The focus of implementation research (IR) is on the systematic approach to understanding and addressing barriers to implementation and scale-up of effective and quality health interventions, strategies and policies. TDR undertakes a range of activities aiming to strengthen IR capacity in low- and middle-income countries, including the development of training tools, such as the IR Toolkit (https://www.who.int/tdr/publications/topics/ir-toolkit/en/).

The IR Toolkit highlights the importance of the submission of IR proposals to research ethics committees. Research ethics committees may not be familiar with reviewing IR protocols. The need was therefore identified to develop guidance for researchers and research ethics committees on the ethical implications of IR.

TDR and WHO’s Global Health Ethics team have jointly developed a training course on the important ethical considerations in IR, with guidance for course facilitators and participants. The ultimate aim of these training materials is to help strengthen national and international capacity for review and conduct of IR.

This facilitator’s guide is comprised of 6 modules:

Module 1 begins with an introduction to IR and an explanation of how IR differs from basic science, clinical research, epidemiology and surveillance. Overlaps with quality improvement and public health practice are also discussed.

Module 2 broadly discusses the ethical frameworks of medical ethics, research ethics and public health ethics and how these are all relevant to IR.

Module 3 addresses ethical issues related to the planning phase of IR, with an emphasis on the ethical principles and values underpinning the importance of community and stakeholder engagement.

Module 4 addresses the ethical issues related to the conduct of IR, with emphasis on ethical challenges raised with respect to autonomy of research subjects, promotion of justice, and data collection and management. Specific concerns regarding informed consent, standards of care and ancillary findings are discussed.

Module 5 addresses ethical issues in the post-IR phase, including obligations to disseminate research findings effectively and considerations regarding sustainability of successful interventions.

Module 6 permits consolidation of the learnings from prior modules using a case study to illustrate the relevance of the ethical considerations of IR in-depth.

All modules are intended to be interactive with didactic material interspersed with activities including case studies, role-playing and quizzes.

Additional cases for discussion and activity guides are included in 10 Annexes.

This facilitator’s guide accompanies the participant’s guide and contains all teaching materials, including explanations and notes for each slide and activity. It guides facilitators on the conduct of the training course and provides background information. A proposed agenda with time allotments for each module is provided to facilitate planning and conduct of the course.

The participant’s guide contains all teaching materials and copies of activities without guidance explanations. The participant’s guide is intended for distribution during the teaching course to maximize interaction and learning during sessions.
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- Georg Marckmann, Institute of Ethics, History and Theory of Medicine, Munich, Germany
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• Rose Assan, Dodowa Health Research Centre, Dodowa, Ghana
• Edward Asumanu, 37 Military Hospital, Accra, Ghana
• Cynthia Bannerman, Ghana Health Service, Accra, Ghana
• Okyere Boateng, Noguchi Memorial Institute, University of Ghana, Accra, Ghana
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• Paulina Tindana, School of Public Health, University of Ghana, Accra, Ghana
• Alfred Yawson, School of Public Health, University of Ghana, Accra, Ghana

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<th>Title</th>
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<td>7</td>
<td>LIST OF ABBREVIATIONS</td>
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<td>8</td>
<td>AGENDA OF THE COURSE</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>CAB</td>
<td>Community advisory board</td>
</tr>
<tr>
<td>GPS</td>
<td>Global Positioning System</td>
</tr>
<tr>
<td>HMM</td>
<td>Home–based management of malaria</td>
</tr>
<tr>
<td>HMIS</td>
<td>Health management information system</td>
</tr>
<tr>
<td>HSR</td>
<td>Health systems research</td>
</tr>
<tr>
<td>HSV</td>
<td>Herpes simplex virus</td>
</tr>
<tr>
<td>IC</td>
<td>Informed consent</td>
</tr>
<tr>
<td>ITN</td>
<td>Insecticide–treated net</td>
</tr>
<tr>
<td>IR</td>
<td>Implementation research</td>
</tr>
<tr>
<td>LF</td>
<td>Lymphatic filariasis</td>
</tr>
<tr>
<td>LMIC</td>
<td>Low– and middle–income country</td>
</tr>
<tr>
<td>MDA</td>
<td>Mass drug administration</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
</tr>
<tr>
<td>OR</td>
<td>Operational research</td>
</tr>
<tr>
<td>PAR</td>
<td>Participatory action research</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother–to–child transmission</td>
</tr>
<tr>
<td>QI</td>
<td>Quality improvement</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>RDT</td>
<td>Rapid diagnostic testing</td>
</tr>
<tr>
<td>SA</td>
<td>Situation analysis</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
</tr>
<tr>
<td>SOT</td>
<td>Special outreach team</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>TBA</td>
<td>Traditional birth attendant</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Below is a proposed template agenda for the two and a half-day course. Adequate time has been allocated for tea breaks. In the event of challenges in time management, tea breaks could be used as a buffer by shortening the break by 10 minutes at the most. Tea breaks can also be arranged to suit cultural norms and standards. Timings can be re-arranged to best suit the context, for example, if in a particular setting, the course should finish at 16:00, it could either start earlier, or be run over three days.

### Day 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30–09:00</td>
<td>Registration of participants</td>
</tr>
<tr>
<td>09:00–09:30</td>
<td>Opening&lt;br&gt;Introduction of participants and facilitators&lt;br&gt;Training objectives and overview</td>
</tr>
<tr>
<td>09:30–10:30</td>
<td><strong>Module 1.</strong> Introduction to implementation research (IR)&lt;br&gt;– interactive lecture</td>
</tr>
<tr>
<td>10:30–11:00</td>
<td>Coffee break</td>
</tr>
<tr>
<td>11:00–12:30</td>
<td><strong>Module 2.</strong> Ethical considerations in IR&lt;br&gt;Interactive lecture&lt;br&gt;Small group activity</td>
</tr>
<tr>
<td>12:30–13:30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:30–15:00</td>
<td><strong>Module 2.</strong> (Continued.)</td>
</tr>
<tr>
<td>15:00–15:30</td>
<td>Coffee break</td>
</tr>
<tr>
<td>15:30–17:00</td>
<td><strong>Module 3.</strong> Ethical issues in planning IR&lt;br&gt;Interactive lecture&lt;br&gt;Small group work</td>
</tr>
</tbody>
</table>

### Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00–10:30</td>
<td><strong>Module 3.</strong> (Continued.)&lt;br&gt;Interactive lecture</td>
</tr>
<tr>
<td>10:30–11:00</td>
<td>Coffee break</td>
</tr>
<tr>
<td>11:00–11:30</td>
<td><strong>Module 3.</strong> (Continued.)&lt;br&gt;Role–play&lt;br&gt;Participants led by facilitators</td>
</tr>
<tr>
<td>11:30–12:30</td>
<td><strong>Module 4.</strong> Ethical issues in conduct of IR&lt;br&gt;Interactive lecture&lt;br&gt;Small group activity</td>
</tr>
<tr>
<td>12:30–13:30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:30–15:00</td>
<td><strong>Module 4.</strong> (Continued.)&lt;br&gt;Interactive lecture&lt;br&gt;Small group activity</td>
</tr>
<tr>
<td>15:00–15:30</td>
<td>Coffee break</td>
</tr>
<tr>
<td>15:30–16:00</td>
<td><strong>Module 4.</strong> (Continued.)&lt;br&gt;Small group activity&lt;br&gt;Participants led by facilitators</td>
</tr>
<tr>
<td>16:00–17:00</td>
<td><strong>Module 5.</strong> Interactive lecture: ethical issues post-IR conduct&lt;br&gt;Small group activity</td>
</tr>
</tbody>
</table>
## 2. PLANNING FOR THE COURSE

### 2.1 PLANNING AHEAD

#### 2.1.1 Planning the course

- Ideally the course should be advertised at least three months before its planned start date. Calls can be put up on the institution websites, and emails can be sent to the organizing contacts. At times, there may be a specific request from the specific ministry of health/university/research institution.
- The frequency of courses can be based on a waiting list of interested delegates.
- Ensure that invitations, visa support letters and any other supportive documents for travel/participation in the course are provided ahead of time to all the participants.
- Ensure that the training hall has sufficient space for all the delegates, with possibilities for an area where participants can break into small groups, if needed.
- If you are providing lunch, ensure that the caterers take into account any dietary restrictions.
- Ensure there is sufficient time during the breaks and lunch to be able to walk to where tea/coffee/lunch will be served, and that there is time for the delegates to relax and eat before heading back to the course hall.

- If delegates are coming from far away, it is a good idea to provide them with details of a hotel where they can stay not too far from the training venue. You should also provide hotel details for any external facilitators who may also be attending. If all delegates are staying at the same hotel, you could also arrange transport to and from the training venue. The training should ideally not take place in a hotel, unless that is the only space available.

#### 2.1.2 Number of facilitators needed

- A minimum of two facilitators is recommended to deal with any logistical issues that may need to be resolved (e.g. ensuring lunch is on time, photocopying, etc.) whilst the other facilitator is presenting.
- All facilitators should have attended the course at least once, and possibly have had specific train-the-trainer’s training, and should have read this guide.

### Day 3

<table>
<thead>
<tr>
<th>Time</th>
<th>Module 6. Group activity – case study</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00–10:30</td>
<td>Discuss the various ethical issues in planning, conducting and evaluating the given IR</td>
</tr>
<tr>
<td></td>
<td>Participants led by facilitators</td>
</tr>
<tr>
<td>10:30–11:00</td>
<td>Coffee break</td>
</tr>
<tr>
<td>11:00–12:30</td>
<td>Presentation by groups Discussion in plenary</td>
</tr>
<tr>
<td></td>
<td>Participants led by facilitators</td>
</tr>
<tr>
<td>12:30–13:00</td>
<td>Evaluation of course Issuance of certificates; closing</td>
</tr>
<tr>
<td>13:00–14:00</td>
<td>Lunch</td>
</tr>
</tbody>
</table>
2.1.3 Audio-visual equipment

- At a minimum, you will need a laptop, projector, screen and flipcharts. It is a good idea to have a device for the facilitator to remotely control the presentation.
- Depending on the size of the room, and the facilitators’ ability to project their voice, microphones might be needed. Additional cordless microphones may be kept on the table when the participants speak.
- If supported with simultaneous translation, test the devices/earpieces before the course begins.
- Additional equipment, such as a printer and photocopier may be required.

2.1.4 Setting up the room

- Make sure there is a clock in the room that can easily be seen by the presenting facilitator.
- Seating arrangements can either be a U-shape around the projector screen, with a separate area where the groups can sit at tables for the exercises; or consider grouping tables of four for lecture and exercises, if space is inadequate; ensure the screen is readily visible to all the participants, and does not cause undue discomfort.
- If possible, put the participants’ names on place cards at each seat.
- It is a good idea to change the seating arrangements each day to allow participants to mix and interact with each other.

2.1.5 Preparing the delegates’ packs

- Printing out all the slides as handouts can be an option; this may be required in settings with possible power interruption to allow participants to follow the lecture; hand them to delegates on the first day.
- Remember that some of the PowerPoint presentations contain mini exercises that participants will do during the lecture. The subsequent slide might ruin the exercise so, if you are printing, remove the answer slide!
- A more environmental friendly option is to share electronic versions of the training materials. Slides can be emailed or posted on a Drop-box folder to delegates at the end of each day.
- You may want to provide note pads and pens for the participants.

2.2 ON THE DAY

2.2.1 Final equipment check

- Before the arrival of all the participants, make sure the room is set up as detailed above from 2.1.3 to 2.1.5.
- Make sure all presentations to be used have been installed on the laptop.
- Create a folder on the laptop to keep copies of the presentation files from the participants.
- Turn on the laptop and projector – make sure that all the presentations work, the screen has a good resolution and is an appropriate size to be seen well for those seated in the back of the room.

2.2.2 Delegates’ arrival

- Ensure there are signs directing the delegates to the training room and that everyone is welcomed with a smile!
- Try to have tea and coffee available for them and perhaps a snack (depending on what would be expected for a course in that area).

2.2.3 Registration

- Set up a registration table and assign a person to sign in delegates each day.
- Use a day-specific sign-in sheet so it is clear that delegates have attended all the days.
- Ensure the correct spelling of each participant’s name, as this will go on their certificates.
- Name badges make it easier for all the delegates to remember each other’s names; hand over the name badge.
- Show participants to their seats.

2.2.4 Materials to have on hand

- Ensure that you have all the materials ready, e.g. flipcharts, pens, paper, any other requirements based on the activities planned for the day, such as printed case studies, colour cards, post-it notes, etc. Attendance certificates: templates approved by the conducting organization with all the logos used; check with the TDR focal point on the contents of the certificate and the signatories before printing them; names can either be handwritten or pre-printed on the certificates.
3. COURSE INTRODUCTION AND OVERVIEW

Timing: 30 minutes.
This session is the introduction and background to the full course. The presentation Ethics in implementation research objectives and overview guides the facilitator through this session. Participants will be asked to introduce themselves and articulate their expectations for the course. It is highly recommended to write the list of expectations on a flipchart to be revisited at the end of the course. In order to ensure efficient learning, it is good to lay some ground rules, and to review the goals and objectives of the course. The facilitator highlights that the course has specific objectives and scope, thus some expectations may fall beyond these. They provide an overview of the course methodology and the topics that will be covered, and touch upon the evaluation methods, pre-testing and post-testing, if any, so that the participants are not taken by surprise. They quickly review and agree on the agenda and, if required, make minor adjustments to suit the context.

MODULE PLAN
Module 1. Introduction to IR
Module 2. Ethical considerations in IR
Module 3. Ethical issues in planning IR
Module 4. Ethical issues in the conduct of IR
Module 5. Ethical issues post-IR conduct
Module 6. In-depth ethical analysis of IR using case studies
MODULE 1
INTRODUCTION TO IMPLEMENTATION RESEARCH
4. MODULE 1 INTRODUCTION TO IMPLEMENTATION RESEARCH

**SPECIFIC LEARNING OBJECTIVES:**

- to describe the breadth of health-related research, the spectrum of health systems research (HSR) and the sub-domains of operational research (OR) and implementation research (IR);
- to differentiate HSR and specifically IR from biomedical/traditional clinical research;
- to describe the interrelationship between HSR and epidemiology, and surveillance;
- to distinguish potential differences between quality improvement and IR;
- to define the specific features of IR including the rationale and goals, study design and context within which research takes place.

**LEARNING METHODOLOGY:**

Interactive lecture with discussion encouraged between participants; quizzes using the different case scenarios to define and differentiate the different types of HSR.

**REQUIRED RESOURCES:**

PowerPoint presentation; illustrations; case scenarios; colour cards – three colours.

**TIMING:**

1 hour

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FACILITATING MODULE 1

**SLIDES 2 AND 3: LEARNING OBJECTIVES AND SESSION OUTLINE**

Take the participants through the learning objectives; put IR into the context of the spectrum of health-related research and specifically as a sub-type of HSR.

Mention the need to identify specific ethical concerns in the conduct of IR that require special consideration beyond those for biomedical (clinical) research.

Briefly touch on the components of IR that will be elaborated in subsequent modules.
SLIDE 4:

This is an introductory slide to the next few slides discussing and placing the various common forms of health-related research. Basic science does not always relate directly to humans; it may, for example, be conducted on tissue samples or animals, so, in addition to ethical obligations to humans, there may be animal ethics considerations. Emphasize that all forms of research complement our comprehensive understanding of health and disease, and how to maintain health, and prevent or treat disease in individuals and populations.

SLIDE 5:

Using the diagram of WHO building blocks of the health system as one framework (not the only one) to look at the health system, illustrate how it is an overarching system that affects all aspects of health and health-care delivery, and how each component is necessary for the best functioning/effectiveness of the other components.
SLIDE 6:

Using a major global public health problem, such as malaria, illustrate how understanding the pathophysiology of the disease, for example, that it is transmitted by mosquitoes, and how understanding the life-cycle of the parasite was crucial in combating the disease, and in studying the compounds that might be effective in curing the disease.

SLIDE 7:

Once pathophysiology is understood and products are identified as being effective through basic science, they must be tested in humans to determine safety. This requires clinical research. Once safety is determined, clinical trials should be conducted to determine whether the drug does indeed have the desired effect of curing malaria, and reducing morbidity and mortality. The trials need to be conducted rigorously (the gold standard is the randomized controlled trial or RCT) to objectively assess and quantify the benefits and harms. Multiple RCTs can be analysed in meta-analyses to provide best current evidence for individual treatment.

SPECIAL NOTE TO FACILITATOR: In this slide, one could discuss the RCT and what randomization and having a true control group means as well as the principle of clinical equipoise, i.e. true clinical uncertainty as to whether drug X is effective or better than drug Y, etc. The difficulty here is time; if only 1 hour is allocated for Module 1, then discussion of RCT shortens the time for the module. However, it is important that the participants understand the difference between clinical trials and IR. Therefore, it may be worth having this discussion here.
SLIDE 8:
Discuss how much research in the past decades has focused on understanding medical diseases and the development of disease-specific therapies and products with the goal of improving health and minimizing associated risks in **individuals**. In the past, less attention had been paid to how these treatments/products reached the individuals affected on a broader scale.

SLIDE 9:
Introduce the idea that when studying disease pathophysiology and developing effective treatments for the individual, it should not be assumed that all who need the treatment will receive it. Attention must be paid to understanding whether a specific disease is indeed a relevant clinical burden within a country/region (i.e. responsiveness of research to the needs of the population) as well as the prevalence of the risk factors, or specific populations at risk, in order to develop strategies for disease control and management. This requires diligent epidemiological investigation including human disease incidence and prevalence, vector surveillance, etc. In the malaria example, population surveillance assists in the identification of the population most at risk (children under 5 years and pregnant women), and helps to target treatment to those who need it the most. Understanding vector control permits development of public health strategies to reduce transmission, e.g. increase uptake and the proper use of insecticide treated nets (ITNs).
SLIDE 10:
Epidemiology and surveillance provide more information and lay the foundation for research to improve health-care delivery and health systems functioning, and provide information about access to care and health needs in the population. All components of the health system need to function well and in conjunction with each other for effective management, especially of diseases affecting public health.

SLIDE 11:
This slide illustrates the continuum of health-related research and the feedback loop between epidemiology and surveillance and HSR. In themselves, epidemiology and surveillance are NOT IR but they provide the data upon which IR can be developed. Once a disease is recognized as a health priority, it is the responsibility of the health system to ensure equitable access to effective treatment. HSR, including IR, is designed to test potential solutions to improve access to and uptake of treatment or preventive interventions for highly relevant local health-care needs, for example, malaria in endemic areas. Such research is conducted in real-time and under real-life conditions. After the IR is conducted and an intervention is rolled out in a community, ongoing monitoring is necessary to detect effectiveness or failures, or any changes in disease patterns or in the health-care delivery process that require feedback and optimization of intervention strategies. Therefore, a continuous flow of information must be fed back to the health system to facilitate decision-making and resource allocation.
SLIDE 12:

A review article by Remme et al. (2010) depicts the positions of operational research (OR) and IR within HSR. There are various ways to depict the position of IR within HSR; emphasize to the participants that this diagram is one illustration of the domains of HSR. Given the simplicity of this diagram, this is used here for practical purposes to illustrate where IR fits along the spectrum of HSR. This slide also identifies the target users of the information generated by the various forms of research and the generalizability of the research findings.

There is a progression from OR, which studies the very local application of interventions and the feedback loop is local, to IR, which studies interventions within local contexts but has broader applicability and generalizability. It is, therefore, of interest to programme managers who can feedback to the greater health system. HSR is the overarching form of research and also includes research into policy development and policy decision-making, financing and other health systems functioning; questions that may not include direct patient involvement although patients and/or the community are always the ultimate target of the research.

Once certain therapies are known to be effective in large numbers of patients, and given the responsibility of the health system to ensure equitable access to treatment, the next question is how to deliver this treatment optimally to as many people who need it, and in an affordable way that is accepted by the target communities and health-care workers. To answer these questions, OR and IR are required; OR and IR must be conducted in real-life circumstances to gain as accurate and realistic a picture of whether an intervention works under the local conditions, what barriers are encountered, how the intervention is accepted and how the strategy can be improved. Such information is crucial prior to scale-up and the widespread roll out of effective interventions.
The health system cannot function without a continuous flow of information and it, therefore, requires research to inform its policy development, decision-making, interventions and feedback.

Put the three questions to the participants one after another as a quiz. Distribute a set of the three colour cards to each participant to allow for the following three choices 1. HSR (yellow), 2. IR (blue), and 3. OR (red). Once the question is asked, participants raise the colour cards of their choice – drive the discussion [using the facilitator’s notes for Slides 15–17] starting from the inappropriate to the most appropriate choice. Using the contents in slides 15, 16 and 17, summarize the definition of the three types of research.
SLIDE 15:

More details on the specifics of HSR in its broadest form with the example of user fees - it is not intuitive to understand whether making users pay a very small fee for services will positively or negatively impact the uptake of services and misuse of services. Therefore, a study would need to be conducted on the impact of user fees. One can discuss some possible study designs as examples, e.g. the patients would be impacted if clinics were randomized to user fees or no user fees, or the study could be conducted using historical comparative data before or after the introduction of user fees in a specific district, in which case patients may be less directly impacted. Whether patients would need to sign consent for such a study is questionable, as they would have no alternative except not to attend the clinic where fees were introduced. Such studies would inform policy about user fee implementation or not. Routinely collected clinic attendance data, with no patient identification could be analysed, and patients and health-care workers may, therefore, be unaware that the study was being conducted.

SLIDE 16:

Description of IR using the example of testing whether giving rapid malaria tests to community health workers, instead of requiring patients to attend the health centre for diagnosis of malaria or the community health workers initiating empirical anti-malaria therapy. Delay in diagnosis and inappropriate treatment for malaria are identified as local health problems. Such a strategy could improve the rapidity of correct diagnosis and initiation of appropriate anti-malarial therapy, but studies would be needed to determine whether the strategy actually improved malaria diagnosis rates, treatment delays and outcomes, and whether it would also improve the appropriateness of referrals for non-malaria associated fever. Such a strategy could be rapidly scaled-up and rolled-out, and could be implemented elsewhere if found to be effective. It would, therefore, have implications beyond the community in which the intervention was tested.
SLIDE 17:
Description of OR focusing on a local problem. Stress that OR is essentially a ‘trouble shooting’ process to address very specific and localized implementation problems, related, for example, to a specific health centre or small area where problems may not be occurring on a broader scale and would, therefore, have very little potential for generalizability. However, it may help to identify or overcome local bottlenecks that may not occur elsewhere, such as how to communicate medication instructions to refugees speaking various languages, at a specific location and with unknown literacy levels. A study of various packaging strategies could be conducted at the local health centres, which would provide feedback from participants on their comprehension and use of the medication. The most successful strategy can then be implemented locally to address the particular local barrier.

SPECIAL NOTE TO FACILITATOR: Participants may feel it is crucial to differentiate between OR and IR. However, from an ethical standpoint this distinction is not very relevant, as the ethical issues arising in both are very similar, and the lines between them may not be clear cut. Try to avoid prolonged discussion on this point and refer participants to the Remme (2010) article cited in Slide 12.
EXAMPLES OF WHY IMPLEMENTATION RESEARCH IS NECESSARY...

We know insecticide-treated nets (ITNs) work
- How do we increase consistent use by appropriate individuals?

We know antiretrovirals (ARVs) prolong life in HIV
- How can we improve the proportion of HIV-positive people treated effectively?

We know Mass Drug Administration (MDA) reduces incidence of lymphatic filariasis (LF)
- How do we engage the community to participate and achieve optimal community protection?

SLIDE 18:

Presents more examples of the practical application of known successful IR interventions in real-world situations. For example, on the one hand, how the use of ITNs reduced malaria infection, and, on the other hand, despite free distribution of ITNs, how the nets may not be used correctly. This may relate to the colour of the net, e.g. white signifying death or misinformation about how to use them, or the fact that it is free means it is not valued. Another example is saving lives with the use of antiretroviral (ARV) drugs for HIV. There may be barriers that reduce uptake, such as stigmatization engendered by specific clinic attendance, or the requirement for an escort to bring a patient to clinic, or not being able to take time off work. Carrying out a campaign for mass drug administration (MDA) is not an end in itself, and clinical outcomes must also be monitored to assess the effectiveness of the campaign.

SLIDE 19:

Demonstrates the important delays in translating knowledge into practice and highlights the need for IR to understand and overcome these delays.
SLIDE 20:

IR studies practical application of known successful interventions in real-world situations where there may be different challenges anticipated with delivery and uptake of an intervention compared to what is already known. For example, the local understanding of disease may affect health-seeking behaviour. If fever is thought to have a spiritual origin, a community may be resistant to accepting a cure in the form of a tablet, or, in a very remote community, consistent delivery of drug supplies may be a challenge and undermine trust in the health system/clinics. It is important to study the process in order to carry out the intervention. In theory, the management of HIV and TB in the same patient should be easy to carry out in one visit. However, the extra time required for patients and health-care workers, and the broader scope of knowledge required may be barriers to successful implementation, and should be identified and studied to develop successful solutions. It is not enough just to study the process and to implement an intervention, but it is crucial to determine whether the ultimate goal, i.e. modification of the disease outcome has been successfully achieved. Clinical end-points should, therefore, be defined and evaluated in addition to monitoring the uptake and process of implementation, cost-effectiveness, etc. All of these components should be anticipated and incorporated into the study design.

SLIDE 21:

The target audience of IR is people who can develop or change health policy, who can implement health policy and who can change local practice. These people also serve as important sources of information and feedback before, during and after a study. Their cooperation and collaboration is critical. It is also crucial that communities be informed of the results of IR, and that the outcomes of participation be fed back to them as research partners, to motivate them to continue with the uptake of behaviour change interventions. Because the participants do not often comprise researchers and scientists, it is important that the information be presented in an intelligible and concise way.
SLIDE 22:

IR is conducted in the real world and, therefore, if a particular study intervention is the only local option to address a specific problem, it is fully understandable that the ‘research’ may seem indistinguishable from clinical care or public health practice. The line between clinical/public health practice and IR may not be easily drawn in certain circumstances. Similarly, where is the line or is there a line between quality improvement and IR?

This is a controversial topic, as many may feel that quality improvement or public health interventions do not require ethical review because they are a form of ‘practice’, whereas anything labelled as ‘research’ should be subject to ethical review. In reality, any intervention that has anything to do with a ‘subject’ or ‘patient’ should be conducted ethically, regardless of whether it is research or practice. If it is research, this implies something is unknown, there may be risk, and there may be opt-out possibilities, which may not always be the case with quality improvement or public health interventions.

There are differing views about whether or not quality improvement should be subject to ethical review. How could one determine whether a study is IR or quality improvement? Should consent be obtained in IR as well as quality improvement and public health interventions or only for IR?

SPECIAL NOTE TO FACILITATOR: This could be interactive asking the participants how they would address the questions and which of the various proposals may be quality improvement or IR or public health. Ask them why and how they make the distinctions and whether it matters in terms of ethical protection from harm/risk? For example, cluster randomized trials or an intervention everywhere, and track rates pre- and post-change, etc. Highlight the fact that it is important to consider the ethical implications, irrespective of whether it is practice or research; it is not the label that matters.
SLIDE 23:
Discuss strategies. IR is research, however, there are many factors that must be taken into consideration before a study is implemented and an intervention is tested that might then generate expectations that cannot be fulfilled. In the case of planning any IR, prior community and stakeholder engagement is crucial to assess the local acceptability of a proposed intervention. This is the case whether the intervention itself is appropriate as a potential solution to the identified problem, whether the study is feasible within the local circumstances, whether the intervention is/will remain cost-effective, equitable and sustainable and can, therefore, be scaled-up and rolled-out. All these factors will be elaborated in subsequent modules.

SLIDE 24:
Discuss the main goals of IR, i.e. take evidence into practice, to improve practice and to provide information to policy-makers to inform decision-making/policy development.
SLIDE 25:
Examples of the complexity of contextual/socio-political factors that impact design, conduct and uptake of IR and, therefore, must all be acknowledged, understood and considered before designing IR.

SLIDE 26:
Examples of IR interventions. Discuss the examples. Bring up the point of EQUIPOISE that is most often contextual in IR, and invite participants to suggest possible approaches to answer the questions.

- **Education:** condoms reduce HIV transmission.
- **Incentives:** taxi vouchers to encourage institutional deliveries.
- **Monitoring tools:** in–house vector monitoring traps for malaria.
- **Guideline implementation:** timing of initiation of ARV in HIV.
- **Multi–faceted packages:** delivery of MDA and education about family planning and HIV prevention simultaneously in remote communities.
- **New treatment methods:** using Genexpert to diagnose multidrug–resistant tuberculosis (MDR–TB).
- **Change in delivery systems:** community health workers dispensing malaria treatment using rapid diagnostic testing (RDT).
SLIDE 27:
Introductory slide of the phases of IR and the major ethical considerations within those phases which will be discussed in much further detail in the coming modules.

SLIDE 28:
Conclusion slide. Emphasize the importance of IR – it is about translating knowledge into practice on a broad scale.
REFERENCES AND READING MATERIALS (1)

MODULE 2 ETHICAL CONSIDERATIONS IN IMPLEMENTATION RESEARCH
5. **MODULE 2 ETHICAL CONSIDERATIONS IN IMPLEMENTATION RESEARCH**

**SPECIFIC LEARNING OBJECTIVES:**
- to describe the existing frameworks of ethical reasoning in medical ethics, research ethics, public health ethics and bioethics as a whole;
- to differentiate between medical ethics and public health ethics;
- to describe the key ethical considerations in public health ethics as a background for ethics of health systems and implementation research (IR);
- to describe the ethical considerations of health systems and IR;
- to apply the ethical considerations to health systems research (HSR) addressing various building blocks of the health system;
- to apply the ethical principle of health systems and IR to practical situations.

**LEARNING METHODOLOGY:**
Interactive lecture; group discussion; small group work with plenary discussion.

**REQUIRED RESOURCES:**
PowerPoint presentation; case study one handouts in Annex 1; one laptop per team.

**SLIDES 2 AND 3: LEARNING OBJECTIVES AND SESSION OUTLINE**

This module will cover the important aspects of health systems’ ethical principles and IR.

The following aspects will be covered:

1. **the key ethical frameworks of medical, research, public health ethics, bioethics as an overarching framework;**
2. **differences between medical and public health ethics;**
3. **key characteristics of public health ethics;**
4. **key ethical principles of health systems and IR;**
5. **ethical justification for IR.**

Introduce these concepts to the participants.
SLIDE 4 AND 5: ETHICS OF HEALTH SYSTEMS RESEARCH AND IMPLEMENTATION RESEARCH

Draw attention to the fact that health systems and IR is an emerging field, and ethical reflection in this area is also fairly recent. It draws upon the various existing frameworks, which are:

- medical ethics
- research ethics
- bioethics
- public health ethics.
SLIDES 6–10: MEDICAL ETHICS, RESEARCH ETHICS, PUBLIC HEALTH ETHICS

Among all these existing frameworks the most recent is the public health ethics framework, which is highly relevant to IR. This framework is unique and has its characteristic differences from the older medical ethics framework.

Slide 6:
Use Slide 6 to describe the differences between medical, research and public health ethics. While medical and research ethics deal with individual patients and study participants, public health ethics considers the welfare and risks to populations.

CENTRAL QUESTIONS AND CURRENT TOPICS IN PUBLIC HEALTH ETHICS

- What extent of risk is acceptable at the individual and community level?
- Is coercion justifiable?
- Individual interest vs. the common (public) good
- Health promotion: how much should the government interfere with personal choices on health?
- How to ensure fair participation in decision-making?
- Priority-setting and rationing: who will get what if resources are short?

Slide 7:
In this context, present Slide 7 to raise some of the most important questions and ethical considerations in public health ethics.

- What level of risk is acceptable?
- How much coercion is justifiable?
- How to weigh individual interest vs. the common (public) good?
- Health promotion: how much should the government interfere with personal choices on health?
- How to ensure fair participation in decision-making?

Priority-setting and rationing: who will get what if resources are short?

From these considerations emerge a unique set of ethical principles as discussed below.
Slide 8:

**Introduce substantive ethical principles:**

1. **Substantive principles** – they establish the rules for what is right and wrong, and the right and wrong actions in public health.

2. **These principles facilitate ethical conduct** in public health, producing benefits and minimizing harms.

   - Discuss the potential benefits of the herpes simplex virus (HSV) screening strategy – detection of asymptomatic carriers, prevention of neonatal HSV infections, and improvement in child health.
   
   - Discuss the potential harms – stigmatization of men and women detected to have a sexually transmitted infection (STI) – problems of marital discord and infidelity problems when screening positive.
   
   - Infringement of individual autonomy and compromises that individuals make should be proportional to the benefits to the community. Is being detected as having an asymptomatic sexually transmitted affliction proportional to the reduction in burden of newborn deaths in this community?
   
   - In support of the compromises that individuals make for the sake of common good, the community should reciprocate the gesture by upholding their interests. How can the community uphold the interests of people who reveal their HSV status for the sake of common good? Can efforts be made to protect their confidentiality? Can treatments be offered in an affordable and respectful manner?

   - **Equity** – justice, fairness – is the programme likely to benefit/harm all sections of the community in a similar manner? Do women bear a greater burden of stigma and domestic violence after having been detected as having HSV?

   - **Trust** – belief that the public health intervention is intended for the common good – trustworthiness.

   - **Solidarity** – the feeling of standing united for a common cause, willingness to stand up for the common good.

   - **Stewardship** – the act of protecting the health of the community, accepting responsibility for the well-being of the community as a service and not as a control. For example, during an influenza outbreak, the state should act by increasing awareness and providing specific vaccinations. The state may also take measures to isolate infected patients. However, all this is done in a spirit of service and not as a controlling measure. This is called stewardship.
**Slide 9:**

**Introduce procedural ethical principles:**

1. Procedural principles – they establish the rules by which public health should be practiced and decisions made. They are concerned with the process of delivery of public health services.

2. These principles lay down the following rules for due process in public health.

   - **Transparency** – openness, honesty.
   - **Relevance** – appropriateness – is the screening programme for HSV the most relevant in this community? Are there other more important causes of morbidity?
   - **Inclusivity** – non-discrimination.
   - **Responsiveness** – being able to adapt to community needs and respond to the requirements.
   - **Accountability** – being answerable to the community.
   - **Participation** – were stakeholders involved in deciding on the best strategy to screen men and women for HSV?
   - **Sustainability** – being able to sustain public health action and public health impact.
Potential conflicts between substantive ethical principles.

The limitation of a principle-based approach to public health ethics is that substantive principles will sometimes be in conflict with one another. Some examples of the conflicts are listed below.

1. Quarantine during pandemics – autonomy versus common good, autonomy versus solidarity.
2. Targeted interventions – improves efficiency and produces common good, but not equitable.
3. Name-based reporting of sexually transmitted diseases and contact screening – confidentiality versus disclosure and common good.
4. State taking responsibility for public health interventions such as introducing a ban on smoking – autonomy versus stewardship.
SLIDE 11-20: ETHICS OF HEALTH SYSTEMS RESEARCH AND IMPLEMENTATION RESEARCH

Ethical principles of health systems and IR are derived from the disciplines of medical, research and public health ethics.

Slide 12-13:
Introduce examples in Slide 12 and then use Slide 13 to highlight important ethical considerations in HSR and IR.

In HSR, it is often challenging to identify who the beneficiaries are and who is bearing the risks. For example, during research to improve the performance of the community health-care provider, if a new method of information collection is introduced, and it is studied whether the health outcomes at the community level are improved, the beneficiaries are at two levels, both the community health workers as well as the communities. Likewise, the risks are also at both these levels. Therefore, identifying the beneficiaries and those at risk can be challenging.

Following from the same description, in ensuring autonomy, it is difficult to identify whether the health workers or the community should give informed consent.

While planning HSR it is also important to involve participants from vulnerable communities, as it is important for the health-system services to reach them.

Other important ethical considerations in HSR include: (a) the research should be responsive to the community and health-system needs; (b) the research intervention should be sustainable and scalable; and (c) appropriate standards of care and ancillary care responsibilities should be identified.
SLIDE 14:

HSR includes all forms of research in various building blocks of the health system. Use Slide 14 to describe these building blocks, namely: (a) leadership and governance; (b) health care financing; (c) health workforce; (d) medical products and technologies; (e) information and research; and (f) service delivery.
Following this introduction, use slides 15–20 to highlight examples of HSR (specifically IR) in the various health system building blocks, and discuss the various ethical issues related to each of these examples. Read out the case example and then open the discussion for participants to mention the various ethical considerations in that example. Finally, wrap up the discussion.

**SLIDE 15:**

In country X, abolishing unofficial payments to health-care workers by regularizing them leads to lower overall health-care expenditure.

Can this be adopted in your country?

**Discussion**

Are corruption and unofficial payments a major problem in your country?

What are the risks of making unofficial payments regular? For example, legalizing unofficial payments? Will the community accept it? Should the root cause of corruption be tackled rather than making corruption official?

What are the benefits of making unofficial payments regular? Reduced health-care costs?

What research design can be used? Is it ethical to have a control arm where corruption is known but there is no intervention? What intervention can be given to the control group?

How will the research participants be selected? How will research participants be protected against punitive action for past corruption?
Social insurance schemes have been shown to be an effective method for introducing universal health coverage. Can this be implemented in your country?

**Discussion**

Is social insurance a felt need? Is it appropriate for your country?

What are the benefits of social insurance (universal health access, reduced out-of-pocket expenses)?

What are the risks of social insurance (moral hazard, cherry picking)?

What is the best research design?

Who gives informed consent?

Is there justice in the selection of participants?

Solidarity principle.

<table>
<thead>
<tr>
<th>Health systems building block</th>
<th>Example of implementation research</th>
<th>Ethical considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care financing</td>
<td>Social insurance schemes have been shown to be effective method for universal health coverage. Can this be implemented in your country?</td>
<td></td>
</tr>
</tbody>
</table>
SLIDE 17:

The mHealth system is known to improve data collection and timeliness of data collection by community health workers. Will this be feasible in your country? Will it be acceptable?

Discussion

Research on data.

Data protection and confidentiality.

Data ownership.

Is consent from participants needed?

Who are the participants?

What can the data be used for?
**SLIDE 18:**
Performance-based incentives for treatment of malaria has been shown to improve health-worker performance. Can this be adopted in your country?

**Discussion**
Can incentives be sustained?

Will incentives create sustainable change in health workers’ practices?

Will incentives lead to over diagnosis and false diagnosis of malaria?

What is the most appropriate study design?

<table>
<thead>
<tr>
<th>Health systems building block</th>
<th>Example of implementation research</th>
<th>Key ethical considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human resources for health</td>
<td>Performance-based incentives for treatment of malaria has been shown to improve health-worker performance. Can this be adopted to your country?</td>
<td></td>
</tr>
</tbody>
</table>


SLIDE 19:

A newer vaccine for prevention of rotavirus diarrhoea has been shown to be effective and safe in children. Can this new vaccine be introduced into the immunization programme of your country?

Discussion

Is rotavirus diarrhoea an important health problem in your country?
What are the risks of rotavirus vaccines? What are the benefits?
What is the best study design?
What are cultural beliefs?
Does the community have trust in vaccines?
Household-level campaigns for MDA to eliminate lymphatic filariasis (LF) has been shown to be an effective strategy to improve MDA acceptance rates. Can this be adopted in your country?

Discussion
Is LF a major problem in the community?
Is MDA the most appropriate strategy?
What are the risks of MDA? What are the benefits?
What is the most appropriate study design?
What cultural and local contexts will influence MDA acceptance?
Ancillary care issues may arise during door-to-door visits.
SLIDES 21–29: ETHICAL JUSTIFICATION FOR IMPLEMENTATION RESEARCH

Introduce the case study 1 in Annex 1 [slides 21-28] to highlight the key aspects of the IR study. Present the findings of the IR study and moderate a discussion between the participants on what was learnt from the study.

CASE STUDY

- The mHealth application was developed by a German technological organization for use by frontline community health workers in Bangladesh.

CASE STUDY

The application would guide the health worker in delivering maternal services such as:
- registration of pregnancy
- reminders for antenatal care (ANC) visits
- alerting for birth preparedness
- motivation for institutional delivery
- post-natal visits
- immunization of the child
- infant and young child feeding practices
- growth monitoring
CASE STUDY

- Application was developed entirely in Germany with local input from experts in Bangladesh
- The application was developed in the Bengali language
- It was field tested among some people who knew the Bengali language in Germany and found to be useful

CASE STUDY

- To study the use, acceptability of the application by the frontline health workers, ease of its use, perceptions of the frontline workers and the community about the application and its effectiveness in improving quality of maternal and child health-care delivery in a district in Bangladesh

CASE STUDY

- The study revealed that the frontline workers found the application extremely useful
- They felt empowered by the use of the mobile phone application
- Some questions and data formats in the application needed to be changed based on the feedback given by the health workers
- The data were captured accurately and in a timely manner
CASE STUDY

- This improved data driven public health decision-making at the district level
- There were practical issues with the maintenance of the handheld device in some of the remote villages
- In some villages where there was no electricity, so charging the handheld devices was a problem

CASE STUDY

- Discuss the findings of the study
- If the country plans to adopt and implement the strategy on a wider scale, how will these findings influence this decision?
Use Slide 29 to describe the benefits of doing IR and, therefore, the ethical obligation to conduct IR.

1. IR is ethically justified because it helps in the understanding of the benefits and harms of a public health intervention in the local context.

2. By appropriately understanding the reach, acceptability and contextual issues, it helps to optimize the public health intervention; its use was optimized by modifying the application format to suit the local needs. This was a direct by-product of IR.

3. Practical problems and logistical issues can be understood by IR and this helps in ensuring fairness – by understanding that remote villages may not have electricity for charging the handheld devices, appropriate action can be taken, such as providing power banks to ensure fairness in implementation.

4. Understanding and adapting to local needs ensure responsiveness.

5. By providing the mHealth application, the quality of maternal and child health-care services were improved. This led to better stewardship.

6. IR also gives cost effectiveness estimates helping in the assessment of the programme’s sustainability and its impacts.

REFERENCES AND READING MATERIALS

- Barr DL. Ethics in public health research: a research protocol to evaluate the effectiveness of public-private partnerships as a means to improve health and welfare systems worldwide. AMH. 2007;97:18-25.


MODULE 3 ETHICAL ISSUES IN PLANNING IMPLEMENTATION RESEARCH
6. **MODULE 3 ETHICAL ISSUES IN PLANNING IMPLEMENTATION RESEARCH**

**SPECIFIC LEARNING OBJECTIVES:**
• be able to recognize the value of and describe the following:
  • implementation research (IR) questions and ethical considerations;
  • responsiveness of IR to community needs;
  • IR design and its ethical considerations;
  • ethical considerations in community and stakeholder engagement in IR.

**LEARNING METHODOLOGY:**
Lecture with illustrations; case study 1 discussion; activity tables (Annex 2 and 3) and role-play (Annex 4, 5 and 6).

**REQUIRED RESOURCES:**
PowerPoint presentation; case study, activity tables and role-play.

**TIMING:**
3.5 hours

**SPECIAL NOTE TO FACILITATOR:** This module is quite long and dense and the facilitators should take advantage of natural breaks to deliver the content in portions. Day 1 can end after table activity and day 2 can begin with a quick review assisted by Slide 34 to introduce the concepts of stakeholder and community engagement. Depending on the allocated time for this module, facilitators should distribute the tables in Annex 2 and 3. The activity in Annex 2 is more suitable for advanced level participants. The blank version of Annex 3 should be distributed.

**FACILITATING MODULE 3**

**SLIDES 2 AND 3: LEARNING OBJECTIVES AND SESSION OUTLINE**
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 AND 7: EARLY THOUGHTS ON AN IMPLEMENTATION RESEARCH STUDY 2: HOW TO INCREASE THE APPROPRIATE USE OF ITNs?

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 awareness of cultural sensitivity?
Is there an idea why uptake is not optimal? What is the potential for ancillary care needs and follow up?
What is the intervention type? What are acceptable standards of care?
Who/what will be the research subjects? Who will be the units of intervention?
Who/what will be the units of observation? Who will be the control groups, are they required and ethically justifiable?
Who needs to give informed consent and how? Who will have responsibility for data management and data ownership?
Who/what bears risks? Who will have responsibility post-study?
Who/what gains benefits? Does the research strengthen the local health system?
Are vulnerable group included fairly? Is this research vs. practice?
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.
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.
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.

SPECIAL NOTE TO FACILITATOR: Driven through an open discussion, ask the participants to list the various harms; note them down on post-it notes on the flipchart; categorize the various entities listed and then summarize them using the contents in the slide.
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.
### ACTIVITY TABLE 2 – FACILITATOR’S COPY

#### ETHICAL RELEVANCE OF DIFFERENCES BETWEEN BIOMEDICAL/CLINICAL RESEARCH AND IR

<table>
<thead>
<tr>
<th>No.</th>
<th>Domain</th>
<th>Biomedical/clinical research</th>
<th>Implementation Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Subjects</td>
<td>Individuals</td>
<td>Countries\n\nInstitutions\nCommunities\nIndividuals</td>
</tr>
<tr>
<td>2</td>
<td>Informed consent</td>
<td>Individual\nAssent (in minors/those unable to give consent after it is given by guardian)</td>
<td>Individual\nGroup/gatekeeper permission Waived</td>
</tr>
<tr>
<td>3</td>
<td>Equipoise</td>
<td>Clinical</td>
<td>Contextual</td>
</tr>
<tr>
<td>4</td>
<td>Research question</td>
<td>Testing efficacy, safety of a new intervention targeting a specific condition</td>
<td>Testing implementation of a proven intervention or process in a new context/country\nGoal to scale-up successful interventions</td>
</tr>
<tr>
<td>5</td>
<td>Research conditions</td>
<td>Generally controlled research environment</td>
<td>‘Real-life’</td>
</tr>
<tr>
<td>6</td>
<td>Control groups</td>
<td>Usually required especially for randomized controlled trials (RCTs)\nMay not be required for phase 1 and 2 clinical trials</td>
<td>May be questionable ethically because testing a proven intervention</td>
</tr>
<tr>
<td>7</td>
<td>Anticipated outcomes</td>
<td>Pre-specified, most often disease-specific</td>
<td>Multi-faceted holistic impact on health systems functioning with regard to intervention tested</td>
</tr>
<tr>
<td>8</td>
<td>Risks assumed by:</td>
<td>Individual research subject</td>
<td>Individuals\nGroups\nCommunities\nInstitutions\nHealth systems</td>
</tr>
<tr>
<td>9</td>
<td>Benefits accrued by:</td>
<td>Same individual research subject experiencing risk\nFuture potential users of research outcome\nCommon good</td>
<td>Individuals\nCommunities\nInstitutions\nHealth system functioning\nBenefits may be gained by individuals/groups different from those experiencing risks\nCommon good</td>
</tr>
</tbody>
</table>

This table compares differences between clinical research and IR as an important step in understanding/illustrating how the ethical implications may be different for the two forms of research. With this, the Day 1 session concludes.
### Differences Between Biomedical/Clinical Research and Implementation Research That May Have Ethical Implications

<table>
<thead>
<tr>
<th>Domain</th>
<th>Biomedical/Clinical Research</th>
<th>Implementation Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Subjects</td>
<td>Individuals</td>
<td>Countries</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Institutions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Communities</td>
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<tr>
<td></td>
<td></td>
<td>Individuals</td>
</tr>
<tr>
<td>2 Informed Consent</td>
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<td></td>
<td>leather or minors/those unable to consent after consent given by guardian</td>
<td>Individual</td>
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<td></td>
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<td></td>
<td></td>
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<td>Clinical</td>
<td>Contextual</td>
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<td>4 Research Question</td>
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</tr>
</thead>
<tbody>
<tr>
<td>1 Subjects</td>
<td>Individuals</td>
<td>Countries, Institutions, Communities, Individuals</td>
</tr>
<tr>
<td>2 Internal consent</td>
<td>Individual</td>
<td>Individual, Group/Institutional permission, Waived</td>
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<td>Clinical</td>
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<td>Testing implementation of a proven intervention or process in a new context/setting</td>
</tr>
<tr>
<td>5 Research conditions</td>
<td>Randomly controlled research environment</td>
<td>&quot;Black box&quot;</td>
</tr>
</tbody>
</table>

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<td>Pre-specified, most often disease-specific</td>
<td>Multi-faceted, highlights impact on the functioning of health systems with regard to intervention tested</td>
</tr>
<tr>
<td>8 Risks assumed by</td>
<td>Individual research subject</td>
<td>Individuals, Groups, Communities, Stakeholders, Health Systems</td>
</tr>
<tr>
<td>9 Benefits accrued by</td>
<td></td>
<td></td>
</tr>
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<td></td>
</tr>
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</table>
SLIDE 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.
7. STAKEHOLDER AND COMMUNITY ENGAGEMENT

Case study: mHealth in Bangladesh

- The mHealth application was developed by a German technological organization for use by frontline community health workers in Bangladesh.
- The application would guide the health worker in delivering maternal services such as:
  - registration of pregnancy
  - reminders for antenatal care visits
  - alerting for birth preparedness
  - motivation for institutional delivery
  - post-natal visits
  - immunization of the child
  - infant and young child feeding practices
  - growth monitoring.

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.
SLIDE 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.
SLIDE 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.
WHAT CONSTITUTES A ‘COMMUNITY’ AND WHO MAKES THIS DETERMINATION?

What constitutes a ‘community’?
- Group of people who are linked by social ties, share common perspectives and engage in joint action in geographical locations or settings
- In the context of research, community can also be defined by ethnicity/disease/illness under investigation
- Common identity shared by its members, a commitment to a shared CULTURE

Who makes or should make this determination?
- Community self-characterization?
- Classification by others, such as authorities, civil society, industry, academics, scientists, sponsors?

SLIDES 40-42: WHAT CONSTITUTES A ‘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?
WHAT CONSTITUTES ‘REPRESENTATION’?

- Election?
- Nomination (by whom)?
- Self-appointed?
- Appointed?
- State official?
- Traditional official?
- Community elder?
- Political figure?
- A member of the proposed target group of the intervention (for example, an adolescent)?

WHAT CONSTITUTES ‘REPRESENTATION’?

Consider the impact of, amongst other factors:
- patriarchal norms;
- sexism;
- institutional and systemic oppression (for example, repressive state policies and practices);
- economic power;
- conflicts of interest;
- cultural norms and beliefs on legitimacy and authenticity of a community representative.
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.
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.
SLIDES 47 AND 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.
ROLE PLAY – mHealth in Bangladesh – Stakeholder Engagement

**Community**
- Community as a whole
- Community chief
- Pregnant women
- Woman with child of immunization age
- Health care workers
- Traditional birth attendants
- Cellphone air-time sellers
- Health clinic workers
- Field workers/volunteers
- Families of women and children
- Religious leaders
- Neighbourhood watch

**Other Stakeholders**
- German company
- Ministry of health
- Local authorities
- Cellphone companies
- Cellphone service providers
- Electrical company
- Bengali translators
- Data handlers

---

Separate participants into two large groups

- **Group 1:** Stakeholder engagement with all the stakeholders except the community
- **Group 2:** Community engagement

In each group there will be two researchers and the rest of the group will be assigned roles which will be outlined on a sheet of paper to be kept to themselves and information shared only if asked

---

**Participants** will be given 5–10 minutes to familiarize themselves with their individual roles

- The researchers must plan their strategy beforehand along the lines of:
  - When?
  - Where?
  - What?
  - How?
  - Duration?
  - With whom?

- Researchers can divide the group up if they wish or communicate with individuals one-on-one if they feel it is necessary.
SLIDE 56 AND 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.

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**KEY MESSAGES**

- Effectiveness of successful strategies is often lost because of inadequate implementation
- Implementation research must be responsiveness to a community’s needs
- Study design must be flexible often requiring collaboration from multiple research disciplines
- Implementation research strategies must consider local contextual factors to avoid harm and optimize success
- Selection of research participants is crucial to ensure valid results and to include true target populations
- Risks and benefits may not accrue to the same individuals and communities and require diligent consideration
- Community and stakeholder engagement is key throughout
- Study adaptation through an iterative process is important to minimize unforeseen harms and optimize research outcomes
REFERENCES AND READING MATERIALS - 1


REFERENCES AND READING MATERIALS - 2


REFERENCES AND READING MATERIALS - 3

REFERENCES AND READING MATERIALS - 4

7. **MODULE 4 ETHICAL ISSUES IN THE CONDUCT OF IMPLEMENTATION RESEARCH**

**SPECIFIC LEARNING OBJECTIVES:**
- to describe the ethical aspects of upholding research participants’ autonomy in implementation research (IR);
- to describe ethical issues related to promoting justice during the conduct of IR;
- to describe various ethical issues related to data collection and management in IR.

**LEARNING METHODOLOGY:**
Interactive lecture; case study discussion.

**REQUIRED RESOURCES:**
PowerPoint presentation; case study.

**TIMING:**
3 hours

### FACILITATING MODULE 4

**SLIDES 2 AND 3: LEARNING OBJECTIVES AND SESSION OUTLINE**

Slides 1 and 2: Introduce the session and list the various ethical considerations that will be discussed in the session:
- ethical aspects of upholding participant autonomy in IR
  - informed consent
- ethical issues related to promoting justice during the conduct of IR
  - standard of care in the IR design
  - ancillary care
- ethical aspects of data collection and management
  - data ownership, data sharing, data dissemination
  - privacy and confidentiality.
SLIDE 4-6: INFORMED CONSENT IN IMPLEMENTATION RESEARCH

Using this slide, introduce the participants to further information in part 1 of case study 1 in Annex 7. The participants discuss only part 1. After the participants discuss the questions in Slide 5 in the large group, use Slide 6 to discuss the issue of identifying the research participants in the study. In the case study, there are three groups of research participants, namely, the pregnant women, mothers and babies in the intervention, control villages, the community health workers, programme managers, policy-makers and district health officials. The data will be collected from the mothers and the babies.
Slide 7:
Highlight the differences between individual level and community level IR. Read out examples 1 and 2 and ask the participants to identify the research participants in both of the examples.
Slide 8:
Explain that in example 1 – the study of a new insecticide spray against mosquitoes – the study is at the level of the village and no individual household can be effectively prevented from being sprayed, thus the intervention is non-excludable. Thus, obtaining informed consent from each household may not be meaningful or feasible. However, in the case of MDA – administering a drug against LF to the entire population on the same day – individual participants can meaningfully refuse to take the medicines and it may not be difficult to explain and obtain informed consent from each individual before giving them the drug.

Slide 9:
Describe the various options for obtaining informed consent in IR. For community-level intervention, the options may be waiver of consent or community gatekeeper consent. For individual-level consent, the options may range from waiver of consent to individual-level consent up to dual-level consent from the gatekeeper and the individual.
Explain that sometimes informed consent may be waived in group-level IR and defines the conditions under which this can be done. The decision to waive informed consent is made by the ethics committee after detailed deliberations.

Move on to discuss the alternative options for group-level or community-level IR.

Discuss the concept of gatekeeper consent as an informed consent option for group-level IR. A community gatekeeper is a person who represents the interests of the community and has the community's welfare in mind.

Highlight the ethical concerns in the selection of gatekeepers. The gender of the gatekeeper should be a consideration in the context of the study. Justice considerations and the representation of the most vulnerable people should be considered in gatekeeper selection.

In case of individual-level studies in IR, there are some unique ethical issues, especially in the cluster-randomized design as described in the case study. Use Slide 11 to highlight these issues.
Slide 12:

**Individual consent questions**

**Is individual consent required even after obtaining gatekeeper consent?**

Sometimes individual consent may also be required as a second-stage informed consent process when risks and benefits directly concern the individual. For example, in the MDA campaign, apart from community-level consent from a gatekeeper, individual-level consent may also be necessary because individual risks are definite.

**Is it possible to obtain individual consent for randomization as cluster randomization happens a priori even in individual-level IR?**

Consent in research is for four different components – consent for randomization, consent for intervention, consent for sample collection, and consent for data collection.

In a cluster randomized trial, participants may not be able to give consent for randomization.

**If there is a no-intervention control group, what amount of information should be provided to them?**

Even to the no-intervention control group, full information should be provided. It is ethically appropriate that they know that they are part of a study in which the arm they belong to does not receive any intervention. Sometimes, providing information to the no-intervention control group may adversely affect their behaviours and their perceptions. This may distort the findings of the study.
SLIDE 13:

Following the above, summarize the discussions on informed consent in IR using the flow diagram in Slide 13.

The researcher asks whether there is a need for informed consent. If not, are the conditions for waiver of informed consent met? If there is need for informed consent, then is obtaining it at the individual level feasible? If obtaining individual consent is not feasible, the researcher considers gatekeeper consent. If the individual consent is feasible, then the researcher asks whether it is meaningful. Can an individual participant meaningfully refuse to participate in a study? In case of non-excludable public health interventions to which the individuals cannot refuse consent, gatekeeper consent is considered. Finally, the researcher has to also consider whether the local ethics committee approves the waiver of consent or the informed-consent process.
SLIDES 14-16: JUSTICE IN THE CONDUCT OF IMPLEMENTATION RESEARCH

Introduce the concept of justice in the conduct of IR and talk about fairness in participant selection. All segments of the community should have fair representation in the research. There is an ethical obligation to work with vulnerable communities in IR as the IR is more likely to be beneficial to them.

During the process of conducting IR, there are two main justice issues, namely, fair standard of care for control groups and the provision of ancillary care.

Introduce the participants to part 2 of case study 1 in Annex 7. Discuss the concept of acceptable standard of care with the participants given in issue 1.

Given the knowledge of the poor nature of the de facto care, can this be continued in the control clusters? What would be an acceptable standard of care for the control clusters?

The researchers should reflect on whether the de facto care is so poor that it is not acceptable in the opinion of the local experts. Is the clinical equipoise clause relevant? Will outcomes be similar in both the arms in the reasonable judgement of the researchers and local experts? If these two questions are answered in the negative, then the de facto care cannot be the acceptable standard. In fact, no-intervention control is no longer an ethically viable alternative in the research project.

Case study 1 – part 2

The mhealth application was developed by a German technological organization for use by frontline community health workers in Bangladesh.

An implementation research was designed to study the use, acceptability of the application by the frontline health workers, ease of use, perceptions of the frontline workers and the community about the application, and its effectiveness in improving quality of maternal and child health-care delivery in a district in Bangladesh.
SLIDE 17:
Introduce the alternative of a stepped-wedge design and describe how it overcomes the problem of standard of care, namely, everybody in the study gets access to the intervention in a phased manner so that nobody is left out of the intervention.
SLIDE 18 AND 19: ANCILLARY CARE

Next, direct the discussion to issue 2 of part 2 of case study 1 in Annex 7. There is an increase in the incidence of severe acute malnutrition among children between 6 months and 1 year of age in the research population. Although this is not directly related to the study, the finding is very important. What is the ethical responsibility of the researchers to provide ancillary care for this incidentally detected problem in the community? If the researchers are connected to the public health system, they should ensure at least a safe referral system for treatment of these children. The ancillary care may involve setting up robust referral systems within the health system.
SLIDES 20–24: ETHICS OF DATA COLLECTION AND MANAGEMENT

Initiate a discussion on the ethics of data collection and ask the participants the purpose of data collection. Data collection in IR helps to:

- establish the efficacy, safety and efficiency of public health interventions;
- identify disease states and outbreaks;
- allocate resource;
- improve population health (by translating data findings into interventions).

Thus, there is an ethical justification for data collection.

SLIDE 21:

Discuss the various sources of data for IR. Primary data are from people and communities participating in the IR. Secondary data may be obtained from health-system records, health management information systems and programme management information. The ethics of data protection in health systems are similar to those in biomedical and clinical research.
SLIDE 22:

After introducing the participants to data sources and the ethical justification for data collection.

**SPECIAL NOTE TO FACILITATOR:** introduce case study 2 in Annex 8 and encourage the participants to divide into four small groups. All the groups read part 1. Pose questions for discussion.

**What specific data is collected in this IR?**

The special outreach teams (SOTs) contact these groups and enumerate the names, family details, demographic characteristics, health details and vaccination status of all the children below 5 years of age in the five groups. The SOTs will maintain an ongoing registry of new births, new entrants into the nomadic groups, marriages, etc. They will follow up the pattern of immunization coverage over the years using a time-series analysis.

**Who benefits from data collection? Who might be burdened? What are the risks?**

The children born into the community may benefit from the intervention and the data collection. The nomadic communities will be tracked for immunization coverage and, hence, immunization rates may improve. This may protect the community. It may also protect the larger community in the country X. By collecting private information from the nomadic communities their privacy is invaded. This may be thought of as a burden. Being constantly tracked and having their movements monitored could be a burden.

**What will the data be used for?**

The data will be used for tracking all new-born babies and vaccinating them, and thus protecting them. The data will also be used to supplement the existing health management information system (HMIS) of the country.

Should the data be collected if there is no capacity or willingness to use them?

There is a demonstrated willingness to use the data if it is clearly articulated how they will be used (provide immunization, supplement the HMIS records). Thus, data collection is ethically justifiable.

**Is confidentiality required, how can it be maintained?**

Confidentiality is the protection of the data obtained from the communities. It may be difficult to maintain strict confidentiality as children’s names and contact details may have to be shared with SOTs in order to administer vaccinations. However, such information sharing may be kept to minimum as long as it only provided to those who absolutely need to know.
SLIDE 23:
Highlight some ethical issues in data use. The ethical burden of data use can be high in some public health activities, such as:

- contact tracing – identifying and tracing people who are not direct beneficiaries or participants in the IR, whose consent has not been obtained;
- quarantine of children who are not vaccinated, but are exposed to a particular vaccine preventable infection;
- mandatory vaccination of children – even in situations where parental consent for immunization is not available.

SLIDE 24:
Group 1 – Sharing data with public health
The public health system is requesting the IR team to share the name-based information on which children were vaccinated, the type of vaccines and when. The reason for this request is to optimize the use of scarce resources and ensure that all children are vaccinated, and, at the same time, make sure no child’s vaccination is duplicated. Is it ethical to share this information with the public health system? There are several points of discussion below.

- Did the IR team obtain informed consent to share the information?
• Provided that the public health system has a duty and responsibility for the health of the community in Country X, can this information be shared from a stewardship perspective?

• As the IR is operating within the purview of the larger public health context, is it important to support the greater public good?

Whilst the name-based immunization status of the children is already being shared, the public health system is also asking for location information. In order to discuss the ethical merits of this, one needs to consider the burden of making their location known to the public health system. Does it invade the privacy of this community? Is it essential to share location information with the public health system in order to ensure public health stewardship?

Group 2 – Sharing with forestry officials

The forestry officials of the country want to keep the nomadic community under surveillance to monitor poaching in the forest. However, the original intention of Global Positioning System (GPS) tracking was only to facilitate access to the communities in order to vaccinate them. While the GPS tracking of their movements for vaccination itself is a debatable move (with respect to breaching their privacy), sharing this data with the forestry department to prevent poaching is even more debatable. Also, it may seriously damage the trust of the community in the research team as well as the health system.

Groups 3 – Dissemination during an outbreak

Country X suffers from an outbreak of polio. The vaccination rates in the nomadic community are low. Should this information be disseminated to the larger community of Country X? The risk of disseminating the information about poor vaccination rates in the nomadic community is the isolation and labelling of the community from the rest of the country. Their nomadic movements may be restricted. They may suffer from livelihood restrictions. Dissemination of information about their poor vaccination rates may also cause panic in the larger community, which may blame the nomadic populations for the outbreak, with serious social consequences. If there is an outbreak of polio within the nomadic community, this may also endanger the public health safety of the neighbouring communities. However, the action of disseminating the information to the wider community is not an easy decision. Although there are strong benefits (preventing the outbreak from spreading), the potential risks for the vulnerable community members who are participants of the research has to be considered. Careful weighing of risks and benefits for all groups involved is strongly defensible.

Groups 4 – Disclosure

The research team in this case has become privy to information about a stigmatizing STI in the parents of the children with congenital syphilis. If they disclose this information to the public health officials, the parents, especially the pregnant women may receive treatment and congenital syphilis may be prevented in the unborn child. Moreover, if these parents are treated, they may also stop spreading the infection to their other sexual partners. However, there is a risk that this couple could be stigmatized and isolated from the community. Even if the information about their syphilis were kept confidential, the presence of public health personnel within the nomadic community, visiting the parents and offering them treatment, would in itself amount to public disclosure, as everybody within the small nomadic community would come to know about the treatment. The balance between these two circumstances is very delicate.
SLIDE 25:
Close the session after this discussion by summarizing the key ethical issues in the conduct of IR, namely, issues related to informed consent, issues of ensuring justice in the conduct of the IR, and finally issues of data collection and data management.

REFERENCES AND READING MATERIALS

- George AS, Mehra V, Scott K, Siram V. Community participation in health systems research: a systematic review assessing the scale of research, the nature of interventions involved and the features of engagement with communities. PLoS ONE. 2015:10:e0141091.
MODULE 5 ETHICAL ISSUES IN THE POST-RESEARCH PHASE OF IMPLEMENTATION RESEARCH
8. MODULE 5 ETHICAL ISSUES IN THE POST-RESEARCH PHASE OF IMPLEMENTATION RESEARCH

SPECIFIC LEARNING OBJECTIVES:
• to describe the ethical obligation to disseminate the findings of implementation research (IR);
• to describe the ethical implications of the sustainability of interventions studied in IR.

LEARNING METHODOLOGY:
Interactive lecture with illustrations.

REQUIRED RESOURCES:
PowerPoint presentation.

TIMING: 1 hour

SLIDES 2 AND 3: LEARNING OBJECTIVES AND SESSION OUTLINE

Introduce the module and highlight the various ethical obligations of the implementation researcher in the post-research phase of IR. The key considerations are:

• ethical obligations of researchers and donors to disseminate the findings from IR;
• role of IR in research capacity building and health system strengthening;
• post-IR access to interventions;
• ethical obligation to translate IR findings into policy and practice.

SESSION OUTLINE
- Ethical obligations of implementation research to disseminate research findings
- Role of implementation research in research capacity building and health system strengthening
- Post-implementation research access to interventions
- Ethical obligation to translate implementation research findings into policy and practice
SLIDES 4-9: ETHICAL OBLIGATIONS OF RESEARCHERS AND DONORS TO DISSEMINATE FINDINGS FROM IMPLEMENTATION RESEARCH

The session opens with a case study in Slide 4 to demonstrate why results should be disseminated. The Declaration of Helsinki, one of the leading ethical codes for the conduct of research in human subjects, states that all researchers have an ethical obligation to publish and disseminate all results. It is recognized that negative results are often difficult to publish, but there are other options to traditional publication, e.g. abstracts at conferences. Sufficient time should be spent discussing this as non-publication could mean the likelihood of another investigator spending human, material and monetary resources redoing the same activity, when the answer has already been obtained. Introduce the possibility of publishing negative results in the Journal of Negative Results in Biomedicine.

Slide 5:

Explain that implementation researchers have an ethical obligation to disseminate the IR findings. This ethical obligation is threefold:

- the data emerged from the community and it belongs to the community;
- justice requires that the IR should be given back to the community;
- there is a need to empower communities with knowledge.
Slide 6:
The information should be disseminated to all relevant stakeholders.

Slide 7:
The dissemination of the research findings to the community requires a delicate balance between the persuasive language of activism and that of honesty. The researcher should disseminate information with the intent of increasing knowledge and empowering the community.
Slide 8:
Initiate a discussion on data ownership. In donor-initiated research, the donors are the primary users of the data and so they often determine the nature and method of disseminating the findings.

Slide 9:
Describe a real-life example of how a donor influenced the publication of a negative research finding.

Often, researchers may incidentally stumble upon findings of systemic inefficiencies during their research and it is their moral obligation to report it or take corrective action, if possible. This is part of the post-research dissemination of information to those who need to know.
SLIDE 10:
Describe the ethical obligations to empower the local research capacity and to strengthen the health system.
IR may lead to a vertical system within the larger health system and this tends to drive substantial funding away from other important interventions. Therefore, there is a need to strengthen the health system by creating horizontal and integrated interventions. Horizontal health-care delivery refers to delivery of services through publicly financed health systems comprised of a comprehensive package of services. On the other hand, if a selective intervention to control a specific disease or condition is delivered without integrating it into other essential services, it is referred to as vertical service delivery. Horizontal and integrated services strengthen the overall health system.

SLIDE 11:
In IR, the interventions are usually system wide and ensuring post-trial access to them is an ethical obligation. Another important obligation is engaging with policy-makers and the health system to adopt and scale-up the successful intervention. Involving the health system at the design phase of the mhealth study and obtaining, from the beginning, a commitment to its sustained use and scale-up is a good strategy in ensuring its post-trial access.
SLIDE 12:

Usually, there is a delay in translating research findings into practice. In IR, there is an ethical obligation to convert the research findings into practice. Having a policy adoption plan at the beginning of IR is very important and stakeholder engagement is, therefore, useful.
If implementation research introduces an intervention into a system, there is an ethical obligation to scale up the intervention.

There is also an ethical obligation to sustain the intervention.

Community engagement at the beginning of the implementation research helps in ensuring sustainability.

Stakeholder engagement in terms of the public health system helps in scalability and sustainability.

Sometimes donor-initiated research may not have provision for long-term sustainability.

Local health system may not be able to afford to take over and sustain the intervention.

In such situations, should the research be done? Is it ethically right to conduct implementation research where scale-up and sustainability is a challenge?

Are there justice implications to anyway conduct such implementation research to generate knowledge?

Will political priorities and policy circumstances change and make the implementation research knowledge usable at a later date?

SLIDE 13 AND 14: SCALABILITY AND SUSTAINABILITY

If IR introduces an intervention into a system, there is an ethical obligation to scale-up the intervention. There is also an ethical obligation to sustain the intervention. Community engagement at the beginning of the IR helps to ensure sustainability. Stakeholder engagement in terms of the public health system helps in scalability and sustainability. However, issues of sustainability and scalability are not free of challenges. Sometimes, donor-initiated research may not provide for long-term sustainability. The local health system may not be able to afford to take over and sustain the intervention. Such a situation begs the question should the research be undertaken? Is it ethically right to conduct IR where scale-up and sustainability are challenging? Are there justice implications to conduct such IR in any case to generate knowledge? Will political priorities and policy circumstances change and make the IR knowledge usable at a later date? These are important ethical questions to be discussed.

Finally, summarize the various considerations in the post-trial phase of IR and stress that, in the post-trial phase, there is an ethical obligation to disseminate the data to all relevant stakeholders. There is also an obligation to ensure post-trial access to the successful intervention and to engage with the health system to ensure sustainability and scalability. In the post-trial phase, there is also an ethical obligation to empower the community, build research capacity in the local area, and strengthen the health system.
KEY MESSAGES

- Ethical obligation to disseminate and use implementation research findings.
- Ensure post-research access to interventions.
- Implementation research to play a role in ‘health system and research capacity strengthening’.
- Scalability and sustainability are a must.

REFERENCES AND READING MATERIALS

MODULE 6 IN-DEPTH ETHICAL ANALYSIS OF IMPLEMENTATION RESEARCH USING CASE STUDIES
MODULE 6 IN-DEPTH ETHICAL ANALYSIS OF IMPLEMENTATION RESEARCH USING CASE STUDIES

SPECIFIC LEARNING OBJECTIVES:
• to analyse in-depth the various ethical issues in the given case study;
• to apply the ethical considerations taught in this course.

LEARNING METHODOLOGY:
Group activity and plenary discussion (no power point presentations provided).
Two groups can be assigned one case study, two other groups another case study; this allows the opportunity for discussion on a wide range of ethical issues.

REQUIRED RESOURCES:
Case studies 3-7: Choose one or two case studies provided in Annex 9 and related facilitators note in Annex 10, which are best suited to the participants’ needs, or the ones they are most comfortable with, to allow for meaningful discussion. If appropriate, make minor modifications/adaptation to them to suit the context/settings.

TIMING:
3 hours
1.5 HOURS group work
1.5 HOURS plenary discussion

The ultimate goal of IR is to improve access to proven methods of care in communities where access had been lacking or suboptimal. As a prerequisite to the design of a successful implementation strategy:
• the clinical problem must be identified;
• the epidemiology of the disease must be understood;
• a situation analysis must be performed to identify why access is suboptimal;
• the actual bottlenecks/gaps in care should be identified (not merely presumed), so that interventions can be targeted to reduce them.

In the case of the adoption of a successful intervention from one country by another country, or the scaling up of interventions from a pilot phase, a situation analysis should also be carried out to determine the similarities and differences between the communities where the intervention has been successfully implemented and the communities in which it is planned to test the intervention. When the analysis justifies the full-scale implementation of the intervention, then the research is IR (which is designed to find out whether it will improve access to services).
The key components to be considered when designing an IR study are outlined as follows.

**Identification of the public health concern/problem disease and the concern/problem/disease burden.**

1. Determine the current standard of care (established treatment, guideline, protocol, evidence-based treatment for the condition) that is known to be effective.

2. Determine the implementation status/current performance data/quality gap. How widely is the standard of care currently implemented?

3. What is known about the implementation challenges? Why is implementation low?

4. What implementation strategies (approaches) will be tested for their ability to increase implementation of the standard of care?

5. In whom will the intervention be tested? How many groups? Similarity? Differences?

6. What is the major goal of the intervention study? What is the project trying to accomplish in terms of implementation outcomes? Broader spread? Acceptability? Sustainability?

**Points 1** is important as an aid in prioritizing the health problem within a country, to determine if a study is indeed necessary (i.e. the problem is an important health burden for the country). Ethical considerations here involve equity and justice, addressing the needs of the most vulnerable (Health Capability Paradigm, Accountability for Reasonableness, Benchmarks for Fairness, etc.).

**Points 2–4** relate to the need for a thorough and appropriate situational analysis, to engage with the community, to identify real needs and barriers on the ground, as a prerequisite to beginning to develop a strategy to tackle the barriers.

Ethical challenges here include those related to community engagement inclusion of the most vulnerable; avoiding shaming; understanding if an intervention would be acceptable locally; realistic understanding of the capacity of the local health system/health-care workers; identifying potential ancillary care issues that may arise; consideration of the potential sustainability and scale-up challenges, if the intervention were to be successful, etc.

**Points 5–7** relate to the design of the implementation to be tested. Ethical challenges here relate to equipoise, scientific rigour, quality of care or access to care for control groups, issues around informed consent, confidentiality, stigmatization, identification of appropriate community representatives, community engagement etc.

The cases presented in this module have been designed following this template, but, in some cases, some steps have intentionally been omitted or have not been appropriately addressed, in order to highlight the ethical challenges that are associated with interventional research.

**TABLE 3. CASE STUDIES**

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<th>Ethical challenges</th>
<th>Case 3 Antenatal syphilis screening</th>
<th>Case 4 Vouchers for delivery</th>
<th>Case 5 HMM malaria</th>
<th>Case 6 PMCT clinics</th>
<th>Case 7 Nomadic population</th>
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<tr>
<td>Transfer of a test/policy/procedure from one country to another</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td>Confidentiality/safety of contact tracing</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>False positive/negative test implications</td>
<td>✓</td>
<td></td>
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<tr>
<td>Who bears cost of study medication if standard of care?</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td>Sustainability</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Scalability</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Competing interests/duties of clinic staff, overwhelm clinic staff with extra work – decrease quality in other areas</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Vertical vs. horizontal programmes</td>
<td>✓</td>
<td></td>
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<td></td>
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<tr>
<td>Decentralization of laboratory testing</td>
<td>✓</td>
<td></td>
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<tr>
<td>Excluding vulnerable populations?</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Vouchers</td>
<td></td>
<td>✓</td>
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<tr>
<td>Incentives/gifts/inducements</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>Create need that cannot be met by health system/clinics</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Quality control</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>Induce over-treatment or over-use of services</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>“cherry picking”</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possibility for fraud/theft</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collateral impact (not on study subjects), e.g. taxi drivers, drug sellers</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group consent</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Selection of community representatives</td>
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<td></td>
<td></td>
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<tr>
<td>Ancillary findings/care responsibility</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Adequacy of follow up</td>
<td></td>
<td></td>
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<td>✓</td>
<td></td>
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<tr>
<td>Opt-out possibilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Subject confidentiality</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Consent in illiterate subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Stigmatization through subject identification/participation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Blurred line between research and clinical care</td>
<td>✓</td>
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</tr>
</tbody>
</table>
10. PRESENTATION AND FACILITATION SKILLS: GENERAL TIPS

10.1 SKILLS REQUIRED TO BE AN EFFECTIVE TRAINER/ FACILITATOR

• Technical expertise in the subject matter.
• Understand background and material.
• Able to facilitate the discussions and provide inputs to participants on the various case studies.
• Good presentation skills.

10.2 PRESENTATION SKILLS

• Project your voice if microphones are not used.
• Listen to participants:
  • reply to questions in a concise manner
  • respond to comments.
• Stay calm under pressure:
  • deep breathing exercises may help.
• Be organised.
• Although an expert, always be open to learning new things!
• Act as a good facilitator for discussions.
• Practice and rehearse the material beforehand.
• Avoid jargon, slang and colloquialisms:
  • for example, in South Africa, people often say "shame" to show that they are feeling sad for you, or to express solidarity when an event has gone wrong; however, in other cultures, shame is used to project a negative feeling onto someone, to actively shame them.
• Ask questions to keep the participants engaged:
  • at the beginning of the course, participants might be shy and reluctant to speak up, so when you ask a question, provide them with silence so that they will feel the need to fill it; count to 10, if after that time no one has replied, provide them with a hint – this should hopefully prompt them to start responding.
• Define abbreviations.

• Keep in mind the non-verbal cues:
  • appearance – be culturally sensitive, and dress as you would for a business meeting; after the first day, you may dress more business casual, depending on the audience;
  • do not cross your arms too much, stay relaxed;
  • do not jingle the keys or change in your pockets, it might be distracting.
• Maintain eye contact.
• Keep a bottle of water close by in case your throat becomes dry. Try to avoid iced water as that can cause the throat to constrict.
• Vary your voice through pitch, volume, pauses and speed.
• Remember that humour is not universal! What is funny in one setting might not be in another. This is particularly true when using simultaneous translation as the joke might not translate:
  • use humour with caution – if you know your audience, then it will elevate the presentations, relax participants, and create a friendly atmosphere ripe for learning;
  • if you are in a new setting, use humour with caution – get to know the group, the culture, the setting.

10.3 HOW TO ANSWER QUESTIONS FROM THE PARTICIPANTS

• Wait before immediately responding.
• Ask the other participants if anyone has ideas, or wants to contribute.
• Avoid making judgements – participants are here to learn.

10.4 FACILITATION SKILLS

Facilitation skills may be described as the process of making something easier; the role may vary from doing nothing to actively directing the activities. In guiding the participants, a facilitator helps them: interact with each other; gain new information; build upon their experience; and reach the stated goals and objectives within the allotted time.
10.5 THE ROLES OF A FACILITATOR

• Main focus is on making content meaningful to learners.
• Basic approach is ‘How can I help you learn what you want to learn?’
• Usually help learners deal with content using a wide variety of approaches.
• Use a lecture to obtain something else from the learner, e.g. application of content to personal experience.
• Usually asks the learners many questions.
• Encourages learners to develop their own view of reality by using the subject matter. Do these objectives reflect all what you want to achieve? Do you have a way to measure that you have achieved them?
• Commit to sharing the responsibility for the learning situation with learners.
• Involve the learners in participating in every aspect of the course.

10.6 A GOOD FACILITATOR

• Keeps the group focused on task and process.
• Remains as objective as possible.
• Is an informed guide, helping the group to accomplish its objectives.
• Listens more than talks.
• Adopts various learning styles.
• Encourages everyone to participate while remembering that individuals participate in different ways; some may talk only in small groups, still be participating, while others may talk constantly but be contributing little.
• Protects members of the group from attack by others.
• Is sensitive to gender and cultural issues.
• Energizes a group or slows it down as appropriate.
• Recaps occasionally on what has happened in the course and helps groups to make connections between sessions.

10.7 GENERAL TIPS FOR THE TRAINERS

The delivery of the material can be adapted to the local context, as long as the slides are not altered or deleted. This guide is to familiarize the facilitator with the contents of the training material and not to be used verbatim in the teaching. As the trainers/facilitators will have been working in research and ethics for a number of years, they are likely to have experienced many situations, which would make great examples during the sessions. Although the course has been developed to ensure consistency in the teaching, if a trainer has a great example that will clarify a teaching point, they should feel free to use it!

Participants will be asked to come to the course as a team. Over the two and a half days of the course, they will have the opportunity to learn from and exchange ideas with their peers. The exercises provide the opportunity to apply their learning. During the exercises, facilitators should walk around the groups and spend time with each group so participants can ask specific questions. As the trainers are ‘experts’ in the field, they should be able to help each team with any issues that might come up.

Summary and recapitulation: Each day could end with a quick summary of what was learnt during the day; every morning can begin with a re-cap of the previous day. This has two purposes: (1) it wakes up the participants; and (2) it provides a useful summary so the material is fresh in everyone’s minds. The participants should do the re-cap with small prompts from the trainer as required.

10.8 EVALUATION

• Following each course, review what did and what did not work.
• Make notes for the next course while it is fresh in the minds of all the trainers.
• Ask for feedback from all the participants using either a structured questionnaire or qualitative interview. Analyse the data and modify training materials/methods as appropriate.
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Barr DA. Ethics in public health research: a research protocol to evaluate the effectiveness of public-private partnerships as a means to improve health and welfare systems worldwide. AJPH. 2007;97:19–25.


George AS, Mehra V, Scott K, Sriram V. Community participation in health systems research: a systematic review assessing the state of research, the nature of interventions involved and the features of engagement with communities. PLoS ONE. 2015;10:e0141091.


King KF, Kolopack P, Merritt MW, Lavery JV. Community engagement and the human infrastructure of global health research. BMC Medical Ethics 2014;15:84


Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. BMJ 2013; 347


Su X-Z; Miller LH. Discovery of artemisinin and the Nobel Prize in Physiology or Medicine. Sci China Life Sci. 2015;58;1175–9.


An mhealth application was developed by a German technological organization for use by frontline community health workers in Bangladesh. The application would guide the health worker in delivering maternal and child health-care services such as:

- registration of pregnancy
- reminders for antenatal care visits
- alerting for birth preparedness
- motivation for institutional delivery
- post-natal visits
- immunization of the child
- infant and young child feeding practices
- growth monitoring.

The application was developed entirely in Germany with local input from experts in Bangladesh. The application was developed in Bengali, the local language. It was field tested among 10 health workers who knew the Bengali language in Germany and found to be useful. An implementation study was designed to study the use, acceptability of the application by frontline health workers, ease of its use, perceptions of the frontline workers and the community of the application and its effectiveness in improving quality of maternal and child health-care delivery in a district in Bangladesh.

The study revealed that the frontline workers found the application extremely useful. They felt empowered by the use of the handheld device with the application. Some questions and data formats in the application needed to be changed based on the feedback given by the health workers. The data were captured accurately and in a timely manner. This improved data driven public health decision-making at the district level. There were practical issues with maintenance of the handheld device in some of the remote villages. In some villages where there was no electricity, so charging the devices was a problem.

Discuss the findings of this study. If the country plans to adopt and implement the strategy on a wider scale, how will these findings influence this decision?
# Module 3: Activity Table 1

## – Research Designs –

### Facilitator’s Copy

#### Types of Implementation Research (IR)

<table>
<thead>
<tr>
<th>Type of IR</th>
<th>Features</th>
<th>Example</th>
<th>Ethical concerns particularly relevant to study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cluster randomized trials (group randomized, place-based, community intervention trials)</td>
<td>Random allocation of groups of ‘clusters’ of subjects to study arms and outcomes are measured in individual subjects within clusters</td>
<td>Randomization of clusters of obstetrics unit staff to education on hand washing or usual practice, measurement of rates of puerperal sepsis in women delivering at study clinics</td>
<td>Different units of intervention and outcomes measurement&lt;br&gt;Unit of randomization&lt;br&gt;Consent before and after randomization, who gives consent?&lt;br&gt;Unit of consent?&lt;br&gt;Choice of gatekeepers&lt;br&gt;No opt-out option within cluster&lt;br&gt;Risk: benefit balance&lt;br&gt;Ethics of randomization to known intervention, equipoise&lt;br&gt;Identification of vulnerable groups</td>
</tr>
<tr>
<td>Effectiveness–implementation hybrid trials</td>
<td>Assess both effectiveness and implementation strategy simultaneously Identify intervention – implementation interactions</td>
<td>Evaluate the impact of sleeping under insecticide treated nets (ITNs) on reduction of malaria infection compared to historical controls (quantitative), and assess costs, consistent availability of nets, affordability and uptake of ITNs in the community (quantitative and qualitative)</td>
<td>Community engagement&lt;br&gt;Reaching most vulnerable&lt;br&gt;Informed consent</td>
</tr>
<tr>
<td>Mixed–methods research</td>
<td>Use of both qualitative and quantitative methods&lt;br&gt;Understands various perspectives&lt;br&gt;Rationales: ‘participant enrichment’, ‘instrument validity’, ‘implementation validity’, ‘meaning enhancement’</td>
<td>Integration of HIV and TB management in single clinics to enhance quality of care. Patient experience (qualitative), adherence, clinical outcomes and cost (quantitative) will be studied over a 1 year period to determine the clinical impact and impact on quality of life in comparison to ‘usual care’ where patients attend HIV and TB clinics separately.</td>
<td>Inclusion of vulnerable groups&lt;br&gt;Informed consent&lt;br&gt;Stigmatization</td>
</tr>
<tr>
<td>Type of IR</td>
<td>Features</td>
<td>Example</td>
<td>Ethical concerns particularly relevant to study design</td>
</tr>
<tr>
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</tbody>
</table>
| Participatory action research | Control of research held by research subjects                            | Community itself proposes a study to test whether peer support groups in local communities improve adherence to ARV in HIV + subjects. An iterative research process will engage in continuous programme evolution as challenges and successes become apparent. Adherence and incidence of new opportunistic infections in HIV + subjects over 1 year will be compared to that in a control community where peer support will not be introduced but their access to treatment remains as ‘usual’ care. | Community engagement  
Inclusion of vulnerable groups  
Gatekeeper selection and representativeness  
Stigmatization  
Does study question represent a true health-care priority in the community?  
How similar are the two study communities (scientific rigour)?  
How to obtain/need for consent community? |
| Pragmatic trials              | Effects of intervention in routine practice  
Maximize variability of settings, practitioners, patients                  | Introduction of community health workers (CHWs) for home-based management of malaria (HMM) into one district and another comparable district continues with current standard of care (patient presents to clinic for diagnosis and treatment). Outcomes of malaria infections in both districts over 1 year are evaluated. In addition, tracking of costs and acceptability of CHW in the community are also studied. | Community engagement  
Informed consent  
Opt-out options?  
Ancillary care responsibilities |
| Quasi-experimental study      | Real-life conditions  
No control group                                                             | Open-label demonstration project of the effectiveness of self-reported use of pre-exposure prophylaxis for HIV                                                                                     | Lack of control group reduces scientific rigour                                                                 |
| Realist view                  | Explanatory analysis on how and why an intervention works in a specific context relative to a priori theoretical presumptions  
Combines theory and empirical evidence                                    | Integration of traditional healers into HMM strategies based on theoretical assumptions of positive impact  
An in-depth literature review of available empirical data on the topic from elsewhere is conducted to understand and identify factors that impact on implementation, and to apply this understanding to the local context as a step in policy development. | Relevance of literature to local context  
Accuracy/relevance of pre-study assumptions |

Source: Adapted from Peters et al. (2013); Weijer et al. (2011).
### Annex 3. Module 3: Activity Table 2

- Participant’s Copy

**Ethical Relevance of Differences Between Biomedical/clinical research and Implementation Research**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Biomedical/clinical research</th>
<th>Implementation research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Subjects</td>
<td></td>
<td></td>
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<tr>
<td>2 Informed consent</td>
<td></td>
<td></td>
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<tr>
<td>3 Equipoise</td>
<td></td>
<td></td>
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<tr>
<td>4 Research question</td>
<td></td>
<td></td>
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<tr>
<td>5 Research conditions</td>
<td></td>
<td></td>
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<tr>
<td>6 Control groups</td>
<td></td>
<td></td>
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<tr>
<td>7 Anticipated outcomes</td>
<td></td>
<td></td>
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<tr>
<td>8 Risks assumed by</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Benefits accrued by</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table compares differences between clinical research and IR as an important step in understanding/illustrating how the ethical implications may be different between the two forms of research.
4. ANNEX

MODULE 3
COMMUNITY ENGAGEMENT ROLE PLAY:

RESEARCHERS (THERE SHOULD BE AT LEAST 2)
- Study background given for this case
- Plan community entry and engagement carefully before starting
- Ideally, you need to engage with all community members to understand their acceptability and willingness to engage in the research
- Be aware that multiple community members have differing points of view and personal situations and power relationships
- Plan according to last slide: When, Where, What, How, with Whom?

COMMUNITY REPRESENTATIVE/S
- Male chief, 65 years old
- Tries to speak a lot, interrupts others frequently, very confident
  - Married to third wife and 8 children, lost 2 children in childbirth and lost his first wife in childbirth
  - Speaks Bengali and local dialect fluently
  - Is fully literate, was previously a high school teacher
- Has large ego, wants to be recognized as the chief and respected and revered
- Wants a cell phone as well
- Wants better electricity delivery to the village to facilitate cell phone charging, has been approached by a solar-panel company and tries to convince researchers to use this company to provide electricity
- Is concerned about the German company (a foreign company) entering their village and collecting their data. Is skeptical about how their information will be used.
- Some tension about community leadership with the imam (Islamic religious head)
PREGNANT WOMAN 1

- 24-year-old woman, second pregnancy (first pregnancy was uneventful besides low-birth weight infant)
- Shy and cautious to express her opinion
- Only speaks local dialect, cannot read well
- Went to school for 4 years
- Works in fields
- Husband works in the city 200 miles away and comes home every 6–8 weeks, main source of income is what the husband sends
- Family pressure, strong belief in traditional birth attendants
- Has never used a cell phone, has heard of them
- Worries that she may not be able to use the phone, feels ashamed

(Only volunteer this information if asked in some way – problem not commonly acknowledged in the village.) Clean water is available for the village in a borehole constructed by an NGO, but women are afraid to walk the 1 km to get water as many have been harassed and raped along the way (husbands are away) The major preoccupation for women in this village is this violence which concerns them more than the risks of childbirth

PREGNANT WOMAN 2

- 18-year-old woman, was raped on way to water source (others not aware of this unless they really engage well, you are humiliated and do not want to divulge this in public), HIV positive
- Is literate and speaks Bengali
- Went to school for 8 years, spent 1 year with relatives in the city before returning to the village for an arranged marriage
- Works as a seamstress
- Family pressure, strong belief in traditional birth attendants
- Is very eager to get a cell phone
- Worries about privacy of messaging and about the village knowing of her diagnosis and medical history
- Problems with vision and so find it difficult to constantly peer into the mobile phones (these workers are reluctant to use the application)
- Working in clinic with erratic supplies
- Worried about cell-phone initiative because it will bring more women and children to the clinic and will increase their workload
- If she leaves the adult polyclinic section there will be no experienced staff in that section, all are juniors
- Worried patients will call them at home when they are off duty and how to respond then?
MOTHER OF AN INFANT (5 MONTHS)

- Has so far not taken her infant for any vaccinations as the imam had advised against vaccination of male children
- Believes that anything foreign is suspicious
- Is also uneducated and is apprehensive of mobile phones
- Worried about imam’s approval
- Feels trapped between her allegiance to the imam and potentially doing something good for her child

HEALTH–CARE WORKER(S)

- 50–year–old health worker, very senior, burned out, very interested in this study which she thinks will increase her prestige
- Thinks the study medically worth doing
- She wants a cell phone to keep up with other village nurses
- Has poor eyesight, worried she may not be able to read the phone, embarrassed about this
- Will likely move from her section – she is the head of polyclinic for hypertension (HT) and diabetes mellitus (DM) management – and when she leaves there will be no senior nurses in that clinic
- Worried about her privacy that people will call her up at all times and expect her to solve other problems unrelated to the project

TRADITIONAL BIRTH ATTENDANTS

- Understand sometimes pregnancy ends badly but this is natural
- Cell phones are suspicious
- Speaks only local dialect, illiterate
- Not eager to speak out unless really coaxed
- Clinic is trying to steal her clients
- Might be interested in collaborating with the clinics and relaying information about home visits if the study provides a bicycle so she can get around for shopping and taking her child to school, etc.
- Worried about imam’s approval

AIRTIME (PHONE TOP–UP) SELLERS

- Interested in the study because likely will increase sales of airtime
- If demand increases can increase his prices
- Worried that airtime will be provided by the study from a more centralized place and he would lose business
**FEMALE ELDER**
- Supports traditional birth attendants
- Suspicious of cell phones
- Speaks only local dialect, illiterate
- *(Do not volunteer this information too easily.)* Is worried about violence against young women with absent migrant worker husbands in the village
- Worried about imam’s approval

**LOCAL IMAM**
- The whole village respects and reveres him as the intellectual of the village; they look to him for moral and religious advice
- Is a well-educated man and is fairly well informed about mHealth
- Has a feeling that there is a strong anti-Islamic sentiment in the western world and the innocent peace loving members of his village should not become victims of this paranoia
- Very confident in his views

**NEIGHBOURHOOD WATCH**
- Concerned about violence and robberies of phones
- Worried the study will bring more crime to the area

**CHURCH LEADERS**
- Potential conflict with imam
- Judgemental about unmarried mother

**FIELDWORKERS**
- Want the job and phones so very supportive
5. ANNEX

MODULE 3 STAKEHOLDER ENGAGEMENT ROLE PLAY

RESEARCHERS (THERE SHOULD BE AT LEAST 2)

- Study background is given for this case
- Plan your entry and engagement with the stakeholders before starting
- Ideally, you need to engage with all stakeholders to understand acceptability and willingness to engage in the research
- Be aware that multiple stakeholders have differing points of view and personal situations, power relationships
- Plan according to last slide: When, Where, What, How, with Whom?

GERMAN COMPANY

- Eager to test their product and create a market
- Have other apps ready to be marketed in developed countries for weight loss, need proof of principle
- Study cheaper to do in Bangladesh than in Germany or the United States
- Has collaboration with cell–phone company they plan to co–fund the study with, App at present only functions on specific cell–phone platforms
- Know the local authorities are interested in their district being seen as pioneers
- Know ministry of health is under pressure to achieve health-related targets
- Want ownership of the data

MINISTRY OF HEALTH

- Pressure to reach targets for maternal mortality and child mortality
- Cell phone study is new and innovative
- Costs may be manageable over the longer term if prices not raised by company and participants have their own cell phones
- Concern about diversion of staff from other clinic areas to this project
- Wants ownership of the data as most interesting data is the patient outcomes that will come from the clinics
- Needs assurance of confidentiality
- Needs upgrading of existing computer systems in clinics for data capture, would require funding from study for this
LOCAL AUTHORITIES
• Pressure to reach targets for maternal mortality and child mortality
• Cell–phone study is new and innovative
• Concern about diversion of staff from other clinic areas to this project
• Concern clinics may be overwhelmed with clients and not have reliable enough stock and facilities to manage all the cases
• Feel a major priority before such a study would be to improve efficiency of stock tracking and deliveries

CELL–PHONE COMPANIES
• Has collaboration with App development company they plan to co–fund the study with, App at present only functions on specific cell–phone platforms
• Know the local authorities are interested in their district being seen as pioneers
• Want to broaden market for their specific cell–phone platform
• Bengali language is adequate on phone
• Batteries can be charged with electricity or via regular batteries through a small device [would need to be purchased by end–user or provided by the study]
• Solar charger device very slow, takes 8 hours to charge

CELL–PHONE SERVICE PROVIDERS
• Can provide large numbers of SIM cards and airtime at a reduced price during the study?

ELECTRICAL COMPANY
• Eager for study to take place because they know the chief and have negotiated with him to use the study as potential leverage to improve electricity delivery to the district

BENGALI TRANSLATORS
• Translations done by second generation Bengali’s who were born in Germany and are fluent in German
• Do not have any medical knowledge
• Did translation as best they could, some terms were culturally sensitive and awkward to translate (e.g. last menstrual period)
• Translations ‘testers’ felt pressure from the company to perform well in the hope of future work and were, therefore, not very critical of the translation
DATA HANDLERS

- Explain how cell-phone data will remain confidential, how study participant identity will be protected, risks of hacking of phones, risk of loss of phone and, therefore, loss of confidentiality
- Paid for my German company
- Need to get access to clinic records in order to record patient outcomes if deliveries are at the clinics, follow ups, etc.
IMPLEMENTATION RESEARCH

STUDY AIM

To study the use, acceptability and effectiveness of an mHealth intervention to improve the quality of maternal and child health-care delivery in a district in Bangladesh

ABOUT THE STUDY DESIGN AND GOAL

• The mHealth application for use on mobile phones was developed by a German technological organization for use by frontline community health workers in Bangladesh

• The application would guide the health worker in delivering maternal services, such as:
  • registration of pregnancy
  • reminders for antenatal care visits
  • alerting for birth preparedness
  • motivation for institutional delivery
  • post-natal visits
  • immunization of the child
  • infant and young child feeding practices
  • growth monitoring.

• Application was developed entirely in Germany with local input from experts in Bangladesh.

• The application was developed in the Bengali language.

• It was field tested among some people who knew Bengali language in Germany and found to be useful.

IMPORTANT CONSIDERATIONS IN COMMUNITY AND STAKEHOLDER ENGAGEMENT

1. What are the core imperatives of stakeholder engagement?
   • Identify and manage non-obvious risks and benefits.
   • Expand respect beyond individual to stakeholder community.
   • Build legitimacy for research project.

2. Does the study meet the community’s needs?
   • This is the first crucial step in determining whether it is ethically justifiable to conduct the study at all. This must therefore be ascertained in the earliest stages of study conception. Potential sources of this information include the public health officials and the health ministry. But the community itself must also be consulted to determine whether even though this study may address a prevalent need, it may not be a top priority for the community members who may wish to address another competing need first.
3. How should community or stakeholder engagement occur?

- When? Timeline? Stakeholder engagement should occur as early as possible
- Where? State facility? Town/community hall? Traditional venues? The location must be accessible to all relevant stakeholders and not be threatening or impose discomfort or re-enforce inequalities.
- With whom? Identify all the stakeholders.
- Why? To listen to the community first, understand needs, desires and similar with all other stakeholders.
- How? What method/medium, e.g. posters, group meetings, media, pamphlets, face-to-face meetings, in town halls or at village meetings? Pay attention to literacy and most vulnerable stakeholders’ access to means of communication and ensure appropriate means of communication for each group.
- How long should it take, should it be before, during or after the study? Ideally ongoing to gain feedback and adjust if required.

4. Who are the stakeholders in this study?

- Communities
  i. Selection of research participants/location/inclusion of vulnerable groups is crucial to ethical considerations, which assist in identification of appropriate stakeholders.
    1. Frontline health-care workers will need to accept the mhealth intervention be confident enough to use it.
    2. Pregnant women and mothers will need to accept their health-care worker using mhealth.
  ii. Will all health centres have access to mhealth, e.g. wireless availability, electricity? Need to ensure more vulnerable/remote centres and women are not excluded.
  iii. The German Bengali translation should be checked and determination should be made if Bengali is indeed the predominant language, and how the study will benefit those who do not speak/understand/read Bengali.
  iv. Is literacy a study participation requirement? How literate is the local community?
- Researchers: German organization; any other partners; for-profit or NGOs or universities, etc.? All may be ethically relevant.
- Funders.
- Sponsors, institutions.
- Collaborators.
- Government: need to engage with health ministry to investigate sustainability of mhealth long term in the region where study will take place and plans/potential for scale-up countrywide if intervention is successful.
- Local authorities: need their buy-in and ownership of the project.
- Health-care workers (HCWs), community health workers, volunteers, traditional healers: need to ensure local traditional birth attendants do not feel threatened or marginalized; consider ways of including them in the project. Need to understand any unforeseen barriers to mhealth among HCWs.
- Handheld device manufacturers, distributors: need to engage with them to assess potential market impact, commitment to affordable pricing over long term, maintenance of infrastructure, etc.
- Others impacted by study, e.g. cell phone service providers: need to engage to assess buy-in, negotiate fair pricing for their services, etc.
- Who is the research’s audience? Plans for publication in relevant journals/websites/nongovernmental organizations (NGOs), etc. to maximize reach of study results.
- Who should represent the community?
  i. Consideration will need to be given to local customs and if local women can give their own consent or whether consent should be community-based. Who would be a legitimate representative, e.g. a female community elder, pregnant women or mothers? How should such individuals be identified and selected?
  ii. Separate consideration must be given to who will represent the HCWs?
6. Risk assessment

- Individual harms

  i. Three sources of vulnerability

1. Inherent: pregnant women especially if from vulnerable populations may be willing to accept participation thinking they will receive better care or attention. They may be influenced by technological nature of the study. If a woman has a bad outcome or does not comply with all recommendations she may be subjected to shame. Not all pregnant women may have cellphones and be able to participate and therefore may attend clinic even less frequently from a feeling of inadequacy and shame. HCWs may experience shame if they struggle to use the hand-held devices if they forget to charge the devises or the devices malfunction. They may also be subjected to extra workload involved with the study, documentation, tracking of women, etc., as well as being potentially more 'accessible'. Privacy and confidentiality in capturing and transmitting electronic data must be considered.

2. Situational: because of social, political, cultural milieu, e.g. socioeconomic status. Local poverty and perception that technology must be good may influence use and participation in the study and bias results because of a ‘novelty’ factor. Some communities may be intimidated by the technology? The technology would further undermine the role of traditional birth attendants, which may create stress and dissonance within the community.

3. Pathogenic: HCWs or mothers having study devices may be subject to theft and violence, they may be subject to over-spending if they have access to a SIM card and use of the device for personal communication. Thus, they may be made worse by attempts to reduce vulnerability.

- Social harms: the study may change the perception of traditional birth attendants or create distrust of other health services not supported by mHealth.

- Financial harms: women or HCWs may be subject to over-spending if they have access to a SIM card and use of the device for personal communication.

- Communal harms: new infrastructure may be built for the study to support mHealth devices, which could facilitate use of other devices by general community members. If the study is not sustained, services may stop.

- Harm to health system: if the study were successful but not rolled out or sustained, this could create disappointment and distrust in future studies and the health system. Trust in non-technology-based health care may decrease, HCWs/demand for services may be overwhelmed and divert attention/resources from other areas.

7. Risk levels: benefits and risks to each stakeholder group should be considered and if necessary weighed against each other to ensure fair distribution of risks and benefits especially if not accrued in the same individuals. Close follow-up and frequent feedback should continue throughout the study to identify any unforeseen harms/consequences of the intervention, e.g. the development of dependence on technology and a reduction in the use of other services, or overuse of services, etc.

8. Commitment to scale up, if successful: important to have prior commitment from the government. Requires realistic estimation of costs, commitment from manufacturers, distributors, and service providers to ensure affordability.
This case study uses the same case study as in the other modules. In this case study, some specific issues related to ethical considerations in the conduct of IR are explained.

**PART 1.**

The mhealth application was developed by a German technological organization for use by frontline community health workers in Bangladesh. An IR was designed to study the use, acceptability of the application by the frontline health workers, ease of use, perceptions of the frontline workers and the community about the application and its effectiveness in improving quality of maternal and child health-care delivery in a district in Bangladesh. It was a cluster randomized controlled study with 10 villages randomized to intervention and 10 villages to routine maternal and child health care by the community health workers.

Who is the focus of intervention in this study? On whom are the outcomes assessed? Who are considered as research participants? Who should give informed consent?

Can any woman in the intervention clusters refuse to have her data collected by the mHealth system? What are the implications of this refusal? Is individual informed consent meaningful in this context?

**PART 2.**

**Issue 1.** In the same case study described above it is known that data capture using the routine paper based system has a significant delay in being reported to the information system. Because of this delay there have been several instances of poor data based planning for maternal and child health care delivery services which have resulted in poor outcomes.

Given this knowledge of poor nature of the de facto care, can this be continued in the control clusters? What would be an acceptable standard of care for the control clusters?

**Issue 2.** During the conduct of the IR, it is found that there is an increase in the number of children with severe acute malnutrition in the age group of 6 months to 1 year.
The Ministry of Health of Country X has committed funds towards designing a successful implementation study to determine the optimal strategies to deliver childhood vaccinations to nomadic and remote communities in the country.

Special outreach teams (SOTs) will be deployed to a selected sample of known nomadic and remote communities. The teams will be supplied with all logistical requirements, i.e. vehicles, ice boxes, adequate vaccine stocks, translators, etc., and be trained to deliver the required vaccinations to all children under 5 years old in these communities and collect quantitative data on the existing level of vaccination coverage, numbers vaccinated, document feasibility challenges and tracking costs. The SOTs will work in coordination with the regular community health workers in the area delivering routine vaccination services in addition to other primary health–care services.

In addition to the SOTs’ intervention, in a selected subsample of communities, a key individual from each community will be identified to participate in a smart phone–based GPS tracking study, to assess the feasibility and utility of locating nomadic communities in real–time. Solar–powered battery packs will be supplied to these key individuals. Their location will be tracked in real–time and reported to the SOTs for more effective delivery of services.

PART 1. DATA COLLECTION

The implementation is rolled out in five nomadic groups in the area. Two of these groups are selected for the real–time GPS location study and key members of these groups are provided with the smart phones for GPS tracking of their location. The SOTs contact these groups and enumerate the names, family details, demographic characteristics, health details and vaccination status of all the children under 5 years old in the five groups. They administer the first dose of vaccine to all eligible children and conduct community meetings.

The SOTs will maintain an ongoing registry of new births, new entrants into the nomadic group, marriages, etc. They will follow–up the pattern of immunization coverage over the years using a time–series analysis. They will also work in close coordination with the local public health system and share the data with them for their health management information system records.

PART 2. DATA SHARING, DISSEMINATION AND DISCLOSURE

For the following scenarios, assume that a group outside the formal public health system (perhaps an NGO or research organization) has already been collecting data.

GROUP 1. SHARING WITH PUBLIC HEALTH

Keep in mind the information we added to the vaccine case above and consider the following development. Public health officials are interested in boosting vaccination rates in the country. They want to start a vaccine registry. Given the richness of these data, they are asking for name–based information. They argue that it is important to ensure that all children receive all vaccinations, that resources are not wasted, and that children are not put at unnecessary risk by duplicating vaccinations.

Consider the questions below.

- Can identifiable health information be shared with public health for the purposes of creating a registry?
- Can the GPS location information be shared with the public health system?
GROUP 2. SHARING WITH FORESTRY OFFICIALS

It is not only public health officials who want your data. While this study is ongoing, the local forestry officials approach the research team. They complain that some of these nomadic groups are engaged in poaching wild animals for their hide and teeth in the forest area. They know that GPS tracking is being done for these nomadic groups for research purposes. They want the research team to share the data so that they can keep them under surveillance.

GROUP 3. DISSEMINATION IN AN OUTBREAK

The researchers regularly report vaccination levels back to the nomadic populations that they are tracking. Imagine an instance in which nomadic populations have particularly low levels of vaccination for polio.

Consider the questions below.

• In the context of an outbreak in the broader population, can they, should they, and must they also disseminate information about vaccination rates in nomadic communities more broadly?
• In the context of an outbreak in the nomadic community, should researchers disseminate the information to neighbouring communities and those that the outbreak has the potential to reach?
• What risks are associated with this decision to release this information?

GROUP 4. DISCLOSURE

Imagine that our researchers find a case where two children under 5 years old have congenital syphilis. The mother is pregnant with a third child.

Consider the questions below.

• Should the researchers disclose the name of the children and parents to health officials so that they can offer testing and treatment?
• Could the involvement of health officials and their subsequent interaction with the family effectively amount to public disclosure? If so, is disclosure still warranted?
• Are there ever circumstances when the names of individuals with disease should be disclosed to the public?

CASE STUDY 3: ONE-STOP SERVICE FOR ANTENATAL SYPHILIS SCREENING

Congenital syphilis is a highly preventable condition that is associated with significant morbidity. A full course of penicillin completed prior to 30 days before delivery in pregnant women testing positive for syphilis will prevent congenital syphilis in her child. Syphilis screening is recommended at the first antenatal clinic (ANC) visit and in the 3rd trimester of pregnancy. The ANC syphilis screening guideline includes pre-test counseling and after obtaining consent, a vial of blood is sent to a reference laboratory for diagnosis (RPR, rapid plasma reagin and TPHA, Treponema pallidum hemagglutination). The pregnant woman is then requested to return to clinic for the result, post-test counseling and if the test is positive, she is referred to a specialty clinic for treatment with 3 weekly doses of intramuscular Penicillin G (if not allergic). The woman is also invited to inform her partner who would also be tested and treated similarly for free. Testing and treatment has been freely available in ANC in country A (Central Asia). Despite 98% of women attending ANC however, the frequency of syphilis testing was low and the incidence of congenital syphilis rose over 20 fold between 1995 and 2006. To address this problem, a cluster-randomized trial of a “one-stop” syphilis screening and treatment protocol was carried out in country A. The screening test involved a previously validated point-of-care finger prick syphilis test where a result was obtained in 15 minutes. If a woman tested positive, blood was drawn to be sent to the lab for confirmation; she however received a first dose of Penicillin G at the same visit. She was asked to return weekly for 2 more doses of Penicillin, unless the confirmatory test was negative in which case Penicillin was discontinued. She was also invited to inform her partner who would be screened in the same way. This one-stop screening/treating policy resulted in a significant rise in testing and treatment of syphilis in pregnant women and their partners and a significant decline in the incidence of congenital syphilis.

As the head of preventive services in the Ministry of Health in country B (Central Africa), you have been approached by a company that manufactures the point-of-care syphilis diagnostic test, which is offering to fund an implementation study in your country. Congenital syphilis is a problem in country B and at present antenatal syphilis screening is carried out according to a standard guideline as in country A, with suboptimal uptake. Currently in the country only 60% of the antenatal women undergo syphilis testing and among those who screen positive only 40% complete treatment. The rest are lost to follow up. The antenatal clinic is overburdened and so does not have enough manpower to follow up and ensure adherence to treatment. You are impressed with the outcomes of the one-stop syphilis screening study reported in country A. The advantages you see are the following: a) obtaining a result within minutes avoids delay in diagnosis, b) women who test negative do not need to return to clinic for results, c) case detection rate increases, d) treatment can start immediately, e) partners can be screened with the one-stop protocol, f) rates of congenital syphilis will be reduced. You wish to implement the one-stop syphilis screening protocol in your country, but realize there are many issues that you will need to consider before designing your implementation study to test the feasibility.

In order to design and conduct the implementation research in your country, you set up a consultation group comprised of public health specialists, policy makers, members of the local governance body of the districts, and representatives of local women’s self-help groups. This consultation group decides to implement the one stop antenatal syphilis testing protocol in all the antenatal clinics in ten districts in the country. The rest of the country will continue with the routine syphilis testing protocol. The data of congenital syphilis in the various districts was analyzed and the districts with the highest burden of congenital syphilis were selected for the implementation. Representatives of women’s groups and local governance bodies of these ten districts were organized into a task force to closely monitor and follow up the process of the implementation research. These representatives were also encouraged to go to their respective districts and spread the message about the implementation research project.
In order to measure the impact of the implementation, the consultation committee plans to collect data on the following characteristics:

- Name, age, marital status, education, occupation, income and social status of the pregnant women.
- Details of the partner’s education, occupation, income
- One stop syphilis testing rates
- Syphilis screen positive rates
- First treatment acceptance rates
- Complete treatment rates
- Rate of confirmatory test negative among those who screened positive
- Reduction in congenital syphilis
- Partner notification and screening
- Experiences of pregnant women in participating to the implementation

After 6 months of implementation the monitoring team reported an increase in cases of domestic violence in the households of pregnant women who screened positive. On enquiry it was found that the health worker in the antenatal clinics were making phone calls to schedule screening tests for the partners without confirming with the women whether they had already informed their partners and invited them for screening. Interviews with some of these pregnant women revealed the truth that they had not notified their partners fearing the violent consequences.

**REFLECT ON THE FOLLOWING QUESTIONS**

1. What is the most appropriate study design for this implementation research? Discuss the ethical issues of the design.
2. Is there a need for control group?
3. Discuss why there is an ethical imperative to engage with the communities in this case.
4. What is the nature of community engagement described in this study? Is it appropriate for this implementation research?
5. Are the community representatives selected for the engagement appropriate? Will they truly represent the community interests?
6. List the potential stakeholders in this study.
7. What are the possible competing interests among the stakeholders? How can this affect the study and future adoption of the intervention?
8. Who are the research participants? Pregnant women? Their partners? The health workers? The health system?
9. Is there a need for informed consent? If yes, who should give informed consent?
10. Why do you need identifiable patient information in this case? How can the data confidentiality be protected?
11. The health workers in the clinic who had access to the contact details of the screen positive patients and their partner’s contact details, made phone calls to schedule tests for the partners. Is it ethically right for the health workers to have access to the data of the partners who are not actually the study participants? Is it right for them to contact them without the knowledge of the participants?
12. After the completion of the study what is the obligation of the research team regarding the data sharing and data driven action?
13. In case the same study is conducted as a cluster randomized controlled trial with 10 clusters randomized to intervention with the one stop syphilis protocol and 10 clusters to control, in the control group which of the following care should be provided:
   a. Existing standard of care
   b. A syphilis education intervention
   c. A voucher scheme for transport of antenatal mothers who screened positive in order to travel to the health facility and complete their treatment
14. During the conduct of the study it is found that a particular ethnic tribe in the intervention clusters have very high prevalence of anemia during pregnancy. It is noticed that they are very poor and subsist on meagre cereal based diets. What is the responsibility of the researchers towards this ethnic tribe?

ANNEX 9. CASE STUDY 4: VOUCHER SCHEME TO INCREASE DELIVERIES IN HEALTH CENTRES AND REDUCE MATERNAL MORTALITY

The latest results from a demographic health survey show that Country C is not on track to meet its target to reduce maternal mortality, although it is well recognized that it can be reduced by the presence of skilled birth attendants at delivery. Safe delivery in a health centre is strongly encouraged to maximize the detection of complications early on and appropriately manage or refer women to a higher level of care promptly. Despite improvements in the standard of care for delivery – training midwives in delivery techniques and infant resuscitation, expanding facilities for Caesarean sections, and running community education campaigns to encourage women to deliver in health facilities – the overall maternal mortality rate in Country C has only fallen by 42% over the past decade, far from the target of 75%. Maternal mortality is especially high in rural areas where teenage pregnancy rates are high. This is because health centres are not necessarily within comfortable walking distance from villages, men are often away from home working as migrants and are unable to provide their consent for a woman to go to the centre or assist her in getting there. Also, there is a strong tradition of using traditional birth attendants (TBAs) during home delivery.

Based on success reported from other parts of the world, a voucher incentive scheme will be piloted as a strategy to increase deliveries in health centres. Using a quasi-experimental study design, maternal outcomes before and after the introduction of the voucher scheme were compared in one health district and in a highly similar control district where there was no voucher scheme. The two districts were chosen because they served rural populations and included a variety of health facilities, i.e. public, not-for-profit private and for-profit private. Further, they were far enough apart that it was thought unlikely that clients would travel from one district to the other. In the intervention district, pregnant women, identified during the first antenatal clinic (ANC) visit, received 1–4 vouchers to attend the ANC (the number of vouchers depended on the stage of gestation), a voucher for a health-care facility delivery, and vouchers for transportation to the ANC and for delivery/referral to higher level of care, if required. The women could choose to receive their health services at any public or private health-care facility in the district. The fixed redeemable value (for the health-care provider/facility) of the voucher was higher for the private facility than for the public service to encourage private health-care providers’ participation. Taxi vouchers were reimbursed according to distance travelled to motivate taxi providers. To minimize the fraudulent use of vouchers, each voucher was usable only once during a specified time period, and the pregnant woman’s name, village and estimated date of delivery were written on the vouchers for identification purposes. No intervention was carried out in the control districts. Data were collected by the midwives during the clinical care visits at both intervention and control clinics.
To assess the feasibility of implementation and scale-up of the voucher scheme, in randomly selected subsets of private and public health centres within the voucher intervention group, further qualitative studies were conducted to investigate the practicalities of operating the voucher scheme, perceptions of the scheme among various stakeholders (clinic staff, patients, husbands/family members, taxi drivers, and private and public facilities), and the contexts in which the scheme was implemented. Costs and charges were also tracked.

REFLECT ON THE FOLLOWING QUESTIONS

What are the ethical challenges arising in this case? Specifically focus on the following:

1. Ethical issues in study design – how could these ethical challenges have been avoided by better study design?

2. What are the risks and benefits?

3. What are the potential implementation challenges to be considered in the design stage?

4. Are there general ethical concerns with vouchers and cash inducements?

5. How could this affect scale-up and sustainability?

Despite global successes in reducing the burden of malaria, according to the 2014 World Malaria Report, only 26% of children with malaria in Africa received the appropriate recommended treatment in the past year. An important reason for this alarming statistic is that many children with fevers are not brought to health-care centres. Most childhood deaths resulting from malaria occur within the first 48 hours of symptom onset. Rapid, appropriate treatment may, therefore, be life-saving.

Over the past decade, implementation research (IR) projects have been conducted in several African countries with the goal of ensuring that children receive prompt access to appropriate anti-malarial therapy. A HMM strategy was tested to assess the acceptability and efficacy of the administration of pre-emptive anti-malarial therapy with pre-packaged medication to children under 5 years of age with fever, at home, in rural communities. Communities were selected by size (>10,000 population) and homogeneity (same languages/dialects). Mothers were educated to recognize the signs of malaria in children with fever and obtain medication within 24 hours from trained local community care workers. The underlying rationale for these studies was based on the knowledge that because of the lack of access to, or mistrust of the formal health services, most malaria episodes in rural Africa were being treated inappropriately at home with herbs, incorrect medication or incomplete courses of therapy. The results of these implementation studies showed that HMM was feasible, the community was largely receptive, rates of febrile children receiving appropriate treatment increased, episodes of severe malaria were reduced and mortality declined. Based on these studies, many African countries have included HMM in their national malaria strategies.

Feedback from mothers engaged in the initial studies was generally very positive. They appreciated the dedication of the community care workers, they witnessed the effectiveness of the medication in most cases, and were usually appropriately referred to the health centre, if the child was too sick for HMM or the community care worker suspected another illness. Over the years, the community developed trust in the process because they could identify the medication packages and consequently most completed the required three-day therapy.

A major drawback of these IR studies was that the diagnosis of malaria was presumptive; no confirmatory tests were performed unless a child was referred to a health centre. Therefore, many children may have been treated for malaria unnecessarily, whilst other causes of fever, for example, pneumonia, may have remained untreated.

Two major developments in the treatment and diagnosis of malaria have occurred in recent years:

1. Artemisin combination therapy (ACT) became the first-line treatment regimen (most often twice daily for 3 days), replacing chloroquine, (one tablet daily for 3 days) in most regions of the world because of emerging drug resistance. Chloroquine was the drug used in the implementation studies.

2. A point of care rapid diagnostic test (RDT) has been developed for malaria, which involves a finger- or heel-prick for blood with results being obtained within minutes. To improve the accuracy of diagnosis and appropriateness of therapy, WHO recommendations now include testing with RDT prior to pre-emptive HMM in children with fever.
You work for the health ministry in Country X, where HMM has been implemented in multiple rural communities in province Y with some success. The latest results show that around 60% of mothers seek care within 24 hours of a child developing fever. Of those, 80% are compliant with the pre-packaged medication use. Given your success, you have obtained a large grant to scale up the HMM programme in your region and expand to the neighbouring province Z where civil unrest has now subsided. In the communities familiar with the current HMM in province Y, you anticipate that there may be some scepticism to the implementation of RDT prior to initiation of therapy, and to the change in the medication’s appearance and dosing (ACT versus chloroquine). You wish to design a cluster randomized intervention to test the acceptability of ACT and RDT in 15 communities in province Y (clusters A and B) to assess any unexpected changes in health-seeking behaviour and medication use, and to compare uptake and outcomes with people in 10 communities in province Z where HMM will be implemented for the first time (Cluster C). Cluster A will be randomized to continue existing HMM strategy but switching from chloroquine to ACT, without RDT (five communities). Clusters B and C will be randomized to RDT + ACT (10 communities each).

In order to facilitate the seamless implementation of the intervention in all three clusters, community engagement is planned. Information about HMM for children is presented in all local newspapers, television channels and radio broadcasts. The changes in the original home-based management, the need for the changes and improvement in outcomes are explained in a way that is easy for the community to understand. In addition, the village headmen of all the selected villages in the three clusters are contacted and the details of the IR project explained in detail.

After finalizing the research design and initiating active community engagement the implementation is rolled out in the three clusters. Country X has an ongoing fever surveillance that is carried out through community health workers. This is a syndromic- and laboratory-based surveillance. Whenever a person presents to a health worker or a clinic with fever, the details are reported to a central surveillance unit. In addition, all laboratories also report cases of fever where positive blood smears for malaria are reported. The reporting is done along with the name and the address of the person with fever/blood smear positivity. The community health workers involved in syndromic surveillance are trained and enrolled into the IR project. They are instructed to actively look for children with fever and report the case to the project investigator in the field, who will then visit the family and collect information on the characteristics of the child and the family, utilization of HMM intervention, and clinical outcomes. In addition, in-depth interviews are also conducted among the mothers to understand their experiences and opinion about the HMM system.

**REFLECT ON THE FOLLOWING QUESTIONS**

With respect to community engagement:

1. **Why should you engage with the communities in provinces Y and Z?**

2. **In this case, the community engagement was started after the design of the study had been finalized. When should it ideally begin? What aspects of the IR project should the community be engaged with?**

3. **What should be the terms of the engagement with the community?**

4. **Village headmen have been selected as community representatives for the community engagement process. Who is an ideal representative? Who should decide on representation?**

5. **What do you think about the community engagement strategy used in this study? Will newspaper, television and radio broadcasts effectively reach women in the households, who are the true implementers of the intervention?**
With respect to ethics of data collection in IR:

6. What is the nature and type of data that are required in order to understand the effectiveness, acceptability, reach and utilization of the HMM? Is surveillance necessary? If yes, is name-based reporting necessary?

7. Given that the surveillance activity is name-based case reporting and given that identifiable patient information (characteristics of the child and the family) will be available to the researchers, what data confidentiality issues should be considered? How should confidentiality of patient data be protected?

8. Who owns the data collected as part of the surveillance? Who owns the data collected by the researcher for the IR?

9. When the people of provinces Y and Z provide information for the public health surveillance for fever, does it imply that they give their consent to it being shared with researchers? Should specific consent be required before data are shared with the researchers?

10. Is there an ethical obligation to share the data obtained from the IR with the community? Is there an ethical obligation to share the data with the scientific world?

With respect to study design:

11. In designing implementation studies, implementation researchers must take a structured and holistic approach to maximize the chances of success. The crucial components in designing an IR study include the following:

- selection of study sites;
- engagement with the community;
- identification of relevant stakeholders;
- conduct a situation analysis;
- select medication manufacturer and supplier;
- need for special medication packaging;
- decide on drug pricing;
- select community care workers who will distribute the medication when indicated;
- training of study staff/volunteers at all levels, development of training materials;
- training of mothers/child carers on how to identify possible malaria and seek care;
- ongoing tracking of medication use and outcomes as well as feedback from the community and refining of the processes;
- consideration of scalability and sustainability.

What are the ethical implications of each of these components that may have an impact on this study?

ANNEX 9. CASE STUDY 6: IDENTIFICATION OF BARRIERS TO SCALING UP THE SUCCESSFUL “TEST AND TREAT” OPTION FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) OF HIV (OPTION B+)

Mother-to-child transmission of HIV is reduced by treating the HIV-positive mother with antiretroviral therapy (ART) during pregnancy and lactation. In the guideline, option B is recommended to treat all HIV positive women with ART during pregnancy, but to stop therapy six weeks post-partum or at cessation of breastfeeding if the mother’s CD4 cell count is above 500 cells/mm³ and she has asymptomatic HIV infection. Future care would occur through referral for follow-up to a HIV clinic. In countries where access to CD4 cell count testing at diagnosis of HIV is limited (i.e. HIV infection cannot be accurately staged), Option B+, continuing all pregnant women with positive HIV tests for life on a fixed-dose triple drug ART combination tablet, has been shown to be pragmatic and successful. Anticipated benefits of Option B+, in addition to PMTCT, are that mothers on life-long HIV treatment would be more likely to survive to look after their children and less likely to transmit HIV to their sexual partners or subsequent children. However, the drawbacks of such a policy are the increased cost of treating many women earlier than they would otherwise have been eligible for ART. Logistically, there are questions on whether or not the ART in Option B+ should continue to be administered through the antenatal clinics (ANCs) and, if so, for how long, and the optimal timing for transitioning care to specialized ART clinics. These factors may all have an impact on the long-term success of the policy.

To test the transferability of Option B+ to Country E, a pilot roll-out of Option B+ was carried out over three years in 100 clinics across the country with a plan for rapid scale up, if effective. As part of the evaluation of the pilot implementation in Country E, it was noted that outcomes of Option B+ from individual ANCs were quite different. Even within similar socioeconomic and geographical health districts, where patient populations are considered highly similar, some clinics had excellent retention and follow-up of HIV positive women receiving ART (>95%), whereas others had very high dropout rates (>50%). The standard operating procedures (SOPs) were the same for all clinics. Prior to initiating countrywide roll out of Option B+, a further pre-implementation study must be carried out to identify barriers to successful implementation.

Using mixed-methods, a situation analysis (SA) will be conducted in two groups of clinics that had been identified previously as the 20 best and the 20 worst performers. Pairs of best and worse performing clinics will be matched for similarity of socioeconomic and geographic factors. The outcomes will be used to assess the clinics’ performance and effectiveness and will include the number of women: (a) tested for HIV; (b) initiated on ART; (c) returning for follow-up; and (d) taking treatment appropriately. In addition, it is proposed to assess through a qualitative study the comprehension of the rationale and acceptability of Option B+ among the clinics’ workers and HIV-positive women, and potential additional barriers (e.g. inadequate supplies, overwhelming of clinic staff, diversion of clinic staff to other ongoing research projects or vertical programmes, and local acceptability/barriers within the community).
The Ministry of Health has consented to the enrolment of the selected clinic sites. Staff from all selected clinics will attend a mandatory information session on the study that will take place in their clinics and will help them “understand the emotional reactions of pregnant women receiving a diagnosis of HIV”. The clinic staff will intentionally not be informed about the true nature of the study as it is believed that the behaviour of health-care workers may change if they are aware that their daily operations are being observed. Clinic staff will participate in data collection (as they had done in the pilot study) and inform patients that researchers may approach them after their clinic visit. Quantitative data will be collected on how many women are diagnosed with HIV, started on and continued on Option B+ during the study period. Qualitative data will be collected on all processes carried out relating to HIV diagnosis and Option B+ treatment enrolment, including: what is done, by whom, how, when and where; the adequacy of follow-up; medication availability; the triggering of screening of family members; and transition of care. All HIV positive women attending ANC will be approached as they leave the clinic to give consent for participation [signature or thumb print] and will be asked to complete an exit survey in return for a clinic voucher. A random group of women from each clinic will be selected for in-depth interviews about their clinic experiences and receive a bag of food to thank them for participating.

A researcher on the study team is not comfortable with the decision to not inform the clinic staff and has approached you as a member of the local university ethics committee to review this study protocol.

**REFLECT ON THE FOLLOWING QUESTIONS**

From clinic staff perspective:

1. Discuss the issues around informed consent in this study.

2. Discuss the implications of the decision that the clinic staff should not be fully informed of the research goals. Are there potential reasons why this might or might not be acceptable? How might this impact on the validity of the research findings?

3. Are there any conflicts of interest in this study?

From the patient perspective:

4. When should patients be eligible to enter the study? Are the challenges relating to patient confidentiality with different approaches to patient consent? How would scientific validity be affected by varying approaches to gaining patient consent?


6. Are there any unanticipated potential risks to patients from this study?

What are the obligations for the future?

Source: based on study protocol.
A recent outreach activity in Country X identified that up to 70% of children in nomadic populations and remote communities had not been vaccinated. Childhood vaccination is important in improving children’s health and reducing mortality. It is also a key public health mechanism for the successful eradication of diseases such as poliomyelitis. Unvaccinated communities can become reservoirs of infection, which may then spread to the wider community. Factors that have been identified as barriers to reaching these communities include insufficient knowledge of their location, and the lack of logistical support and community engagement in developing successful strategies. The Ministry of Health of Country X has committed funds towards designing a successful implementation research (IR) study to determine the optimal strategies to deliver childhood vaccinations to these nomadic and remote communities.

Special outreach teams (SOTs) will be deployed to a selected sample of known nomadic and remote communities. The teams will be supplied with all logistical requirements, i.e., vehicles, ice boxes, adequate vaccine stocks, translators, etc. They will be trained to deliver the required vaccinations to all children under 5 years of age in these communities and collect quantitative data on existing levels of vaccine coverage, numbers vaccinated, document feasibility challenges and track costs. The SOTs will work in coordination with the regular community health workers in the area delivering routine vaccination services in addition to other primary health-care services.

In addition to the SOT intervention, in a selected subsample of communities, a key individual from each community will be identified to participate in a smartphone-based Global Positioning System (GPS) tracking study, to assess the feasibility and utility of locating nomadic communities in real-time. Solar powered battery packs will be supplied to these key individuals. Their location will be tracked in real-time and reported to the SOTs for more effective delivery of services.

In order to increase awareness of the need for immunization and facilitate the utilization of the immunization services among the nomadic and remote communities, notification of the date and location of each community outreach vaccination event will be posted in local schools and clinics that serve the nomadic and remote populations, starting one month before the planned event. The SOT members will be trained to conduct community meetings immediately after the first vaccination event, through which to engage with the local population in developing strategies to ensure ongoing adherence to childhood vaccination programmes. They will gather all the women available in the village at the time of their field work and deliver messages emphasizing the need for immunization, the advantages of immunization and the risks to the children, and the community if they are not immunized.

The intervention is rolled out in five nomadic groups in the area. Two of these groups are selected for the real-time GPS location study and key members of these groups are provided with the smartphone for GPS tracking of their location. The SOTs contact these groups and enumerate the names, family details, demographic characteristics, health details and vaccination status of all the children under 5 years of age in the five groups. They administer the first dose of vaccine to all eligible children and conduct community meetings. The SOTs will maintain an ongoing registry of new births, new entrants into the nomadic groups, marriages, etc. They will follow up the pattern of immunization coverage over the years using a time-series analysis. They will also work in close coordination with the local public health system and share the data with them for their health management information system records. While this study is ongoing, local forestry officials approach the research team. They complain that some of the nomadic groups are engaged in poaching wild animals for their hide and teeth in the forest area. They have learned that GPS tracking is being carried out on these nomadic groups for research purposes. They want the research team to share the data so that they can keep them under surveillance.
REFLECT ON THE FOLLOWING QUESTIONS

With respect to community engagement:

1. Is there an ethical imperative to engage with the community in this case before implementation?
2. What is the type of community engagement planned for this study? Is it appropriate for this research project?
3. What are the terms of engagement with the community? Does the community engagement plan in this study adequately cover these terms?
4. What do you think about the community engagement strategy used in this study?

With respect to data collection:

1. What is the type of data required to achieve the outcomes of this IR?
2. What is the obligation of the research team to share the data with the local public health system?
3. What are the implications of the GPS tracking data on the privacy of the nomadic community, especially the key informant?
4. Is the research team obliged to share the GPS location data of the nomadic communities with the forestry officials who want to track them in case they are poaching wild animals?

With respect to additional and specific ethical issues pertaining to this study:

1. Engagement with the community.
2. Is the study blurred between research and clinical care?
3. How to ensure their needs will be reliably met, i.e. maintain trust?
4. How to identify key barriers to vaccination in their communities?
5. What if vaccination is not perceived as an important issue in the community, or there is resistance in the community against vaccination?
6. It is likely other health issues will come up during the community meeting, how will these be handled, and what are the SOTs’ ancillary care responsibilities?
7. Are smart phones being imposed on the communities, are these acceptable to the communities, how realistic is it that they will work and be used?
8. The obligation of the research team to empower the local health system and the communities.

**CASE STUDY 3: ONE-STOP SERVICES FOR ANTENATAL SYphilIS SCREENING**

1. What is the most appropriate study design for this implementation research (IR)? Discuss the ethical issues of the design.

There are various interesting study designs in IR, namely, effectiveness–implementation hybrid, quasi-experimental study, pragmatic design and cluster randomized controlled trials (RCTs), etc. Since the one-stop testing protocol is of established efficacy and safety, a quasi-experimental study without a control group would be sufficient to understand implementation issues. However, this may have questionable scientific rigour. So a pragmatic trial design or a CRT may be performed. The ethical issues of importance to be discussed here is the balance between denying the control group of a proven intervention and the need for scientific rigour that is achieved by a control group.

Consideration should be made for a 3-phase IR study as follows.

**Phase 1** – Formative study to develop a theory of change about the main implementation problem in Country B.

Study design for this could include qualitative, or participatory action research (PAR).

We do not know why uptake is low in Country B. One would need to first establish where the barrier lies. As written in the case, it seems the main barrier in the past in Country A has been the need to return to the clinic for results and referral for further treatment, which was largely overcome with the ‘one-stop’ model. Other barriers could exist, such as women declining tests (would need to assess why) or women being tested, but maybe not returning for follow up for some reason and not completing the required therapy. It is important to assess prior to launching the study whether the barriers/acceptability of the strategy would be similar in countries A and B. If different in Country B, the one-stop model may not solve the problem. Transfer of implementation from one country/culture to another (one size fits all?)

Is the clinical problem as relevant in Country B as it is in Country A?

How does the epidemiology of the disease/social environment differ between countries A and B, e.g. do women attend antenatal clinics (ANCs) with same frequency or at similar times during gestation (i.e. early enough for testing and treatment to prevent congenital syphilis). For example, in Africa most women present late, may be too late to successfully treat before delivery in some cases. But eventually word might get around of this direct benefit to the child/parents and may have the extra benefit that more women might attend ANC earlier?

**Phase 2** – If implementation problems are similar to Country A, an initial pilot study to establish the effectiveness of the one-stop strategy and identify specific factors that would facilitate or hinder the adoption of the strategy in Country B. Study design for this could include effectiveness–implementation hybrid trial, pragmatic trials, and quasi-experimental studies with well-defined treatment and IR outcomes. Details about study design could be discussed. Ideally choose two regions/metropolises with similar syphilis incidence/prevalence. One will be the rapid test site and the other will be the conventional care site (control group). Another option is to use historical data from the prior year in the same clinic, for example, if there are data suggesting the rates have been very stable in that community. Careful attention would need to be paid for possible confounders to ensure any changes are related to the intervention and not an external factor (although this is probably less relevant because each syphilis–positive woman should have the same risk of transmitting congenital syphilis).

Phase 3 – Scale-up study in Country B; study design for this could include process documentation, qualitative case studies, PAR, quasi-experimental studies for specific implementation research outcomes.

2. Is there a need for control group? Why?

The presence of a control group is required to ensure the scientific rigour of findings. However, designs without control groups can also provide the required information for IR.
3. Discuss why there is an ethical imperative to engage with the communities in this case.

Syphilis is a sexually transmitted infection (STI) and it has a strong stigma associated with it. Therefore, there is a social risk of stigmatization and discrimination associated with a diagnosis of syphilis in an asymptomatic antenatal woman. In this situation, it is essential to engage with communities in advance of the implementation in order to gain their support, and buy-in to the project and acceptance. The community engagement will also help in identifying the potential problems that could arise in the community because of the implementation of the testing protocol.

4. What is the nature of community engagement described in this study? Is it appropriate for this IR?

In this study, the research itself is designed by a consultation committee of stakeholders, which includes community members. The community members are also involved in the process of identifying districts with a high burden of congenital syphilis and including them into the research. Further, the sub-committee of community representatives has also been formed to monitor the research project. It has also been encouraged to increase awareness about the protocol in the community. All these community engagement activities will increase trust, acceptance and reach.

5. Are the community representatives selected for the engagement appropriate? Will they truly represent the community interests?

The community members who are selected for representation in the engagement process are the members of the women’s self-help groups and a member of the local governance body of the district. These members are likely to be representing the true experiences of the community. Is there a need to have male representatives? Is there a need to have representation from health workers in the local community?

6. List the potential stakeholders in this study.

The potential stakeholders in this study are:

- the health system, programme managers;
- the health-care providers, doctors, nurses, community health workers;
- the community – pregnant women, their partners, the general community;
- the one-stop syphilis testing kit manufacturer;
- policy-makers.

7. What are the possible competing interests among the stakeholders? How can these affect the study and future adoption of the intervention?

Financial conflicts of interests are to be considered. The policy-makers and the syphilis kit manufacturers have to declare their conflicts of interest. For example, some of the policy-makers may hold stocks in the kit manufacturing company. These kinds of conflicts of interest may influence the way the findings of the research are interpreted and reported.

8. Who are the research participants? Pregnant women? Their partners? The health workers? The health system?

Is there a need for informed consent? If yes, who should give informed consent?

All of the above can be said to be research participants. Informed consent may be obtained from them all. However, the primary research participants are the pregnant women and getting their consent is mandatory. The discussion may also lead to the spouses of the research participants being indirectly included in the study. Do they need informed consent too? Is the health system a research participant? Are the staff who provide the one-stop syphilis testing service research participants? Is their consent warranted?

9. Why do you need identifiable patient information in this case?

Identifiable patient information may be necessary for the delivery of the implementation, for follow up of patients who screened positive and for completion of treatment. However, this information may not be necessary for the research team whose objective is to study acceptance and utilization of the testing and treatment.

10. Is there a need for data confidentiality in this research? How can data confidentiality be protected?

This research is specifically looking at the detection of a sexually transmitted disease, which is stigmatizing. In such conditions data confidentiality is of utmost importance.
11. The health workers in the clinics who had access to the contact details of the patients who screened positive and their partners, and made phone calls to schedule tests for the partners. Is it ethically right for the health workers to have access to the partners’ data as they are not actually the study participants? Is it right for them to contact them without the knowledge of the participants?

If proper community engagement has been done and the spouses are also informed about the participation of pregnant women in such a study, these ethical issues could have been averted. However, despite CE and active engagement with the spouses, there should be checkpoints in place to confirm or inform the pregnant women about contacting their spouses. It was not right for the researchers to have contacted the spouses without the prior knowledge and permission of the women.

12. After the completion of the study, what is the obligation of the research team regarding the data sharing and data-driven action?

It is the ethical obligation of the research team to use the data appropriately for public health action.

13. In case the same study is conducted as a cluster RCT with 10 clusters randomized to intervention with the one-stop syphilis protocol and 10 clusters to control, in the control group which of the following care should be provided:
   a. existing standard of care
   b. syphilis education intervention
   c. a voucher scheme for transporting antenatal mothers who screened positive in order to travel to the health facility and complete their treatment.

The existing standard of care is very poor as the uptake and utilization of syphilis screening is not acceptable. Therefore, something else needs to be done in the community. There are pros and cons for the voucher system. It may not be able to sustain a voucher system in the long term. Moreover, it may not produce a sustained change in behaviour. The syphilis education intervention should be well planned and should induce behaviour change. Such an education system may be an acceptable standard of care.

14. During the conduct of the study, it is found that a particular ethnic tribe in the intervention clusters has very high prevalence of anaemia during pregnancy. It is noticed that they are very poor and subsist on meagre cereal-based diets. What is the responsibility of the researchers towards this ethnic tribe?

It may not be possible for the implementation researcher to manage the severe anaemia of the population on a long-term basis. Therefore, there is a need for community engagement and stakeholder engagement. Appropriate referral to anaemia treatment facilities may be required.


10. FACILITATOR’S NOTES

CASE STUDY 4: VOUCHER SCHEME TO INCREASE HEALTH-CENTRE DELIVERIES AMONG PREGNANT WOMEN AND REDUCE MATERNAL MORTALITY

1. Study design

The case study states the health problem (high maternal mortality), the standard of care, implementation problem (women are not using the clinics, i.e. demand-side problem), and an implementation strategy to address the demand-side problem (vouchers).

- Context: Prior to embarking on the study in Country C, there is a need to understand the context before any implementation of a new strategy. Why are the women not using the health system appropriately? This may require preliminary anthropological observation (situation analysis) to understand the main barriers. Is transport a major barrier? How similar is Country C to the countries where this strategy has been implemented successfully? (Point 6 on template.) The investigators have an obligation to ensure they truly understand the relevant issues before attempting to embark on changes.

- Community engagement: The proposed changes also need to be acceptable to the community, e.g. men who are away at work may not agree to their wives can be taken unaccompanied to the clinic in a taxi driven by another man. The funding of chaperones or female taxi drivers may need consideration. Addressing the transportation hurdle does not address the belief in the use of traditional birth attendants (TBA), for example. An additional, ideally complementary strategy may be considered, which somehow incorporates TBA into the health centres, or provides intensive training to health workers to detect and refer complications early with a fast track to the taxi system, or could the clinics distribute the vouchers in addition to providing the antenatal clinics (ANCs)?

- Ethical issues relating to study design: There is a control group here. Is there a need for a control group? Why not just do a comparison study before and after in the implementation group? Could discuss that contextual equipoise exists (justifying a control group) despite the fact it is well recognized that from a clinical point of view health-centre deliveries have improved outcomes.

- Alternative study designs for IR?

- Should discuss who are the actual research participants: Here there is a distinct difference between implementation participants (health system, taxi drivers) and those who have the outcomes (mother and their babies). Research is conducted among both. This leads to issues with informed consent. Who gives consent? How is it obtained? Also the issue of the implementation on one party and outcomes measured in another party, which is a characteristic of implementation research (IR) (as opposed to clinical research where intervention and measurement are generally on the same individual).

- Determining cost/use of vouchers:
  - what if a neighbour has a car but is not a taxi, can they redeem a voucher;
  - is it correct that the price of the voucher is different between public and private health centres – do patients know this?
2. Risks and benefits

Benefits:
- attendance likely to rise significantly
- taxi providers will probably encourage women to attend clinics
- increased revenue for health facilities – may permit improvement standards/services.

Risks:
- over-treating is likely as providers might carry out interventions not necessarily required in order to get paid for them;
- ‘cherry picking’ – providers choose the least complicated patients so they make most profit, leaving the sickest patients who would require more resources to care for less well attended;
- high administration and transaction costs – how to reimburse, with cash or cheque; if cash, where would it be safe; it may expose the health-care worker to robbery, physical harm, etc.;
- vouchers can be faked, sold;
- does the use of name and village in the vouchers to avoid fraud pose privacy concerns; explore possible mitigation measures applicable in the setting;
- taxi providers might start to expand in anticipation of ongoing business, and might lose a lot if the programme were withdrawn.

3. Potential Implementation challenges to consider at the design stage

- If the health system is not strengthened in parallel with implementation, does this make the implementation itself unethical?
- It might not be possible to reach those who did not attend an ANC at least once (ANC coverage is not 100%, so even if 5–10% never attend, a large number of women are left at risk) – issue of equity of participation.
- Initial flat fee for taxis did not work, as taxi drivers did not want to travel longer distances for the same fee, so they were later reimbursed for the longer distance (how to check?).
- Need to ensure that the health centres can cope with the increased numbers of women who may potentially use the voucher scheme.
- What if there were complications, but the taxi voucher only covered a ride to the referral hospital? If referral to a higher level hospital outside the district were required, would the voucher ‘price’ be considered too low? Would the woman have to pay the difference?
- No control of quality of care delivered.
- Should be anticipated as part of the study design and also consider the possibility of diversion of clinic resources/staff to locations with increased deliveries, possibly leaving other sections less well served than previously (issues of equity, vertical versus horizontal programmes).
- Paperwork and tracking was extra work for midwives.
- When demand increases, need to be prepared with an increased supply of staff, equipment, drugs, etc. Otherwise, clients lose confidence, can undermine trust in the health system for other conditions and future projects.

Suggest ethical imperative for monitoring and evaluation to ensure the study is well done, data collection is rigorous, and the outcomes are reliable so the study is of maximum use. Discuss whether there is a moral and ethical imperative to convert research findings to policy and public health action.
4. General concerns with vouchers/cash inducements

- Positive if it empowers people to do what they would have done themselves had they had the money for the taxi/user fee, etc.
- Negative if it induced a change in behaviour that the person would otherwise not have done (impact on autonomy), e.g. if a pregnant woman chooses to travel further to a clinic where she will get a bigger voucher/cash than at her local clinic, she may put herself at increased risk.
- May create an expectation that it is not sustainable in the long term.
- May create expectations of rewards for other health-seeking behaviours, e.g. if TB patients were given inducements to come for therapy if they refused treatment, this could lead to more people refusing treatment in order to get the inducement, e.g. food, etc.
- How big should the inducement be?
- How to ensure cash/vouchers are administered properly and not given as bribes, sold or stolen, etc.
- Ethics of collateral benefit, e.g. taxi drivers getting paid. They may be advantaged in the community, and raise their prices for everyone else, etc.¹
- Considerations:
  - size of incentive, attractiveness
  - what is being incentivized, is it in the best interest of the recipient?
  - “degree of recipient familiarity with activity”
  - distribution of risks and benefits
  - fairness/justice concerns
  - sustainability.

Incentives may:

- undermine autonomy
- hinder disclosure
- exacerbate social inequalities, make a person a target for robbery, etc.
- may misuse the system
- lead to exploitation/degradation of vulnerable populations
- help bring about a change the person’s wishes
- can be autonomy enhancing.

5. Scale up and sustainability

- How sustainable are the costs? Would redemption of vouchers go back to health centre as fee-for-service and enable for provision of better infrastructure?
- Can this be scaled-up countrywide?
- If such a scheme were taken up, would the health system have a responsibility to ensure the taxis are safe? Is the health system endorsing this mode of transport? Would it introduce a complex layer of regulation?

1. Why should you engage with the communities in provinces Y and Z?

There is an ethical obligation to engage with communities in provinces Y and Z before the implementation research (IR). It is clearly explained in the case study that there is going to be a change in the way HMM is delivered in Province Y where an older model is already being implemented. There is likely to be skepticism in the areas in Province Y, which are already familiar with the existing HMM implementation. Moreover, in Province Z there has been civil unrest, which has been resolved in the recent past. Therefore, it is likely that levels of trust are low in Province Z. Community engagement helps the people in the two provinces develop trust in HMM, especially in Province Z where it is going to be implemented for the first time. Community engagement also leads to a high level of self-determination, self-reliance, self-efficacy and empowerment of the communities in these provinces. In the absence of community engagement the skepticism about the change, introduction of a new invasive blood test and the overall distrust due to recent civil unrest, will lead to poor uptake of implementation.

2. In this case, the community engagement has began after the design of the study had been finalized. When should community engagement ideally begin? With what aspects of the IR project should the community be engaged?

Implementation of HMM is already ongoing in some areas in Province Y. Now this is going to be scaled-up throughout Province Y with some changes and be introduced afresh in Province Z. The engagement with community should begin before the design of the IR. Community engagement should ideally begin before the design stage of the study and community stakeholders should be part of the decision-making regarding the study design. In this case, it seems the study has been designed in advance of any form of community engagement. Community engagement should ideally begin before the design stage of the study.

3. What should be the terms of the engagement with the community?

Firstly, the community should decide whether HMM is an immediate priority for them. Although there is strong evidence to show improvement in malaria cure rates following early HMM, unless it is a priority for the community, both the research as well as the implementation will fail. The community should engage in finalizing and agreeing to the research design. In this case, is a cluster randomized controlled trial (RCT) ethically appropriate given that one cluster is going to receive only artemisin-based combination therapy (ACT) without rapid diagnostic tests (RDTs). Knowing from previous experience of IR that this leads to higher rates of unnecessary malaria treatment among children, will this be acceptable to the community? The community should be made aware of this ethical issue and should be empowered and encouraged to participate in decision-making regarding the study design. If the community agrees to such a design, it should be engaged in monitoring the safety of the participants during implementation. The community should also engage in efforts to recruit research participants, retain participants in the implementation and facilitate data management. However, there is no generic formula for community engagement. It has to be tailored to the social and cultural context of the IR project. After the IR project is complete community engagement should continue to disseminate the research findings back to the community.
4. Village headmen have been selected as community representatives for the community engagement process. Who is an ideal representative? Who should decide the representation?

In the case of HMM, it might be important to have representatives who are mothers and who will be actively implementing the intervention in the households. The representative should be selected by the community. They should be in a position to truly represent the opinions and ideas of the main participants in the implementation, in this case, the mothers.

5. What do you think about the community engagement strategy used in this study?

Will newspaper, television and radio messages effectively reach women in the households, who are the true implementers of the intervention? Given the poor social status of women, lower educational attainment, and lack of health literacy among these women, can we expect such methods of awareness generation to have their impact? Alternative approaches for community engagement, especially when targeting lower income, lower socioeconomic populations, such as street theatre, inter-personal communication, etc.

6. What is the nature and type of data that are required to understand the effectiveness, acceptability, reach and utilization of the HMM?

Is surveillance necessary? If yes, is name-based reporting necessary?

Based on the design of the IR, a cluster randomized controlled trial, to understand the reach, effectiveness and acceptability of the HMM protocols, children with fever have to be identified and their caregivers interviewed to understand these aspects. Therefore, surveillance data will be useful to identify the children. Name-based reporting is necessary in this case in order for the research team to track the children with fever and collect data.

Surveillance is generally classified as a public health activity and not as a research. Even though the surveillance that is used for gathering the data on fever among children is a routine ongoing public health activity in Country X, the intent of this surveillance in the context of this IR is to identify specific participants for the research. Therefore, it may be considered as research. Moreover, the data that is collected is likely to identify children and their families. This leads to a whole set of data confidentiality issues.

7. Given that the surveillance activity undertakes name-based case reporting and given that identifiable patient information (characteristics of the child and the family) will be available to the researchers, what data confidentiality issues should be considered? How should confidentiality of patient data be protected?

The ongoing syndromic surveillance for fever in Country X is a public health activity that the government of Country X is performing in order to protect the health of the community. Therefore, it is a public good and hence the community may be willing to share the data [even in an identifiable manner] for the sake of the greater good. However, the surveillance data are being used here to identify participants for a research project. The participants are not obliged to do this as part of the public health surveillance mandate. So there is an ethical obligation to protect the confidentiality of the participants’ data. While the data may be made available for the researchers to contact participants and collect information, the surveillance data and research data can effectively be de-linked to protect the confidentiality of the participants’ research data. Some sensitive information regarding the child and his/her family may be collected during the data collection process. This should definitely be de-linked from the surveillance data and protected.

8. Who owns the data collected as part of the surveillance? Who owns the data collected by the researchers for the IR?

Data ownership is a major ethical issue in research. Country X’s ongoing fever surveillance is collecting data on fevers. This is used by the public health system for public health action. These data are clearly owned by the public health system for the public health action. This implies that the data are publicly owned for the sake of public good. However, the research data which are collected by the researchers for the sake of the IR – relating to effectiveness, use of HMM, outcomes of treatment and opinions, and experiences of the users – is owned by the researchers.
9. When the people of provinces Y and Z give their data for the public health surveillance for fever, does it imply that they are consenting to the sharing of this data with researchers for IR? Is specific consent required for sharing the data about their fever with the researchers?

Data shared by people for the sake of a public health activity are intended for that purpose only. When these data are being shared for research purposes, then this raises the issue of whether consent is required from the participants before the information regarding their fever is shared with the researcher. Whether mandatory consent should be obtained from each mother whose child has fever to share her information with a researcher, or whether an opt-out option should be introduced is to be discussed and decided in consultation with the community. Provision of community-wide awareness about this form of data collection, and the possibility of opting out from participation in the IR is essential.

10. Is there an ethical obligation to share the data obtained from the IR with the community? Is there an ethical obligation to share the information understood from the data with the scientific world?

There is an ethical obligation to use the data collected in a scientifically rigorous analysis and interpret the information to guide public health action. This is an obligation to the participants as well as to the community at large.

11. Prior to designing your study you should consider the ethical implications of each of the following components that may have an impact on the study.

i. Selection of study site. In the source studies and grant application used to develop this case, only large communities were selected (> 10,000 people), where malaria was highly endemic, populations were chosen if homogeneous within regions and understood similar dialects:

- this design will continue to leave smaller underserved communities un-served, to discriminate against small communities/groups that may have their own language;
- need to justify the addition of Province Z. If an intervention is planned then baseline malaria prevalence data will be needed, etc.

ii. Identification of relevant stakeholders. Policy-makers, drug manufacturers and distributors, community members, local media:

- need to gain their interest, avoid corruption or ulterior motives especially with companies;
- ensure stakeholders represent all involved top to bottom, and that voices of all are heard and respected;
- need to consider all implications of study for health-care providers, will they feel undermined, or resist because of loss of authority/status, loss of income; similar issues for traditional healers;
- consideration of extra work for local health centre, e.g. pharmacy staff, if the are packaging drugs.

iii. Conduct a situation analysis. This is to determine baseline data, understand current concepts around malaria and its treatment, local health-care resources, understand the community, where medical care is sought, where medication is procured, engage with local health-care workers and stakeholders, etc.:

- there is an ethical imperative to conduct this kind of public health research before embarking on an intervention. In fact, such a situational analysis is a prerequisite even for the IR. The IR may not be justified if malaria is not a major problem and if HMM is already operating well in Province Z, then there is no point in conducting the IR;
- is the situation analysis a separate study in itself or is it part of the IR? This is an important practical ethical consideration. It has to be a separate study, because the conduct of the IR will depend on the findings of the situational analysis. This will have implications for ethical considerations such as for the institutional review board (IRB), informed consent, etc. In the studies and protocols this was done simultaneously which allowed the identification of stakeholders and other participants during the SA process to be more efficient;
- requires delicacy, should engender trust, understand current choices and why they are being made, must be careful not to show any judgement of current conditions or choices made, and avoid creating guilt or distrust;
- special care when interviewing mothers who may have lost children to malaria because of ‘inappropriate care’, these may fear the community’s judgement as education progresses and they realize they may have made incorrect choices.
iv. Select medication manufacturers and suppliers. It is likely that some competition exists, between the need for high-quality drugs, affordable prices and reliable supply:

- if the strategy is successful, it must be scalable and sustainable, it will need reliable drugs and manufacturers willing to produce them at low costs – should government subsidize or not; possibility of corruption; need for transparent tender process;
- may generate significant competition within the community, drug sellers face loss of business, especially threatens fake drug market; there may be intimidation of study drug distributors by existing drug vendors in community;
- should compensation be given to drug vendors who will lose business, or should they be engaged in drug distribution with an overhead; how would one control price rises if they did become drug distributors in the community [become community care workers]; BUT, if an overhead were given to drug sellers, then the implications for giving incentives to other study workers/volunteers must be considered.

v. Select medication distributors within the community, i.e. community care workers. They may create unwanted competition, and pose a threat to existing providers. Therefore there is a need to consider incentives – if they are only volunteers, they may lose work time, be less available; they may need to track information as well:

- community care workers were often older mothers or respected community individuals, who had attained some status with the role; in studies, many were very committed and followed patients up, etc.; the community’s acceptability of these people, males and females; etc., needs to be assessed;
- a criterion in some studies was that a community care worker “must be trustworthy” – if someone were rejected for the position, this could create shame even if they were rejected on different grounds;
- must be literate, or at least one in each community had to be literate to fill in the tracking forms, etc., this discriminates against candidates who are not literate; a solution in one community was to have a literate care worker supervise a non-literate one; this creates difference in status and awkwardness;
- in Nigeria, the drop out of existing local drug vendors acting as community care workers was very high, their motives for participation were different from others; would it be ethical to judge someone’s motivation to participate;
- question of incentives or compensation – should these care workers receive money or items for participation; this may be effective, but may attract people who will not have the same dedication; how sustainable and scalable would the incentives be;
- issue of moral hazard incentivizing drug distribution;
- some studies allowed the care worker to charge 10% extra, thereby, making some money; would this affect their drug distribution practices, i.e. give medication when it was not really indicated, sell extra medication to adults, register fake patients in their tracking lists or maybe sell extra packets for people to keep at home.

vi. Medication packaging. Who would do this; would they cover their costs; medication packaging should be understandable; different doses should be easily distinguishable from each other and dosing instructions clear:

- explore acceptable colours, images on packages, consider low literacy instructions otherwise they may intimidate and confuse; ideally, in collaboration with community consultation, e.g. white represents milk so acceptable for a child, etc.
vii. Medication pricing. In some countries, care is free for children under 5 years and, therefore, should not be sold, whilst in others all medication is sold:

- consideration of cost is important; it is often a major reason why appropriate formal health care is not sought;
- the HMM strategy reduces the indirect costs of seeking health care by reducing travel to the clinics, and the need to lose days off work for travel, etc.; therefore, may not be unreasonable to charge for the medication as it still represents a saving;
- what is a reasonable and fair price; should the price be the same for all community members or scaled according to their ability to pay;
- how to control prices are not inflated at point of sale and mothers taken advantage of;
- some mothers may try to share the pills among more children or stop prematurely if the child improves and save a pill for another episode if considered too expensive;
- mass drug administration (MDA) drugs are often free, why charge for malaria;
- could the price force a choice between medication and a bednet.

viii. Training of participants at all levels, training materials. Trainers, supervisors, distributors require some literacy from all participants; if literacy rates were low in the community some chose one care worker who was more literate and this person supervised the other one. Training not one off but requires booster sessions. Training must be appropriate for the community, simple to understand, durable if left in place, varied, etc.:

- need to ensure material taught in a respectful way, not patronizing, intimidating or judgemental which will otherwise exclude more vulnerable groups within the community;
- respect for local beliefs and customs, consider where and how to do the training in collaboration with community representatives;
- should there be remuneration for time taken for trainings; if yes, then why not for other things.

ix. Training of mothers/child carers how to identify possible malaria and seek care.

- Can engender guilt if mothers realize their perceptions or actions in the past may have caused harm;
- strong feelings about traditional medicines, disease causality must be considered;
- may create tension within families if grandmother has different ideas, mothers may feel overrided;
- mothers may feel overwhelmed when being taught by other studies/groups about diarrhoea, pneumonia, use of bednets, etc., which may create confusion;
- ideally would like to check the ‘accuracy’ of a subset of the mothers’ judgement about fever/malaria, to test comprehension, may create stress/fear.

Participants could use the table below as a guide by filling in their concerns, and considering differences between implementation in provinces Y and Z.
OTHER CONSIDERATIONS

1. Why is there no cluster randomized arm to continue chloroquine + RDT – continuation of chloroquine not appropriate (especially with emerging resistance) with better drug availability – could lead to actual harm.

2. Is Cluster A ethical with no RDT if it should be standard of care?

3. It is good to educate the mother about malaria? Is there also an obligation to educate them about other major child killers, i.e. pneumonia and diarrhoea? Even if not treated through the HMM, mothers should know to go to hospital or seek other medication.

   • Ethical issue of vertical vs. horizontal programmes, i.e. good vertical approach to malaria but what is neglected, etc. It is an ethical imperative, especially in resource-poor settings to integrate the malaria programme into existing child health programmes. Efforts should be made to achieve an integrated strategy.

4. Could a study focused so strongly on malaria possibly dilute efforts of other education programmes, i.e. should it rather be packaged as a holistic child-care management programme? Would the mothers gain too much confidence in the malaria tablets and try to use them for alternative problems, if not appropriately educated?

5. The introduction of a new medication in Province Y may create suspicion of the prior study and may erode trust unless very well explained.

6. Use of RDT may be problematic in some communities, which do not like blood tests. May seem somewhat like ‘magic’. RDT costs money, need to consider who pays, ensure regular supplies, etc. What if false negative? Should there be criteria to ‘treat anyway’, how would this undermine goals?
7. Community care workers may be put in position of moral distress if a mother insists on medication when the care worker suggests she must go to hospital instead? Giving tablets would be under-treatment with small chance of success, but no tablets may mean higher chance of dying if the mother refuses?
   • Need support system in place for care workers faced with ethical dilemmas.

8. Evolution of this strategy is to treat malaria and pneumonia together. Ethics of treating both simultaneously, because by definition it is very likely that one treatment would be unnecessary, but which one if there is no RDT? Would this also mean extra costs to a mother for the two drugs?
   • There are some studies looking into this, which found a small trend towards improvement in outcomes with addition of amoxicillin to malaria Rx.
   • Ideally, one should differentiate between malaria and pneumonia and not gunshot treat both, especially with risk of allergies, e.g. amoxicillin, or issues with co-trimoxazole and G6PD deficiency, etc.

9. Care workers may become overwhelmed if many cases/additional diseases are added (e.g. pneumonia, diarrhoea). It may affect their ability to earn their livelihood but their sense of responsibility may be very strong together with the status their work affords them, etc. May be a reason for compensation. Is there a percentage threshold for the time donated to the study that might justify compensation? If one compensates at one study site (e.g. particularly poor communities), should one compensate at all study sites?

10. Care workers who visit patients for a follow up may note a lack of insect treated nets (ITNs) or other illnesses – what are the ancillary care obligations?

11. Province Y statistics show that only 60% of children seek care, this will not be addressed with the current study. Should alternatives be sought? Should a new situation analysis take place in Province Y first to understand why 40% do not use HMM?
1. Study design

- This study has a complex design and uses multiple strategies. Participants should identify the study components and implications for research integrity. It also raises multiple ethical issues that are integral to the study design and planning, and must consider the perspectives of all affected groups, from which groups to gain consent, assent, opt-out options, as well as the potential for unanticipated harm to multiple parties for various reasons, including non-disclosure, inducements, and identification of potential subjects based on their HIV status prior to consent.

- The study describes the clinical problem, current standards of care, implementation status, what will be tested, group tests and the goal is testing what is known about implementation challenges?

- This study uses a mixed methods approach. The research outcomes for both qualitative and quantitative components must be pre-specified and ethical issues within each component identified. Quantitative data collected involves patient identification, issues of anonymity, accuracy of numbers, etc. Qualitative data accuracy may depend on trust developed between researchers and the study subjects, and community engagement. Both forms of research share many ethical pitfalls, as outlined below.

**Ethical challenges from clinic staff's perspective**

- Is it correct for the ministry of health to consent to the clinics’ participation? Individual consent of the staff was not sought. How could a staff member opt out if they felt uncomfortable?

- Information given to clinic staff (study participants) was misleading, the actual aim was to observe all behaviours and processes around Option B+ in the clinic.

- Why did the researchers not disclose their true aim?

- Is such an approach ethical?

- It is possible that astute health-care workers will realize that more is going on, how will/should this be anticipated/addressed?

- Should nursing representatives have been informed of the true nature of the study? At what administrative level should consent be obtained/acceptability of the study be discussed beforehand, to ensure cooperation? How can clinic staff be protected from punitive action? Considering the study is very delicate, should those ‘representing’ the nurses and doctors at the clinic be informed ahead of time of the deception and the reasons why this may be justifiable?

- Is there consideration to later inform the clinic staff that they were actually observed; that this was for research purposes and that no punitive action would be taken?

- Is there a conflict of interest for staff who both collect data and are study subjects/care providers?
Ethical challenges from the patient’s perspective

- Patients’ consent to the survey was sought when they left the clinic, therefore, their HIV status had already been disclosed to the research team. Should their consent be sought on entering the clinic instead? As noted above, there is a delicate balance between maintaining scientific rigour (so that results reflect reality), and honesty to patients and clinic staff. Would this exit consent lead to research bias anyway (probably not likely as all HIV + patients would be approached for participation).

- How to ensure participants are fully informed, are aware of opt-out possibilities – they will see others getting vouchers and or food after doing the survey so will most likely have an inducement to participate. Are inducements ethical? What if stakes were higher than a mere interview?

- There is no physical risk to the patients here, but a patient signing with a thumbprint is unlikely to be able to read the consent form, how to get around this? If there were some physical risk to the patient (e.g. further blood testing as a control for actual CD4 cell count purely for research purposes, with the results not being fed back to clinic), how would one guarantee that consent information had been understood, how would adequacy of comprehension be tested, and cultural sensitivity, and language be taken into account?

- Selection of HIV + patients leaving clinics may lead to stigmatization as their HIV status can be inferred.

- News of receipt of food for participation in in–depth interviews on site at the clinic will spread. Many women will want to be selected, may even result in violence/unrest? Is it ethical to give food even after the interview (on day 1 this may be a surprise, but it will not be on subsequent days, clinics may be inundated with clients because of this possibility. How to get around this? Provide food at the clinic to all mothers? How sustainable would this be? What expectations would there be during subsequent clinic visits or subsequent study participation?

- Can discuss the nature and size of the inducements. The ethical perspective mass contentious than if inducements were large. However, the size of the inducement must be determined if inducements were very small – may be leaned from the recipient’s perspective and not the researcher’s perspective, e.g. a bar of soap may seem negligible to the researcher but may be an exceptional luxury to a study participant, etc.

- Issue of standard of care for patients who opt out of the study.

- Issue of ancillary care responsibility for women on antiretroviral therapy (ART) for those who develop adverse events or for those who develop complications of HIV/AIDS.

Obligations for the future

- Obligation to use the data obtained from the IR for policy change.

- May need a second implementation pilot study to test validity/generalizability of observations identified in situation analysis.
Reflect on the following questions with respect to community engagement.

1. Is there an ethical imperative to engage with the community in this case before implementation?

The nomadic communities have poor economic resources, are marginalized and lack the health literacy to actively engage with the health system to obtain their entitlements. Such communities tend to be apprehensive and distrustful of the health system. Therefore, community engagement is important from the start of the implementation research (IR) project in order to allay anxieties and promote community buy-in to the project.

2. What is the type of community engagement planned for this study? Is it appropriate for this research project?

One month before the planned events, the research team is posting notices in the schools and clinics to notify them about the intervention. This is a passive form of engagement. Ideally, this kind of intervention, especially in remote and nomadic groups, should be implemented only after active engagement with communities even before the design stage of the study. The problem with passive engagement with communities is that they do not foster the community’s sense of ownership of the project. Apart from this, the special outreach team (SOT) members also engage with communities immediately following the first immunization event. This is planned in order to sustain the other doses of immunization. The participants in this community engagement activity are all women present in the community during the day of the field visit. It is important to see whether such representation is sufficient in this cultural context. Who are the key decision-makers regarding immunization? What is the role of women in decision-making in these societies? These will influence the decision on who should participate in the community engagement.

3. What are the terms of engagement with the community? Does the community engagement plan in this study adequately cover these terms?

The community should be engaged in deciding whether immunization and this implementation are of priority to them. If their children are dying from more serious problems before complete immunization can be achieved, then immunization may not be a priority. Moreover, if there are other competing health problems, which are more serious and more common than vaccine-preventable diseases, then the priority may change. These have to be understood and planned after active community engagement before the start of the IR. The community should also be engaged in deciding the research design. In this case, the study is a before and after comparison of immunization coverage rates. Therefore, the ethical risks are less than a typical randomized controlled trial (RCT). However, the community should participate in making the decision regarding the design. The SOTs should be acceptable to the community. Ideally a community member can be recruited to play a role in the SOTs. This will increase the acceptability of the implementation.

4. What do you think about the community engagement strategy used in this study?

In this study, they have planned to put up notices in the schools and clinics about the date of the vaccination campaign. The appropriateness of this strategy should be assessed. Are all the nomadic people literate? Are the women literate? Can they seek, read and understand the notices put up in these places? Alternatively, should some kind of street theatre/interpersonal communication/media messaging be used?
Reflect on the following ethical dimensions of data collection based on the case study.

5. What types of data are required to achieve the outcomes of this IR?

In order to understand the utilization of immunization among these nomadic groups and to identify the effectiveness of the SOTs and Global Position System (GPS) tracking intervention, the coverage of the immunization and trends in immunization of the children under 5 years of age is required. This can be obtained by immunization coverage tracking. Although the data on family details, demographic characteristics, etc., may be useful for the SOTs to identify and track the children, this information may not be necessary to understand the coverage and effectiveness of the intervention. Therefore, the essential 'need to know' data alone can be made available to the research team and the SOTs can protect the other identifiable participant information.

6. What is the research team’s obligation to share the data with the local public health system?

Dates of birth, deaths, marriages, migration and other demographic data from nomadic populations often elude routine census data because of the difficulty in accessing these populations. Therefore, it is important to consider the ethical imperative to share the data collected from these populations through research initiatives such as this with the local health system. This will help them plan better.

7. What are the implications of the GPS tracking data on the privacy of the nomadic community, especially the key informant?

The data gathered by GPS tracking have the potential to invade the privacy of the nomadic community, especially the key informant. The question remains whether such an invasion into the privacy of a person is warranted in order to ensure the community’s immunization. Are there less invasive alternatives? Rather than tracking the location using GPS, can the key informant/community member just be given a phone and asked to touch base with the SOT on a regular basis?

8. Is the research team obliged to share the GPS location data of the nomadic communities with forestry officials who want to track them because they suspect that they are poaching wild animals?

The use of research related data intended for the specific research purpose has certain protections. The participants give consent for the tracking of their location only for research purposes. However, sharing of these data for other purposes, such as for the protection of forest animals is questionable. If data collected for research purposes are made available for other purposes, which are not obviously related to the intended research activity, it grossly undermines the trust in the IR and the health system as a whole. Therefore, there should be some protection of participants’ data. Confidentiality of data should be ensured to retain trust, and ensure compliance with the IR.

Reflect on additional and specific ethical issues pertaining to this study.

1. Engagement with the community at the community meetings to understand perceptions, barriers, and pros and cons are important IR questions if framed properly. It would benefit from participatory action research design.

2. Study blurs the lines between research and clinical care. Is this SOT intervention a pure research activity or is it an intervention? This raises the issue of what differentiates research vs. practice in public health.

3. How to ensure their needs will be reliably met, i.e. maintain trust?

4. Will services be linked to one clinic or multiple clinics along livestock routes?

5. How to identify key barriers to vaccination in their communities?

6. What if vaccination is not perceived as an important issue in the community, or there is resistance in the community against vaccination?

- Do they need adequate background information on the concerned community?
- Are there religious reasons, political reasons, or are they suspicious of Western medicine? Perhaps they do not understand why the system gives them vaccinations but nothing else.
7. It is likely other health issues will come up during the community meeting, how will these be handled, e.g. with ancillary care?
   • Would women have equal opportunity to raise issues, e.g. family planning/family violence if men are present?

8. Are the phones being imposed on the communities, is this acceptable, how realistic is it that they will work and be used? It may have been better to explore with the community what would be the best way to track them. They may know they will be in specific places at specific times of the year.

9. Need to evaluate satisfaction/comprehension, etc., after the meeting.

10. Need to set up feedback sessions to work on the community engagement process to ensure IR is following its intended path.

11. The obligation of the research team to empower the local health system and the communities.

Important ethical concepts/framework to consider:

• identifying and managing non–obvious risks and benefits:
  • cultural significance of blood/tissue samples *(not truly relevant in this case but listed for completeness)*
  • minimize offence
  • acceptability of research/protocol
  • responsibility to avoid harm > obligation to benefit;

• expanding respect beyond the individual and stakeholder community:
  • identify subjects as people, recognition
  • identify range of stakeholders;

• building legitimacy for the research project:
  • justification
  • perceived social value, nature of risks, trust in researchers, funders, accountability
  • formal ethics review, etc.
  • informal discussion and listening, collaboration.

Ethical issues identified:

• relational personhood
• social justice
• relational autonomy
• relational solidarity
• sustainability.

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1 King KF, Kolopack P, Merritt MW, Lavery JV. Community engagement and the human infrastructure of global health research. BMC Medical Ethics 2014;15:84

The Special Programme for Research and Training in Tropical Diseases (TDR) is an independent global programme of scientific collaboration established in 1975. It has a twin mission to improve existing and develop new approaches for preventing, diagnosing, treating, and controlling neglected infectious diseases, and to strengthen the capacity of developing endemic countries to undertake this research and implement the new and improved approaches.

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