

## Module 8 or 3a

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

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## Background for trainer

Kilifi District Hospital is the base for a number of research projects, which gives the staff opportunities to be involved in a number of supporting research activities (e.g. requesting consent from patients or parents/relatives for participating in studies, informing research participants about various aspects of the research work, requesting extra samples from the patients, etc). To be able to carry out these tasks with confidence and ensure smooth running of research activities, participants require a good understanding of the research, and – they need good skills to communicate with emotional competence.



As specified in module 4 in the first workshop, the knowledge and skills participants are exposed to in the open day seminar on research (during phase 1) and the two research modules in the workshops during the course process is a **supplement** to the specific training staff directly involved in research projects will have (where they are trained in aims, objectives, contents, procedures etc of the specific research project they will work for).

In our 9 months' course process, participants are trained to communicate with emotional competence and provide patient centred care by learning the following main skills:

- Developing awareness of how they communicate, and the effects of their communication on the other person(s);
- Recognizing and managing well their own emotions, as well as those of their patients (and sometimes - colleagues);
- Recognize and step back from their own automatic reactions to emotional challenges;
- Develop trust and build a professional relationship with patients, as a basis for cooperation and good care;
- Respect patients and treat them as persons (not as “medical cases”)
- Not judging patients who do not want to cooperate, but rather respect and explore the reason(s) for the reluctance;
- Appreciate and explore patients' concerns;
- Recognize that patients who come to the hospital feel vulnerable and require empathy;
- Be present and listen well – with ears, eyes and heart;
- Communicate clearly about their intent, both verbally and non-verbally;

- Continuously observe and reflect on their actions and on the effects of these actions on patients and colleagues, and keep learning.

These skills are directly relevant to relating to patients involved in research processes. Thus, the awareness, attitudes and skills presented in “**Communicating about research**” and “**Working confidently in a research environment**” have a much larger place in this manual than it seems from these two modules. 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.

**In this module, the focus is to deepen the participants understanding of research work and the reasons for conducting this work.** Furthermore, it is to gain and practice skills to communicate about research with patients and parents/relatives, with emotional competence and with confidence. When providers gain confidence in conducting a task, they will feel safer in their role, and are thus better able to be aware and present and focus on the needs and concerns of the other person (the patient/parent). When feeling unsafe or insecure, they may have a tendency to not really “see” the patient as a person, nor see her/his real needs – but rather focus on their own need to obtain consent and recruit patients for the study. This has often been the case before, as many providers say they do not feel safe in their skills to deal with research. One consequence of this can be staff “under-communicating” important information about research, such as that participation is voluntary. Thus obtained “consent” may not have been based on the participant understanding the research – and her right to refuse and still be treated well, medically – well enough. If many patients are ill-informed, or feeling “forced” into participating, this may lead to a negative attitude to research in general, and may influence negatively participation in the research in future. In the short run, it may influence negatively the cooperation between the provider and the (reluctant) research participant.

For patients to understand fully their right to voluntarily participate in the research, or say no to participation – they need to understand the difference between what is standard treatment for the patient, and research. They need to understand that they will get good care, even if they say no to the research. **And – to be able to explain this crucial difference well, providers must understand it well for themselves.**

The dilemma presented in the first research module (in the basic workshop) is further explored:

- *The patient (or parent to a child patient) has come for treatment at the hospital. He/she is often worried or scared because of the illness – and is faced with questions about participating in research, and explanations of what the research involves – before getting treatment (unless the case is an emergency).*

This is a “classical” communication challenge requiring the provider to have awareness of and respect for the patient’s main need (treatment), as well as for the need of the PI or research coordinator to recruit patients into the study.

Managers involved in research in Kilifi hospital report that the providers having undergone the training seem to balance this dilemma well, and now communicate better with patients 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, as opposed to before the training, where they used to allow people to join studies even where they did not seem to understand. Course participants report that they now have better informed research participants who trust providers’ explanations. They establish a good relationship and cooperation with the research participants, and this has made the research more straightforward. For example, it is no longer a problem to obtain consent for taking

e.g. extra blood samples, as the research participants trust the providers' explanation about why the samples are necessary.

Understanding and communicating with emotional competence about the difference between research and treatment, or clinical care, is the focus of this module.

### **Emotional competence enables providers to work responsibly with research:**

- **The provider feels safe about recognizing her own emotions related to the research**, and to take responsible action on these before meeting the patient/potential participant.
- **For example**, if she recognizes that she is unsure about why and how the research will be conducted, and how to explain this to the patient – she will decide to get more knowledge. She may also watch a colleague conducting a consent request and discuss afterwards with the colleague. She may ask the colleague to observe her while requesting her first consent, and to give her constructive feedback.
- **The provider feels safe about recognizing the patients' emotions**, and to respect these regardless of what the patient decides.
- **For example**, if a patient with a sick child is worried and very reluctant to have her child involved in a research project, the provider may empathize with the mother and build trust by reassuring her in a kind way about her right to refuse. She will emphasize that her child will get good treatment, regardless of the decision about the research. She may then explore the reasons for the mother's reluctance, if appropriate, and communicate with her about these. If the reasons can be addressed, they may do so together, and then make a final decision.
- **The provider has a clear perspective about the purpose of her work:** To clearly communicate that participation in the research is voluntary, and that the patient will get good treatment regardless of what she decides. When the patient feels genuinely free to decide, she will usually be more open to listen to and understand reasons for why she could participate in the research. The patient does not feel pushed – as the provider is communicating clearly, using her emotional competence and genuinely respecting the patient's choice, while also doing her work to recruit research participants.

**Learning about research is done in 3 stages in Kilifi: The open day on research during phase 1 (observation and reflection phase), Module 4 in the basic workshop, and this module in the follow-up workshop. Please see Module 4 for a description of the three stages.**

### **There are 5 sections in this module. An overview:**

1. **Introduce the topic and establish relevance**, by relating the topic to earlier discussions about research during the course process: The open day, and the module in the basic workshop. 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. **Setting objectives, reviewing reasons why we do research and reviewing their experiences and questions related to research:** Objectives are explained, and linked to earlier learning on research. Participants review their own experiences with research (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. They add the knowledge and new perspectives gained during the course process so far, to this "picture" (slides 3-6)



3. **Examples of research projects in Kilifi, and review of the project presented in the open day:** Examples of research conducted in Kilifi are reviewed, including the project presented in the open day, to re-establish the connection with the work conducted in the institution, and provide a common base for which to relate principles and further learning to (slides 7-8)
4. **The difference between research and medical care:** The difference is reviewed, further explored and exemplified. Reasons why research and medical care is often confused, and why it matters that providers know the difference well and can explain it to patients, are explored. Skills to communicate with emotional competence about the difference are reviewed and practiced (slides 9-17)
5. **Attitudes and skills which help or hinder communicating about research, and summing up the communication challenge:** Review of attitudes and skills influencing how participants communicate about research, and summing up the communication challenges (slides 18-23)



**Time needed:** 2 hours



**Preparation:** Select participant trainers for the demonstration, and practice it.





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

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

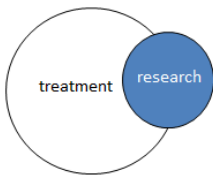
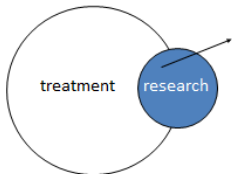


<p style="text-align: center;"><i>Working with emotional competence in a research environment:</i></p> <p style="text-align: center;"><b>Understanding and communicating about the difference between research and treatment</b></p>  <p style="text-align: center;">Follow-up workshop Ane Haaland, Ayub Mpoya, Mwanamvua Boga</p>	<p><b>Ask</b> if anyone has been involved with research since you last met; get a show of hands.</p> <p><b>Confirm</b> that you will discuss their experiences soon.</p> <p><b>Review</b> briefly and refer to open day and module 4 in basic workshop to learn about research in KEMRI.</p> <p><b>Review:</b> Conducting research is one of our core activities at Kilifi district hospital. The hospital is an internationally recognized research institution, and has, in collaboration with the KEMRI Wellcome Trust Programme, participated in research projects that have informed both local and international health policies.</p> <p><b>Explain:</b> The focus of today’s module is to strengthen your confidence to communicate with emotional competence about research, and especially about the crucial difference between research and treatment.</p>
<p style="text-align: center;"><b>Objectives</b></p> <p><b>To strengthen awareness and understanding of</b></p> <ul style="list-style-type: none"> <li>• The difference between research and treatment</li> <li>• Why it is important to understand this difference, and what can be the consequences for the patient if the two are mixed up</li> </ul> <p><b>To strengthen skills of</b></p> <ul style="list-style-type: none"> <li>• Communicating with emotional competence about the difference between clinical care and research to a patient/parent, by explaining and discussing it and by addressing the questions and concerns of the patient/parent</li> </ul>	<p><b>Read</b> out the objectives</p>
<p style="text-align: center;"><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 for a show of hands</b> - who among the participants has been involved in research?</p> <p><b>Direct</b> the “research resources” to different groups, to ensure each group of participants who are less familiar with research, has at least one resource person</p> <p><b>Ask:</b> What should be the function of the resource persons?</p> <p><b>Get</b> some responses</p> <p><b>Agree</b> that the resource persons should help the others explore issues, and help facilitate participants talking and discussing.</p> <p><b>The resource person should NOT act as an “expert”</b> and answer questions FOR the others. He/she should act as a facilitator/trainer, and help others learn – guiding and providing answers and clear confusions only when needed.</p>



<p><b>Why do we need research?</b> <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>Review this slide</b>, which is from Module 4 and contains suggestion from their baselines. <i>(NB – update the slide – if you added reasons during the basic workshop)</i></p> <p><b>Ask them to buzz</b> briefly if they now will add other reasons we need research</p>
<p><b>What do you do differently in relation to research now?</b></p> <ul style="list-style-type: none"> <li>• <b>Share experiences on changes</b> you have made in relation to dealing with <b>patients involved in research</b></li> <li>• Also discuss <b>changes in how you talk with colleagues</b> about research, and <b>how you feel</b> about research now</li> <li>• Identify further <b>learning needs</b></li> </ul> 	<p><b>Exercise 1: What do you do differently now?</b></p> <p><b>Ask</b> them to share experiences on changes they have made when communicating with patients involved in research, and with colleagues</p> <p><b>Ask</b> them to reflect on how changes they have made, have made them feel about dealing with research now, and of any impact on their ability to carry out research work now</p> <p><b>Also ask</b> them to take note of further learning needs they now have</p> <p><b>Let</b> them discuss and reflect at their tables.</p> <p><b>Ask</b> for examples and reflections on one question at a time; discuss</p> <p><b>Ask</b> – what is the effect of the changes you have made, on your ability to carry out this work?</p> <p><b>See purpose and procedure at the end of the slides</b></p>
<p><b>Examples:</b></p> <p><b>Research projects conducted in your institution/area</b></p>	<p><b>Review and discuss briefly examples from research conducted in your institution.</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>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 (<i>see full background on this in Open Day section</i>)</p> <p><b>Ask</b> for reflections, comments and questions.</p>


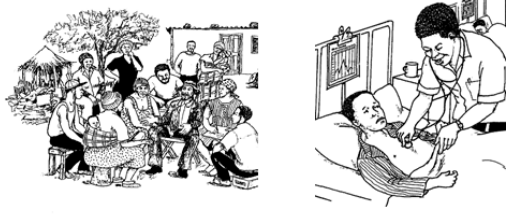
<p><b>What is the difference between research and clinical care?</b></p>  <p><b>Matibabu</b> Faida kwa mgonjwa mmoja</p> <p><b>Utafiti</b> Faida kwa jamii wote</p>	<p><b>Ask:</b> What is the difference between research and clinical care?  <b>Let</b> them buzz.  <b>Get</b> suggestions, write on flipchart.  <b>Main points:</b>  <b>Treatment</b> 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 always be so important for them to make decisions about treatment.  Exceptions – surgical procedures?  <b>Research</b> is basically <b>FOR society</b>, of which the patient (and their family) is a part. However, mostly patients do get advantages through being in research projects, including closer care.  <b>Ask</b> for comments, and questions</p>
<p><b>In our study: What is the difference between research and clinical care?</b></p> <ul style="list-style-type: none"> <li>• Parents are asked to consent to participate</li> <li>• Participation is voluntary – child will be treated well regardless of whether they agree or not</li> <li>• <b>If participate – the child will:</b> <ul style="list-style-type: none"> <li>– Be observed closely (more closely than others)</li> <li>– Blood samples to monitor the treatment</li> <li>– Incase of side effects – necessary Rx offered</li> <li>– Come back for follow-up after 28 days</li> <li>– Transport costs – reimbursed</li> <li>– Access to free treatment incase of any problem with the child during the follow up period</li> </ul> </li> <li>• <b>BUZZ: What is research, what is treatment?</b></li> </ul>	<p><b>Animate this slide</b>  <b>Ask:</b> Reflecting on our malaria drug project, what can you say is the difference between research and clinical care?   <b>Let</b> them discuss briefly at their tables   <b>Get</b> suggestions – add to the list above</p>
<p><b>Demonstration:</b>  <b>Mama’s fears: Will Mary get good care?</b></p> <ul style="list-style-type: none"> <li>• Mama Mary brings her baby to hospital, with severe malaria</li> <li>• Asked to participate in research: Artemeter vs quinine</li> <li>• She is scared, just wants her baby to be treated</li> <li>• She fears that if she says no, her baby will not get good treatment</li> <li>• <b>She reluctantly agrees to participate in the research, because she believes this is the same as treatment</b></li> </ul> 	<p><b>Ask</b> trainers to demonstrate   <b>See</b> section after slides for description of roles, and procedures</p>

<p style="text-align: center;">Discussion in groups:</p> <p style="text-align: center;"><b>What is the difference between research and clinical care?</b></p>  <ul style="list-style-type: none"> <li>• Does this happen?</li> <li>• Why does Mama Mary confuse research and clinical care/treatment?</li> <li>• Does it matter?</li> </ul>	<p><b>Exercise 2: Difference - research and clinical care?</b></p> <p><b>Ask after the demo:</b> Does this happen?</p> <p><b>Get</b> responses (likely: Yes)</p> <p><b>Ask</b> them to discuss the questions in their groups</p> <p><b>Get</b> feedback on the question of WHY research and treatment are often confused, and discuss</p> <p><b>Main points:</b> See below slides</p>
<p style="text-align: center;"><b>Why are research and treatment confused?</b></p> <ul style="list-style-type: none"> <li>• Language e.g. technical, hard to understand</li> <li>• Lack of experience of research, treatment very familiar</li> <li>• Also, these situations often overlap – especially in clinical research</li> </ul> 	<p><b>Animate the slide</b></p> <p><b>Ask:</b> Why is research and treatment confused by our clients?</p> <p><b>Get</b> a few responses, refer to the discussion above</p> <p><b>Read</b> out/add reasons from slide, and discuss</p>
<p style="text-align: center;"><b>Why does it matter if research activities are confused with treatment?</b></p>  <ul style="list-style-type: none"> <li>• Patients refuse treatment – confuse with research</li> <li>• Agree to participate in research because think it is treatment</li> <li>• Participation is not voluntary, thus not ethical</li> <li>• Can influence patient's attitudes to research</li> <li>• Can influence others negatively</li> </ul>	<p><b>(Animated)</b></p> <p><b>Ask:</b> does it matter if research is confused with treatment?</p> <p><b>Get</b> responses, discuss</p> <p><b>Ask</b> – “if it matters, why is this so”?</p> <p><b>Get</b> responses, discuss</p> <p><b>Show</b> the points, discuss further if necessary (to clear confusion, etc)</p>
<p style="text-align: center;"><b>Communicating about research:</b></p> <p style="text-align: center;"><b>How would you explain difference to Mama Mary?</b></p> <p><b>In groups:</b></p> <ul style="list-style-type: none"> <li>• <b>Discuss and demonstrate:</b> how to explain and dialogue about <i>the difference between research and clinical care</i> to Mama Mary</li> <li>• Volunteer to show how you would do it, in front of big group</li> </ul> 	<p><b>Exercise 3: How would you explain to Mama Mary?</b></p> <p><b>Ask</b> them to discuss how they would explain and dialogue with Mama Mary about the difference</p> <p><b>Ask</b> a group/pair to show it in front of the big group</p> <p><b>See</b> procedures and main points, below the slides</p>



<p style="text-align: center;"><b>The overlap between treatment and research</b></p>  <ul style="list-style-type: none"> <li>• Any examples of confusion or overlap??</li> </ul>	<p><b>Explain</b> how the confusion is experienced by using the diagram on the slide.</p> <p>Using our malaria drug trial, patients enrolled in this trial will receive treatment as well as participate in a research project</p> <p><b>Ask</b> for examples from their work place, where they thought research overlapped with care</p>
<p style="text-align: center;"><b>The overlap between treatment and research (2)</b></p>  <p><b>Overlap:</b></p> <ol style="list-style-type: none"> <li>1. Drug trials (the study is ABOUT treatment)</li> <li>2. Research with treatment (you get treatment because you are part of research)</li> <li>3. Ward 1/KEMRI ward (provide routine care too, so people not pressured to join)</li> </ol>	<p><b>Explain</b> the overlap in more depth.</p> <p><b>Give</b> examples, if relevant</p> <p><b>Ask</b> for questions, comments and reflections</p>
<p style="text-align: center;"><i>Communicating about research, with emotional competence:</i></p> <p style="text-align: center;"><b>Skills and attitudes needed to facilitate constructive dialogue</b></p>  <ul style="list-style-type: none"> <li>• Creating <b>safe environment</b> to talk</li> <li>• Recognize and <b>manage emotions</b></li> <li>• <b>Respect</b> person, culture, concerns</li> <li>• <b>Empathy</b>; Authenticity, Appreciation</li> <li>• Asking <b>open questions</b></li> <li>• <b>Listening</b> with ears, eyes and heart</li> <li>• Engage in <b>dialogue</b></li> <li>• <b>Encourage discussion</b> among patients/parents</li> <li>• <b>Professional</b>, friendly, competent care – with awareness and kindness</li> </ul>	<p><b>Animate this slide</b></p> <p><b>Ask them to buzz:</b></p> <p>Which are attitudes and behavior that can facilitate constructive dialogue about research?</p> <p><b>Ask for feedback</b></p> <p>Relate the points from the discussions above, to these points, and discuss</p>
<p style="text-align: center;"><i>Communicating about research, with emotional competence:</i></p> <p style="text-align: center;"><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, opinionsetc</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> <li>• <b>No recognition</b> or understanding of your own emotions</li> </ul>	<p><b>Animate this slide</b></p> <p><b>Ask them to buzz, and refer to the discussion above:</b></p> <p>Which attitudes and behavior can hinder constructive dialogue about research?</p> <p><b>Ask for feedback</b></p> <p><b>Relate</b> the points from the discussions above, to these points, and discuss</p> <p><b>Review</b> potential consequences (for patient, research in short and long term, and for provider) of provider behaving as described in this slide</p>

<p><b>A challenge to health providers...</b></p> <ul style="list-style-type: none"> <li>• Ensuring patients have free informed choice about participating in research</li> <li>• Explaining vs convincing? Long term effect of persuading someone to participate if not really comfortable?</li> <li>• Recognizing critical importance of research in improving health of individuals/populations in future</li> </ul>  <p><b>COMMUNICATION SKILLS – with emotional competence!!</b></p>	<p><b>Sum up the learning, and the challenge</b></p> <p><b>Main points:</b></p> <p><b>Explaining well</b>, while making it clear that patient is free to say “No”, is a challenge – which requires respect for the patient, and skills to communicate with emotional competence.</p> <p><b>Convincing someone</b> who is reluctant or does not want to join, may “solve the problem” of getting study participants in the short term.</p> <p><b>However, it can be unethical, and may backfire:</b> If e.g. the child dies or has serious health problems, the parent may blame the research, and spread negative info about participating in research, in her community.</p> <p>This may affect recruitment in the long term.</p> <p><b>A provider</b> who is well informed about and positive to research and its importance, and alleviate fears where necessary, can inform patients and parents without putting pressure on them, using respect and communicating with emotional competence.</p> <p><b>When patients feel free to decide</b>, they may also listen better to the information, consider it, ask questions, and come to their own (informed) decision.</p> <p><b>Such patients will feel respected for their views</b>, and will likely get a positive view about research. They will in turn influence other community members to join research projects in the future.</p> <p><b>Ask if there are questions</b></p>
<p><i>Staff skills on communicating with emotional competence:</i></p> <p><b>Essential for communicating well about research</b></p>  <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 communicating with emotional competence for staff responsible for ICF</li> <li>• Training +support supervision</li> <li>• <b>This training!</b></li> </ul>	<p><b>Read</b> out the points to sum up skills needed, add your own words</p> <p><b>Reflect</b> together</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>If your research institution is collaborating with e.g. a Government hospital (KDH = Kilifi District Hospital), you may need to discuss how this collaboration functions. You can adapt and use this slide.</p> <p>In Kilifi, there were challenges – many of them linked to communication (or lack of c.), and related to emotions. With the training, these challenges were addressed and collaboration was much improved.</p>
<p><b>Questions?</b></p>  <p><b>Thankyou!</b></p>	<p><b>Let</b> participants buzz and reflect on main points or questions that need to be cleared up, or discussed.</p> <p><b>Run</b> the role-play on Informed consent. <b>See</b> instructions at the end of the module</p> <p><b>Close</b> the session.</p>

## Exercises, Demonstration and role-play

### Exercise 1: What do you do differently now?

**Purpose:** To strengthen awareness of different ways and methods of dealing well with research challenges with patients by sharing experiences about how each of them has related to such situations over the last months, and reflecting on the experiences. Furthermore, to strengthen awareness of methods they have used to successfully relate to colleagues about research, also by sharing experiences and reflecting on them. Finally, to strengthen awareness of how new ways of handling research challenges (by communicating with emotional competence) may have impacted their feelings about and confidence in dealing with research issues, and identify further learning needs.

#### Procedure

- **Ask** them to share experiences on changes they have made when communicating with patients involved in research, and with colleagues
- **Ask** them to reflect on how changes they have made, have made them feel about dealing with research now, and of any impact on their ability to carry out research work now
- **Also ask** them to take note of further learning needs they now have
- **Let** them discuss and reflect at their tables.
- **Ask** for examples and reflections on one question at a time; discuss
- **Ask** – what is the effect of the changes you have made, on your ability to carry out this work?

#### Main points to bring out

Experiences they share – and conclusions to draw from these.

#### **Some examples from a group:**

- *“Realized – feedback needs to be given to patients...”*
- *“Realized – some patients are vulnerable, need to...”*
- *“Research also involves care and treatment, rather than looking at them as research objects”*
- *“Forgot about the person before – saw as a research subject”*
- *“Now – being able to explain better about research to patient, and using examples. I have cleared doubts”*
- *“Before – colleagues used to say – that is for KEMRI. Now – we realize, it is not for KEMRI only. I tell my colleagues that we are working for the community. Colleagues are now cooperating on this”*
- *“If now I am asked to enroll my child to participate in the research, I would not refuse”*

#### **Examples of learning needs**

- Everyone needs to learn about good clinical practice, research ethics and GCT
- The research which is going on in the hospital
- The outcome of the research that has been done

### Demonstration 1: Will Mary get good care?

**Purpose:** To strengthen awareness of what could be parents’ fears when bringing their (severely) sick children to hospital and being asked to participate in research, and how such fears may influence her to agree to research, for fear of not getting good treatment if she doesn’t. Furthermore, to strengthen awareness of how providers can push the parent to agree inappropriately, if provider is not sufficiently aware of and skilled to recognize and manage patient/parent’s emotions well, and respect her right to give voluntary consent. Finally, to motivate empathy with the parent, and enable participants to view the issues from the parent’s perspective.

### Role 1: The provider

You are a provider working in the pediatric ward. This morning you have seen a mother bringing in her three year old daughter Mary with a history of high fever and vomiting. You took blood sample to test for malaria. The results show that Mary has severe malaria.

There is an ongoing study in the ward looking at the effects of a new drug, artesunate, to treat severe malaria. The aim is to compare the effect of artesunate vs the standard treatment, which is quinine. Mary is eligible for enrollment into this study. You walk to Mama Mary and find her seated with her child in bed.

You explain to Mama Mary that her child has malaria, and you would like to enroll her into a study on malaria treatment. You don't pay much attention to see if the mother understands the information you give, nor do you tell her that participation is voluntary. You use some technical words to impress her that this is a good study. You inform her that she will receive very good care if she participates in the study. All you want is for her to sign the consent as you want to achieve your targets for the PI. The mother reluctantly agrees to participate as long as her child gets treatment.

### Role 2: Mama Mary

You are a mother of 5 children from a rural village. Your three year old daughter fell ill with fever and vomiting 3 days ago, and you have been giving her aspirin and plenty of fluids, and watching her closely. This morning she seemed worse, and you decided to bring her to hospital to get proper medicines. The Dr said Mary is too unwell and needs admission, and you reluctantly agree. While in the ward the Dr removed some blood to check if Mary has malaria. She comes back to tell you that Mary does have malaria, and that she would like to enroll her into a study that is looking at the effects of a new drug (artesunate) vs the old drug (quinine) to treat children with severe malaria. The doctor tells you a lot about the study, but you don't quite understand what is the difference between what they are telling you, and simply treating your child. She says that children who participate in the study get extra good care. You feel unsure about the whole thing, and about what happens if you say no. All you want is your child to get well.

You reluctantly agree to participate for fear that if you say 'No' your child will not get good care.

### Procedure

1. **Prepare the demo** with two trainers (and/or participants who are familiar with research). Be sure to have the mother show (nonverbally) that she is uncomfortable with the research, and that she does not understand, and that she is worried and confused. The provider should explain nicely, but quickly and using some big words, and s/he should not pay attention to the mother being uneasy.
2. **Run the demo** in front of the group, and move to Exercise 2 for questions and discussion.

## Exercise 2: What is the difference between research and treatment?

**Purpose:** To strengthen awareness of reasons why patients (and providers) often confuse research and clinical care. Furthermore, to strengthen awareness of the potential consequences of such confusion for patient/parent's participation in care and in research, and for patient/parent's knowledge about and attitudes to research participation and cooperation in the future. Finally, to strengthen awareness of potential consequences for provider's ability to obtain patient's real voluntary consent to the research project, and for his/her ability to establish good relationship and cooperation with the patient/parent.

**Procedures:**

1. **Ask** (in relation to the demonstration): Does this happen? Do you recognize this from practice in your department? Get responses (likely – a yes).
2. **Ask** participants to discuss and list reasons why patients/parents often confuse research and treatment/clinical care.
3. **Ask** them to also discuss the potential consequences of this confusion for the parent/patient's participation in care and research now, and for attitudes to research participation in the communities.
4. **Ask** them to discuss potential consequences for the provider's ability to obtain real voluntary consent to the research project, and for (potential) ability to establish good relationship and cooperation with the patient/parent.
5. **Ask** for feedback on reasons for confusion between research and treatment, and discuss.
6. **Show** the next slide – add the reasons to the discussion. (*Animate the slide*)
7. **Show** the next two slides, on overlap between treatment and research, with examples
8. **Ask** for feedback on "Does it matter" if research and treatment are confused; discuss
9. **Show** the slide "Why does it matter...." – add reasons here to the discussion above.
10. **Conclude the discussion.**

**Main points:**

From the slides.

**Exercise 3:**

**Explaining the difference between research and treatment**

**Purpose:** To strengthen skills to explain and dialogue constructively about the difference between research and clinical care. Furthermore, to strengthen confidence in their ability to carry out such a dialogue, and stimulate motivation to do so in different hospital contexts as and when opportunities arise – with the intention of spreading more knowledge about research.

**Procedure:**

1. **Ask** groups to discuss how they would explain and have a dialogue about the difference between research and treatment, with Mama Mary.
2. **Ask** them to demonstrate to each other in the group how they would do it (i.e. not just "talking about it", but also "showing it")
3. **Ask** a volunteer pair/group to come up and show how they would do it, in front of the big group
4. **Ask** participants to give constructive feedback: what did they do which was good, and where would others have done it differently. Note points on flicharts (good practices, and points to improve), and discuss

**Main points:**

1. **Method:** Explanation must not be too long, provider must engage the mother in a dialogue (e.g. by asking her questions, not "just" explaining, in a monologue)
2. Provider must refer to her concerns, not just "spout off" a general explanation
3. Provider must show empathy
4. Check for understanding
5. **Contents:** Essential to make it clear that the child will get good quality treatment, regardless of whether the mother agrees to participate in research, or not. Also essential to make clear that participation is voluntary.
6. **Form:** The provider should be friendly, encouraging and respectful

## Role-play 1: Giving Informed Consent

**Purpose:** To strengthen awareness of the need to communicate with emotional competence, the difference between research and clinical care. Furthermore, to strengthen skills to do so  
To strengthen awareness of reasons why parents refuse to participate in research, and strengthen skills to discover what these reasons are, and to step back from any automatic reactions to judge the patient. How to recognize and step back from a sense of feeling like a failure. From taking it personally, to using communication skills to explain informed consent to a parent.

### The field worker

You are the Fieldworker with 5 years experience working in the children's ward involved in clinical care and research. You have admitted a 1 year old boy with malaria who is eligible for enrolment to the ongoing malaria research project in the ward. You have talked to the mother if she would be willing to have her child be enrolled into a research project but she has said her husband warned her not get into any research.

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

### Parent:

You are a mother of 7 children from a rural village admitted with your 1 year old boy who has had fever and convulsions for a day. The doctors have taken blood to find out what wrong with your child and they have told you that she has malaria and needs to be in hospital for a while to receive treatment. You are worried about your child condition as you did not expect to be admitted. The health provider has approached and would like to talk to you about a malaria research project that they would like to enrol your child to. You are really worried about having your child enrolled into a 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. You look really worried over your child's 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 explains to you more about it.

### Observer's task

#### Does the Fieldworker

- Try to find out ( by observing, listening, asking) what the parent needs
- Give the parent emotional care
- Listen actively to the parent
- Ask open ended questions to explore parent's fears about research
- Explain the difference between research and clinical care
- Use positive body language
- Judge the parent

#### Procedure

- How was it seeing the roleplay?

#### Main points to be brought out

- Doing this roleplay is not easy
- The mother had a lot of concerns based on misconceptions

- What are perceptions based on lack of information and understanding
- Culture – respect – husband needs to be here: Not to take them as not empowered enough, and force a decision on them
- Look at - if forcing a decision, what could be the implications for the mother
- The mother was worried about the child being very sick – need to recognize the worries, and take care of them – before explaining research: Very important
- Recognize that the primary objective is to seek treatment – that’s what they need to hear about. Their need is not to hear about research – this is OUR need.
- Have her worries taken care of
- Whether research or clinical care – approach of HW should be the same – seeing the pas P, being friendly etc. Individuals. Core values – cutting across: Be polite, being there for them