Ethical sharing of health research data in low- and middle-income countries: views of research stakeholders

- **This project examined the views and experiences of research stakeholders in India, Vietnam, Thailand, South Africa and Kenya about ethical issues raised when sharing public health and epidemiology research data.**

- **Four key elements of best practice in data sharing emerged: assessing value, minimising harm, promoting fairness and reciprocity, and embedding trust.**

- **Several priorities for future research and stakeholder engagement were identified, around consent, governance, data policy development and capacity building.**

- **An online toolkit was created to bring together knowledge on data-sharing ethics and provide a platform for pooling resources.**

Background and context

Health research funders around the world are increasingly requiring the timely and appropriate sharing of research data. There is growing awareness that making data more widely available can unlock new avenues of research and maximise the health benefit from research investments. At the same time, it is also widely recognised that sharing data from research involving human participants raises ethical and governance challenges.

Where such research is conducted in low- and middle-income countries (LMICs), these challenges can be more complex. Inequities in resources and power relationships lead to concerns that data-sharing requirements may unfairly disadvantage the researchers who collect the data and may fail to benefit the participants' communities. There may also be heightened concerns about risks to vulnerable individuals and groups.

To develop effective and fair data-sharing policies that are locally appropriate requires a good understanding of the views and expectations of stakeholders in the research process in LMIC settings. To date, however, there has been a dearth of empirical research on this topic.

The study

On behalf of the Public Health Research Data Forum, the Wellcome Trust supported this multi-site collaborative study on stakeholder experiences and views of best practices in sharing individual-level data from clinical and public health research. It aimed to provide evidence to inform the development, implementation and evaluation of data-sharing models and identify future research priorities.

Interviews and focus groups were conducted with key stakeholders – including health professionals, researchers and community representatives – The research team coordinated protocols to ensure that the research at each site was a robust stand-alone study, adapted to the local context, while allowing for cross-centre comparison.
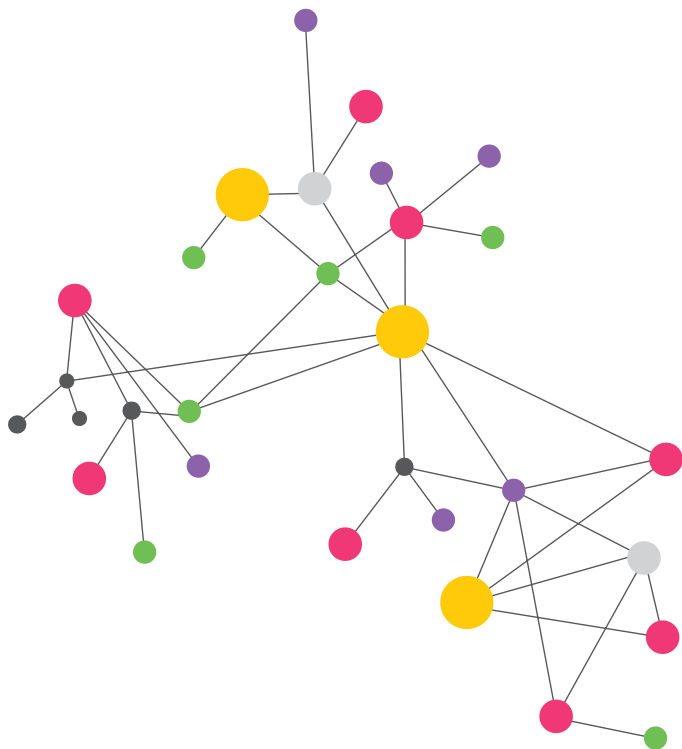

The research team

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- Thailand (Wellcome Trust Thailand Major Overseas Programme): Phaik Yeong Cheah, Decha Tangseefa, Aimatcha Somsaman, Tri Chunsuttiwat, François Nosten and Nicholas Day.

- Vietnam (Oxford University Clinical Research Unit): Laura Merson, Tran Viet Phong, Le Nguyen Tranh Nhan, Nguyen Tranh Dung, Ta Thi Dieu Ngan and Nguyen Van Kinh.

Findings: four elements of good practice

Across the sites, stakeholders identified four critical elements of good practice in data sharing.

1. Assessing the value of sharing: there was a high level of support for data sharing among researchers. Community representatives and research participants were more cautious, although support rose as they became more familiar with the concepts and potential safeguards. The potential benefit was, however, seen as just one piece of the jigsaw.

2. Minimising harm: Protecting the privacy and confidentiality of participants was clearly and consistently seen as paramount. Anonymisation of data was not necessarily felt to be sufficient to prevent harm to participants, and there were concerns that re-identification of participants could lead to the stigmatisation of communities, populations and countries. Researchers also emphasised the need to ensure that data sharing did not disadvantage research and capacity building in LMICs.

3. Promoting fairness and reciprocity: It was felt that policies for data sharing should promote the interests of local stakeholders – for example, supporting secondary analyses of data that address health issues relevant to the communities involved. Researchers also stressed that due recognition must flow to primary researchers who produced the data. There was a view that data sharing should help to increase local analytical capacity, with some stakeholders proposing routine requirements for collaboration in secondary data analysis.

4. Building trust: Participants, communities, researchers and the wider public will only accept data sharing if it is carried out in a trusted and trustworthy manner. Policies and processes for data release and governance must be proportionate and promote the interests of stakeholders while minimising potential harm.

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Moving forward

The research identified a number of priorities for future work, seen as building blocks of good practice in ethical data sharing.

1. Consent for data sharing: The practice of obtaining broad consent from participants, allowing for unspecified future uses of data, is becoming more widely adopted. At each site there was support for this (given appropriate data-sharing governance). Further research should determine what information to provide in varying contexts when data sharing is anticipated, and how to explain these largely unfamiliar concepts to participants.

2. Governing data sharing: Researchers strongly preferred to share data within established and trusted collaborative relationships. In some cases, therefore, there may be a case for sharing data in the context of collaborations as a first step – before sharing more widely. Wider data sharing requires transparent, accountable, efficient and fair governance; further work is needed to establish governance models of this type.

3. Data sharing policies: A range of issues were identified in which best-practice policies and standard operating procedures would be helpful – including data quality, metadata, consent, and data access and governance processes. International and national guidance on data sharing, and clear guidance on funder expectations, were likewise seen as necessary.

4. Capacity building: Developing the skills and resources necessary to manage and share data, implement policy priorities, and participate in secondary analyses were acknowledged as priorities for future action.

The project also developed an online resource centre focusing on ethics and best practice for data sharing in LMICs.

Ethics and best practice in sharing research data – an online resource centre

This open access website created as part of the project assists in addressing educational needs around the ethics of data sharing in LMICs. It includes a free online certified course designed for researchers and ethics committee members to build capacity in data sharing. It also brings together guidance, policies and articles, as well as links to data-sharing repositories from a range of settings. Open access discussion groups and blogs hosted on the site will enable stakeholders around the world to further develop the resource and discuss these issues.

bioethicsresearchreview.tghn.org/research-data-sharing/

This research provides important insights into LMIC stakeholders' views on data sharing. The partners in the Public Health Research Data Forum hope it will pave the way for further research and stakeholder engagement activities, informing the development of data-sharing policies that are sensitive to context, and ensuring that the huge potential benefits are realised ethically and equitably.

Further information

The full results have been published as a special edition of the Journal of Empirical Research on Human Research Ethics, with a range of commentary pieces.

Find out more about the Public Health Research Data Forum: **wellcome.ac.uk/phrdf**