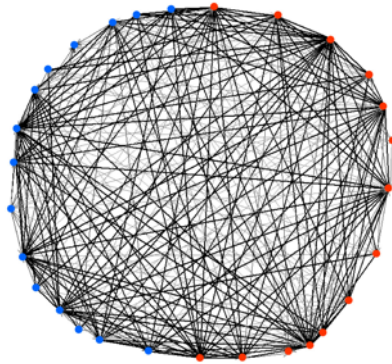


Ethics in emerging forms of global health research collaboration



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Introduction

- Bioethics has historically focused on:
 - Ethical issues in clinical practice
 - Ethical issues in medical research
- In past decade there has been an increasing interest in public health ethics
 - Resource allocation
 - Ethics of population level health interventions
 - Ethics of research on populations
- There is now a pressing need for bioethics to engage with the ethics of research collaboration

An example of collaborative global health research

- The Malaria Genomic Epidemiology Network (MalariaGEN) is a collaboration involving 31 partners in 24 countries.
- It aims to investigate biological mechanisms of susceptibility and resistance to severe malaria in childhood.
- Biological samples and clinical information have been collected from 100,000 people in 16 low-income countries.
- Samples are subjected to genomic analysis at the Sanger Institute in the United Kingdom.
- Data are fed back to local researchers and anonymised data shared with the wider international scientific community through a data access committee
- There are many other examples e.g. H3Africa, WWARN

Is there anything special about research collaboration?

- Collaborative research in low income countries raises many enduring and familiar ethical issues:
 - valid consent
 - acceptable levels of risk
 - distinction between research and health care
 - responsibilities to communities
 - benefit sharing
 - standards of care
 - what should happen when the research is over
- But there are ethical issues that are unique to research involving multi-partner collaborations between low and high-income countries partners?

1. Ethical issues arise differently across multiple, diverse but interconnected locations

- Collaborative research brings partners in many settings together in the 'same project'
- Scale, diversity and distribution of the project is much greater than in other forms of collaboration
- This means it is highly likely that views about what is ethically important, problematic about research will vary considerably across the collaboration
- This might happen in three ways:
 - Different ethical worries in different places
 - Different views about a shared worry
 - Different views about acceptable solutions to shared worries

Why are these differences important?

- These three kinds of ethical disagreement present important practical ethical challenges for collaborations:
- How in practice to go about identifying, analysing and reaching agreement about the emerging ethical issues?
- Important because the partners are part of the same project
- It is going to involve complex ethics work across multiple settings because these differences may be multiplied many times over
- Raises the issue of moral relativism not as a theoretical, philosophical problem but as a problem in practical ethics and project management.
- Is it acceptable to adopt different ethical solutions in different settings?

2. Ethical issues will arise and need to be resolved at multiple levels of analysis

- The fact that ethical problems can arise in different settings across the same project in different ways raises questions about responsibilities at the global level i.e. at the level of the 'project'
- There are a number of reasons why decision-making can not always simply be devolved to the local partner to resolve.
- I want to pick out two:
 - The need for accountability at the level of the 'project'
 - Shared moral responsibility

Need for accountability at level of the project

- There will be situations in which the project as a whole will be called upon to give an account of and justification for its practices and of how it addresses ethical issues across the whole range of its activities.
- This might occur when:
 - obtaining ethics approval
 - applying for funding
 - when publishing
- Unlikely that a completely devolved approach to ethical responsibility would be acceptable

The Shared nature of moral responsibility

- Another limitation on the scope for radically different approaches in different settings is that partners in one country may have an ethical interest in what happens in sites other than their own.
- They may find some solutions adopted elsewhere to be unacceptable and feel that their own reputation or sense of moral integrity is at stake in decisions made in other settings.
- Local researchers may also take the view that they are responsible to at least some degree for the practices of the collaboration as a whole.

3. Research will involve communities (or a community) in many different and disparate locations

Community engagement presents a number practical ethical challenges in the context of collaboration:

- How should the relevant community be identified?
- Is it research with multiple communities in different settings or is it research on a single, distributed and very diverse community?
- how to identify procedures, principles and mechanisms of engagement that are fair, effective, inclusive, accountable ?
- Balancing good practice in community engagement across the collaboration and sensitivity to local variation e.g. issues of fairness in benefit-sharing

4. Ethical issues will arise in relation to the nature and form of research collaboration

- Successful collaboration brings together diverse yet interdependent forms of expertise and institutions with different potentially competing interests and concerns e.g. hospitals, ministries of health, universities, funders
- Against this background, key ethical areas include:
 - Fairness, Justice and respect against a background of inequality
 - Trust and trustworthiness
 - sharing of data and samples,
 - Responsibilities for scientific capacity,
 - allocation of scientific resources,
 - setting of scientific priorities,
 - authorship and ownership of intellectual property

5. Developing practical ethical solutions in the context of multiple, ambiguous and conflicting guidance

- The governance environment within which global collaborations operate is highly complex.
- OHRP 2013 lists more than 1300 guidelines
- The effective functioning of ethics review in many countries is undermined by the complexity of the international guidance and inadequate training and resources.
- A problem for ethics committees is how to review research which only makes sense in the context of activities going on in a number of distant and diverse settings.
- The problem for researchers is that they need to put in place practical, justifiable methods for developing ethical solutions to what is to count as good practice.

6. Morally significant change will be a pervasive feature of the ethical landscape

- The scale, diversity, distribution and institutional complexity of collaborations means change will be a feature of research context
- Likely that change will occur in guidelines, regulations, the views of partners and of research ethics committees, and in public and community attitudes
- Such change will be ethically important because:
 - technological developments may require ethics approval
 - research collaborations often have long-term relationships with RECs and communities beyond the life of a project
 - the existence of change means that researchers are going to have to think about ethics throughout the project

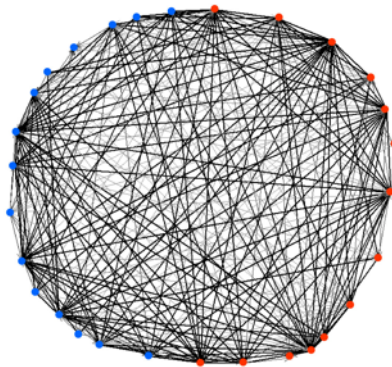
Issues of global justice and health inequalities will be foregrounded

- Collaborations are distributed across high and low income countries with wide disparities in power, wealth and resources
- They have to engage with issues of fairness, inequality and justice in relation to research communities and with each other
- Is it the responsibility of better resourced partners in high-income countries to build the capacity of those in low-income countries?
- Ethics committees are likely to see themselves as having a role in questions of fairness in research collaboration and the responsibilities of researchers to research communities
- These issues will tend to cluster around a number of key activities such as the international shipment, storage and access to biological samples and data

A research agenda on ethical Issues in collaborative research

- Ethical issues will arise differently across multiple, diverse but interconnected locations
- Ethical issues will arise and be resolved at multiple levels
- Research will involve communities (or a community?) in many different and disparate locations
- Ethical issues will arise in relation to the nature of the collaboration itself
- There will be a need to develop practical ethical solutions in the context of multiple, ambiguous and sometimes conflicting forms of guidance
- Change will be a pervasive feature of the ethical landscape
- Global justice and health inequalities will be foregrounded

Identifying, understanding and engaging with these ethical issues calls for a greater emphasis on collaborative, networked approaches to bioethics research





The Global Health Bioethics Network



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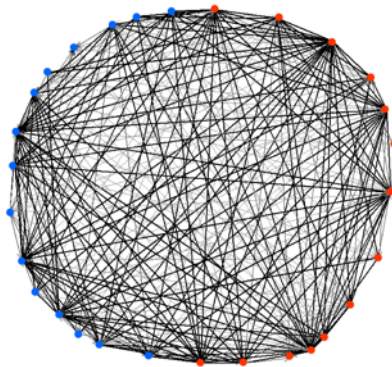


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