Slide 2 & 3, Learning Objectives and Session Outline

Slide 2

Outline the learning objectives and the session outline. Reinforce the message that IR must be responsive to the community's needs.

All stakeholders must be engaged as part of this process and ensure the appropriateness of study design.

Slide 3

Outline the learning objectives and the session outline. Reinforce the message that IR must be responsive to the community's needs.

All stakeholders must be engaged as part of this process and ensure the appropriateness of study design.

Slide 4

Quickly review the rationale for IR highlighting the fact that interventions may not be effective, although they may be known to work. List the many potentials for weak links along the chain between having a good intervention and implementing it successfully, linking to the fact that engagement with relevant stakeholders at each link of the chain is critical.

Slide 5

Present case study example – suboptimal uptake of ITNs for malaria prevention.

Special Note to facilitator: Also mention policy-makers' motivation to reach Sustainable Development Goals (SDGs) rather than focusing on the issue of whether malaria is an actual priority in that particular district.

Slides 6 & 7 Early Thoughts on an Implementation Research Study 2: How to Increase The Appropriate Use of ITNS?

Slide 6 & 7

Make it **interactive**, before going through the slides, by asking participants how they might approach the study to improve uptake of ITNs in the community; brainstorm all aspects that should be considered. Summarize the participants' responses and quickly take them through the questions in slides 6 and 7 – spending less time on points already discussed and more time on entities that were missed.

In planning IR, think of all components from start to finish that are to be considered and taken into account (identify early on the potential challenges and barriers, all the appropriate actors/stakeholders and generate plans to best engage them for optimal collaboration).

Special Note to facilitator: Questions to ask during the planning stage:

Is research question demand-driven?

Is there an idea why uptake is not optimal?

What is the intervention type?

Who/what will be the research subjects?

Who/what will be the units of intervention?

Who/what will be the units of observation?

Who needs to give informed consent and how?

Who/what bears risks?

Who/what gains benefits?

Are vulnerable group included fairly?

Is this research vs. practice?

Is there awareness of cultural sensitivity?

What is the potential for ancillary care needs and follow up?

What are acceptable standards of care?

Who/what will be in the control groups, are they required
and ethically justifiable?

Who will have responsibility for data management
and data ownership?

Who will have responsibility post-study?

Does the research strengthen the local health system?

Characteristics of IR. All IR should originate from the identification of a relevant problem that is a local priority. To have maximum impact, the IR must be 'systematic' and strive to achieve the best possible scientific results within realistic circumstances. It should be multidisciplinary as there are many stakeholders who should be involved at all stages. It must be relevant to the local context and should have inherent flexibility to respond to changes in local circumstances, or adapt fast and respond to feedback in a timely and effective manner.

Slide 8

Characteristics of IR. All IR should originate from the identification of a relevant problem that is a local priority. To have maximum impact, the IR must be 'systematic' and strive to achieve the best possible scientific results within realistic circumstances. It should be multidisciplinary as there are many stakeholders who should be involved at all stages. It must be relevant to the local context and should have inherent flexibility to respond to changes in local circumstances, or adapt fast and respond to feedback in a timely and effective manner.

Slide 9

Depicts the interacting domains that must be considered in planning any IR study. Discuss the importance of each of these features in the feasibility/impact/success of an intervention. All need to work together and complement each other.

Slide 10

Summary of main steps/considerations in planning IR which will be discussed individually more fully in the rest of the module:

- Responsiveness to a community's needs
- Scientific rationale
- Study design
- contextual factors
- Selection of research participants
- Weigh risks and benefits
- Community and stakeholder engagement
- Iterative process

Slide 11

Emphasize that the main purpose of IR is to be responsive to the community's needs and NOT to be driven purely by external actors with diverse agendas. The ethical obligation is to conduct studies that are relevant and responsive, and to address the local problems as effectively as possible.

How does one determine that a study is indeed responsive to the needs of the community? Ideally this requires some data, as the existing data may not always be reliable. The best efforts should be made to use the best available data, which is often generated by the health system and in the hands of policy-makers, thereby having enough information to permit engagement with policy-makers and determine the relative priority of the particular problem. Ethical consideration should be given to conducting IR on issues of high priority where the impact could be expected to be highest, or possibly those that are highly cost-effective. This engagement with the policy-makers ensures that they have identified the same health issues that need to be addressed and, therefore, should be motivated to participate and support the IR. If the IR is successful, the policy-makers should commit to ensuring the financing and sustainability of the intervention. This step requires a certain robustness of the health system; weaknesses in the health system functioning could be identified and highlighted as subjects for future IR studies.

Slide 12

Once the problem is identified and study is planned, the rationale for the study and consideration to intervene should be reviewed. Is the study worth doing, what are the available tools to address the question, how reliable are the tools? Bear in mind the important obligation not to do harm. Has something similar been done elsewhere, what similarities or differences may impact on the new study? This leads to the ethical concept of equipoise, for example, if true uncertainty exists for generalizability of prior studies to current context to justify study.

See more detail in the next slide.

Slide 13

The **ethical concept of equipoise** (meaning there is genuine uncertainty whether an intervention is beneficial or not) is fundamental to any study otherwise it would be unethical to include a control/untreated group if the treatment were already known to be beneficial. In IR, the equipoise may no longer lie in the clinical effectiveness of a known intervention (e.g. ITNs do reduce malaria transmission and proof of concept that an effective intervention does exist), but in how to achieve the target ITN distribution and appropriate use in the new context in which the study will be conducted. The equipoise may, therefore, be contextual and the study worth doing ethically.

Equipoise is necessary to justify any study, especially as some subjects may be exposed to harm and this would only be potentially justifiable if true equipoise exists.

Slide 14

Various study designs are listed; examples could be **discussed for each study design. Depending on the time availability,** *the facilitator could either give this as an activity or ask participants to identify potential ethical issues that might arise in each design.* A printout of activity table 1 in Annex 2 can be distributed to participants to enable the discussion.

Slide 15

It is also important to determine whether a proposed intervention will be tested as a study, or as quality improvement. This may not be easy to determine, and may be important as in some places QI does not require ethical review. The labelling of a study as IR or quality improvement may be less relevant; understanding the ethical considerations for the study is key (this is discussed to some degree in Module 1). Any exposure to potential risk, having a control group, need for consent, questions on whether or not the existing standards of care are acceptable, etc., may all be relevant considerations of any quality improvement or IR that should be subject to ethical review. Engaging with research ethics committees at an early stage will help researchers to determine if their proposed research is exempt from ethics review. When in doubt, the rule is to ask, discuss and deliberate with the ethics committee. Investigators should not make the choice.

Slide 16

Contextual factors must be considered at all times, cultural sensitivity, geographical location/challenges, community structure, political climate, etc., which will all potentially have an impact on the study's conduct and outcomes. Therefore, close monitoring should be in place to ensure a responsive iterative process to adapt the study as and when potentially unidentified barriers/problems arise.

Slide 17

The selection of the study's participants is crucial to determining the true effectiveness of an intervention, to understand uptake in all groups, and to ensure that the most vulnerable are also reached appropriately. Selection of research participants must be careful to consider: (a) all affected groups; (b) fair inclusion of vulnerable groups without disproportionately burdening or omitting them; (c) justice implications of inclusion, distribution, or risks and benefits.

Slide 18

In every community there are vulnerable individuals or groups. Ask the participants how they would identify vulnerable groups. They must be identified and engaged with equitably as they may often be the group in most need of the intervention. Vulnerability may not be obvious and careful attention should, therefore, be paid to potential sources of vulnerability within a community, to ensure equitable participation in the research, and to ensure that the research does not exacerbate people's vulnerable status.

Slide 19

Determination and discussion of all possible harms/risks is crucial in study design, and need to be clearly identified and discussed with the stakeholders. This will ensure that the risks are either avoided or mitigated through appropriate measures and consent. There may be broader risks possible in IR compared to clinical research; risks beyond those experienced by individual study participants must, therefore, be anticipated. As with clinical research, any direct risk to an individual participant, e.g. a medication side effect should be identified and communicated effectively prior to obtaining informed consent. Risks beyond the individual may include social harm, e.g. stigmatization of communities or health centres, disruption of social order, financial harms, especially if incentives are used, as these may lead to fraud and abuse, and the destabilization of the local economy. Communal harms may involve neglect of other health priorities or strong promotion of one aspect of health; harm to the health system may occur if workers/resources are diverted to specific areas whilst neglecting others. Trust can be undermined if a study does not deliver as promised, etc.

There may also be undue benefits from a study, e.g. taxi vouchers benefit the taxi drivers financially, although

a commitment to service provision is necessary as well for out-of-hours service, e.g. at 02:00 or on weekends.

The mHealth programme benefits the mobile-phone providers. Care should be taken that these providers do not take advantage of their clients, or that other groups are further disadvantaged because of these advantages, e.g. taxi prices are increased for all users.

Slide 20

Unanticipated harms or hidden harms are important to consider at the study planning stage. Discuss the importance of unforeseen risks or the imbalance of a benefit accrued by different groups from those who experienced the risk (reliance on solidarity). Careful and comprehensive stakeholder engagement and discussion should help to identify and, if possible, minimize these unforeseen risks or ensure that they are discussed openly in the consultation and consent processes.

Slide 21

How to identify the non-obvious risks? This requires 'meaningful' engagement, which is open, honest, sincere and transparent, and truly aims to bring the community together as equal partners in the research process. This should allow open discussion, no judgement, no patronization, and a willingness to take feedback and adjust the research process based on the community's needs, understanding, culture and response. It is important to understand the community's culture during the design of an intervention so that it is respected and so that no cultural barriers are defined. Similarly, the roles of the village head, women, etc., must be understood in context. If the community is successfully engaged, has a strong interest in benefiting from the IR, and is convinced that it will address an important problem for them, collaboration, acceptance, adherence and participation are much more likely to be achieved. The aim of 'Community Engagement' is not only to garner participation but also to develop a fully participatory relationship that develops joint strategies to answer relevant questions for the community.

Slide 22-33, Introduction of Activity

Ask the participants to form three small groups and give them a blank copy of activity table 2 which can be found in Annex 3.. Each group fills in three rows (total nine rows). The time allocated for this activity is 10 minutes. They then come together for a plenary discussion on the potential ethical issues that might require different consideration in IR because of these differences. The facilitator could suggest a few options to illustrate how the exercise should be conducted before the group discussions.

S

lide 34

This slide indicates the various stakeholders with whom engagement would be necessary using the example of immunization; it is an animated slide. Ask the participants to propose the various stakeholders; summarize and emphasize the need for community engagement at various stages, without which uptake of vaccination could be low.

Slides 35–37: Stakeholder and Community Engagement

Activity: See case study 1 in Annex 1 on mHealth in Bangladesh. Read through the contents of slides 35 and 36 and ask participants to identify potential stakeholders. Allow 5 minutes for discussion with their neighbours. List the stakeholders on a flipchart. Highlight the fact that they are likely to be different for each project. The list needs to be as comprehensive as possible and an effort must be made to engage with each of them. Consideration of the ultimate audience for the research is also important at the planning stage although engagement is not likely at that stage. The thoroughness of stakeholder engagement will improve the rigour of the results and, if the process is well described by the researchers, can assist in the interpretation of generalizability of the research findings to elsewhere.

Slides 38

Important points relating to the stakeholder engagement. It is important to identify all relevant stakeholders who might be impacted by the study or who might have an impact on its execution; this includes those not obviously relevant at first. Stakeholder engagement is important to develop collaborative and respectful relationships and to demonstrate transparency in the research process. This will ensure open channels of communication and feedback providing the most 'true' (rigorous) outcomes of the intervention. In order to gauge stakeholders' attitudes, understanding and potential resistance to the intervention, their reasons for this, and to develop joint strategies to improve collaboration, all stakeholders should be engaged in an open and honest way. It is crucial that the community in which the study will be implemented is fully engaged early on to ensure that they feel the problem to be addressed is a priority for them, that the proposed methods are acceptable to them, and to ensure that vulnerable groups within the community are identified and heard. Identification of appropriate community representatives is also important.

What criteria should be used to identify the representatives (discussed later)? These representatives should be core members of the research team.

Slides 39

Community engagement is a component of stakeholder engagement. It is a collaborative process of engaging with the 'community', and will be defined in a subsequent slide. It must be made clear to participants that community engagement should never be regarded as a required formality in order to obtain ethics approval for a proposed study. Instead, it must be regarded as a core activity of a research endeavour and integral to the research process. Any engagement with the community must be meaningful and respectful, and not comprise rhetoric and/or symbolic gestures. Without community support and participation, a proposed research endeavour may not be possible.

Slides 40–42: What Constitutesa 'Community' and Who Makes This Determination?

Description of possible definitions of community (there can be others). The 'community' that must be engaged should preferably, and when/where feasible, be drawn from the proposed study's target cohort and there should be a match for factors such as sex, gender, age, culture, etc. For example, a study focusing on women should not consult only male members of a community, as they cannot legitimately claim to represent women. The target disease group is fundamental in determining the community, but tactful attention should be paid to avoid stigmatization. Patient groups and community organizations could be ways to select representatives. Investigators could consider establishing a Community Advisory Board (CAB) to engage with a community or identify existing CABs with which to work. Such a body must have legitimate representation. How to choose the community representatives is a challenge. In some communities and depending on the research question, it may seem relatively clear, e.g. the local chief could represent the community in determining participation in vector control activities for malaria. However, an elderly male chief is unlikely to be the best representative for activities aimed at young women to reduce the risks of HIV transmission. Similarly, if a certain group within a community is relatively marginalized, e.g. a group of Muslims in a Christian community or vice versa, it is important to ensure that the more vulnerable groups are equitably represented, and their concerns are heard and needs respected. These determinations are challenging and there should be some form of ongoing monitoring of how fairly the representatives do indeed represent the interests of the community. Participation of local researchers and anthropologists is likely to be valuable in this contextual understanding process.

Conflict of interest should also be considered, e.g. if the local chief owns the local taxi, should he be the one to consent to community participation in a taxi voucher incentive scheme?

It is important to respect local cultural norms. However, the impact of these norms on the IR process or participation should be considered, e.g. can patriarchal males adequately represent the needs/concerns of pregnant women? An ethical dilemma may arise when the target group, e.g. pregnant women, cannot culturally speak for themselves. Is it then legitimate to enrol them in a study without their true consent? Culturally, the women may implicitly accept participation without question once the patriarch has consented. How does a participant opt-out if their representative has given consent? Should a process be in place for this? If yes, what would be the social consequence for this individual? If homosexuality is illegal in a country, how could one target HIV prevention in the homosexual community? Who would be the correct representative of that community? How would one avoid stigmatization?

Slide 43

Differences between community engagement and public engagement. Both are necessary, community engagement might concern the specifics of a study whilst public engagement may be to manage fears and anxieties in the broader community or to educate the public about the need for research studies, etc.

Slide 44

Community engagement is not a one-time event but a continuous process. The continuum of community engagement can range from stressing the importance of two-way communication, so that researchers can understand the needs, fears, points of view, suggestions of the community, to empowering the community as research partners by consulting and developing a collaborative relationship.

Slide 45

The value of community engagement, i.e. 'intrinsic' relating to value for the community and to building the relationship with the community. 'Instrumental' value works to enhance the operationalization of the research through communication and feedback.

Slide 46

Strategies for community engagement. Emphasize the importance of community ENTRY as the first step to the engagement process. This must be done carefully and respectfully, and information must, therefore, be obtained to understand cultural norms, local hierarchy, etc., before engaging with the community. Community engagement can be approached as a direct process with the target community or through their representatives.

Direct community engagement by the researchers with the community could include using community meetings or town hall meetings. Caution must be exercised to ENTER the community in a culturally appropriate and respectful manner, and not to destroy all trust and respect from the start. Researchers should have some prior knowledge of the community and its structure. Depending on the context, researchers might need to do some form of social mapping to identify the key stakeholders with which to engage, and the appropriate entry process.

Community engagement can also be carried out through representatives. Representatives could always be selected from patients and community organizations or investigators could consider establishing a CAB to engage with a community. Such a body must have legitimate representation. The Board can liaise with the research team to optimize feedback and information flow.

An example of community engagement is 'The Navrongo model' which is drawn from experiences in Northern Ghana. This process begins with a community entry process where permission is initially sought from the chiefs and leaders. This is followed by a step down approach to meet people at various levels of the community's hierarchy to gain progressive trust and demonstrate respect for the social structure and culture. Ultimately, if possible and relevant, informed consent is obtained from the individuals, after gaining permission at higher levels within the community (Tindana PO et al., 2011).

Encourage participants to share experiences of a community engagement model that they have used in IR, or other types of research, describing the challenges and what worked well.

Demonstration of true respect for the stakeholder community is crucial. IR is multidisciplinary and studies many facets of the implementation process in addition to examining clinical effectiveness. All aspects of the proposed process must, therefore, be understood from the community's point of view. It is crucial that information is exchanged in an understandable and culturally appropriate way. The value of multidisciplinary researchers, e.g. anthropologists, add value to the researchers' understanding of the context in which they are working and assist in the development of appropriate communication tools. The line between clinical care or public health activities and research are often blurred in IR and, therefore, the interactions between the community and the researchers are not as clearly understood or defined. In much clinical research, 'traditional' research consent is often obtained from individuals, opt-out possibilities exist and standard of care is established and acceptable. In IR, the intervention may be the only clinical option available, the community may be randomized and individuals may not have opt-out possibilities, and consent may be obtained at a community level. Therefore, good engagement with the community is essential in ensuring that these factors are understood and the community has an opportunity to voice concerns and question the intervention. Similarly, engaging the community is crucial for researchers to understand the risks, practice respect and build legitimacy.

Slide 47 & 48: Ethical Norms That Underpin The Notion of Community Engagement

Provide examples of how these concepts apply to the research context.

Special Note to facilitator: As these principles have been covered at length in the previous modules, it would be ideal to actively engage the participants in a quick round of discussion. In this way, the knowledge gained in the previous sessions can be evaluated. Do not repeat verbatim the contents detailed here; it has been elaborated for the facilitator to familiarize with the concepts.

Respect for persons: Ensuring that research participants (especially vulnerable participants) can decide independently whether or not they want to participate in a proposed research initiative. This respect also includes respect for their unique needs, preferences, values and independence. From a stakeholder engagement point of view, it is important that research participants are fully informed and all options for participation or opting out of the research are explained and understood. The choice of gatekeeper is also a question of respect for everyone because it ensures that they are truly representing all subgroups fairly and equitably. Also, understanding the culture and context in which the study is to take place ensures that potential cultural or other barriers/problems are identified so that they can be addressed or the process modified accordingly.

Beneficence: Researchers should ensure that they always act in the best interests of the research participant. Stakeholder engagement ensures that the researchers become aware of the research participants' perspectives, culture and context to avoid any unanticipated harmful consequences, such as stigmatization, etc. Understanding the participants' and researchers' responsiveness to the research study is crucial to minimizing harm.

Justice: Researchers should act fairly in selecting research participants and make sure that they are not unduly burdened by their participation. Stakeholder engagement is important so that all relevant actors and participants are identified and included equitably, with special attention being paid to identifying and including vulnerable groups. Any non-obvious risks should also be identified. Engagement with different groups on topics such as relative risks and benefits is important for transparency and informed consent. In addition, early engagement with policy-makers and finance actors is important to ensure sustainability over the long term should the intervention prove effective.

Accountability: Researchers must assume responsibility for the consequences of their actions and decisions in pursuit of their research. Stakeholder engagement is important to identify the potential risks and those with the responsibility for them, such as ancillary findings, or protection in the case of health workers operating outside of their normal roles, etc. Engagement and communication about clear accountability structures is part of respect and transparency.

Solidarity: Arises from having common responsibility and interest within a group, which includes concern for those who are less fortunate or vulnerable, and action to help such people. Meaningful objective stakeholder engagement is important to discuss risks and benefits. In some interventions, risks and benefits are borne by different groups, the group experiencing the risk must, therefore, understand the principles of solidarity and decide whether they agree.

Transparency: Researchers must act in a way that facilitates information disclosure, clarity, and accuracy, thus making it easy for others (including research participants, the host community, and authorities) to see what actions they are performing, and why. Transparency is at the heart of stakeholder engagement, demonstrating respect for the research participants and permitting objective evaluation and feedback of the design, planning research goals, process, risks, potential outcomes, data handling, data analysis, accountability chains, sustainability, etc. All are important factors in demonstrating true respect for the research subjects, and permitting maximum autonomy, buy-in and participation.

Sustainability: If an intervention proves to be effective and sustainable, further financial resources will be directed towards it to permit it to be rolled-out on a broader scale, which is the ultimate goal of IR. Early engagement with health policy-makers and financers/funders is important to initiate sustainability planning should an intervention be effective. If there is no possibility of sustainability, it is ethically questionable whether an intervention should be tested in that particular context.

Public justification: Researchers must make sure that a proposed study is acceptable to potential research participants and the host community. At the heart of stakeholder engagement to ensure that all actors understand the necessity for the research, the goals, the process, the potential risks and benefits, and the long-term implications. The research must be responsive to the needs of the community and this should be determined through open and effective community engagement. It is important that the researcher should be able to explain to the community why specific decisions have been made.

Ask participants for any other principles?

Choice and empowerment: As partners in health-care decision-making affecting their lives, patients have a right and responsibility to participate to the level of their ability and preference. Stakeholder engagement takes full advantage of the exercise of choice by sharing all relevant information to maximize autonomy.

Informed consent: Participants must be given the choice of whether or not to participate. Stakeholder engagement should provide space and time so that all community members can voice their concerns, ask questions and participate in their community's decision-making process. Where possible, opt-out possibilities must be clearly communicated before obtaining informed consent.

Patient/community involvement: This is important so that they can share responsibility in health-care policy-making. This is done through meaningful and supportive engagement at all levels, and at all points in the decision-making process to ensure the patients are at the centre during the design of the intervention.

The public does not have equal responsibility with policy-makers for decision-making and policy-making, but their input must be considered, although not all groups will be equally satisfied with the outcome. However, if it is transparent, at least the process will be understood.

Slide 49

Reiterate the three core imperatives:

1. Identify and manage non–obvious risks, largely only identifiable through effective community engagement.
2. Demonstrate and practice respect for the community.
3. Be transparent and honest to build the legitimacy of the project.

Stress the importance of building the legitimacy of the project.

Legitimacy is an ethically important cornerstone for any IR project. It guarantees the project is relevant for the community, is based on addressing needs they perceive as important, ensures trust that the ultimate goal is to improve the health-care delivery process for them, and contributes to strengthening their health system, and will have ongoing benefits. Transparency is a key component when building legitimacy – explaining where funds come from, who has allegiances, where and why the study is being conducted, what will happen with any samples, explaining the process of maintaining confidentiality, etc. Such relevant information should be shared with all groups of stakeholders to ensure trust at all levels. Legitimacy and trust should also be maintained throughout the research process with regular feedback to and from the community.

'External' legitimacy must also be achieved through the review of the research proposal by experts for scientific rigour and by research ethics committees for public assurance.

Slide 50

Despite the compelling rationale for community engagement, it is important to anticipate the practical challenges that may arise.

This could be an interactive process by asking participants to identify any potential challenges and then go through the practical challenges listed in the slides. It should also be highlighted that they have implications in terms of time and possibly resources. They should, therefore, be planned and budgeted for early on

Slide 51

Brief review of how to go about embarking on stakeholder engagement which is a transparent, fair process aiming to engage them as research partners. Practical issues, such as timelines and engagement venues, need to be given consideration. These will likely vary from study to study but must be carefully considered. They may require some pre-information or a preliminary meeting and may need to be revisited at a later date, after contextual and cultural considerations have been understood, to ensure effective information transfer in both directions. NO 'one-size-fits-all'! Needs to be 'TAILOR-MADE'.

Slide 52–55: Case Study 1: mHealth In Bangladesh

Allow the participants to refer to the contents of the mHealth case study; then introduce the role play on stakeholder engagement .

Separate participants into two large groups. Group 1: stakeholder engagement with all the stakeholders except the community, and Group 2: community engagement.

In each group, there will be two researchers and the rest of the group will be assigned roles . Their role is outlined on a sheet of paper to be kept to themselves and the information shared only if requested. Roles listed in Annex 4 and 5. Print, cut and distribute one role per participant.

In some cultures, participants are very shy and inhibited and it may not be helpful to do role-play spontaneously. It would be ideal to form the groups and assign roles a day prior to this activity. Share the document on the role each actor is expected to play in the 'community engagement' and 'stakeholder engagement', as this will allow participants to read and be prepared for their role.

Timing: 45 minutes.

10 minutes – instructions from the facilitator and planning by participants.

20 minutes – to do the activity (followed by a tea break).

15 minutes – debriefing.

Two researchers should be given 7 minutes to plan how they wish to engage (as per Slide 51).

Individual participants will each be given only the description of their character, some will have suggestions to be loud, others may be quiet and shy, and not volunteering information which is relevant or have other priorities (e.g. women being raped on their way to get water is more a problem for them than the study topic). Do not necessarily tell researchers there is hidden information, but let them know that they can engage with different groups separately, if they wish.

Slide 56–57: Case Study: mHealth in Bangladesh

If the participants are unwilling to carry out role-play, group discussion can be encouraged, using case study 1 in Annex 1. See related guiding questions in Annex 6.

Slide 58

Emphasize the need to continuously monitor and communicate with the stakeholders. Similarly, emphasize how imperative it is to project forward into the study to ensure responsiveness, scientific rigour and ethical conduct.

Slide 59

Summarize the key messages.