

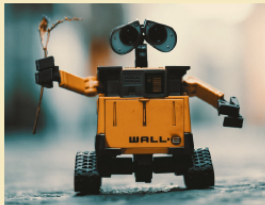


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## *The Ethics of Data Sharing in Low and Middle Income Countries*

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### *Author's Biography*

*Sharon is a senior lecturer at the Faculty of Law, University of Malaya. She teaches Medical Law and Ethics to both undergraduate and graduate students. Her research interests have primarily revolved around medical research ethics and issues of competency and consent. She recently spent a year as a Visiting Research Fellow with the CENTRES programme at the Centre for Biomedical Ethics at NUS where she developed an interest in issues relating to Global Health Ethics and the rights of marginalised populations.*

## ***Data sharing in biomedical research***

Data sharing is rapidly becoming a vital part of biomedical research. Researchers are increasingly required to share data as many funding agencies and scientific journals commonly adopt data sharing policies. There are however, a number of ethical challenges involved in sharing data. Much of the current literature on the ethics of data sharing has focused on issues of privacy, confidentiality, informed consent, and the different models of consent that might be used for the storage and sharing of data.

These discussions are played out against an evolving landscape as new issues emerge. Take for example two emerging trends in data sharing. First, there is a move towards linking health and social data to genomic data and other existing research data, which may challenge accepted notions of privacy and run the risk of the public losing trust in the medical profession.

Second, there is a growing concern about the ethical implications of an increasing move to link large databases (data linkage) and permit exploration with machine learning or Artificial Intelligence (AI) approaches. The sharing of data can be particularly useful in low and middle income countries (LMICs) where such activities can be used to maximise the utility of data and minimise unnecessary duplication. Clinical and public health data have the potential to generate valuable datasets to address the challenge of disease burden that is disproportionately faced by LMICs.

International collaborative platforms such as the WordWide Antimalarial Resistance Network (WWARN), the Infectious Disease Data Observatory (IDDO) and H3Africa have the ability to consolidate large datasets and generate reliable evidence that will enable research driven responses to some of the major challenges faced by these countries. As data sharing practices expand to LMICs, new ethical, legal and social concerns have emerged. This article will consider two of the key ethical issues associated with data sharing in LMICs: promoting equity and advancing good governance.

**Researchers are increasingly required to share data...may challenge accepted notions of privacy...there is a growing concern about the ethical implications...**

## ***Promoting Equity***

It is important that data sharing activities should recognise and balance the needs of different stakeholders involved in data sharing. This includes researchers who generate the data, secondary users of the data, the communities from which the data or specimens came and funders of the collection effort. Data sharing practices are still relatively uncommon in LMICs and in many cases, policies, expertise, and infrastructure to ensure the meaningful use of available data are not well established. The issue of promoting equity will be considered in relation to two stakeholders:

(i) Researchers in LMICs and (ii) The communities that provide the data.

**Data sharing practices are still relatively uncommon in LMICs...There remain significant knowledge and infrastructure gaps between researchers in high-income countries (HICs) and researchers in LMICs.**

### ***(i) Researchers in LMICs***

There remain significant knowledge and infrastructure gaps between researchers in high-income countries (HICs) and researchers in LMICs. Significantly, with the development of new approaches and technologies in HICs mentioned above such as data linkage and AI technology, there is a danger that these inequalities may be compounded. In order to avoid exacerbating existing inequalities, steps need to be taken to promote the collection and use of data in measures that promote equitable outcomes.

There are two situations in which researchers in LMICs may face difficulties in data sharing activities. First, when researchers in LMICs generate data, which may be the basis of secondary analyses and second when researchers in LMICs seek to engage in secondary analyses of existing data.

#### ***(a) Researchers in LMICs who generate data***

Researchers in LMICs may generate data and/or collect samples in a number of contexts. They may do this as part of local or national studies with no immediate intention of sharing, or they may engage in international collaborations where processes for data sharing have been negotiated and established. In both situations, the researchers who generate the data have a valid interest in using their data effectively. However, unlike their counterparts in HICs, they may require more time to conduct analyses of their findings.

Researchers in HICs may have higher analytical capabilities and may be able to use the same data more quickly and more efficiently resulting in the publication of articles in high impact journals, while the researchers who have generated the data may struggle to get published in the same journals. This is likely to affect the career advancement opportunities of researchers from LMICs. In many cases, they may not even be acknowledged in secondary analyses of the data.

International collaborations provide great opportunities for researchers to work with partners to develop mutually beneficial data sharing arrangements. There are a number of good practice initiatives such as INDEPTH (<http://indepth.network.org>), MalariaGEN (<https://www.malariagen.net>) and WWARN (<http://www.wwarn.org>).

These initiatives have established and publicised policies and processes for curating and sharing research outputs which have been developed in consultation with a wide range of relevant stakeholders. However, there is evidence that suggests that researchers in LMICs may face challenges in negotiating equitable contractual relationships with researchers in high resources settings.

It is important that researchers in LMICs are able to use their data effectively in a timely manner. These researchers are in the best position to ask questions that are relevant to their immediate environment and to curate data in ways that maximise their utility and minimises the possibilities of flawed secondary analyses. Ethical research would, therefore, require promoting fairness and building capacity of researchers in LMICs.

Data sharing should also be conducted in a way that does not adversely affect the careers of researchers or impede their ability to conduct research that is relevant to the needs of the communities in which they work. At present, professional recognition and progression are determined by the ability to publish in high impact journals.

There is a need to consider the ways in which the contribution of data sharers can be recognised and acknowledged with a view to safeguarding career paths for data scientists. Additionally, there should be greater discussions about how researchers from LMICs can be empowered to lead research projects, data analysis and the write-up of manuscripts that get published in high impact journals.

### ***(b) Researchers in LMICs conducting secondary analyses***

Researchers in LMICs may want to access data generated by others for their own secondary analyses. Currently, researchers in LMICs rarely make requests for secondary data analyses as they often lack the capacity to analyse datasets. In the case of genomic research, many researchers struggle to even download datasets they have applied for and may need support to help them through this process. There is a concern that many researchers merely have theoretical access to data but in reality, are unable to utilise the data in a practical manner.

Nurturing strong research capacity in LMICs to allow researchers to conduct secondary analyses is important as they have contextual information that helps them articulate good (context specific) research questions and interpret data meaningfully. If these gaps in knowledge and capacity are left unmet, researchers in LMICs might be consigned to the role of data collection, thus exacerbating existing inequalities.



To promote long term sustainable research and collaboration, the capacity to curate, share and analyse high-quality data sets needs to be built and fostered in LMIC settings. The CIOMS International Ethical Guidelines for Health-Related Research Involving Humans states that "Health-related research often requires international collaboration and some communities lack the capacity to assess or ensure the scientific quality or ethical acceptability of health-related research proposed or carried out in their jurisdictions. Researchers and sponsors who plan to conduct research in these communities should contribute to capacity building for research and review. Capacity in this context includes "research infrastructure building and strengthening research capacity."

**Communities involved in research have interests in sharing the benefits of research arising out of their contributions...In the context of data sharing and secondary analyses of the data, indirect benefits are particularly relevant.**

### ***(ii) The Communities that provide the data***

Communities involved in research have interests in sharing the benefits of research arising out of their contributions. However, there is still much debate as to what would constitute a 'benefit' and how to identify persons to share this 'benefit'. Stakeholders have highlighted the importance of both direct and indirect benefits.

In the context of data sharing and secondary analyses of the data, indirect benefits are particularly relevant. Secondary research may not address health issues that are directly relevant to communities. In such cases, indirect benefits such as the ability to advance health more generally may be of interest to the community.

For example, the AWI-Gen project in Africa aims to identify genetic factors that contribute to body composition, including among other factors, obesity. Suggestions were made at a workshop that AWI-Gen could provide additional indirect benefit through public education on obesity and link to existing patient organisations to provide relevant information.

The use of data sharing platforms for commercial gain can be a sensitive issue in some communities. Community expectations and views may vary considerably depending on historical, political, and cultural contexts. For example, in Vietnam, commercialisation is said to be welcomed because it is viewed as the best likelihood to advance health. Members of the public in Mumbai, however, were warier about the objectives of researchers.

In 2006, Indonesia decided not to share influenza A virus samples with the World Health Organisation (WHO), because an earlier sharing of avian flu specimens resulted in the commercial development of an avian influenza vaccine, which was patented and subsequently sold at unaffordable prices to developing countries.

Without access to these samples, the development of diagnostic tools and intervention strategies was jeopardised. It is thus important to explore the opportunities and challenges of commercialisation in the communities whose data are being shared.

Community engagement is an important aspect of promoting equity in the situations described above. It is a valuable tool in raising awareness and providing information to stakeholders. There are various approaches to community engagement and strategies should be in keeping with the nature of the research and the goals of engagement. There also needs to be more discussions as to what constitutes 'genuine' community engagement for research incorporating data sharing in LMICs.

### ***Advancing Good Governance***

Promoting equity is an important aspect of supporting ethical research but it can only be effective if incorporated in ethically appropriate governance frameworks. The literature suggests that there is a lack of appropriate regulation and governance mechanisms for data sharing in LMICs. Regulations are often absent, outdated, inefficient and difficult to navigate. There is a need to develop robust governance processes to ensure that research is carried out efficiently, effectively and ethically.

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Note: This paper is based on an earlier background paper written by the author for the 13th Forum of the Global Forum on Bioethics in Research, 2018 at Stellenbosch, South Africa ; <http://www.gfbr.global/past-meetings/13th-forum-stellenbosch-southafrica-13-14november2018>



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