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 participant’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 9 Annexes.

This participant’s guide contains all teaching materials and copies of activities without guidance explanations. It is intended for distribution during the teaching course to maximize interaction and learning during sessions.

The 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.
ACKNOWLEDGEMENTS

The development of this participant’s guide was led by Mahnaz Vahedi, TDR (The Special Programme for Research and Training in Tropical Diseases), in collaboration with Andreas Reis, WHO Global Health Ethics Team (GHE).

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• Bagher Larijani, Tehran University of Medical Sciences, Tehran, Iran
• Florencia Luna, Latin American University of Social Sciences [FLACSO], Buenos Aires, Argentina
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• Cynthia Bannerman, Ghana Health Service, Accra, Ghana
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• Alfred Yawson, School of Public Health, University of Ghana, Accra, Ghana

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## LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<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>
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<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>TBA</td>
<td>Traditional birth attendant</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</tbody>
</table>
Below is a proposed template agenda for the two and a half-day course.

### Day 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<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>
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<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>
Day 3

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

2. COURSE INTRODUCTION AND OVERVIEW

**Timing:** 30 minutes.
This session is the introduction and background to the full course.

**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

World Health Organization

For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO
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.

TIMING: 1 hour

FACILITATING MODULE 1

LEARNING OBJECTIVES

- To describe the breadth and spectrum of health systems research, and the sub-domains of operational research and implementation research
- To differentiate health systems research and specifically implementation research from biomedical/traditional clinical research
- To describe the interrelationship between health systems research, epidemiology and surveillance
- To define implementation research including the rationale and goals, study design and context within which research takes place

SLIDE 2:

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SLIDE 3:

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SESSION OUTLINE

1. What is health systems research?
2. How does implementation research differ from biomedical/clinical research?
3. How does implementation research differ from epidemiology and surveillance?
4. Distinction between implementation research, quality improvement and public health
5. Focus on implementation research
   - Rationale and goals
   - Study design
   - Context
6. Considerations in planning and conduct of implementation research
SLIDE 4:

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SLIDE 5:

---
SLIDE 6:

BASIC SCIENCE RESEARCH: e.g. MALARIA

- Identification of malaria parasite
- Understanding pathophysiology of disease
- Development of targeted medical therapy

The discovery of artemisinin and the Nobel Prize in Physiology or Medicine

White et al., Lancet 2014, Su & Miller (2016)

SLIDE 7:

CLINICAL RESEARCH: e.g. MALARIA

- Phase 1, 2, 3 clinical trials to determine efficacy and safety of drugs to treat malaria
- Randomized controlled trials (RCTs) to determine effectiveness of drug and to compare new therapies with old therapies meta-analysis

White et al. (2014)
MUCH RESEARCH IN PAST YEARS HAS BEEN BIOMEDICAL...

SYSTEM BUILDING BLOCKS
- Leadership / Governance
- Health Care Financing
- Health Workforce
- Medical Products, Technologies
- Information and Research
- Service Delivery

GOALS / OUTCOMES
- Access Coverage
  - Improved Health
  - Level and Equity
  - Responsiveness
- Quality Safety
  - Financial Risk Protection
  - Improved Efficiency

SLIDE 8:

EXAMPLE OF EPIDEMIOLOGY AND SURVEILLANCE: e.g. MALARIA

SLIDE 9:
SLIDE 12:

[Diagram of domains of health system research]

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SLIDE 13:

“the brains of the health system”

“also the eyes and ears…”

[Quote from WHO (2014a)]
SLIDE 14:

Quiz

1. How does abolition of user fees change access to primary health care?
2. Does using pictures instead of words on tablet packaging improve correct usage of home-based malaria management (MMI) in a border region of the Democratic Republic of Congo where invisible communities speak many languages?
3. Does deployment of trained for community health workers using rapid malaria testing methodology in initiation of appropriate malaria management?

SLIDE 15:

Definitions and Aims

Health systems research
- Addresses health system and policy questions
- Not disease-specific
- Systems functioning
- Impacts performance of the whole health system
- Broad scope of questions including health financing, governance, policy, planning, management, human resources, service delivery, and quality of care

Rennie et al. (2010)
DEFINITIONS AND AIMS

Implementation Research
- Develop systematic strategies to take a proven intervention and apply it in the real world
- Goal is to improve access to and use of effective interventions in populations in need
- Focus on diseases where a control tool exists and would significantly reduce burden of disease
- Demand-driven

---

SLIDE 17:

DEFINITIONS AND AIMS

Operational research
- Find solutions to local operational problems within specific health programmes
- ‘Trouble shooting’ local bottlenecks
- Focuses on service delivery components of the health system
- Addresses problems under control of programme managers

---
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:

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SLIDE 19:

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SLIDE 20:

WHAT DOES IMPLEMENTATION RESEARCH STUDY?

Factors which affect implementation
- e.g. geographical location, poverty, understanding of disease

Processes of implementation
- e.g. distribute insecticide treated nets at ante-natal clinics, co-management of HIV and TB

Outcomes of implementation
- e.g. impact on deaths from malaria, improved cure rates of TB in HIV-positive patients

SLIDE 21:

TARGET AUDIENCE OF IMPLEMENTATION RESEARCH

- Health managers and teams
- Policy-makers
- Practitioners
- Communities
- Individuals

Often not research 'experts' therefore they need clear, evidence-based outputs
**SLIDE 22:**

**SLIDE 23:**
**GOALS FOR IMPLEMENTATION RESEARCH**

- Optimize health-care delivery
- Improve uptake of research findings
- Ideally an effective process can be generalized to other settings
- Multi-stakeholder engagement to jointly address problems
- Inform policy development for sustainable solutions

**SLIDE 25:**

The health system is complex and must be considered in implementation research.
TYPICAL IMPLEMENTATION RESEARCH INTERVENTIONS – EXAMPLES?

- Health education
- Provision of incentives or subsidies
- Introduction of monitoring tools
- Guideline implementation
- Implementation of multi-faceted packages
- Implementation of new treatment methods
- Change in delivery systems

Byler et al. (2014)

SLIDE 26:

 PHASES OF IMPLEMENTATION RESEARCH AND MAJOR ETHICAL CONSIDERATIONS

Planning phase
- Engagement of local stakeholders
- Feasibility
- Study design
- Sustainability
- Engagement of CEE stakeholders
- Assessment of risks and benefits

Implementation phase
- Assent and informed consent
- Privacy and confidentiality
- Standard of care
- Monitoring
- Dissemination

Post-research phase
- Dissemination of research findings
- Data accessibility
- Translating knowledge
- Impact assessment
- Sustainability
- Access to care

Gopichandran et al. (2016)

SLIDE 27:
IMPLEMENTATION RESEARCH

“Implementation research takes what we know and turns it into what we do”

- Integral to policy development and execution
- Requires active and ongoing engagement with all stakeholders throughout the process to optimize chances of success

SLIDE 28:

REFERENCES AND READING MATERIALS (1)


SLIDE 29:
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, case study 1 in Annex 1.

**TIMING:** 3 hours

**FACILITATING MODULE 2**

**SLIDE 2:**
- To describe the existing frameworks of ethical reasoning in medical, research, public health and bioethics
- To differentiate medical and public health ethics
- To describe the key ethical considerations in public health as a background for ethics of health systems research and implementation research
- To apply the ethical considerations of health systems research and implementation research
- To apply the ethical principles of health systems research and implementation research to practical situations

**SLIDE 3:**
1. Ethical frameworks
2. Key ethical considerations in health systems research and implementation research
3. Case study one
4. Ethical justification for health systems research and implementation research
ETHICS OF HEALTH SYSTEMS RESEARCH AND IMPLEMENTATION RESEARCH

- Relatively new discipline
- New framework needed
- Draws on different ethical traditions and frameworks:
  - medical ethics
  - research ethics
  - bioethics
  - public health ethics

ETHICAL FRAMEWORKS

- **Medical ethics**: over 2,000 years old (Hippocrates, Sun Tse Miao, Ibn-Sina)
- **Research ethics**: Germany, Nuremberg Code 1947, Declaration of Helsinki 1964, etc.
- **Bioethics**: whole biosphere – humans, animals and plants – formulation of four basic principles
- **Public health ethics**: relatively recent discipline; addresses issues in public health
MEDICAL ETHICS, RESEARCH ETHICS, PUBLIC HEALTH ETHICS

Medical ethics focuses on:
- individual patients
- doctor-patient relationship
- duties of doctors/nurses

Public health ethics focuses on:
- population health
- health programmes and policy issues
- scientific evidence
- public participation
- preventive measures

Research ethics focuses on:
- protection of study participants
- informed consent
- risk-benefit analysis
- equitable selection & access etc.

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?
**Substantive Ethical Principles**

- Maximize benefits to the population
- Minimize harms to the individual and community
- Proportionality
- Respect individual autonomy
- Reciprocity
- Equity
- Efficiency
- Trust
- Solidarity
- Stewardship

**Procedural Ethical Principles**

- Transparency
- Relevance
- Inclusivity
- Responsiveness
- Accountability
- Participation
- Sustainability
SLIDE 10:

- Potential conflicts between principles:
  - Autonomy vs. benefits/risk
  - Autonomy vs. solidarity
  - Equity vs. efficiency
  - Confidentiality vs. disclosure
  - Autonomy vs. stewardship
  - Importance of procedural principles

SLIDE 11:

- Ethics of Health Systems Research and Implementation Research

- Venn diagram showing
  - Medical ethics
  - Research ethics
  - Public health ethics
  - Implementation research ethics

- Overlapping circles representing the intersection of medical ethics, research ethics, and public health ethics.
ETHICS OF HEALTH SYSTEMS RESEARCH AND IMPLEMENTATION RESEARCH

- Relatively new
- Draws on different ethics frameworks
- Example: Ebola surveillance and contact tracing

- Medical ethics and research ethics: focus on protecting confidentiality; informed consent
- Public health ethics: focus on benefit to community; solidarity, often no informed consent

SLIDE 12:

SLIDE 13:

KEY ETHICAL CONSIDERATIONS IN HEALTH SYSTEMS RESEARCH

Balancing benefits and risks
- Who are the beneficiaries?
- Who are at risk?
- Is there balance between risks and benefits?

Upholding participants' autonomy
- Levels of research participants
- Who should give consent?
- Is consent necessary, feasible, meaningful?

Justice
- Fairness in participant selection
- Need for health systems research among vulnerable populations

Other issues
- Responsibility
- Sustainability
- Standard of care/quality care
- Empowerment
### Slide 16: Health Care Financing

<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: Health Information Systems

<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>Health information systems</td>
<td>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?</td>
<td></td>
</tr>
</tbody>
</table>
### SLIDE 18:

<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:

<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>Essential medical products, vaccines and technologies</td>
<td>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?</td>
<td></td>
</tr>
</tbody>
</table>
### Slide 20:

<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>Service delivery</td>
<td>Household-level campaigns for mass drug administration (MDA) for elimination of lymphatic filariasis (LF) has been shown to be an effective strategy to improve MDA acceptance rates. Can this be adapted in your country?</td>
<td></td>
</tr>
</tbody>
</table>

### Slide 21:

**Ethical justification for implementation research**

- Case study
- 45 min. in groups
- 15 min. reporting back
- 30 min. plenary discussion

**Note to Participant:**
For slides 21-28, see case study 1 in Annex 1.
SLIDE 22:

CASE STUDY

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

SLIDE 23:

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
SLIDE 24:

- 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.

SLIDE 25:

- 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

SLIDE 26:

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

SLIDE 27:
SLIDE 28:

- Discuss the findings of the study
- If the country plans to adopt and implement the strategy at a wider scale, how will these findings influence this decision?

SLIDE 29:

- Understanding the benefits and harms in local context
- Optimizing implementation by contextualizing
- Understanding logistics and practical problems to ensure fairness
- Adapting to local needs (responsiveness)
- Improved quality of service (stewardship)
- Sustainability (cost effectiveness)
### REFERENCES AND READING MATERIALS

- 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.
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).

TIMING:
3.5 hours

FACILITATING MODULE 3

SLIDE 2:

SLIDE 3:
SLIDE 4:

- Many successful strategies exist to control disease.
- Strategies are often not as effective as they could/should be.
- Effectiveness is lost because of inadequate implementation, e.g.: lack of political buy-in/policies in place.
- Poor uptake of practice guidelines.
- Inconsistent supplies.
- Poverty limiting access.
- Cultural differences when programmes transferred.


SLIDE 5:

- The use of insecticide treated nets (ITNs) for Malaria in India was found to reduce the risk of malaria by 65%.
- After these results were published, church groups began distributing ITNs free of charge in a rural district in Cameroon, but local health-care workers have not seen a reduction in incidence of clinical malaria.
- On routine home visits, community workers noted that ITNs were present in only some homes, but were often not being used correctly.
- The ministry of health is concerned that they will not meet the Sustainable Development Goal (SDG) targets, and wants to increase the use of ITNs.

Source: Van Remoortel et al. (2015).
EARLY THOUGHTS ON AN IMPLEMENTATION RESEARCH STUDY 1: HOW TO INCREASE THE APPROPRIATE USE OF ITNs?

1. Is malaria transmission a big problem in this community?
2. Is there any idea why ITNs are not in homes? Why are they not being used appropriately?
3. Is there an understanding of any of the cultural barriers to the use of ITNs?
4. Is there a need for commitment from health policy-makers, funders for sustainability?
5. Does the study design allow for scientific rigour and is it ethically acceptable?
6. Is there a need to identify communities at risk for inclusion in the study, optimal time of year for study?

SLIDE 6:

EARLY THOUGHTS ON AN IMPLEMENTATION RESEARCH STUDY 2: HOW TO INCREASE THE APPROPRIATE USE OF ITNs?

7. Which manufacturer should be engaged to ensure quality ITNs in adequate numbers?
8. How and by whom will reliable distribution of ITNs be done?
9. Is there a need to determine pricing of ITNs so that sellers (formal and informal sectors) have an incentive to sell them, but they are affordable?
10. How to distribute ITNs – voucher schemes, or free distribution?
11. Where and how to distribute the vouchers?
12. How to engage the community to educate them that ITNs are beneficial – radio, community meetings, health centres, schools, antenatal clinics, churches?
13. How best to monitor use of ITNs?

SLIDE 7:
CHARACTERISTICS OF IMPLEMENTATION RESEARCH

- Systematic
  Balances ‘real life’ with scientific rigour

- Multidisciplinary
  Collaborative, researchers, stakeholders

- Contextual
  Relevant locally but ideally generalizable

- Complex
  Dynamic and evolving, cyclical iterative activity


SLIDE 8:

---

SLIDE 9:

---
MAIN STEPS / CONSIDERATIONS IN PLANNING IMPLEMENTATION RESEARCH

1. Responsiveness to the community’s needs
2. Scientific rationale
3. Study design
4. Contextual factors
5. Selection of research participants
6. Weigh risks and benefits
7. Community and stakeholder engagement
8. Iterative process

SLIDE 10:

1. RESPONSIVENESS OF IMPLEMENTATION RESEARCH TO THE COMMUNITY’S NEEDS

- Reliable data on needs within a community will permit appropriate identification of need
- Whose agenda is driving research?
- Prioritization of needs within the health system
- Potentially scalable and sustainable intervention over the long term
- Will intervention reach those who need it?
  - Avoid researching questions to benefit more advantaged communities

SLIDE 11:
2. GOOD SCIENTIFIC RATIONALE?

- Is it worth doing?
- Are technologies available, reliable and affordable?
- Obligation not to do harm
- Does proof of concept exist?
- Is there equipoise?

SLIDE 13:

**IS THERE EQUIPOISE?**

Genuine uncertainty about the effectiveness of an intervention
Clinical equipoise often no longer exists in implementation research
e.g. Vaccination against rotavirus reduces childhood mortality
from diarrhoeal illness
Situation/contextual equipoise is usually present in implementation research
e.g. in a rural religious community, vaccination may not be easily acceptable
3. APPROACHES AND STUDY DESIGNS

**Examples**
- Cluster-randomized trials
- Effectiveness-implementation hybrid trials
- Pragmatic trials
- Participatory action research
- Mixed-methods
- Open label demonstration projects

Each may have specific ethical implications

---

**NOTE TO PARTICIPANT:**
See activity table 1 on research designs in Annex 2.

---

3. APPROACHES AND STUDY DESIGNS

- Distinction between implementation research, quality improvement and public health practice may be blurred
- Service delivery?
- Standard of care?
- Control groups?
**SLIDE 16:**

4. CONTEXTUAL FACTORS TO CONSIDER IN PLANNING IMPLEMENTATION RESEARCH

Examples:
- Racial
- Gender
- Disability
- Class
- Social
- Cultural
- Political
- Environmental
- Historical
- Global

**SLIDE 17:**

5. SELECTION OF RESEARCH PARTICIPANTS

- Institutions, locations
- Individuals, groups
- Inclusion of vulnerable groups
- Identify those experiencing risk vs. those gaining benefit
  - Justice implications
  - Informed consent implications
VULNERABILITY

Vulnerable to “exploitation and overrepresentation in research”
- Need extra protection
- Traditionally understood as:
  - Cependent
  - No capacity to give informed consent
  - Other features?

Source: Rogers & Lange (2013)

SLIDE 18:

6. RISK ASSESSMENT IN IMPLEMENTATION RESEARCH – POTENTIAL HARMs?

Individual harms
- Risks of intervention
- Control groups or standards of care
- Ancillary-care responsibilities

Social harms
- Stigmatization of groups of subjects involved
- Potential excess burden experienced by marginalized groups, especially if not consulted

Financial harms
- Incentives or vouchers may destabilize local economy

Communal harms
- Cultural insensitivity of an intervention, distortion of health promotion messages leading to misinformation

Harm to health system
- Overworking/overwhelming healthcare workers, diversion of resources towards research area

Source: Hyder et al. (2014)

SLIDE 19:
EXAMPLES OF POTENTIAL HARMs IN VACCINE TRIALS

HIV
Selection of ‘high risk’ participants to test HIV vaccines may lead to stigmatization.

Malaria
Transmission-blocking vaccines do not protect the individual but prevent transmission to others.

Rotavirus
Is administering a pneumococcal vaccine in a control arm ethical for a rotavirus vaccine study?

Source: Mamotte et al. (2010).

SLIDE 20:

6. IDENTIFYING NON-OBVIOUS RISKS OR BENEFITS IN IMPLEMENTATION RESEARCH

Requires meaningful engagement with the community
  • Non-obvious harms e.g.:
    • cultural norms
    • gender roles
    • beliefs about blood samples
    • pregnancy, etc.
  • Consider undue benefits to certain groups

Source: King et al. (2014).

SLIDE 21:
WHAT ARE THE FEATURES OF BIOMEDICAL/CLINICAL RESEARCH AND IMPLEMENTATION RESEARCH THAT ARE DIFFERENT, REQUIRING DIFFERENT APPLICATION OF ETHICAL PRINCIPLES?

NOTE TO PARTICIPANT:
Group activity, an extra blank copy of activity table 2 is provided in Annex 3.
### 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></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Informed consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Equipoise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Research question</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Research conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Control groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Anticipated outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Risks assumed by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>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 for the two forms of research.
SLIDE 24:

NOTE TO PARTICIPANT:
Slides 25-33 appear only in the facilitator’s guide.

SLIDE 34:

CONTRIBUTORS TO SUCCESS OF AN INTERVENTION EXAMPLE: IMMUNIZATION

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.

NOTE TO PARTICIPANT:
See Annex 1, case study 1 on mHealth in Bangladesh.

CASE STUDY: mHealth in Bangladesh

- 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 people who knew Bengali language in Germany and found to be useful.

Who would all the relevant stakeholders be in this case?

SLIDE 36:
SLIDE 37:

- Community as a whole
- Community representative/s
- Pregnant women
- Health-care workers
- Traditional birth attendants
- Cell-phone air-time sellers
- Health clinics
- Families of women and children
- Others?

SLIDE 38:

- Democratic process, power sharing
- Identify the full range of stakeholders up front
- Engagement early in the process
- Agreements and disagreements are acknowledged and discussed
- Stakeholders’ perspectives must be considered
- Determination who/which bodies may legitimately consent to the research process at various levels
- Channels of accountability are agreed upon
- Stakeholders feel empowered, respected
- Researchers are seen as partners, not dominant
- Overriding obligation is to avoid harm – potential benefit

Source: King et al. (2014).
WHAT IS COMMUNITY ENGAGEMENT?

“A process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest or similar situations to address issues affecting the well-being of those people.”

Source: CDC (2013).

SLIDE 39:

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?

SLIDE 40:
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)?

SLIDE 41:

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 42:
COMMUNITY VS. PUBLIC ENGAGEMENT?

- Same principles and similar goals
- Largely depends on the research context
- Community engagement targets communities that are directly affected by or involved in research
- Public engagement targets a broader audience and uses different (less targeted) means of engagement such as:
  - public meetings or meetings with policy-makers
  - science cafes
  - radio or television programmes or newspaper articles.


SLIDE 43:

THE COMMUNITY ENGAGEMENT CONTINUUM

Sharing information: two-way communication
- Creating awareness and improving understanding about research and local culture and traditions that might have implications for the conduct of research
- Opportunity for co-learning
Consulting the community on key aspects of research
- Community as consultants
- What is locally and culturally relevant and acceptable/permission?
Community as consultants
- All aspects of the research: from inception to dissemination
  ➔ Empowering the community to improve health outcomes

SLIDE 44:
SLIDE 45:

VALUE OF COMMUNITY ENGAGEMENT

Intrinsic Value
- Extending the principle of respect to the community’s values, culture, traditions, and social practices
- Ensuring the relevance of research
- Establishing relationships and building trust
- Protective measure to limit harm to individuals

Instrumental value
- Support consent process
- Provide ongoing channels of communication
- Address local fears, anxieties and rumours about research, i.e. blood sampling
- Feedback of research findings


SLIDE 46:

SOME STRATEGIES/MODELS FOR COMMUNITY ENGAGEMENT IN AFRICA

- Community ENTRY is sensitive and crucial and must, therefore, be planned and conducted carefully
- Direct community engagement models
  - Community meetings/durbars
  - Town hall meetings
  - Focus group discussions
  - Engagement through representatives
  - Community advisory boards/groups
- Example: The Navrongo Model of community engagement

Sources: Tindana et al. (2011), Tindana et al. (2015).
ETHICAL NORMS THAT UNDERPIN THE NOTION OF COMMUNITY ENGAGEMENT

- Respect for persons
  Recognizing the community’s right to be involved in decisions that will affect them

- Beneficence
  Involving the community in creating common good for themselves and deciding what is good for them

- Justice
  Recognizing that the community is the best judge of fairness and justice

- Accountability
  The acknowledgement and assumption of responsibility for actions and decisions

SLIDE 47:

SLIDE 48:

- Solidarity
  Sense of shared responsibility and interests, concern for those who are less fortunate or vulnerable, and action to help such people

- Transparency
  Acting in such a way that it is easy for others to see what and why actions are performed, thus ensuring information disclosure, clarity, and accuracy

- Sustainability
  The ability to maintain something at a certain rate or level

- Public justification
  A proposed initiative should be acceptable to those who stand to be affected by the proposal

Other normative ethics principles?
ETHICAL FRAMEWORK FOR STAKEHOLDER AND COMMUNITY ENGAGEMENT

Three core imperatives:
1. “Identify and manage non-obvious risks and benefits”
2. “Expand respect beyond individual to stakeholder community”
3. “Build legitimacy for research project”

Source: King et al. (2014)

SLIDE 49:

COMMUNITY ENGAGEMENT CHALLENGES

- Identifying relevant community representatives and legitimacy of representation
- Power imbalance between researchers and communities
- Power imbalances within or between communities
- Involving minority groups
- Voluntary consent if community agreed to participation?
- Finding appropriate methods of engagement
- Handling community expectations
- Time and resources, where is the budget?
- Little empirical evidence to support practice

SLIDE 50:
SLIDE 51:

COMPONENTS OF COMMUNITY ENGAGEMENT

- **When?** Timeline? How early?
- **Where?** State facility? Town hall/community hall? Traditional venues?
- **What?** Engage about what?
- **How?** What method/medium?
  - Posters? Group meetings? Media? Pamphlets? Face-to-face meetings?
- **Duration?** Before study? During study? After study?
- **With whom?**

*No one-size-fits-all*

SLIDE 52:

CASE STUDY: mHealth in Bangladesh

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.

As the researchers, you now need to conduct community and stakeholder engagement during the planning phase of the study.

NOTE TO PARTICIPANT:
See Annex 4 and Annex 5 for role-play on stakeholder engagement.
SLIDE 53:

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

SLIDE 54:

ROLE PLAY – mHealth in Bangladesh – Stakeholder Engagement

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
ROLE PLAY – mHealth in Bangladesh – Stakeholder Engagement

- 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 55:

CASE STUDY: mHealth in Bangladesh

- Please discuss the case from the perspective of stakeholder engagement
  - When?
  - Where?
  - What?
  - How?
  - Duration?
  - With whom?

- Anticipate ethical challenges that may arise and how to plan to mitigate these through effective engagement

SLIDE 56:
CASE STUDY – mHealth in Bangladesh
Considerations in Stakeholder Engagement

- What are the core imperatives of stakeholder engagement?
- Does the study meet the community’s needs?
- How should stakeholder engagement occur?
- Who are the stakeholders in this study?
- Who should represent the community?
- Risk assessment:
  - Individual harms
  - Social harms
  - Financial harms
  - Communal harms
  - Harm to health system
- Commitment to scale up if successful

NOTE TO PARTICIPANT:
As an alternative to the role-play, guiding questions for discussion can be found in Annex 6.

8. Iterative Process

- Ongoing monitoring, evaluation and community and stakeholder engagement throughout the research process to detect and understand barriers and potential harms early on
- Channels for communication should remain open in all directions to obtain constructive feedback
- Protocols may require adjustment or adaptation once the project has begun to optimize success and minimize harms while maintaining scientific rigor
- Potential adjustments may require rethinking of ethical consequences and requirements at all stages
- It is important that the research remains responsive to the identified needs

SLIDE 57:

SLIDE 58:
**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.

**SLIDE 59:**

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**REFERENCES AND READING MATERIALS - 1**

REFERENCES AND READING MATERIALS - 2


SLIDE 61:

REFERENCES AND READING MATERIALS - 3


SLIDE 62:
REFERENCES AND READING MATERIALS - 4

MODULE 4 ETHICAL ISSUES IN THE CONDUCT OF IMPLEMENTATION RESEARCH
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.

TIMING: 3 hours

FACILITATING MODULE 4

SLIDE 2:

LEARNING OBJECTIVES

To describe:
- ethical aspects of upholding participant autonomy in implementation research:
  - informed consent;
  - ethical issues related to promoting justice during the conduct of implementation research:
    - standard of care in the implementation research design;
    - ancillary care;
    - ethical aspects of data collection and management:
      - data ownership, data sharing, data dissemination;
      - privacy and confidentiality.

SLIDE 3:

SESSION OUTLINE

- Informed consent
- Standard of care
- Ancillary care
- Data collection and management
INFORMED CONSENT IN IMPLEMENTATION RESEARCH

- Read the case study 1, part 1.
- 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 healthcare 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.

NOTE TO PARTICIPANT:
See Annex 7 for further information in part 1 of case study 1.

INFORMED CONSENT IN IMPLEMENTATION RESEARCH

- Who are the participants of intervention?
- Who are the participants of outcome assessment?
- Who are considered as research participants?
- Who should provide informed consent?
WHO IS THE RESEARCH PARTICIPANT IN IMPLEMENTATION RESEARCH?

MODULE 1

SLIDE 6:

INDIVIDUAL- AND GROUP-LEVEL IMPLEMENTATION RESEARCH EXAMPLES

<table>
<thead>
<tr>
<th>Example 1</th>
<th>Example 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research on outdoor spraying of new insecticide in communities.</td>
<td>Research to test effectiveness, reach and acceptability of single dose mass drug administration (MDA) for lymphatic filariasis (LF).</td>
</tr>
</tbody>
</table>

SLIDE 7:
### Slides 8 and 9:

#### Slide 8:

**INDIVIDUAL- AND GROUP-LEVEL IMPLEMENTATION RESEARCH**

<table>
<thead>
<tr>
<th>Group-level implementation research</th>
<th>Individual-level implementation research</th>
</tr>
</thead>
<tbody>
<tr>
<td>No individual participant in the intervention or control clusters can meaningfully refuse to consent to participate as the spraying operation cannot be restricted</td>
<td>Individual participants in the study can meaningfully refuse to consent and refuse to take the MDA Excludable</td>
</tr>
<tr>
<td>It may not be feasible to obtain consent from each household in all the 20 villages before starting the intervention</td>
<td>It may be feasible to obtain consent as each individual taking the intervention will be approached by the research team</td>
</tr>
</tbody>
</table>

#### Slide 9:

**INFORMED CONSENT IN INDIVIDUAL- AND GROUP-LEVEL IMPLEMENTATION RESEARCH**

![Diagram showing informed consent process]

**Slide 9:**

- **Informed Consent**
  - Community-level intervention
    - Consent
    - Information
  - Individual-level intervention
    - Consent
    - Information
  - Two-stage consent:
    - Consent
    - Consent

The diagram illustrates the process of obtaining informed consent in both community and individual-level interventions, highlighting the need for explicit consent and information at each stage.
INFORMED CONSENT IN GROUP-LEVEL STUDIES WAIVER
OF INFORMED CONSENT

When randomization is at the group level, the individual informed consent may be waived if following criteria are met:
- intervention targeted at the group
- individuals only indirectly impacted by intervention
- no identifiable private information collected from individuals
- no more than minimal risk
- rights and welfare of participants not adversely affected
- research could not be carried out if consent were to be obtained.

SLIDE 10:

INFORMED CONSENT IN GROUP-LEVEL STUDIES
GATEKEEPER CONSENT

Who is a community gatekeeper?
- A local leader concerned with the welfare of the community
- A physician/health worker practicing in the community
- A representative of the community interested in its welfare
- A local government representative

Ethical concerns in selecting a community gatekeeper?
- Gender of the gatekeeper should be considered in the context of the study
- Justice considerations in gatekeeper selection – voice of the vulnerable

SLIDE 11:
INFORMED CONSENT IN INDIVIDUAL-LEVEL STUDIES

- Is individual consent required even after obtaining gatekeeper consent?
- Is it possible to obtain individual consent for randomization as cluster randomization happens a priori even in individual-level implementation research?
  - 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 control group without intervention, what amount of information should be provided to them?

SLIDE 12:


INFORMED CONSENT MODEL FOR IMPLEMENTATION RESEARCH

1. IS THERE A NEED FOR INFORMED CONSENT? (YES/NO)
   - Consent conditions for minor
   - Consent conditions for minor
   - Consent conditions for minor

2. IS OBTAINING AN INDIVIDUAL FEASIBLE? (YES/NO)
   - Situations where individual IC is not feasible – large populations/participants

3. IS THE IC MEANINGFUL? (YES/NO)
   - Is case of non-acceptable interventions IC is not meaningful

4. CONSIDER GATEKEEPER CONSENT (YES/NO)
   - Need that ethics committee approv

SLIDE 13:
SLIDE 14:

JUSTICE IN THE CONDUCT OF IMPLEMENTATION RESEARCH

- Issues of fairness in participant selection
- Issues of appropriate standards of care
- Issues of ancillary care

SLIDE 15:

JUSTICE IN THE CONDUCT OF IMPLEMENTATION RESEARCH

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.

NOTE TO PARTICIPANT:
See Annex 7, issue 1 in part 2 of case study 1.
SLIDE 16:

JUSTICE IN THE CONDUCT OF IMPLEMENTATION RESEARCH

It was a cluster randomized controlled study with 19 villages randomized to intervention and 10 villages to routine maternal and child health care by the community health workers.

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 planning for maternal and child health-care delivery services, which have resulted in poor outcomes.

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

SLIDE 17:

STANDARD OF CARE IN IMPLEMENTATION RESEARCH

- What care should be provided to the control group of the implementation research?
- usual care or existing standard
- Acceptable standard of care according to best available evidence
- Clinical equipoise condition
- Researchers should not take advantage of existing poor standard of care
- One way to overcome issue of standard of care is to apply the stepped wedge study design
ANCILLARY CARE

During the conduct of the implementation research, 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.

What should the implementation researchers do about this information?

SLIDE 18:

ANCILLARY CARE

- Provision of care for incidentally detected health issues
- In implementation research, ancillary care may extend beyond medical care
- In implementation research, the ancillary care may pertain to groups and communities rather than to individuals
- It may include measures to address other social determinants of health
- It may also include creating some changes in the health system

SLIDE 19:

NOTE TO PARTICIPANT:
See Annex 7, issue 2 in part 2 of case study 1.
WHY COLLECT DATA?

- Why should we collect data?
- Enables public health research and practice to:
  - identify outbreaks
  - allocate resources
  - direct intervention.
- By gathering information and translating those findings into interventions, public health is able to improve population health

SLIDE 20:

SOURCES OF DATA FOR IMPLEMENTATION RESEARCH

- Primary data is from people and communities
- Secondary data may be obtained from health information systems and programme management information systems

SLIDE 21:
CASE STUDY FOR DISCUSSION

- Read the case study 2, part 1
- Discuss part 1
  - What specific data is collected in this implementation research?
  - Who benefits from data collection? Who might be burdened? What are the risks?
  - What will the data be used for?
  - Can it be collected if no capacity/willingness to use?
  - Is confidentiality required, how can it be maintained?

NOTE TO PARTICIPANT:
See Annex 8, part 1 of case study 2.

DATA USE IN IMPLEMENTATION RESEARCH

Once we have the data in hand, are there ways in which we must use them? Ways in which we cannot use them?
- Contact tracing
- Partner notification
- Quarantine
- Mandatory vaccination
- Mandatory treatment
- Others?
DATA SHARING, DISSEMINATION AND DISCLOSURE

- Read the case study 2, part 2
- Discuss part 2
- Groups 1, 2, 3 and 4 discuss the following 4 scenarios:
  - Group 1 – can identifiable health information be shared with public health for purposes of creating a registry? Can location information be shared?
  - Group 2 – can data be shared with forest officials for other purposes?
  - Group 3 – in the context of outbreaks, can the data be widely disseminated?
  - Group 4 – should researchers disclose names of non-immunized children to the health officials?

NOTE TO PARTICIPANT:
See Annex 8, part 2 of case study 2.

SLIDE 25:

KEY MESSAGES

Informed consent
- Full spectrum from waiver – gatekeeper permission – dual-level consent – individual consent
- Usually in Public health research and implementation research, informed consent does not take the primary position as in clinical research

Justice considerations
- Standard of care – existing standards versus acceptable standards
- Ancillary care responsibilities

Data collection
- Data collected only if ability and intention to use
- Ethical issues with data sharing, dissemination, disclosure to be considered
- Data protection, privacy and confidentiality
REFERENCES AND READING MATERIALS

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.

**TIMING:** 1 hour

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**FACILITATING MODULE 5**

**SLIDE 2:**

- To describe:
  - The ethical obligation to disseminate findings of implementation research
  - The ethical implications of sustainability of interventions studied in implementation research

**SLIDE 3:**

- 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
CASE STUDY

- A PI has just concluded an implementation research study A; contrary to expectation, analysis revealed that the new service tested did not yield favourable results.
- He proposes to move forward with study B as he has recently won a big grant.
- Considering the outcome of study A was not favourable, he has decided neither to publish the findings nor feedback to the community.
- Instructed his team to devote their time instead to study B.

Concerns? Opinions?

SLIDE 4:

ETHICAL OBLIGATION TO DISSEMINATE IMPLEMENTATION RESEARCH FINDINGS

- Implementation researchers have ethical obligation to disseminate research findings:
  - the data emerged from the community
  - justice requirement to give back to community
  - empowerment of community with knowledge.

SLIDE 5:
TO WHOM SHOULD INFORMATION BE DISSEMINATED?

- Health-system officials
- Local community health workers
- Local communities
- Larger communities
- Global community
- Other researchers
- Policy-makers

SLIDE 6:

HOW SHOULD INFORMATION BE DISSEMINATED?

- In a language and manner understandable to the intended target audience
- Use of different media to target lay people as well as technical
- Persuasive language of activism vs. honesty

SLIDE 7:
DATA OWNERSHIP AND DISSEMINATION

- In donor-initiated research, the donors determine nature and method of dissemination of findings and regulate the process.
- Whether donors disseminate the data or not may depend on the findings and whether it is favourable to the donor.
- Irrespective of donor preferences and irrespective of study results, all implementation research findings should be disseminated – good governance is required.

SLIDE 8:

DONOR INFLUENCES ON DISSEMINATION OF IMPLEMENTATION RESEARCH FINDINGS

An implementation research project done by a group of researchers in a low- and medium-income country (LMIC) was sponsored by an international donor.

The implementation research assessed a particular guideline for treatment of an infectious disease of importance in the country.

The implementation research concluded that the recommended treatment was ineffective and not practical in the local context.

However, when an attempt was made to publish this research the donor raised serious concerns.

SLIDE 9:
ROLE OF IMPLEMENTATION RESEARCH IN RESEARCH CAPACITY BUILDING & HEALTH SYSTEM STRENGTHENING

- Usually funding of implementation research does not support long-term interventions
- Long-term and system-level interventions will build implementation research capacity as well as strengthen the system
- Vertical programmes tend to weaken the health system
- Apart from strengthening the health system, implementation research should also strengthen the local capacity to conduct, monitor and evaluate research

SLIDE 11:

POST-IMPLEMENTATION RESEARCH ACCESS TO INTERVENTIONS

- The interventions in implementation research are usually system-wide
- Ensuring post-research access to the intervention can be challenging
- Post-research access may involve cost-intensive system-wide changes
- The researchers may not by themselves be able to bring about policy change, but should engage with political stakeholders at the beginning of the implementation research
- There is an ethical obligation to ensure the research participants benefit because of the intervention

SLIDE 10:
SLIDE 12:

ETHICAL OBLIGATION TO TRANSLATE IMPLEMENTATION RESEARCH FINDINGS INTO POLICY AND PRACTICE

- There is a documented delay in translation of research to practice.
- However, implementation research is a special form of research which is done to study the best method of delivering intervention.
- There is an ethical obligation to adopt implementation research into practice.
- Having a policy adoption plan at the beginning of implementation research is very important and therefore stakeholder engagement is useful.

SLIDE 13:

SCALABILITY AND SUSTAINABILITY

- 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.
CHALLENGES 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 15:

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

- Dowdy DW. Partnership as an ethical model for medical research in developing countries: the example of the "implementationraith". J Med Ethics. 2006;32:367-60.

SLIDE 16:
MODULE 6 IN-DEPTH ETHICAL ANALYSIS OF IMPLEMENTATION RESEARCH USING CASE STUDIES
9. 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, plenary discussion and case studies 3-7 in Annex 9 (no power point presentation provided).

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?

**Point 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**

<table>
<thead>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
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<td></td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
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<td>Study context/relevance</td>
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<td>Acceptability of intervention</td>
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<td></td>
<td></td>
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<tr>
<td>Equipoise</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
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<tr>
<td>Scientific rigour</td>
<td></td>
<td></td>
<td>✔</td>
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<tr>
<td>Treatment obligations in control group</td>
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</tr>
<tr>
<td>Information given to control group/false information</td>
<td>✔</td>
<td></td>
<td></td>
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<tr>
<td>Transfer of a test/policy/ procedure from one country to another</td>
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<td>—</td>
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<td>—</td>
</tr>
<tr>
<td>Confid...safety of contact tracing</td>
<td>✓</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>False positive/negative test implications</td>
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<td>—</td>
<td>✓</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Who bears cost of study medication if standard of care?</td>
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<td>—</td>
<td>✓</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sustainability</td>
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<tr>
<td>Scalability</td>
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<td>✓</td>
<td>✓</td>
<td>—</td>
<td>✓</td>
</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>
</tr>
<tr>
<td>Vertical vs. horizontal programmes</td>
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<td>Decentralization of laboratory testing</td>
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<td>Excluding vulnerable populations?</td>
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<td>Vouchers</td>
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</tr>
<tr>
<td>Incentives/gifts/inducements</td>
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<td>✓</td>
<td>✓</td>
<td>—</td>
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<td>Create need that cannot be met by health system/clinics</td>
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<td>Quality control</td>
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<td>✓</td>
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<td>—</td>
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<td>Induce over-treatment or over-use of services</td>
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<td>✓</td>
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<td>“cherry picking”</td>
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<td>Possibility for fraud/theft</td>
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<td>✓</td>
<td>✓</td>
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<td>—</td>
</tr>
<tr>
<td>Collateral impact (not on study subjects), e.g. taxi drivers, drug sellers</td>
<td>—</td>
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<td>✓</td>
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<td>Group consent</td>
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<td>✓</td>
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<td>Selection of community representatives</td>
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<td>—</td>
<td>✓</td>
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<td>Ancillary findings/care responsibility</td>
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<td>—</td>
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<td>—</td>
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<td>Adequacy of follow up</td>
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<td>Opt-out possibilities</td>
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<tr>
<td>Subject confidentiality</td>
<td>—</td>
<td>—</td>
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<td>✓</td>
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</tr>
<tr>
<td>Consent in illiterate subjects</td>
<td>—</td>
<td>—</td>
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</tr>
<tr>
<td>Stigmatization through subject identification/participation</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<td>Blurred line between research and clinical care</td>
<td>✓</td>
<td>—</td>
<td>—</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
REFERENCES

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 Ethics201415:84


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 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 – PARTICIPANT’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></td>
<td></td>
<td></td>
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<tr>
<td>Effectiveness–implementation hybrid trials</td>
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<tr>
<td>Mixed–methods research</td>
<td></td>
<td></td>
<td></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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<tr>
<td>Participatory action research</td>
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<tr>
<td>Pragmatic trials</td>
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<tr>
<td>Quasi-experimental study</td>
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<tr>
<td>Realist view</td>
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</tbody>
</table>

Source: Adapted from Peters et al. (2013); Weijer et al. (2011).
### 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>
</tr>
<tr>
<td>2 Informed consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Equipoise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Research question</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Research conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Control groups</td>
<td></td>
<td></td>
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<tr>
<td>7 Anticipated outcomes</td>
<td></td>
<td></td>
</tr>
<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.
ANNEX 4.

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
ANNEX 5. 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 form 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.
MODULE 3 COMMUNITY AND STAKEHOLDER ENGAGEMENT – CASE STUDY 1

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?
2. Does the study meet the community’s needs?
3. How should community or stakeholder engagement occur?
4. Who are the stakeholders in this study?
5. Who should represent the community?
6. Risk assessment
7. Risk levels
8. Commitment to scale up, if successful
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 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 healthcare 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?

9. CASE STUDY 5: HOME-BASED MANAGEMENT OF MALARIA (HMM)

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.

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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