

Ethical Considerations in Implementation Research

Slide 2 & 3, Learning Objectives and Session Outline

Slide 2

This module will cover the important aspects of health systems' ethical principles and IR. The following aspects will be covered:

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

Introduce these concepts to the participants.

Slide 4 & 5, Ethics of Health Systems Research and Implementation Research

Slide 4

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

- Medical ethics
- Research ethics
- Bioethics
- Public health ethics

Slide 6-10, Medical Ethics, Research Ethics, Public Health Ethics

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

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Slide 6

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

Slide 7

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

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

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

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

Slide 8

1. Substantive principles – they establish the rules for what is right and wrong, and the right and wrong actions in public health.
2. These principles facilitate ethical conduct in public health, producing benefits and minimizing harms.
 - Discuss the potential benefits of the herpes simplex virus (HSV) screening strategy – detection of asymptomatic carriers, prevention of neonatal HSV infections, and improvement in child health.
 - Discuss the potential harms – stigmatization of men and women detected to have a sexually transmitted infection (STI) – problems of marital discord and infidelity problems when screening positive.
 - Infringement of individual autonomy and compromises that individuals make should be proportional to the benefits to the community. Is being detected as having an asymptomatic sexually transmitted affliction proportional to the reduction in burden of newborn deaths in this community?
 - In support of the compromises that individuals make for the sake of common good, the community should reciprocate the gesture by upholding their interests. How can the

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community uphold the interests of people who reveal their HSV status for the sake of common good? Can efforts be made to protect their confidentiality? Can treatments be offered in an affordable and respectful manner?

- Equity – justice, fairness – is the programme likely to benefit/harm all sections of the community in a similar manner? Do women bear a greater burden of stigma and domestic violence after having been detected as having HSV?
- Trust – belief that the public health intervention is intended for the common good – trustworthiness.
- Solidarity – the feeling of standing united for a common cause, willingness to stand up for the common good.
- Stewardship – the act of protecting the health of the community, accepting responsibility for the well-being of the community as a service and not as a control. For example, during an influenza outbreak, the state should act by increasing awareness and providing specific vaccinations. The state may also take measures to isolate infected patients. However, all this is done in a spirit of service and not as a controlling measure. This is called stewardship.

Slide 9

Introduce procedural ethical principles:

1. Procedural principles – they establish the rules by which public health should be practiced and decisions made. They are concerned with the process of delivery of public health services.
2. These principles lay down the following rules for due process in public health.
 - Transparency – openness, honesty.
 - Relevance – appropriateness – is the screening programme for HSV the most relevant in this community? Are there other more important causes of morbidity?
 - Inclusivity – non-discrimination.
 - Responsiveness – being able to adapt to community needs and respond to the requirements.
 - Accountability – being answerable to the community.
 - Participation – were stakeholders involved in deciding on the best strategy to screen men and women for HSV?
 - Sustainability – being able to sustain public health action and public health impact.

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Slide 6-10, Medical Ethics, Research Ethics, Public Health Ethics

Slide 10

Potential conflicts between substantive ethical principles.

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

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

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Slide 11-20, Ethics of Health Systems Research and Implementation Research

Slide 11

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

Slide 12-13

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

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

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

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

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

Slide 14

HSR includes all forms of research in various building blocks of the health system. Use Slide 14 to describe these building blocks, namely: (a) leadership and governance; (b) health care financing; (c) health workforce; (d) medical products and technologies; (e) information and research; and (f) service delivery.

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Slide 15-20, Ethical Principles Of Health System Research

Slide 15

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

Can this be adopted in your country?

Discussion

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

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

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

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

How will the research participants be selected? How will research participants be protected against punitive action for past corruption?

Slide 16

Social insurance schemes have been shown to be an effective method for introducing universal health coverage. Can this be implemented in your country?

Discussion

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

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

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

What is the best research design?

Who gives informed consent?

Is there justice in the selection of participants?

Solidarity principle.

Slide 17

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

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Discussion

Research on data.

Data protection and confidentiality.

Data ownership.

Is consent from participants needed?

Who are the participants?

What can the data be used for?

Slide 18

Performance-based incentives for treatment of malaria has been shown to improve health-worker performance. Can this be adopted in your country?

Discussion

Can incentives be sustained?

Will incentives create sustainable change in health workers' practices?

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

What is the most appropriate study design?

Slide 19

A newer vaccine for prevention of rotavirus diarrhoea has been shown to be effective and safe in children.

Can this new vaccine be introduced into the immunization programme of your country?

Discussion

Is rotavirus diarrhoea an important health problem in your country?

What are the risks of rotavirus vaccines? What are the benefits?

What is the best study design?

What are cultural beliefs?

Does the community have trust in vaccines?

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Slide 20

Household-level campaigns for MDA to eliminate lymphatic filariasis (LF) has been shown to be an effective strategy to improve MDA acceptance rates. Can this be adopted in your country?

Discussion

Is LF a major problem in the community?

Is MDA the most appropriate strategy?

What are the risks of MDA? What are the benefits?

What is the most appropriate study design?

What cultural and local contexts will influence MDA acceptance?

Ancillary care issues may arise during door-to-door visits.

Slide 21-28, Ethical Justification for Implementation Research

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