

Ethical constraints to open data in a [South] African Health Research context
The Push and Pull

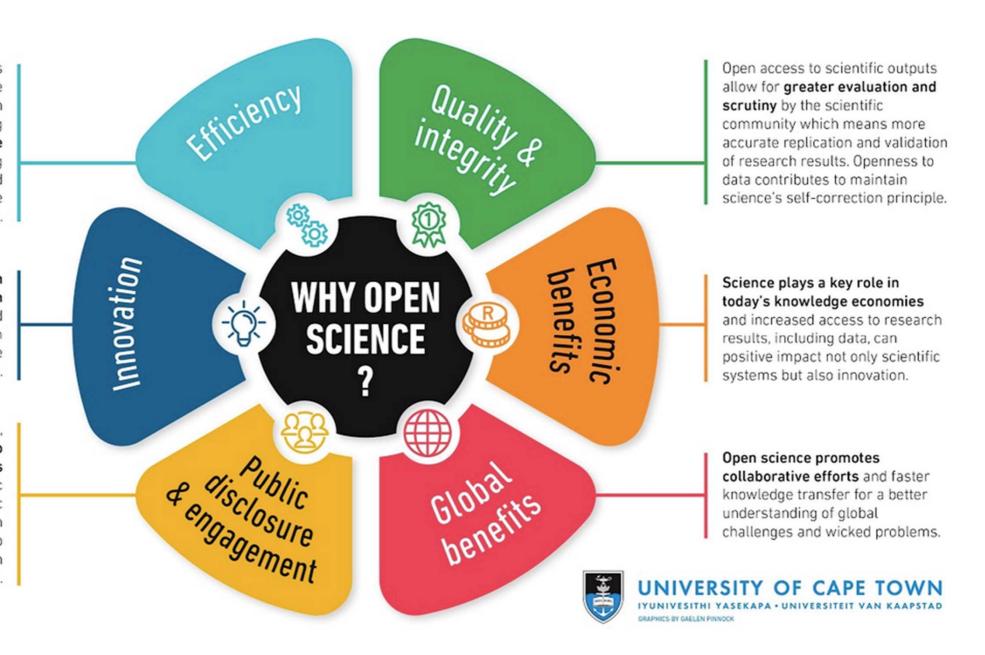
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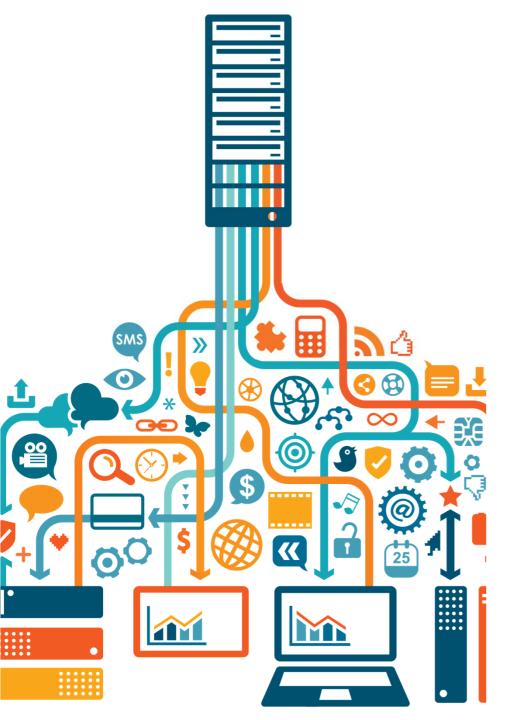
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Greater access to scientific inputs
and outputs can increase
scientific productivity through
reducing duplication, allowing
more research from the same
data and multiplying
opportunities for domestic and
global participation in the
research process.

Open science can reduce delays in the re-use of scientific research including articles and data, and promote a swifter path from research to innovation to produce new products and services.

Science, often publicly funded, should be publicly accessible to promote a greater awareness among citizens and to build public trust and support for public policies and investments in research. Open science also promotes citizen science in experiments and data collection.





Data sharing now becoming an ethical imperative

- 'Open' science is good science: transparent, replicable, verifiable influence policy, public access to findings etc
- Promotion of the 'common good'
- Funder driven (especially if public funds)-utilitarianmaximize the utility gained from a funded project and the resulting data set
- Large research collaborations and consortia, need to transfer data across borders
- Biobanks and data repositories
 - Retention of identifiable 'real-time' data attached to biological samples















African Principles for Open Access in Scholarly Communication

We, the undersigned, declare to adhere to the following Principles for Open Access in Scholarly Communication in and about Africa:

- Academic Research and knowledge from and about Africa should be freely available to all
 who wish to access, use or reuse it while at the same time being protected from misuse and
 misappropriation.
- 2) African scientists and scientists working on African topics and/or territory will make their research achievements including underlying datasets available in a digital Open Access repository or journal and an explicit Open Access license is applied.
- **3)** African research output should be made available in the principle common language of the global science community as well as in one or more **local African languages** at least in summary.
- **4)** It is important to take into consideration in the discussions **indigenous and traditional knowledge** in its various forms

The African Principles for Open Access in Scholarly Communication are based on the following principles and guidelines:

- •Dakar Declaration on Open Access
 Publishing in Africa and the Global South
 (2016) | codesria.org/spip.php?article2595
- •Invest in Open Infrastructure | investinopen.org
- •FAIR Open Access Principles by the FAIR Open Access Alliance (FOAA) | fairopenaccess.org/the-fair-open-access-principles/
- •Scholarly Commons Principles | force11.org/scholarly-commons/principles
- •Vienna Principles | viennaprinciples.org
- •AmeliCA Principles and Values | amelica.org/en/index.php/principios-y-valores/
- •Jussieuu Appell | <u>jussieucall.org/jussieu-appell</u>















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Local[SA] Drivers for Data Sharing

UCT institutional policy

- Open by default; recognises that there are "limits to openness"
- Must motivate for two year data embargo if needed

South African National Research Foundation

- Open data policy; students and researchers who receive funding must commit to sharing data sets, uploading to data repository
- International funders: NIH, EDCTP, Welcome Trust etcdata sharing built in to funding contracts
- **Journals** require supporting data to be uploaded to a data platform that is accessible to reviewers and readers



Hurdles and challenges to data sharing (the 'pull in the opposite direction'!)

Participant

Factors

Community Factors

Researcher factors: Equity and Social Justice

Complex Regulatory framework

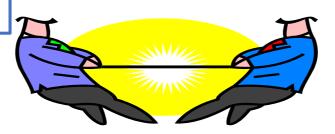
Ethical/Legal Regulatory Framework

CLASH OF COMPETING VALUES AND PRINCIPLES IN A HEALTH RESEARCH ETHICS DATA SHARING CONTEXT

- Deontological
- Rights Based
- Primacy to individual autonomy
- Privacy rights/ Avoiding exploitation of individuals
- Avoiding exploitation of Communities
- Protectionist approach
- MTAs

VS

- Public health ethics; **Utilitarian**
- Maximizing benefit from publicly funded research
- Open science
- Promotion of the Common good
- Communitarian ethic
- Solidarity, Reciprocity, Stewardship



Ethical/Legal Regulatory Framework in SA

- South Africa: National Department of Health
- Ethics Guideline 2015; July 2018 published an MTA template: A step back from UCT 'default=open' RDMP and from NRF push for open science/data

Where data or materials are shared with researchers in other institutions, the recipient institution should agree to comply with the requirements of the donor institution.

Furthermore, use of the data or material should comply also with any additional requirements of the recipient institution.

Inter-institutional sharing agreements should be confirmed in writing. (p.53)

NB Genomic data considered always identifiable

Ethical/Legal Regulatory Framework in SA

EU- GDPR

- SA/African researchers receiving funding from EU are subject to the GDPR via contracts
- Many researchers scrambling to understand implications for collaborations and data management processes
- LMIC institutions often poorly equipped to provide adequate systems and support

- SA Protection of Personal Information Act (POPIA)
- Based on earlier version of GDPR, similarities and differences
- 8 Conditions for lawful processing of information
- May not transfer PHI data across border unless equivalent data protection laws exist in receiving country (implications for Africa and US collaborators)

Researcher factors: Equity and Social Justice

- 1. See Global Forum on Bioethics in Research background paper: The ethics of data sharing and biobanking in health research. Meeting in Cape Town 13-14 Nov 2018
- 2. Bull, Susan (2016) Ensuring global equity in open research. Welcome Trust. https://dx.doi.org/10.6084/m9.figshare.4055181
- Global North-South Collaborations still often very uneven
- Presumption that data will be uploaded and managed by data centers at the institutions of 'global north partners' – (practice ubiquitous with EU funded clinical research)
- LMICs may have limited capacity to curate, share or access/analyse data; even data they have collected
- Secondary analysis of primary data may not address research priorities of the country in which the data was collected

Researcher factors: Equity and Social Justice

Bull, Susan (2016) Ensuring global equity in open research. Welcome Trust. https://dx.doi.org/10.6084/m9.figshare.4055181

- "Although the majority of (Mahidol Oxford Tropical Medicine Research Unit)
 MORU research data is generated in LMICs, to date, no requests for access to
 MORU data have been received from institutions in LMICs. Instead, applicants
 tend to be from well-resourced groups in higher-income settings who have good
 IT infrastructure and the capacity to conduct complicated statistical analyses and
 mathematical modelling." (Cheah et al, 2017)
- "researcher and several others expressed concerns that without more exposure to global datasets and training in complex meta-analysis, scientists from non-endemic countries would be unable to join the "big data" era. They would be increasingly consigned to the data collection end of the research spectrum, their involvement in analytic collaborations such as study groups merely tokenistic." (125, WWARN science group head) (Pisani and Botchway, 2017)

Community Factors

- Community and stake holder engagement critical if interests of communities are to be respected
- Parachute or safari research must be avoided at all cost!
- Discussions need to include
 - Potential risks to communities with sharing of data sets from specific geographical communities e.g. phylogenetic
 - Fair benefit sharing
 - Community research priorities etc







South African San Institute 2017

We require respect, not only for individuals but also for the

We require respect for our culture, which also includes our history. We have certain sensitivities that are not known by others. Respect is shown when we can input into all research endeavours at all stages so that we can explain these sensitivities

Respect for our culture includes respect for our relationship with the environment

Respect for individuals requires the protection of our privacy

Respect requires that our contribution to research is acknowledged at all times.

Respect requires that promises made by researchers need to be met.

Respectful researchers engage with us in advance of carrying out. usearch. There should be no assumption that San will automatically approve of any research projects that are brought to us

We have encountered lack of respect in many instances in the past In Genomics research our leaders were avoided and respect was not shown to them. Researchers took photographs of individuals in their homes, of breastfeeding mothers.

or of underage children, whilst ignoring our social customs and norms. Bribes or other advantages were offered.

Failure by researchers to meet their promises to provide feedback is an example of disrespect which is



We require honesty from all those who come to us with research

We recairs an open and dear exchange between the researchers and our leaders. The language must be clear, not academic. Complex issues must be carefully and correctly described, not simply assuming the San cannot understand. There must be a totally honest sharing of

Open exchange should not patronise the San. Open exchanges imp that an assessment was reade of possible harres or problems for the San resulting from the research and that these possible harms are

Prior informed consent can only be based on honesty in the communications, which needs to be carefully documented. Honest also reases absolute transparency in all aspects of the engagement, including the funding situation, the purpose of the research, and any charges that might occur during the process.

We have encountered lack of honesty in many instances in the past Researchers have deviated from the stated purpose of research. falled to honour a promise to show the San the research prior to publication, and published a blased paper based upon leading question given to young San trainess. This lack of honesty caused much damage among the public, and harmed the trust between the collaborating organization and the San.

Another common lack of honesty is exaggerated claims of the searcher's lack of resources, and thus the researchers' inability so rovide any benefits at all.

FAIRNESS

It is important that the San be meaningfully involved in the proposed studies, which includes learning about the benefits that the participants and the community might expect. These might be largely non-monetary but include co-research opportunities, sharing of skills and research capacity, and roles for translators and research assistants, to give some

Any possible banefits should be discussed with the San, in order to ensure that these benefits do actually return to the

As part of justice and fairness the San will try to enforce consilance with any breach of the Code, including through the use of dispute resolution mechanisms.

In extreme cases the listing and publication of unethical researchers in a "black book" might be considered An institution whose researchers fail to comply with the Code can be refused collaboration in future research. Hence, there will be "consequences" for researchers who fall to comply with the Code

We have encountered lack of justice and fairness in many instances in the past. These include theft of San traditional knowledge by researchers. At the same time, many companies in South Africa and globally are benefitsing from our traditional knowledge in sales of indigenous plant varieties without benefit sharing agreements, proving the need for further compliance measures to ensure fairness

Research should be aligned to local needs and improve the lives of San. This means that the research process must be carried out with care for all involved, especially the San community

The caring part of research must extend to the families of those involved, as well as to the social and physical environment Excellence in research is also required, in order for it to be positive and caring for the San. Research that is not up to a

Caring research needs to accept the San secole as they are, and take note of the cultural and social receivements of this

We have encountered lack of care in many instances in the past. For instance, we were spoken down to, or confused with complicated scientific language, or treated as ignorant, falling to ensure that something is left behind that impro-

high standard might result in bad interactions, which will be lacking in care for the communi



Participant Factors

- Genomic data cannot be fully anonymized
- Vulnerable research populations (low literacy level levels, poor understanding of biomedical concepts)
- Privacy concerns especially with sharing of health records in longitudinal data repositories and biobanks
- Broad Consent- now used extensively in Africa but is broad consent fully legal or an acceptable standard in terms of both EU-GDPR and POPIA?- matter is still being debated.
- Photo credit: Creative Commons Lisence



https://photobucket.com/gallery/user/biopact3/media/bWVkaWFJZDoxNjA0MjM0Mw==/?ref=

Conclusion



- There is much value in the promotion of data access and sharing.
- However, international funders, publication houses and research consortia and collaborators need to be particularly sensitive to research contexts where there are both legal and ethical challenges to the widespread sharing of data that must be considered and accommodated.
- In particular, factors relating to the promotion of equity must be taken into consideration when researchers from Africa and other LMICs are made/requested to share data.



Thank you for listening!

