

## Module 4

### *Communicating about research:*

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

By Ane Haaland, with Mwanamvua Boga

## Background for trainer

In Kilifi, providers work in a district hospital which is the base for a number of research projects. This means that many staff in the hospital will be involved in these projects in one function or the other. The tasks include screening of patients to establish if they are eligible for inclusion in studies and make relevant recommendation, explaining the purpose of the



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

research and requesting consent for participation by patients or parents/relatives of patients in the various projects. It also includes ensuring all study patients are aware of their rights and have signed consent forms. Furthermore, the staff must 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. To do this well, good communication and emotional competence skills are essential

## **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 (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 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<sup>1</sup>. Many issues and recommendations can be broadly grouped under meeting key principles of conducting research, including: respect for persons, beneficence and non-malevolence, and justice. There can be challenges to meeting principles in practice in all settings, but arguably particularly in low-income settings<sup>4-6</sup> where there may be large differences in access to information and resources between researchers and community members, and where basic health needs are great and many public health facilities inadequately supported. In these contexts, the importance of relational ethics – that is an ethics informed by the context of the study, past histories and relationships between participants, research team members and research institutions – become particularly central.

Frontline staff, including those who explain studies, administer consent processes, conduct research and clinical care procedures, and feedback test and study findings, are essential to the implementation of ethical principles in practice, and to relational ethics. They are central to how protocols are actually administered and unfold over time in clinical and community settings. These staff face a range of practical, technical and emotional challenges in conducting research, many of which require significant communication skills. For example, fundamental concepts of health research are challenging to explain and understand in any setting, but in clinical settings are even more complicated by the stress of illness and being away from home. There are particular possibilities of therapeutic (mis)conceptions about research, and anxieties about unfamiliar research activities in these settings. Communicating about research and responding to participant needs can be especially challenging when staff are balancing research and health care roles, as is so often the case for health workers. 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 and 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.

When working with research in the local hospital or institution, the staff who are directly involved in the research projects will have specific training sessions related to each project, including how to obtain informed consent. The training provided in this communication course is seen as an addition to these: Throughout the course process, the training participants receive about relating to and communicating with patients is directly relevant to interacting with patients involved in research processes. Thus, the awareness, attitudes and skills presented in **"Communicating about research"** have a much larger place in this manual than it seems from this module, and from the module in the follow-up workshop: Communicating with emotional competence 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 working to request consent for patients (or parents) to participate in research often face a dilemma: The patient (or parent/relative to a child patient) has come for treatment and care and is often worried or scared because of the illness. The patient or parent is approached with questions about participating in research, and explanations of what the research involves – before getting treatment (*unless the case is an emergency*). A common fear among patients is that they will not get the same good quality of care if they do not give consent to participate in the research. This is a "classical" communication challenge requiring awareness of and respect for the patient's main need (treatment), as well as the need of the Principal Investigator (PI) or research coordinator to recruit patients into the study, and explain the long term benefits of the study to them. To balance these needs, the provider must use good communication and emotional competence skills.

The providers learn to use empathy to recognize the emotions (e.g. fear, uncertainty) and see the situation from the patient's side, to appreciate her concerns, and to step back from their own (*often automatic, judgmental*) reaction when a patient says no to participate in the research. It is common for the provider to take the patient's rejection of the research participation personally, i.e. the provider takes it as a rejection of her/himself (without knowing consciously that this is happening). Learning to recognize her own emotions and step back from her experience of "rejection", and seeing that this has to do with her **role as provider, NOT her as the person "Nancy"** – will enable her to look at the situation with more openness: She needs to practice emotional competence.

Respect for the patient as a person with the right to decide for herself is key here, and to see also the longer term perspective: When patients are well informed about research, and their right to say no is acknowledged and respected, they will also most likely carry a positive message to their community

about the research. Patients who participate on a voluntary basis and have good information and understanding about the research will also carry a positive message back to their communities. When patients feel they are really free to decide whether or not to participate in the research, they may feel more inclined to join a research opportunity the next time.

The provider herself needs to have a clear understanding of what is research, and what is treatment, and be able to communicate this difference well to the patient or parent. This difference will be further dealt with in the follow-up course.

Managers involved in research in Kilifi hospital report that the providers who have undergone this communication skills training seem to balance this dilemma well, and now communicate better with patients eligible to be involved in research. Some course participants themselves have commented that they now obtain **real** consent from patients, making sure those being requested to join studies understand what their participation in the research involves. Before the training they used to allow people to join studies even where they did not seem to understand. Course participants report that having better informed research participants who trust providers' explanations has made the research more straightforward, for example that it is easier to obtain consent for e.g. taking extra blood samples. ***A main reason for the improved cooperation is that providers make sure they explain to patients WHY taking a sample is necessary, and that they communicate the results of the tests to the patients.*** They build trust and a professional relationship with the patient, show respect for the patients as persons, and have the aim to provide patient centered care. Using the emotional competence skills to recognize emotions on both sides (their own, and the patient's) enables them to step back from their automatic reactions, and act with a clearer perspective on how they need to communicate.

The extra time they may sometimes invest in talking with the patients when recruiting is fully "compensated" by having established a good and trusting relationship, which enables good cooperation in further care. Many say that communicating well (*by creating a safe environment by greeting, and meeting the patient with respect*) does not take more time than the "old" way: They now establish trust quicker with the patient, and the decision on whether to participate or not in the research, is reached quicker.

### **Learning about research is done in 3 stages in Kilifi:**

1. **An "open day": To strengthen awareness about and understanding of research:** A one day seminar is held about a month prior to the basic workshop. The seminar is a forum for participants to learn about and discuss broader issues related to research, before attending the basic workshop to gain skills to communicate about clinical care and research issues. The main aim is to strengthen their knowledge and understanding about KEMRI and about the KEMRI-Wellcome Trust programme and its history of growth in Kilifi (since 1989), and about the links with the MOH.

Further topics include major research which has been and is being conducted in Kilifi, and examples of research which has had an impact on health policy in Kenya. Discussing the social value of research, and why we need to conduct research in health is an entry point. Participants are guided through what a research project is in a clinical care setting, how a research project is developed, and how patient safety is prioritized and reviewed. This is applied to a project participants can relate to and can easily see the usefulness of. They are furthermore introduced to the principles of informed consent, and why it is important to make sure to obtain voluntary consent.

The goals of the Community Liaison Group are described - to improve understanding with the community, and main activities the group engages in with the community are described.

Community perceptions about KEMRI activities are described in a video from Takaungu. For a full description of the programme: Please see appendix.

- 2. This module: Communicating about research**, where the purpose is to strengthen awareness and understanding of how a research project is conceived and developed, how safety is prioritized, and how you communicate about research to a patient. The research project explained during the open day is reviewed: this is a project participants can relate to and can easily see the usefulness of. The module also explores participants' own questions around and attitudes to research. Main ethical principles of research and of obtaining informed consent are reviewed, and are linked to the question of safety for the patients participating in the research. Skills needed to communicate about research are addressed, as well as skills to communicate with emotional competence between KDH and KEMRI staff to facilitate better understanding about and cooperation in research.  
Common reasons patients refuse to participate in research are addressed, and skills to address these concerns constructively and respectfully are practiced. At the end of the module, participants are briefly introduced to the difference between clinical care and research, which will be dealt with in more detail in the follow up course.
- 3. A module in the follow-up course:** Participants gain a deeper understanding of the difference between research and clinical care, and how to explain and discuss this with a patient, as well as addressing the concerns and questions the patient may have. Skills providers need to facilitate research activities well are learnt and practiced.

### There are 8 sections in this module. An overview:

- 1. Introduce the topic and establish relevance**, by acknowledging that conducting research is one of our core activities at Kilifi district hospital. The hospital has participated in research projects in collaboration with the KEMRI Wellcome Trust Programme, which is an internationally recognized research institution. These studies have informed both local and international health policies. (slide 1)
- 2. Reviewing learning needs from baselines, setting objectives and assessing their experiences and questions related to research:** The questions asked in the baseline are reviewed, and linked to objectives. Participants share their own experiences (or experiences related to people who are close to them), to establish the basis for what forms their present knowledge, ideas and opinions about research (slides 2-7)
- 3. Review of definition of what research is and why we conduct research, and examples of research projects in Kilifi:** Main aspects of what health research is and aims to do are reviewed, and participants own suggestions for reasons for doing research are revisited and added to. Examples of research conducted in Kilifi are reviewed, including the project presented in the open day (slides 8-13)
- 4. Introduction to research ethics, and to the difference between research and medical care:** A brief introduction to the difference between research and medical care, research ethics and main aspects of giving informed consent, including exercise (slides 14-17)
- 5. Considering the mother's needs and concerns:** Exercise and discussion to step into the shoes of a mother whose child is very ill, and she is asked to participate in research. Considering her needs, concerns and rights, and communication and emotional competence skills needed to dialogue with her to obtain real ethical consent (slides 18-19)
- 6. Attitudes and skills which help or hinder communicating about research:** Brief overview of attitudes and skills influencing how participants communicate about research (slides 20-21)
- 7. Exercises on communicating about research with patients and parents/relatives:** Demonstration, exercises and role play (slides 22-24)


8. **A communication challenge to health providers:** Summing up the challenges for providers, in the short and long term, and defining issues for the follow-up course (slides 25-27).

**Time needed:** 2 ½ hours


**Preparation:**


**Materials needed:** Flipchart, marker pens.

**Presentation slides: Comments, questions, main points to bring out**

<p><b>Communicating about research</b></p> <p><b>How is a research project developed? Is it safe? What is the difference – research and clinical care?</b></p>  <p>Kilifi Basic workshop Ane Haaland, Ayub Mpya, Stevenson Chea and Mwanamvua Boga</p>	<p><b>Introduce by acknowledging</b> that conducting research is one of our core activities at Kilifi district hospital. The hospital has participated in research projects in collaboration with the KEMRI Wellcome Trust Programme, which is an internationally recognized research institution. These studies have informed both local and international health policies.</p> <p><b>Ask:</b> For those who attended the open day, how did you experience this? What did you learn? <i>(Get feedback)</i></p> <p><b>Ask:</b> Do you know any research that was done in Kilifi and has had an impact on policy? What can you remember about research that is or has been conducted here?</p>
<p><b>Referencing and acknowledging the iCARE-Haaland model</b></p> <ul style="list-style-type: none"> <li>• Please feel free to use and adapt the material in this presentation, and the model it is built on, by referring to the model, and the authors</li> <li>• This presentation is adapted from «<b>Communicating about research</b>», which is part of the learning materials in the iCARE-Haaland model.</li> <li>• <b>To reference this content please use the following</b> : Haaland A, with Boga M, 2020. Communicating with awareness and emotional competence: introducing the iCARE-Haaland model for health professionals across cultures. With contributions from training teams, Vicki Marsh and Sassy Molyneux. <a href="https://connect.tghn.org/training/icarahaaland-model/">https://connect.tghn.org/training/icarahaaland-model/</a></li> <li>• The authors' names should remain on the presentation, with a by line recognizing the person who (has adapted and) is presenting the presentation</li> </ul>	<p><b>Please reference the materials you use from this module and the presentation in the way specified on the slide.</b></p>
<p><b>Learning needs: From baseline</b></p> <p><b>What would you like to learn, to understand research better and be able to communicate with patients well about it?</b></p> <ul style="list-style-type: none"> <li>• "I would like to know after the research has been done in the community what are the <b>benefits</b> the community gets? and what are the criteria taken to <b>choice the area</b> of study research.</li> <li>• I would like to learn how to communicate well with the patient such that they don't feel <b>misused as guinea pigs</b> but feel that we are very concerned for their welfare.</li> <li>• To learn about <b>benefits</b> to the provider, patient, researcher, the guardian and the family.</li> <li>• How to make the participants and relatives understand we <b>mean no harm, always, hence improve on consent acceptance</b></li> </ul>	<p><b>Read out the slide</b></p> <p><b>Explain</b> that this is what you said you need to learn about research in your baseline questionnaire.</p> <p>We addressed some of these needs on the open day, and throughout this session we will aim to strengthen your understanding and build skills to communicate about research issues to patients – using emotional competence skills.</p>










<p><b>Learning needs: From baseline</b></p> <ul style="list-style-type: none"> <li>• <i>“The ethical principles involved in conducting research.”</i></li> <li>• <i>“How to undertake the <b>consenting</b> process, especially when the caretaker has just come in and is worried about the condition of the child or patient.”</i></li> <li>• <i>“The role of staff in research’</i></li> <li>• <i>“How to convince those who <b>oppose conventional type of treatment.</b>”</i></li> </ul>	<p><b>Read out the slide, continue from the above</b></p>
<p><b>Objectives</b></p> <p><b>To strengthen understanding of:</b></p> <ul style="list-style-type: none"> <li>• What a research project is in a clinical care setting, how a research project is developed, and how safety and quality is checked (summary from open day)</li> <li>• Main ethical principles guiding research</li> <li>• Skills providers need to explain need for research to a patient</li> </ul> <p><b>To further strengthen awareness of</b></p> <ul style="list-style-type: none"> <li>• The role of KEMRI in planning and conducting research in a national and international perspective</li> <li>• Main achievements of KEMRI researchers in contributing to change in health policies</li> <li>• Sources of information and people to contact for questions and problems related to research</li> </ul>	<p><b>Read out the objectives</b></p>
<p><b>Objectives (2)</b></p> <p><b>To strengthen awareness of and skills on</b></p> <ul style="list-style-type: none"> <li>• Common reasons why patients/parents refuse to participate in research, and how and when to address these with the intention of creating better understanding of the needs for and benefits of research in the long run</li> <li>• Common misconceptions and anxieties patients/parents have about research, and how and when to address these by acknowledging them and having a respectful dialogue, with the intention to create better understanding of the needs for and benefits of research, while maintaining the rights for patients to have a free informed choice to participate – or not.</li> <li>• Common reasons why patients DO choose to participate in research, and how to use this knowledge to communicate constructively about research</li> <li>• Provider attitudes and skills which help facilitate a respectful dialogue about participation in and understanding of a research project, and attitudes which hinder such a dialogue.</li> </ul>	<p><b>Read out the objectives</b></p>
<p><b>Sharing information and skills</b></p>  <ul style="list-style-type: none"> <li>• Some participants have been involved in research projects</li> <li>• You are our resources for this module</li> <li>• Spread yourselves in the groups – make sure there is at least 1 in every group</li> </ul>	<p><b>Ask participants who have been involved in research, to place themselves in the different groups – to be able to be resource persons for those who are less familiar with research.</b></p>




<p><b>Have you ever participated in a research project?</b></p> <ul style="list-style-type: none"> <li>• Share experiences of participating in a research project (<i>or talking with someone who did</i>)</li> <li>• What was the research about?</li> <li>• What made you (or the other person) decide to participate?</li> <li>• What questions did you/the other have about it?</li> </ul> 	<p><b>Exercise 1: 10 min: Participating in research</b></p> <p>Ask them to share experiences of participating in a research project (<i>or talking with someone who did</i>).</p> <p>Let them discuss at their tables and reflect on questions on the slide.</p> <p>Ask for examples and get feedback on the questions from one group at a time.</p> <p>See purpose and procedure at the end of the slides.</p>
<p><b>What is health research?</b></p> <ul style="list-style-type: none"> <li>➤ <b>Systematic learning –</b> <ul style="list-style-type: none"> <li>➤ about health for the benefit of all in the future</li> </ul> </li> <li>• <b>Examples: Bednet study in Kilifi</b> <ul style="list-style-type: none"> <li>• Polio vaccine study: All children protected, disease almost extinct</li> </ul> </li> <li>➤ <b>Research ALWAYS has a question:</b> <ul style="list-style-type: none"> <li>➤ e.g. “can a new drug treat people with malaria in Kenya better than an old drug?”</li> </ul> </li> <li>• <b>Examples: Lumefantrine/Artemeter (Coartem) compared with sulphadoxine/pyrimethamine (Fansidar)</b> <ul style="list-style-type: none"> <li>• Why do so many people with epilepsy not take treatment when there is treatment available?</li> </ul> </li> <li>➤ <b>Working towards health benefits for all = social value</b></li> </ul>	<p><b>Read out the slide</b></p> <p>Add your own words</p>
<p><b>Why do we need research?</b></p> <p><i>Participants’ suggestions</i></p> <p><b>Future benefits for all:</b></p> <ul style="list-style-type: none"> <li>➤ Help in obtaining new effective ways of treatment/interventions/vaccine/drugs</li> <li>➤ Help in improving health to the community/future patients</li> <li>➤ Establish causes of diseases</li> <li>➤ Help in finding evidence based explanations to situations, hence reduce rumours and stigma</li> </ul> <p><b>Benefits to participants involved in research at the time:</b></p> <ul style="list-style-type: none"> <li>➤ Patient gets free treatment/investigation, and close observations</li> </ul> <p><b>Buzz:</b></p> <ul style="list-style-type: none"> <li>➤ Anything you would like to add?</li> </ul>	<p><b>Read out the slide</b>, with suggestion from their baselines.</p> <p>Ask them to buzz briefly if they now will add other reasons why we need research</p>
<p><b>Review of open day:</b></p> <p><b>Examples of Research projects conducted in Kilifi</b></p> <ul style="list-style-type: none"> <li>• Bed net study</li> <li>• PCVIS study (Pneumococcal vaccine )</li> <li>• Coartem study</li> <li>• Aquamat study (Treatment for severe malaria)</li> </ul>	<p><b>Review and discuss briefly examples.</b></p> <p><b>Purpose:</b> To reflect on the usefulness of the work being conducted in your institution, to the community, and to science and “humanity”</p> <p><b>Give examples</b> of current ongoing studies at the hospital that participants can relate to.</p> <p><b>Explain</b> what is the purpose of each of the research studies.</p> <p><b>Ask</b> if participants are familiar with, and/or involved in any of these studies.</p> <p><b>Ask</b> if they have any questions</p>





<p style="text-align: center;"><b>Review of open day</b> <b>Research Review Process</b></p>	<p><b>Explain</b> the research review process in your own words. Let them buzz on how they understand this, and if they have any questions.</p>
<p><b>Summary from open day: Example of research project</b> <b>Research on quinine vs artesunate</b></p> <ul style="list-style-type: none"> <li>• <b>Question:</b> Best drug to treat severe malaria in children?</li> <li>• <b>Quinine:</b> Problems: Long stay in hospital, high cost, complex adm</li> <li>• <b>Research Process:</b> <ul style="list-style-type: none"> <li>– Proposal developed; methods agreed; safety assured</li> <li>– Project reviewed by science and ethics committees, all countries</li> <li>– <b>Implementation:</b> Research teams trained to request consent and administer project. Drugs tested with 1000 children in each of 4 countries</li> <li>– Results analyzed (after 3 years’ research), compared across countries</li> </ul> </li> <li>• <b>Clear results: Artesunate is better than quinine</b></li> <li>• <b>Recommendation to policy makers:</b> Use artesunate to treat children with severe malaria in children, rather than quinine</li> <li>• <b>Policy makers may change</b> national drug policy</li> </ul>	<p><b>Read the slide</b> – review briefly the project described during open day (see full background on this)</p> <p><b>Ask</b> for questions and comments.</p>
<p style="text-align: center;"><b>Research ethics</b></p> <ul style="list-style-type: none"> <li>• <b>What are ethics?</b></li> <li>• <i>Do’s and don’ts of how we interact with other people (written, spoken etc)</i></li> <li>• <b>What are research ethics?</b></li> <li>• <i>Do’s and don’t’ of how we interact with other people <b>in research</b></i></li> <li>• <i>Written e.g. National guidelines, GCP</i></li> </ul>	<p><b>Read out</b> the slide.</p> <p><b>Ask for (and give) examples</b> of how we use ethics in daily life <b>Ask</b> them to buzz – then get suggestions</p>
<p><b>Universal principles of research ethics</b></p> <p><b>Respecting persons:</b></p> <ul style="list-style-type: none"> <li>• <b>FREE CHOICE</b>, based on <b>UNDERSTANDING</b> (autonomy)</li> <li>• Making sure any costs are balanced by benefits to the individual: <b>SAFETY, BENEFITS</b></li> <li>• <b>Fairness</b> in who takes risks and who gains from results of research: <b>NO EXPLOITATION</b></li> </ul>	<p><b>Review</b> the main ethical principles</p>

<p><b>What is the difference between research and clinical care?</b></p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p><b>Matibabu</b></p> </div> <div style="text-align: center;">  <p><b>Utafiti</b></p> </div> </div>	<p><b>Brief intro</b> (<i>topic to be dealt with in detail in the follow-up workshop</i>)</p> <p><b>Explain: Treatment</b> (Matibabu) is basically <b>FOR the patient</b>. Providers often have best information on what care/treatment is needed so they are in best position to decide about this. Important to inform patient but may not be so important for them to make decisions about treatment. Exceptions – surgical procedures?</p> <p><b>Research</b> (Utafiti) is basically <b>FOR society</b>, of which the patient (and their family) is a part, although mostly patients do get advantages through being in research, including closer care.</p> <p><b>Ask</b> for comments, and questions</p>		
<p style="text-align: center;"><b>Difference between Clinical care and Research</b></p> <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top; width: 50%;"> <p><b>Clinical care/treatment</b></p> <ol style="list-style-type: none"> <li>1. <b>Specifies</b> appropriate treatment</li> <li>2. <b>Goal:</b> to provide benefit to the individual</li> <li>3. <b>Care:</b> individualized to each patient</li> <li>4. <b>No consent</b> needed</li> <li>5. It is a <b>right</b></li> </ol> </td> <td style="vertical-align: top; width: 50%;"> <p><b>Clinical research</b></p> <ol style="list-style-type: none"> <li>1. <b>New products</b> on trial /for that illness</li> <li>2. <b>Aim:</b> looking for better ways to prevent diseases/ treat in the future</li> <li>3. <b>Benefit</b> is to entire population</li> <li>4. <b>Written consent</b> is a must</li> <li>5. <b>Voluntary</b></li> </ol> </td> </tr> </table>	<p><b>Clinical care/treatment</b></p> <ol style="list-style-type: none"> <li>1. <b>Specifies</b> appropriate treatment</li> <li>2. <b>Goal:</b> to provide benefit to the individual</li> <li>3. <b>Care:</b> individualized to each patient</li> <li>4. <b>No consent</b> needed</li> <li>5. It is a <b>right</b></li> </ol>	<p><b>Clinical research</b></p> <ol style="list-style-type: none"> <li>1. <b>New products</b> on trial /for that illness</li> <li>2. <b>Aim:</b> looking for better ways to prevent diseases/ treat in the future</li> <li>3. <b>Benefit</b> is to entire population</li> <li>4. <b>Written consent</b> is a must</li> <li>5. <b>Voluntary</b></li> </ol>	<p><b>Explain</b> the differences between clinical care, and clinical research.</p> <p><b>Use</b> (or ask for) examples to illustrate this point.</p>
<p><b>Clinical care/treatment</b></p> <ol style="list-style-type: none"> <li>1. <b>Specifies</b> appropriate treatment</li> <li>2. <b>Goal:</b> to provide benefit to the individual</li> <li>3. <b>Care:</b> individualized to each patient</li> <li>4. <b>No consent</b> needed</li> <li>5. It is a <b>right</b></li> </ol>	<p><b>Clinical research</b></p> <ol style="list-style-type: none"> <li>1. <b>New products</b> on trial /for that illness</li> <li>2. <b>Aim:</b> looking for better ways to prevent diseases/ treat in the future</li> <li>3. <b>Benefit</b> is to entire population</li> <li>4. <b>Written consent</b> is a must</li> <li>5. <b>Voluntary</b></li> </ol>		
<p style="text-align: center;"><b>Exercise:</b></p> <p style="text-align: center;"><b>What information does the mother want, and need?</b></p> <ul style="list-style-type: none"> <li>• <i>Put yourselves in «the shoes of the mother»</i></li> </ul> <p><b>Discuss:</b></p> <ul style="list-style-type: none"> <li>• What information would «you» like to be given – to consider if you give consent to participate?</li> <li>• What would be «your» main concerns?</li> <li>• Which skills would it be important for the provider to practice with «you»?</li> </ul> <div style="display: flex; justify-content: center; align-items: center; margin-top: 10px;">   </div>	<p><b>Exercise 2: What information does mother need</b></p> <p><b>Ask</b> participants to put themselves in the shoes of a mother coming to the hospital with a very sick child, and being asked to participate in research, and to discuss the questions on the slide.</p> <p><b>Get feedback.</b> Relate points to slides above</p> <p><b>Skills needed:</b> Write on a flipchart. Then relate to slides below</p> <p><b>Ask:</b> What might you as a provider feel, if the mother refuses to participate – despite you doing “everything right”, including showing empathy?</p> <p><b>Get feedback.</b> Discuss, with focus on how to recognize and manage providers’ own emotions, and using emotional competence.</p> <p><b>Main point: Recognize your own emotions – step back – and respect parent’s right to refuse</b></p> <p><b>See</b> purpose and procedure at end of slides.</p>		

<p style="text-align: center;"><b>Summary:</b></p> <p><b>What information is the parent given when requested to give consent?</b></p> <p><b>Parents asked to give consent to participate are informed:</b></p> <ul style="list-style-type: none"> <li>• Participation is voluntary – the child will be treated well regardless of whether they agree to participate or not</li> <li>• <b>If participate – the child will:</b> <ul style="list-style-type: none"> <li>– Be observed closely as per the study guidelines</li> <li>– Blood samples taken to monitor the treatment</li> <li>– In case of side effects – necessary treatment offered</li> <li>– Come back for follow-up after 28 days</li> <li>– Transport costs – reimbursed</li> <li>– Free treatment in case of any problem with the child during the follow up period</li> </ul> </li> </ul>	<p><b>Explain:</b> Since research is not primarily for benefit of individual patients, it makes it more important that they have free INFORMED choice about participation.</p> <p><b>Read</b> through the slide: This is what we need to inform potential research participants about when requesting consent</p> <p><b>Ask them to buzz:</b> What things is it permissible to do to people without asking their permission? <i>This leads to questions of ethics –next slides</i></p>
<p style="text-align: center;"><b>Communicating about research:</b></p> <p><b>Skills and attitudes needed to facilitate constructive dialogue</b></p>  <ul style="list-style-type: none"> <li>• Creating safe environment to talk</li> <li>• Respect person, culture, concerns</li> <li>• Empathy; Appreciation</li> <li>• Asking open questions</li> <li>• Listening actively</li> <li>• Engage in dialogue</li> <li>• Encourage discussion among patients/parents</li> <li>• Professional, friendly, competent care</li> <li>• Ability to step back from automatic reactions (e.g if parent refuses)</li> </ul>	<p><b>Animate this slide</b></p> <p><b>Relate</b> the points from the discussion above, to these point</p> <p><b>Discuss, and reflect</b></p> <p><b>Ask them to buzz:</b> Which are attitudes and behavior that can hinder constructive dialogue about research?</p> <p>Discuss briefly (issues are specified on next slide)</p>
<p style="text-align: center;"><b>Communicating about research:</b></p> <p><b>Attitudes and behavior which hinder constructive dialogue</b></p>  <ul style="list-style-type: none"> <li>• <b>Judging</b> patient/parent for their culture, opinions etc</li> <li>• Focus on <b>own needs to recruit</b>, rather than <b>patient's right to volunteer</b>:</li> <li>• <b>Convince, rather than explain</b></li> <li>• <b>No respect</b> or concern for patient's emotions</li> </ul>	<p><b>Animate this slide</b></p> <p><b>Refer</b> points to results of buzzing, above Discuss.</p> <p><b>Review</b> potential consequences (<i>for patient, research in short and long term, and for provider</i>) of provider behaving as described in this slide.</p> <p>Agree that emotional competence and good communication skills are needed by the provider.</p>
<p style="text-align: center;"><b>Demonstration:</b></p> <p><b>Mama Mary refuses to participate</b></p> <ul style="list-style-type: none"> <li>• Mama Mary brings her baby with severe malaria to hospital</li> <li>• Asked to participate in research on artemeter vs quinine</li> <li>• She is scared, just wants her baby to be treated</li> <li>• She says <b>no</b> to participate: «Husband would not agree»</li> </ul> 	<p><b>Demonstration 1: Mama Mary refuses</b></p> <p><b>Ask</b> trainers to demonstrate</p> <p><b>See</b> section after slides for description of roles, and procedures</p>

<p style="text-align: center;"><b>Role play:</b></p> <p style="text-align: center;"><b>Communicating with the mother when the child is stable</b></p> <ul style="list-style-type: none"> <li>In groups of 3 – play roles of nurse, mother and observer</li> </ul> <div style="display: flex; align-items: center; justify-content: center;">  </div> <p style="text-align: center; font-size: small;"><i>Need a drawing of nurse talking with mother at bedside, child lying in bed</i></p> <ul style="list-style-type: none"> <li><b>Tasks:</b> <ul style="list-style-type: none"> <li>Addressing mother's concerns</li> <li>Dialogue on research – to enable her to possibly participate next time</li> </ul> </li> </ul>	<p><b>Role-play 1: Communicating with mother</b></p> <p>Ask participants to divide into groups of 3, discuss questions, and play out the roles.</p> <p>See description below</p>
<p style="text-align: center;"><b>Exercise to dialogue on:</b></p> <p style="text-align: center;"><b>Some possible reasons mother refuses to participate</b></p> <p><b>Lack of understanding about KEMRI, and research</b></p> <ul style="list-style-type: none"> <li>«KEMRI is just interested in research»</li> <li>«KEMRI is a foreign organization»</li> <li>«KEMRI uses patients as guineapigs»</li> <li>«Research only benefits the researchers»</li> <li>«Researchers do what they feel like and when they feel like»</li> </ul> <p><b>Fear – lack of understanding of safety</b></p> <ul style="list-style-type: none"> <li>«Researchers take too much blood»</li> </ul> <p><b>Buzz in pairs (one is provider, the other «patient/parent»):</b></p> <ul style="list-style-type: none"> <li>Pick one concern, dialogue to inform and discuss</li> <li>Repeat, change roles, dialogue about another concern</li> </ul>	<p><b>Exercise 3: Reasons not to participate</b></p> <p>Purpose, procedure and main points: See below</p>
<p style="text-align: center;"><b>Staff skills on communication</b></p> <div style="display: flex; align-items: center;">  </div> <ul style="list-style-type: none"> <li>Policies and guidelines are only as good as the people who implement them!</li> <li>Skills for addressing ethical and communication issues 'on the ground' are critical</li> <li>Training on research, ethics and communication for staff responsible for ICF</li> <li>Training and support supervision</li> <li><b>This training!</b></li> </ul>	<p><b>Read out</b> the points, add your own words</p>
<p style="text-align: center;"><b>Remaining questions – and issues for follow-up course?</b></p> <p><b>Buzz in groups</b></p> <ul style="list-style-type: none"> <li>Bring out questions, discuss</li> <li><b>What is needed</b> – to learn to deal better with research issues?</li> <li>List issues for follow-up course on flipchart</li> </ul> <div style="display: flex; align-items: center; justify-content: center;">  </div>	<p><b>Let</b> participants buzz</p> <p><b>Discuss</b> main points</p> <p><b>Sum up</b> learning, and challenges for providers in short and long term</p> <p><b>Close</b> the session</p>

<p><b>Collaboration KEMRI – KDH: Why collaborate, and how?</b></p>  <p><b>Discuss in groups:</b></p> <ul style="list-style-type: none"><li>• What are advantages of KEMRI-KDH staff cooperating to facilitate smooth running of research projects?</li><li>• What do we do now?</li><li>• What can we do, to improve collaboration?</li><li>• What are sources of information and people to contact for questions and problems related to research?</li></ul> 	<p><b>Exercise 4: Collaboration?</b> Purpose, procedure and main points: See below</p> <p>NOTE 2: This topic is also discussed in the Open Day on research. Can be dropped – or referred to the follow-up course?</p> <p>Collaboration issues are often key when a local institution and a research institution collaborate about conducting and implementing research.</p>
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## Demonstration, role-play and exercises

### Exercise 1: Experiences from participating in research

**Purpose:** To strengthen awareness about aspects that motivate people to participate in a research project, and aspects that may hinder such participation. Furthermore, to strengthen awareness about how experiences participants or their family members or friends have had when participating in research, can influence and shape their opinions about research. Finally, to identify perceptions and questions participants have about research, and give information to address these.

#### Procedure

- Ask participants to share experiences of participating in a research project (or talking with someone who did)
- Let them discuss at their tables and reflect on questions on the slide, especially on what makes a person decide to participate in the research
- Ask for examples and get feedback on the questions from one group at the time. Let a trainer take notes on flipchart on relevant issues – e.g. on what motivates a person to participate in the research
- **Discuss, reflect, and conclude**

**Main points will come from the discussion**

### Exercise 2: What information does the mother want, and need?

**Purpose:** To strengthen awareness of the perspectives, needs and concerns of a parent who comes to the hospital with a very sick child, and of the potential reasons for her responses to a request to participate in research. Furthermore, to strengthen the awareness of the need to practice emotional competence and empathy in this situation, of skills needed to do so, and of potential benefits to the parent, patient, provider and the outcome of the interaction, of using such skills. Finally, to strengthen awareness of what the provider might feel in this situation, and how these feelings might influence the interaction with the parent.

#### Procedure

- **Ask** participants to put themselves in the shoes of a mother coming to the hospital with a very sick child, and being asked to participate in research
- **Ask** them to discuss the questions on the slide.

- **Get** feedback, and relate the info to the slides above, especially to the points about ethics
- **Ask** what skills are needed from the provider, to enable her to identify and meet the needs and concerns of the parent. Write these on the flipchart.
- **Ask:** What might you as a provider feel, if the mother refuses to participate – despite you doing “everything right”, including showing empathy?
- **Get** feedback. Discuss, with focus on how to recognize and manage providers’ own emotions by taking a step back from automatic reactions (e.g. to a perception of being rejected as a person – rather than seeing it a rejection to her professional role as a health provider), and respect the parent’s right to refuse participation.
- **Relate** the points to the slides below

### Main points to bring out

- See points on slides below (skills and attitudes), and above (ethics)
- **Provider’s own reactions:** A common reaction to a refusal will be disappointment, irritation, and maybe anger. The automatic reaction will be to show this, and make the parent feel guilty for saying no.
- **Participants must recognize and acknowledge these reactions,** and learn to take a step back – to recognize and respect the parent’s right to say no to participate in the research. This requires practicing the emotional competence skills.
- **When a refusal is accepted without the parent feeling guilty,** the parent will be more likely to reconsider joining the research later (if this is an opportunity), when she feels her main concern – the health of her child – is under control.

## Demonstration 1: Mama Mary refuses to participate

**Purpose:** To strengthen awareness of parent’s right to refuse to participate in research, and of skills needed to treat the parent ethically. Furthermore, to strengthen awareness of providers’ potential automatic emotional reactions to a refusal, and how to recognize, acknowledge and manage these with emotional competence. Finally, to motivate empathy with the parent, and enable participants to view the issues from her side.

*For more background to the demonstration, see below under Role-play 1. The demonstration is made to show the first stage – saying no to research at admission (when she is scared and worried about her child). The role-play is for the participants to communicate with the parent the next day, when the child is stable, to find out if she is willing to consider participation when she is in a calmer emotional situation.*

### The actors in the demonstration:

#### 1. The provider

You are a nurse/clinician with 5+ years’ experience working in the children’s ward involved in clinical care and research. Last night a parent came with one year old girl with high fever, and reported she had also had convulsions for two days. You suspected severe malaria, and saw the child was eligible for enrolment in the ongoing malaria research project in the ward. You talked to Mama Mary and asked if she would be willing to have her child be enrolled into a research project but she said her husband warned her not get into any research. You tried to convince her, but she persistently said no, she just wanted her child to be treated. You got irritated but tried not to show it. You made sure the child got prompt and effective treatment.



## 2. Mama Mary

You are a mother of six children from a rural village. Today you took your one year old daughter Mary to hospital - she had fever and convulsions for two days before you could get enough money to travel to the hospital with her. You reach the admission desk and are very worried.

You meet a young nurse who receives you well, but then asks your permission to get Mary enrolled in a research project. You say no. Your husband has warned you not to get involved in research, and your neighbours have also had very bad experiences. The provider tries to convince you, but you tell her that your husband would not agree and ask her/him to please just hurry up to give your child treatment.

### Procedure

- Introduce the demonstration to the participants
- **Ask trainers to demonstrate, using the background – above (*be sure to practice with the trainers before the demo in front of the group!*):** The purpose is here NOT to show any “bad” behavior, but simply to demonstrate an acceptance of a parent saying No to participate in research.
- **Ask** the participants to divide into groups of 3, and select roles
- **Explain** – they will now do a role-play to talk with Mama Mary the next day, when the child is stable, to give more info about the research, and discuss her opinions about enrolling Mary in the research project.
- **Give out the role-play** scenario, with relevant roles to relevant actors

Discuss in groups possible reasons why the mother refuses to participate in research

## Role-play 1:

### Communicating with the mother when the child is stable

**Purpose:** To strengthen awareness of a parent’s needs and concerns when she arrives at hospital with a very sick child and is asked for her child to be enrolled in research. Furthermore, to strengthen skills to address the parent’s concerns, and to dialogue constructively with her to give her relevant information about the research. Finally, to strengthen skills to reflect on the possible short term and long term consequences of accepting a parent’s no to letting her child participate in the research.

## Role-play: Mama Mary refuses to participate in research

### 1. The perspective of the Nurse /Clinician

You are a nurse/clinician with 5+ years’ experience working in the children’s ward involved in clinical care and research. You have admitted Mary, a one-year old girl with severe malaria who is eligible for enrolment in the ongoing malaria research project in the ward. You talked to Mama Mary on admission and asked if she would be willing to have her child be enrolled into a research project, but she said her husband warned her not get into any research. The child was very sick on arrival, but is now on medicine and is stable, and settled in the bed.

You have shared the mother’s response with your colleague, and you are now back by the patient’s bedside to talk to her again.

### 2. The perspective of the Parent, Mama Mary

You are a mother of six children from a rural village. Yesterday you took your one-year old daughter Mary to hospital - she had fever and convulsions for two days before you could get enough money to

travel to the hospital with her. The doctors have taken blood to find out what wrong with Mary. They have told you she has malaria and needs to be in hospital for a while to receive treatment. You are worried about Mary's condition as you did not expect to be admitted. The doctor/nurse asked you at admission whether you would agree to enrol Mary in a malaria research project, and explained that if you did, the child would get extra follow-up and care, in addition to the standard care she would otherwise get. At the time you said no, you just wanted them to start treating your child.

You are really worried about having your child participate in the research project as you heard from your neighbours that when a child is enrolled into the research a lot of blood is taken and given to the Kemri "devils" and that your child can even die. Your husband has also warned you not to get involved in "that research business". Although your child is now settled in bed and has received medicine, you are worried about his condition and fear that if you refuse, your child will not be treated well.

You are willing to reconsider having your child be enrolled into research if the doctor/nurse explains to you more about it, and you feel you understand why they do the research, and that it is safe for your child. But you want them to talk to your husband when he comes as well.

You see the nurse/clinician approach your bed, and says she/he wants to talk with you.

### Observer's task

**Please observe:** *Does the nurse/clinician:*

- Try to find out (by observing, listening, asking) what the parent needs?
- Show the parent care and support?
- Respect the parent's views, and his/her right to say no?
- Listen actively to the parent
- Assure parent that the child will have good treatment, regardless of research participation?
- Ask open ended questions to explore parent's fears about research?
- Explain the difference between research and clinical care, and give relevant info?
- Judge the parent?
- Use positive or negative body language?

After the exercise, let the nurse/clinician comment first on his/her own behaviour in the role, and then give feedback (from observer and patient) to the nurse/clinician. Be sure to give positive feedback first, and to be constructive and specific in your suggestions for improvement. Discuss how the nurse/clinician and the parent felt, and how these feelings influenced their actions.

### Main points to discuss after role-play

- Will come from the discussion

### Exercise 3: Some possible reasons mother refuses to participate

**Purpose:** To strengthen awareness of possible reasons parents refuse for their children to be enrolled in research projects. Furthermore, to strengthen respect for the parents' reasons to refuse, and see that these are good reasons – from the parents' perspectives. Finally, to strengthen skills to communicate with emotional competence with parents about these reasons, by identifying the reason, showing empathy, building trust, and giving and discussing relevant information about the research.

#### Procedure

- **Introduce** the exercise by reading out the slide
- **Ask** – which are the most common reasons they think parents have?

- **Discuss briefly.** Emphasize – that fear is often a main reason to refuse, in combination with any of the other “given” reasons like anger (i.e. fear is often the emotion behind)
- **Ask** them to divide into pairs, and carry out the buzzing exercise
- **If possible – ask** a pair to demonstrate how they would communicate with emotional competence with a patient about one of these reasons
- **Ask for learning points, and insights**

#### **Main points to bring out**

- Will come from the discussion

### **Exercise 4: Collaboration KEMRI – KDH: Why collaborate, and How?**

**Purpose:** To strengthen awareness of what are potential advantages (to patients, staff and the institution) of KEMRI and KDH staff cooperating on research projects. Furthermore, to identify what are present actions staff take to facilitate collaboration, and to hinder collaboration, and identify realistic actions that can be taken by specified individuals or sections to improve the situation. Finally, to identify resources on research in the institution whom providers can contact with questions and problems related to research.

#### **Procedure:**

- **Introduce** the exercise by asking if there has been any change in the collaboration since they got enrolled in the communication course. Discuss briefly, acknowledge (e.g. more openness, easier to contact each other, more providers now informed about research, etc). Appreciate the changes.
- **Ask** if there are representatives for KEMRI and KDH at each table. If not – change groups so that both institutions are represented at each table (preferably at least two from each)
- **Ask** the groups to discuss the 3 first points on the slide (explain: the question on resources you will do in plenary)
- **Get** feedback on one question at a time.
- **On question 3** – what can be done to strengthen collaboration – see if you can get volunteers to take action on following up on the points decided on/suggested.
- **Discuss point 4 in plenary**, have a trainer take notes on flipchart. Ask what would be a useful place to make this info available to as many as possible of those who need it. To ensure action – get a volunteer to take responsibility for the task.

#### **Bring out main points from the discussion.**

**Note:** If it is likely that “difficult” issues, or points of conflict may be brought up in this discussion (*you may know this from the discussion on the Open Day*) – bring in someone who can assist you to address these points in the course – someone who is accepted by both sides, and is able to communicate well.

### ***Special section:***

## **An “open day” on research for health providers**

### **Introduction**

Over the years, participants in the communication training courses acknowledged the need to learn more about research activities going on at the hospital 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). 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 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 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 has had impact on health policy in Kenya, and in the world
  - The social values 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 Appendix for a full program and presentations for the open day, and for how to plan the day.

**Timing**

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

**See Appendix in the manual for presentations on the Open Day**