Ethical Issues in the Conduct of Implementation Research

Slide 2 & 3, Learning Objectives and Session Outline

Slides 1 and 2: Introduce the session and list the various ethical considerations that will be discussed in the session:

- Ethical aspects of upholding participant autonomy in IR
    - Informed consent
- Promoting justice during the conduct of IR
    - Standard of care in the IR design
    - Ancillary care
- Ethical aspects of data collection and management
    - Data ownership, data sharing, data dissemination
    - Privacy and confidentiality

Slide 4-6: Informed Consent in Implementation Research

Using this slide, introduce the participants to further information in part 1 of case study 1 in Annex 7.

The participants discuss only part 1. After the participants discuss the questions in Slide 5 in the large group, use Slide 6 to discuss the issue of identifying the research participants in the study. In the case study, there are three groups of research participants, namely, the pregnant women, mothers and babies in the intervention, control villages, the community health workers, programme managers, policy-makers and district health officials. The data will be collected from the mothers and the babies.

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Slide 7

Highlight the differences between individual level and community level IR. Read out examples 1 and 2 and ask the participants to identify the research participants in both of the examples.

Slide 8

Explain that in example 1 – the study of a new insecticide spray against mosquitoes – the study is at the level of the village and no individual household can be effectively prevented from being sprayed, thus the intervention is non-excludable. Thus, obtaining informed consent from each household may not be meaningful or feasible. However, in the case of MDA – administering a drug against LF to the entire population on the same day – individual participants can meaningfully refuse to take the medicines and it may not be difficult to explain and obtain informed consent from each individual before giving them the drug.

Slide 9

Describe the various options for obtaining informed consent in IR. For community-level intervention, the options may be waiver of consent or community gatekeeper consent. For individual-level consent, the options may range from waiver of consent to individual-level consent up to dual-level consent from the gatekeeper and the individual.

Slide 10

Explain that sometimes informed consent may be waived in group- level IR and defines the conditions under which this can be done. The decision to waive informed consent is made by the ethics committee after detailed deliberations.

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

Slide 11

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

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

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

Slide 12

Individual consent questions

Is individual consent required even after obtaining gatekeeper consent?

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

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

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

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

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

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

Slide 13

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

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

Slides 14-16: Justice in The Conduct of Implementation Research

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

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

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

Given the knowledge of the poor nature of the de facto care, can this be continued in the control clusters?

What would be an acceptable standard of care for the control clusters?

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

Slide 17

Introduce the alternative of a stepped-wedge design and describe how it overcomes the problem of standard of care, namely, everybody in the study gets access to the intervention in a phased manner so that nobody is left out of the intervention.

Slide 18 & 19: Ancillary Care

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

Slides 20–24: Ethics of Data Collection and Management

Initiate a discussion on the ethics of data collection and ask the participants the purpose of data collection.

Data collection in IR helps to:

- Establish the efficacy, safety and efficiency of public health interventions
- Identify disease states and outbreaks
- Allocate resource
- Improve population health (by translating data findings into interventions)

Thus, there is an ethical justification for data collection.

Slides 20–24: Ethics of Data Collection and Management

Slide 21:

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

Slide 22

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

Special Note to facilitator: introduce case study 2 in Annex 8 and encourage the participants to divide into four small groups. All the groups read part 1. Pose questions for discussion.

What specific data is collected in this IR?

The special outreach teams (SOTs) contact these groups and enumerate the names, family details, demographic characteristics, health details and vaccination status of all the children below 5 years of age in the five groups.

The SOTs will maintain an ongoing registry of new births, new entrants into the nomadic groups, marriages, etc. They will follow up the pattern of immunization coverage over the years using a time-series analysis.

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

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

What will the data be used for?

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

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

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

Is confidentiality required, how can it be maintained?

Confidentiality is the protection of the data obtained from the communities. It may be difficult to maintain strict confidentiality as children's names and contact details may have to be shared with SOTs in order to administer vaccinations. However, such information sharing may be kept to minimum as long as it only provided to those who absolutely need to know.

Slide 23:

Highlight some ethical issues in data use. The ethical burden of data use can be high in some public health activities, such as:

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

Slide 24

Special Note to facilitator: Now ask the four groups to read one scenario each from part 2 of case study 2 in Annex 8 and discuss the ethical issues in that scenario.

Group 1 – Sharing data with public health

The public health system is requesting the IR team to share the name-based information on which children were vaccinated, the type of vaccines and when. The reason for this request is to optimize the use of scarce resources and ensure that all children are vaccinated, and, at the same time, make sure no child's vaccination is duplicated.

Is it ethical to share this information with the public health system? There are several points of discussion below.

- Did the IR team obtain informed consent to share the information?
- Provided that the public health system has a duty and responsibility for the health of the community in Country X, can this information be shared from a stewardship perspective?
- As the IR is operating within the purview of the larger public health context, is it important to support the greater public good?

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

Group 2 – Sharing with forestry officials

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

Groups 3 – Dissemination during an outbreak

Country X suffers from an outbreak of polio. The vaccination rates in the nomadic community are low. Should this information be disseminated to the larger community of Country X? The risk of disseminating the information about poor vaccination rates in the nomadic community is the isolation and labelling of the community from the rest of the country. Their nomadic movements may be restricted. They may suffer from livelihood restrictions. Dissemination of information about their poor vaccination rates may also cause panic in the larger community, which may blame the nomadic populations for the outbreak, with serious social consequences. If there is an outbreak of polio within the nomadic community, this may also endanger the public health safety of the neighbouring

communities. However, the action of disseminating the information to the wider community is not an easy decision. Although there are strong benefits (preventing the outbreak from spreading), the potential risks for the vulnerable community members who are participants of the research has to be considered. Careful weighing of risks and benefits for all groups involved is strongly defensible.

Groups 4 – Disclosure

The research team in this case has become privy to information about a stigmatizing STI in the parents of the children with congenital syphilis. If they disclose this information to the public health officials, the parents, especially the pregnant women may receive treatment and congenital syphilis may be prevented in the unborn child. Moreover, if these parents are treated, they may also stop spreading the infection to their other sexual partners. However, there is a risk that this couple could be stigmatized and isolated from the community.

Even if the information about their syphilis were kept confidential, the presence of public health personnel within the nomadic community, visiting the parents and offering them treatment, would in itself amount to public disclosure, as everybody within the small nomadic community would come to know about the treatment. The balance between these two circumstances is very delicate.

Slide 25

Close the session after this discussion by summarizing the key ethical issues in the conduct of IR, namely, issues related to informed consent, issues of ensuring justice in the conduct of the IR, and finally issues of data collection and data management.