

Ethical Considerations in the Post-Research Phase of IR

Slides 2 & 3, Learning Objectives and Session Outline

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

- Ethical obligations of researchers and donors to disseminate the findings from IR
- Role of IR in research capacity building and health system strengthening
- Post-IR access to interventions
- Ethical obligation to translate IR findings into policy and practice

Slides 4-9: Ethical Obligations of Researchers and Donors to Disseminate Findings from Implementation Research

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

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Slide 5

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

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- Justice requires that the IR should be given back to the community
- There is a need to empower communities with knowledge

Slide 5

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Slide 6

The information should be disseminated to all relevant stakeholders.

Slide 7

The dissemination of the research findings to the community requires a delicate balance between the persuasive language of activism and that of honesty. The researcher should disseminate information with the intent of increasing knowledge and empowering the community.

Slide 8

Initiate a discussion on data ownership. In donor-initiated research, the donors are the primary users of the data and so they often determine the nature and method of disseminating the findings.

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Slide 9

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

Often, researchers may incidentally stumble upon findings of systemic inefficiencies during their research and it is their moral obligation to report it or take corrective action, if possible. This is part of the post-research dissemination of information to those who need to know.

Slide 10

Describe the ethical obligations to empower the local research capacity and to strengthen the health system. IR may lead to a vertical system within the larger health system and this tends to drive substantial funding away from other important interventions. Therefore, there is a need to strengthen the health system by creating horizontal and integrated interventions. Horizontal health-care delivery refers to delivery of services through publicly financed health systems comprised of a comprehensive package of services. On the other hand, if a selective intervention to control a specific disease or condition is delivered without integrating it into other essential services, it is referred to as vertical service delivery. Horizontal and integrated services strengthen the overall health system.

Slide 11

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

Use Slide 11 to highlight this aspect of the post-research consideration in IR.

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Slide 12

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

Slides 13 & 14: Scalability and Sustainability

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

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