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Benefit sharing in international collaborative health research: The context of South African biobanks.

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Abstract

A review of unresolved practical challenges related to benefit sharing reveals that various perspectives on benefit sharing are somewhat unclear, highlighting the necessity to formulate how the benefits of research should be distributed. An analysis of the current South African scientific community landscape in terms of resources for biobanking activities and research is relevant and thus provided in the paper to determine what benefit sharing should be when biomaterial and data are transferred from biobanks in South Africa to High Income Countries in international collaborative health research. Benefit sharing in the context of cross-border transfers has not been effectively addressed in South Africa, although identifying the relevant components of benefit sharing models can provide useful assistance in this regard. A benefit sharing model should include benefit sharing for all stakeholders in biobank research activities, such as addressing capacity and infrastructure needs, sharing equitable intellectual property benefits, and participating community benefits, while avoiding commodification of biobank materials.

Keywords: Benefit sharing, biobanks, international collaborative research, Material Transfer Agreement.

Background

The use of biomaterials results in benefits for biobanks and health research, and what those benefits look like for different stakeholders relies on their specific needs, expectations, and values (Stellenbosch University (SU), 2017). The South African National Material Transfer Agreement (SA MTA) defines benefit sharing as the practice of transferring a project's benefits in an equitable and fair manner. Benefit sharing is related to the ethical concept of beneficence, which requires researchers to seek strategies to increase benefits for research participants while avoiding risks (United States Department of Health and Human Services, 2018). It also relates with the ethical principle of justice (Lairumbi et al., 2012) through its link between beneficence and fairness in terms of who bears the burdens of research and reaps its benefits. Due to this, benefit sharing has received special consideration in both national and international regulatory frameworks. In SA, the SA MTA specifically specifies benefit sharing as a component of the agreement between parties involved in the sharing of biological resources. Benefit sharing enables the sharing of benefits, and the benefits that are listed include sharing of information, using research findings, royalties, acknowledging providers as the sources of biomaterials and data, transferring technology or materials, publishing rights, and building capacity (SA MTA). The idea is that all parties should agree on declared and negotiated benefits before the materials (samples and related data) are supplied to the recipient. Benefit sharing in cross-border transfers of samples and data still raises conceptual and practical issues that need to be addressed (Chen and Pang, 2015). Even though benefit sharing is strongly emphasized by international regulations like the Nagoya Protocol, Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, and The Declaration on the Human Genome and Human Rights, there may be resistance when a High Income Country (HIC) institution funds research in Low and Middle Income Countries (LMICs) (Mahomed and Sanne, 2015). This opposition advocates for a benefit-sharing framework for biobank research that will improve confidence and trust and create a long-term research environment for both individuals and organizations.

Human Heredity & Health in Africa (H_3Africa) has developed an ethics and governance framework for genomic research and biobanking in Africa that takes into account both financial and non-financial benefits and is more tailored to the African context in terms of values and cultural expectations, such as including representatives from participating communities in the benefit-sharing discussions (SU, 2017). H_3Africa is a consortium financed by the National Institutes of Health (NIH), the Wellcome Trust, and the African Academy of Sciences (AAS)

through its funding platform, the Alliance for Accelerating Excellence in Science in Africa (AESA) (H_3Africa, 2023).

Unresolved challenges pertaining to benefit sharing

It has been demonstrated that research participants expect some form of payment for participating in the study, thus more research is needed to determine the best suited form of compensation. A lengthy debate concerning financial benefit sharing has been going on within the global research ethics community. In the absence of any frameworks to serve as a guide, it may be difficult to achieve an ethical balance between conflicting interests while taking any benefits, including monetary benefits (Lairumbi, 2012). While some opponents view monetary benefit sharing as a just and equitable kind of benefit sharing because participant samples are regarded like commodities, others are opposed because they fear that it will encourage a form of exploitation (Capron et al., 2009). Even among those who argue that participants should receive monetary benefits, there does not seem to be agreement on the right compensation amounts. Additionally, some individuals favor collective benefit sharing over private benefit sharing. This form of benefit sharing, in accordance with Capron et al. (2009), takes into consideration collective ownership of all financial advantages, including intellectual property. As a result of the divergent viewpoints, it is crucial that organizations (including those who fund biobank research) have oversight while using biobank resources. Using MTAs when suitable benefit-sharing mechanisms are set up is equally crucial. 2018's public release of the SA MTA will bring SA one step closer to satisfying this criterion.

Fair and equitable benefit sharing is a key component of distributive justice. It is debatable, however, exactly what constitutes equitable and fair benefit sharing (De Jonge, 2011), hence this idea is contentious. Legal intervention in benefit sharing is also claimed to be important since international treaties that govern benefit sharing frequently fail to address fair and equitable benefit sharing for discussions and agreements between states and within states (Morgera, 2016). This renders this characteristic one of the justifications for the proposed benefit sharing approach. An analysis of the current scientific environment with regard to resources for biobank operations is necessary in order to pinpoint strengths, limitations, and possibilities for progress in that field. The results of this analysis will clarify how the benefits of research should be allocated in SA.

The current SA scientific community landscape regarding resources for biobanking activities and research.

Generally speaking, biobanks were established to support scientific research, and they have evolved over time in response to advancements in both science-related research and the fields of personalized and precision medicine (De Souza and Greenspan, 2013). Since biobanks are usually established to support scientific research, the landscape of the scientific community is portrayed in this section as a representation of the human and infrastructure resource capability for biobanks. It is crucial to comprehend the resources accessible to the SA scientific community before considering about how benefit sharing should operate.

Human capacity for biobank activities and research in SA

In SA, there are numerous human biobanks of all sizes, including small and large collections located in academic hospitals that are associated with universities and pathology laboratories (De Vries et al., 2014). There is not much evidence, nevertheless, that these biobanks follow quality standards or regulatory requirtements. Biobank personnel includes management team, transport staff, administrative staff for receiving samples and data, bioinformatics scientists for database management, and medical scientists for the Quality Management System (QMS) and research activities. The South African Health Professions Act No. 56 of 1974 regulates medical scientists as well as other HCPs who have registered under the Act. Just over 600 registered medical scientists who are qualified to conduct laboratory human health research in accordance with their area of competence are currently registered by the Health Professions Council of South Africa (HPCSA) (HPCSA, 2023). Medical laboratories employ over 6000 medical technologists and nearly 4,000 registered medical technicians (HPCSA, 2022). Health research is however not their primary responsibility (National Health Laboratory Service (NHLS) 2023). The regulations defining the scope of practice for the profession of medical technology (Regulations Defining the Scope of Practice of the Profession of Medical Technology) allow medical technologists to conduct research, nonetheless. The issue in the South African context also stems from the large population, which was projected to reach 60 million in 2021 (Statistics South Africa (Stats SA), 2023), as well as a high prevalence of communicable and non-communicable diseases, which demand more research (De Vries et al., 2014). According to the regulations governing the practice of medical scientists in SA, independent health research cannot be carried out by research scientists who are not registered under the Act (South African Government, n.d.). Therefore, this need should be met through the training of more

medical scientists, and through benefit-sharing mechanisms and agreements between SA biobanks and their collaborators.

Funding available for SA biobanks and infrastructural capacity

Important infrastructure elements for biobanks include the availability of reliable transportation services, liquid nitrogen and dry ice availability, consistent power and backup power in the form of generators, as well as the location of the biobank in relation to climate conditions (De Vries et al., 2014). Although biobanking, a major research resource, requires expensive infrastructure, expenses are often offset by a multidimensional approach. It is common practice to charge persons who submit samples to the biobank fees because the fees for this service frequently fall short of covering the costs of operating the biobank in terms of personnel and equipment (Andry et al. 2017). Therefore, money from extramural applications is required to support and pay for all expenses related to the biobank. There are organizations that provide funds to help researchers overcome this financial barrier to sample storage.

Two notable funding organizations for science research in SA are the National Research Foundation (NRF) and the Department of Science and Innovation (previously, Technology) (DSI). The NRF was established by an Act of Parliament, the NRF Act No.23 of 1998, with the goal of sponsoring research that would advance knowledge across all academic borders (NRF, 2023). The NRF funding database shows a dearth of support for initiatives or studies especially involving biobanks. The DST identified biobank infrastructure is one of the key areas in need of funding in 2016. DST sought to financially support a national biobank through a network of stakeholders and partners in order to support biomaterials and a database (South African Government, n.d.). The envisioned national biobank would work with existing biobanks to coordinate sample collection, storage, and distribution.

H3Africa has created three regional biobanks in Africa, one in each of West Africa, East Africa, and SA, in order to collaborate with other significant Pan-African partnerships, including some that are not a part of H3Africa and exchange information and resources. These collaborations include ones with the Bridging Biobanking and Biomedical Research across Europe and Africa (B3Africa) through bioinformatics collaborations and ones with the African Society for Laboratory Medicine (ASLM) through QMS engagements (Abimiku et al., 2005). The Biobank Cohort Network (BCNET), an agency of the World Health agency (WHO), provides information resources, including procedures, to LMICs through international partnerships with institutions in these countries (IARC, 2023). Due to the challenge of building and sustaining

sustainable biobank infrastructure at high costs and the limited funding available for biobank activities, the development of a benefit sharing model that would identify these problems and solve them is necessary.

Relevant aspects of benefit sharing models

It would be desirable to use a benefit-sharing model that takes into account the capacity of the cooperating biobank and is aware of the ethical and governmental constraints in SA. Better disease outcomes or any other requirement related to it would also be included as benefits for all parties engaged, including the participating communities. The H3Africa Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa (SU, year) emphasizes two aspects of benefit sharing, namely building capacity and taking ethical and legal considerations into account as requirements for benefit sharing agreements between African researchers and international collaborators as well as participating communities, but it is silent on benefits related to intellectual property rights. Similar strategies are used by benefit sharing models and frameworks of various organizations, which include some but not all of the benefits that make up the ideal combination for a SA environment. The Human Genome Organization (HUGO) places a focus on aspects of benefit sharing such as potential prevention or treatment, accessible healthcare for participating communities, community engagement, and benefits to cultural or tribal groups (HUGO, 2000). However, this benefit sharing approach primarily focuses on the participating community and leaves out the benefits of copyright and intellectual property rights for participating biobanks and researchers as well as benefits for capacity-building. The International Declaration on Human Genetic Data of the United Nations Educational, Scientific, and Cultural Organization (UNESCO) mentions copyright and intellectual property rights as participating community benefits, but it does not specifically list them as a benefit (United Nations (UN), n.d.). The Organisation for Economic Co-operation and Development (OECD) Principles and Guidelines for Access to Research Data from Public Funding (2007) mention the protection of intellectual property and adherence to local laws and regulations, but they omit the other benefits of benefit sharing that were mentioned above. Table 1 compares the various characteristics of the benefit sharing models used by various entities.

Table 1: Comparison of the different aspects of the benefit sharing models.

Benefit sharing model features	**Entity**			
	H3Africa	**HUGO**	**UNESCO**	**OECD**
Developing human and physical infrastructure capacity for research or biobanks.	√	X	√	X
Covers return of research findings to involved communities.	√	X	X	X
Includes copyrights and intellectual property rights	X	X	X	√
Benefits, such as medical care, are made available to participant communities.	√	√	√	X

√ = yes; X= no

With regard to funding and the exchange of biobank samples, benefit sharing should be a requirement given the acknowledged limited research capacity and potential for exploitation. It is crucial to develop a viable and equitable benefit-sharing system for biobank collaboration. In order to address the problem of unfair co-authorship and provide shared and equitable authorship based on contribution, every signed contract should include authorship rights based on the proposed standards. Last but not least, it should be made clear in each written agreement between the parties to the collaboration that royalties for alleged patents would be shared.

The benefit sharing model that is being proposed for South African biobanks that collaborate with overseas partners takes a comprehensive approach and would include the following components: (3) Benefits for participating communities; (1) enhancement of human and physical resource capacity; (2) equitable and shared benefits from intellectual property rights in accordance with the law.

Capacity building for human and infrastructural resources

The lack of laboratory health research capacity, which includes the resource of biobanks for human research, caused by the low number of registered medical scientists. As a result, benefit sharing agreements in collaborations, particularly with foreign collaborators from HICs that

support research, should take into consideration increasing the capacity of SA researchers by recruiting additional medical scientists to address this issue. Additionally, since SA biobanks are mostly non-profit and self-funded, funding for the maintenance of existing biobanks may be included in the agreement as a benefit from development by international collaborators. To ensure the biobank's sustainability and develop its capacity, the financial support must be particularly meant to do so. However, funding cannot be contingent on conditions such as allowing the collaborator access to the biobank's resources in exchange for the money; rather, it must be particularly intended to expand the biobank's capacity and ensure its sustainability. By increasing capacity, dependency on HICs should be greatly reduced.

Shared and equitable intellectual property rights benefits in accordance with the law and regulations

Co-authorship of journal articles that are the result of collaborative research is regarded as original literary work and published versions are protected and acknowledged under chapter 1 of the Copyright Act No. 98 of 1978 in the context of biobanking. In collaborative publications, Africans are currently underrepresented, and local authorship might be established as a criterion for benefit sharing (International Committee of Medical Journal Editors (ICMJE), 2023) where there is evidence of substantial contributions based on authorship standards. The three ICMJE-recommended standards must all be met by authors in order for their work to be considered for publication (Ogden, 2007).

The following criteria must be met, according to ICMJE:

1) "substantial contribution to the conception and design or acquisition or analysis and interpretation of data,"
2) "drafting or revising of the article for important intellectual content," and
3) "final approval of the version that will be published" (Ogden, 2007:1).

Journals and publishers should address the practice of not accepting local researchers from low- and middle-income countries (LMICs) as authors when the standard for rejecting such publications is lenient and the data are from LMICs (World Conferences on Research Integrity (WCRI), n.d.)..

In accordance with section 25 of the Patents Act No. 57 of 1978, inventions, hypotheses in science, literary works, and information presentation are all examples of relevant patentable material. According to the Act, patents cannot be granted in circumstances where there is a

likelihood of exploitation or unethical behaviour. From the perspectives of both the individual and the indigenous communities that significantly contributed to or created the work, Section 28B of the Intellectual Property Laws Amendment Act No. 28 of 2013 protects and recognizes indigenous knowledge, including copyright and patent material, as intellectual property. If a created work is utilized for any kind of profit, the person who uses it is required by section 28G to pay the creator royalties, and the amount is subject to an agreement between the user and the work's owner or their representative under section 28H.

The SAMTA Template recommends SA biobanks and biobank researchers to include a legally enforceable agreement for integration of intellectual property rights in compliance with the provisions of the law to protect themselves from exploitation and guarantee application of equity in intellectual rights.

Benefits for participating communities

Deaths from non-communicable diseases increased in South Africa over a three-year period from 2016 to 2018 from 57.2% to 59.3%, whereas communicable disease-related mortality rates ranged from 31.4% to 28.8% (Stats SA, 2018). Ancillary care, which is defined as treatment given to study participants but is not required for the study's scientific validity and includes treating diseases unrelated to its goals, may be offered by sponsors and researchers as one of the benefits of undertaking the research. The fact that such care will assist the State in providing healthcare services may be considered as a benefit. However, there is disagreement regarding the concept. Supporters contend that tracking a research participant's disease without being willing to treat them amounts to treating them only as a "means to an end" of the research (Rachels, 2003:130), while detractors contend that providing clinical care to research participants would use up limited resources because they are not owed anything (Petrini, 2012). Additional benefits for the community include shared and equitable intellectual property rights benefits and continued engagement of the participating communities as a manner of not just furthering the research but also as a respect for their human dignity. Laws and regulations should be used in conjunction with ethical standards to direct how research participants are treated in order to enhance the greater good and general wellbeing.

Conclusion

Rather than funding a number of biobanks, funding organizations frequently only support one or two biobank infrastructures for a predetermined period of time. The issue at hand is how

biobanks can remain sustainable in the long run. This issue might be addressed by an agreement that uses a comprehensive benefit-sharing model. Benefits for all parties involved in biobank research activities would be provided via an ideal benefit-sharing model, which would also address infrastructure and capacity needs and equally distribute the benefits of intellectual property. Benefits would also be provided to the community that is taking part. Benefit-sharing concerns in relation to international transfers have not received enough attention in SA.

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