for participants to learn about and discuss broader issues related to research, thus strengthen their knowledge and understanding about research before attending the communication workshops, where the aim is to strengthen their skills to communicate about clinical care and research.
The brief programme and specific aims are included here. For a detailed version, see module 4.

The specific aims and objectives of the open day were for participants:

To strengthen knowledge, awareness and understanding of:

- **The KEMRI-Wellcome Trust programme:** Basic organizational structure and link with MOH: Who we are, what we do, and why we are here in Kilifi. How KEMRI interacts with communities around Kilifi and how the providers are considered as part of the Kilifi community. History of KEMRI growth – from 1979 till now.
- **The Community Liaison Group**: The main goals of improving understanding with the community, and main activities the group is involved in.
- **Hospital based research and why it is important**
    - What a research project is in a clinical care setting. Examples of research studies going on in the hospital, and the aims of these studies.
    - Major research which has been conducted, and impact it has had on health policy in Kenya, and in the world.
    - The social value of research, and why we need to conduct research in health.
- **Research quality – science and ethics**
    - How a research project is developed and reviewed, and what makes it safe for patients to participate.
    - The principles of informed consent, and why it is important to make sure to obtain voluntary consent. Obtaining consent in emergency situations.
    - The role of staff in research
- **Particular concerns locally about research and effort to redress these concerns**
    - The background for using the snake as a symbol, and why this has now been removed from KEMRI vehicles in Kilifi.
    - Community perceptions about KEMRI activities (The Takaungu video).
    - Activities and functions of the scientific labs (tour around the labs).

To encourage and facilitate

- A motivation to identify with and take pride in being part of important work at KEMRI

To strengthen skills to

- Communicate with a patient/parent about what KEMRI is and does on research, with the aim to create an understanding and a positive attitude to the aims of research in Kilifi

Notes:

- ***The aims for the open day can be flexible depending on what the participants needs are from reading their feedback*.**
- **See Module 4 for a full program and presentations for the open day, and for how to plan the day.**

Timing of the open day

- To be conducted during phase 1 (observation and reflection), preferably early in 3rd month
- Participants' questions and concerns from baseline can be addressed

Part 2: Task 11b: Special observation and reflection task for participants involved in research (in 3rd month of phase 1, before basic workshop)

See Parts B and D for all the tasks. Task 11b can be found in part B.
For the full modules, see parts C and E.

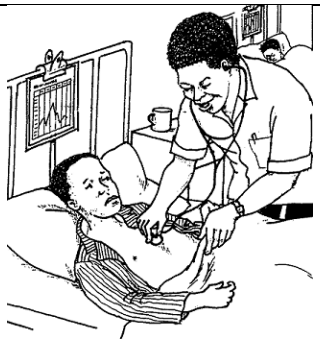
Part 3: Module 4 in the basic workshop: *Communicating about research with awareness and emotional competence:*

How is a research project developed, and how do you explain need for research to a patient?

A key skill for the participants is to be able to explain the need for research, and what it means to the patient, practically, to be included.

Another key skill is to explain clearly that participation in research is voluntary.

See module 4 for these aspects



Difference between treatment (FOR the PATIENT, now) and research (for the COMMUNITY), long term, must be made clear to patients.

An example of a course participant explaining the need for research:

"A patient came the other day when I was on duty the patient was already screened in Ward 1 and was eligible to be recruited into the FEAST study (Fluid Expansion as a Support Therapy). The patient was accompanied by the mother and an uncle who was brother to the father. He was a boy aged 9 years with Anaemia and had all the signs to fit into FEAST A.

So the admission procedures were being done. I started by introducing myself to the parent and uncle then went ahead to explain what was being done to the patient (i.e. blood was being taken to the lab so that we are able to know what exactly is the cause of illness). Then I started explaining the study FEAST. I explained to them that it involved the use of infusion fluids Normal Saline and Albumin and the child is given either of the two, then observations are done at the first hour, 4th hour, 8th hour, 24th hour and 48th hour and the child will come for follow up on the 28th day. I also explained to them that small amounts of blood will be taken during the study and taken to the lab.

Good enough; they were asking questions as I went on e.g. "if what you want to give our child is medicine, why then are you asking for our permission?" I explained it's because the fluids are under study and because of the fact that the child will be monitored closely and is required to come for the follow up; that is why it was important for them to understand the study. I also explained that the drugs were tested not harmful to humans - all we needed is to know which one is more effective than the other.

I told them the study is not only beneficial to them alone but also to other children in the future. I also told them they will be given transport to go home and to come for follow up. All this discussion was a the bedside. I also explained to them the child will also get other necessary treatment as usual and that it is their choice to accept or refuse to be in the study and that even if they refuse, the child will still get the treatment and good care as usual.
Then I asked them what they have understood and they explained back and gave consent to the study.

I was very happy and immediately the study procedures began I assured them they could ask me questions any time during the study. *HCW, Kilifi*

Part 4: Module 8a in the follow-up workshop:

Working with emotional competence in a research environment:
Understanding and communicating about the difference between research and treatment

In this module, participants are trained to explain the difference between research and treatment to patients through exercises and discussions. Ethical aspects of research as well as national and international research processes are explained and discussed. Skills are brought together, and participants train to be able to practice communicating about research, with confidence.

5.1.2 Changing attitudes and practice on research: Providers more aware

In the LVCT evaluation of the training courses in Kilifi[100], the researchers concluded that there was a clear pattern of positive change in participants' self-reports i.e. all feel that the training has led to changes in the extent to which they take account of the patient's situation, try to explain as well as they can and make sure decisions are made freely, with understanding.

Changes were seen particularly regarding how participants related to promoting choice and managing refusals from patients. Before the training, for clinical research on the ward, there was a common pattern of firm personal belief amongst HW that children would benefit directly from participation in studies, i.e. participation was generally in the child's best interests. On this basis, HWs felt that it was fundamentally not important to explain too much about studies; and that mothers were being unreasonable if they refused – not acting in the child's interests. This could make HWs irritated or even angry with mothers who refused.

In addition, HW often felt that:

- Refusals were a sign of personal failure on their part, since they worked in a research institution
- They were under pressure from supervisors to recruit participants, again as part of their job
- As a background issue, getting full informed consent in a ward situation was often very difficult (anxious mothers, mwenye syndrome (*mothers believe all decisions need to be made by the father)*, traditional beliefs, illiteracy etc). As a result, taking short cuts was often seen as unavoidable.

This means that nearly all HWs often did not feel strongly motivated to spend time on the consent process and ensure that decisions were made freely. All understood the concept of voluntariness in research before the training, but this was outweighed by concerns/issues above.

In addition, a particularly serious effect of HW's negative responses to refusals was that some HWs would continue to feel resentment towards mothers who refused participation, deliberately avoiding them or treating them differently to other patients.

Following the training, all HWs spoke about an increased **realisation of the importance of voluntary informed consent** in research. On this basis, areas seen as particularly important to communicate well about were: specific study procedures, the difference between research and care, and voluntariness (in majority of participants); and the research question and benefits & risks (in many); and (in one) contact information.

[100] LVCT (2011): **EVALUATION OF THE HEALTH PROVIDER COMMUNICATION SKILLS COURSE**

An example: Respecting a well informed "No" to a request for research consent

"A father had two children who were invited to our clinic because they were both below the age of 5 years and their mother had sputum smear positive tuberculosis. We were investigating these children for any symptoms and signs of tuberculosis. Moreover, we did some investigations on them. After all our investigations it was clear this children did not have tuberculosis but we still needed to follow them up for a few months just to be sure they don't develop something suggestive. Meanwhile, a study on finding a single and effective way of diagnosing tuberculosis in children is running whereby a blood sample is taken and biomarkers to tuberculosis infection are sought for. All children, regardless of whether they have tuberculosis or not are eligible.

I told this father about our study and its importance. I made it clear that his children were fine. I also made it clear that participating in the research is voluntary.

As we were talking, it was clear to me that this father understood what I was saying and I even predicted he would accept his children to participate in the study.

He kept on asking questions about tuberculosis and the study, which I clarified, to his satisfaction. Finally, I asked him whether we could proceed and enroll his children he said 'Daktari, I have understood all you have said and I think it would be good if scientists discovered a simpler way of diagnosing tuberculosis in children. Am glad participating in this study is voluntary. I don't mind having my children participating in the study but I just don't feel like it'

In my mind I was thinking it could probably be the bad stories that are circulating in the community about our organization. I asked him if that was the case and he told me "I am aware of such stories and please know that my elder children have participated in various studies before of which I did not see any particular problems. I am a member of the body that liaises between your organization and the community so I have the facts and wont be swayed by hearsay. I just won't let my children participate this time round and I have no bad feelings about your organization. If anything I commend what your organization does for this community".
I respected his decision.

I think most of the time I have problems with when a parent doesn't accept his/her child to be involved in a medical research. I may not show it but inside myself I usually feel – 'even after all that talking!' But slowly, I am learning to accept right from the bottom of my heart when consent is denied. What I make sure is that I give a brief overview of the organization I am working with, the importance of a particular study I wish to enroll a child into, I articulate the key points, give room for asking questions and provide my answers. I pay attention to how I am conveying my messages, the parents feelings, and finally respect their decision of whether to participate or not."

HCW, Kilifi

Two health workers described specifically feeling torn over this balance between ensuring free informed decisions were made and supporting the (perceived) best interests of the child. These two health workers and another specifically talk about the confidence they have gained from the training in *balancing these issues.*

From the data, the main underlying reason for this change seemed to be placing greater importance on the idea of people's rights to make their own decisions, based on understanding what's being proposed. This was linked to:

- **a better understanding of the 'weightiness' nature of this principle**, from talking about 'formal' requirements and review processes in research (many committees, international guidelines etc) and perhaps also by its inclusion in this training??
- **the general idea of respect for others being taken more seriously** – from the course as a whole
- **greater confidence** in being able to communicate about these issues, and to answer questions about research and research processes.
- **reinforcement/increasing confidence** through positive experience of using new skills in informed consent situations: this is a mix of situations where new approaches 'succeeded' where other HWs had 'failed' and where new approaches 'failed' but still seen as doing a good job (now feel good about that).
- **the support given by colleagues** and supervisors for using new skills in the workplace (e.g. referring 'difficult' situations).

Other changes in HWs' perceptions and behaviour included a broader understanding of the role of research in the institution. Particularly for HWs with no, or only some, direct involvement in research, perceptions of the role of research often changed from being seen as a very local activity (e.g. to support the interests of individual researchers, in 'making their names' and accessing funding) to being part of larger movement in support of health and social development.