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BIOBANKING IN SUB-SAHARAN AFRICA: A REVIEW OF DATA PROTECTION FRAMEWORKS

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BIOBANKING IN SUB-SAHARAN AFRICA: A REVIEW OF DATA PROTECTION FRAMEWORKS

Anoosh Mohammadzadeh¹, Samira Farjaminejad¹, Poonam Patel¹, Sandra Nanyonga², Raheelah Ahmad¹, Charitini Stavropoulou¹, Zisis Kozlakidis^{3*}

- 1. School of Health Sciences, City University of London, London, UK
- 2. Université Côte d'Azur, Nice, France
- 3. International Agency for Research on Cancer, World Health Organization, Lyon, France

*Corresponding author: Zisis Kozlakidis, PhD International Agency for Research on Cancer World Health Organization 25 Avenue Tony Garnier 69366 Lyon CEDEX 07, France Phone: +33 472 738 411 Email: kozlakidisz@who.int

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ABSTRACT

Introduction: Biobanks are a foundational infrastructure supporting research at scale and contributing to the scientific progress. The increasing collection of human samples and associated data presents challenges both in terms of physical storage and handling as well as digital. In north America and Europe (health) data protection frameworks have been in place for several years, regulating the use of collected personal data, including healthcare data, as those typically used by human biobanks. Yet, regulatory frameworks for biobanking, particularly in low- and middle-income settings, are highly fragmented and a little is known in this area.

Objectives: This review focuses on identifying the health-related data protection frameworks in Sub-Saharan African countries, as they are relevant to biobanking.

Methods: We used complementary literature review approaches to ensure the completeness of our results: for biobanking identified as 'African', as well as for 'disease-based', 'country-based', and artificial intelligence-based approaches. 🥖

Results: In total, 56 articles were identified and reviewed in full, 31 health-related acts and frameworks relevant to biobanking, and 24 general data protection acts and frameworks, from 37 countries. In some countries, such as Kenya and Zambia, these acts were implemented, in some others they were not. In most cases, as these regulatory frameworks have been recently created and implemented, there is little or no data relating to the impact of their implementation.

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 Conclusion: Our findings confirm that regulatory frameworks for biobanking in Sub-Saharan Africa are still in a consistent period of emergence, in an effort by national governments to address the existing fragmented landscape and support the development of research.

Introduction

Human biobanks established themselves as an indispensable part of the research infrastructure ecosystems during the early 2000s, supporting the first large-scale, international genomics projects. They have since grown in number and scope, and become ubiquitous in high-income settings, where the majority of -omics based research has been conducted. (1) However, there is a marked imbalance in the distribution of research infrastructures, including biobanks, between low- and middle-income countries (LMIC) and high-income countries. (2) In turn this contributes negatively to the inclusion of LMIC populations in international research initiatives. Several initiatives are in place to mitigate this challenge, as for example, the Biobank and Population Cohort Network (BCNet) coordinated by the International Agency for Research on Cancer, the executive research agency of the World Health Organization for cancer (IARC/WHO). (3) BCNet was created in 2013 with the expressed aim to bring together biobanking activities in LMICs and through training and educational support, harmonize standard operating protocols to international standards and thus provide the foundation for LMIC biobank participation in international research opportunities. (4, 5)

Within the LMIC context, biobanking has the potential to significantly impact the biomedical research capacity and ultimately healthcare delivery, (6) as by establishing biobanks, scientists can gain access to diverse biological samples, which can lead to a better understanding of regional health challenges and the development of tailored treatments. Additionally, biobanks can act as central research support hubs facilitating collaborations between local researchers and international institutions, fostering knowledge exchange and capacity building. (7) The COVID-19 pandemic highlighted the need for research systems across the globe to respond quickly to healthcare emergencies. A series of publications, with the inclusion of BCNet participating institutions, helped outline the pressures and challenges that biobanking faced during that time within different contexts, including in LMICs. (8-10)

Health systems in sub-Saharan Africa attracted particular attention, as they are often characterized as 'fragile systems', i.e. systems that have previously struggled to respond to the effects of health emergencies and pandemics, such as the Ebola outbreak of 2014 in West Africa (11) or ongoing pressures from non-communicable diseases such as cancer. (12) As such many aspects that can contribute to overall health resilience have come into a sharp focus for this region. One such aspect is the development of infrastructures, e.g., biobanks, -omics centers of excellence, disease registries and others, that can service both healthcare needs (especially at times of national emergency, such as the pandemic) as well as research needs (in times of relatively predictable healthcare needs) and scale up/down their activities as needed.

The state of such infrastructures in sub-Saharan Africa has been described in detail in several publications (12, 13), as well as the challenges for their creation and integration to existing research structures. (14-16) However, the description of the aspects relating to the data governance and data handling in LMIC biobanks are less well characterized with only a few studies focusing on this aspect (17, 18). As each biological sample stored in biobanks can be analyzed by different precision methodologies, the acquisition of data from biobanks is anticipated to increase significantly, generating the need for establishing

standards applicable to big data (19), as well as defining appropriate data governance frameworks at national and regional levels (20-22).

Previous work by IARC/WHO through BCNet reviewed the regulatory frameworks of some sub-Saharan African countries (23), as a primer of the larger study presented here. The findings showed a highly fragmented field of regulatory frameworks across the African continent, yet one that was emerging simultaneously in different countries and further catalyzed by the COVID-19 pandemic. As such it became necessary to conduct an in-depth study on the regulatory frameworks for health-related data protection in sub-Saharan African countries as they relate to biobanking. These frameworks were investigated as a regional whole and not within the confines of an extant network as was done previously.

Methodology

This literature review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) method (24). Databases in English (Pubmed, Google and Google Scholar) were searched using the keywords ("sub-Saharan Africa") AND ("biobank") OR ("biobanking") AND ("healthcare data protection") OR ("privacy policy") OR ("patient confidentiality") OR ("ethical considerations") for papers from database inception to October 2023. This provided a starting point for the literature review providing a wide range of 4802 identified manuscripts.

The search was further refined as follows with the input of the City University of London Library:

a) Looking at an African Continent Approach, as there are multi-national projects specifically mentioning challenges and opportunities posed by the regulatory frameworks.
 Databases: all the databases on the Ovid Online platform (CityLibrary Journals@Ovid, Journals from Ovid, AMED, EBM Reviews, Embase, Global Health, HMIC, MIDIRS, Ovid Emcare, Ovid Nursing Database, Social Policy and Practice, Medline).
 Keywords:

- 1. data protection/privacy policy/confidentiality/ethical regulations/ethical considerations/ biobank.
- 2. sub-Saharan Africa/ Africa/ African countries/ African continent
- 3. 1+2
- b) Disease-based Approach, as some infectious diseases in the region (AIDS, Ebola, and Malaria) have specific funding streams, surveillance mechanisms, biobanks and in some cases, frameworks.
 Database: all the databases on the Ovid Online platform (as in a) above)
 Keywords:
 - 1. data protection, privacy policy, confidentiality, ethical regulations, ethical considerations, biobank.
 - 2. Sub-Saharan Africa/ Africa/ African countries/ African continent
 - 3. Aids/ Ebola/ malaria
 - 4. 1+2+3
- c) Country-Based Approach. All the sub-Saharan African countries searched one by one for the relevant acts and frameworks.

Keywords:

- 1. data protection, privacy policy, confidentiality, ethical regulations, ethical considerations, biobank.
- 2. (name of each country)
- 3. 1+2
- d) Artificial Intelligence (AI) approach. AI was used to identify additional manuscript. We searched with OpenAI on Bing Chat (25) for the "framework for data protection and biobanking in sub-Saharan African countries".

Following the above searches, forward and backward citation tracking was performed on those results. Additionally, the names of the frameworks and acts mentioned in these findings were used as clues to identify more results from the original pool of 4802 manuscripts. At the next stage, Bing Chat was used again for searching for additional results using name of each country individually.

These different search approaches were necessary, as there are several frameworks that have been published, but not yet implemented, and as such their mention in the international scientific literature is severely limited.

Following the removal of duplicates, and the exclusion of articles because of: (1) Irrelevant topic; (2) Inaccessible full text; (3) Retracted articles, 344 articles were reviewed for their title and abstract, and finally 56 studies were identified for full text review and included in the current review (summarized in Supplementary information). The review of the articles took place by three independent researchers (AM, SF and PP) and any contradicting opinions were resolved by a third independent reviewer (ZK, RA and CA).

Results

This review identified 56 articles (listed in Supplemental Material A), within those any act, legislation, framework, or law regarding privacy or data protection that was mentioned and is relevant to biobanking has been included. In total 31 health-related, and 24 general data protection acts and frameworks were identified which are relevant for biobanking in sub-Saharan African countries. In some countries these acts are still awaiting approvement by the authorities and some have been awaiting implementation. By October 2023, 36 African countries had data protection laws and/or regulations. Sixteen countries had signed the African Union Convention on Cyber Security and Personal Data Protection and thirteen had ratified it. These laws which cover general data protection rules and some regulations for data security in IT industry, or cybersecurity were found in the texts and through the literature search more easily than the ones that were health related. The guidelines by the Human Heredity and Health in Africa (H3Africa) initiative (26) have formed the foundation for several of these acts, and some countries have adapted their acts or frameworks to align with the H3Africa recommendations (27-29).

South Africa is well resourced in respect to the number of acts and guidelines in health research data protection, followed by Nigeria, Tanzania, Uganda, and Kenya in no particular order. Tables 1 and 2 below summarize the data protection acts or guidelines. Table 1 contains the acts which are directly health or health research related, and the Table 2 contains the general data protection acts, which are partly applicable to the health and health research sector though not explicitly so. Both Tables are supplemented

with the specific section that would apply to biobanking operations, when there is a specific mention regarding the collection of data associated to physical samples.

While this is all the data that could be identified for the existence of legal and regulatory frameworks for health-related data protection in sub-Saharan African countries as they relate to biobanking, information regarding their implementation was not found in all cases. In most countries these acts took some years to prepare and even more years to be assented. (30, 31) In some cases, the acts were not implemented immediately when they were voted by parliament or signed by the president, but a slower implementation was proposed (32).

The relevant sections of the identified frameworks usually had the following headings: introduction to regulatory authorities, guidelines about researching on animals and humans, key norms and standards, norms of data and biological materials, considerations about research methods and contexts, ethics in research, research ethics committee's introduction and roles and infrastructure.

Discussion

It is appreciated that there are specific differences between laws, regulations, and recommendations. Laws are legally binding rules established by governing bodies that must be followed and enforced within a jurisdiction. They are typically passed by legislative bodies and carry legal consequences for non-compliance. Regulations are specific rules or requirements issued by governmental agencies to implement and enforce laws. They provide detailed guidance on how laws are to be applied in practice. Recommendations, on the other hand, are non-binding suggestions or advice provided by authorities or expert bodies to inform best practices or behaviors without legal mandates or enforcement mechanisms. This review has been maximally inclusive of all the above, as was considered important to display the entirety of the emerging data protection frameworks for healthcare as they relate to biobanking in sub-Saharan Africa. As can be seen in the Tables 1 and 2 most of these instruments have been produced in the last decade. As the field continues to grow and develop the expectation is to witness the creation of the full complement of legal and regulatory instruments, as well as their implementation in practice.

Digital maturity: A common occurrence identified through the literature search is that each country has used its own Data Protection Act to produce associated health or research related ethical guidance. This is important because it demonstrates the indirect impact of these regulations on ethics and is comparable to the impact of data protection regulations elsewhere in the world, e.g., the General Data Protection Regulation (GDPR) in the European Union, which had indirect impacts on ethical guidelines, particularly in fields of healthcare, research and biobanking, where sensitive data, including genetic information, is involved. (33-36) Having said that, the consistent promotion and integration of digital health activities, inclusive of research activities, within the African continent in the last two decades has led to an increasingly public and accurate digital health maturity assessment. For example, the World Health Organization (WHO) regional and national offices, together with the Gates Foundation, GAVI, the Vaccine Alliance, and other partners contribute to the assessment and annual publication of the Health Information Systems Assessment (HIS), additionally publishing the relative HIS maturity for each one of

the African countries, as part of the Global Digital Health Index (37). Importantly, this Index demonstrates a consistent digital maturity within the African continent, and that is certainly reflected on the numbers of legislations and guidelines identified in the present report- it is inevitable that an increased digital maturity creates a bottom-up pressure on specifying operational frameworks including for research data held within biobank infrastructures. As a validation of our findings, we have also compared the identified material against the DLA Piper Global Data Protection Map (a private, international law firm that collates global data protection legislation into a single point od reference). We had a complete concurrence with the associated findings. Moreover, using the Global Data Protection Map, the progress towards digital maturity is evident, as well are the gaps where still a few countries remain with complete absence of any such relevant legislation and/or guidelines (38).

Geographical determinants: From a geographical perspective, the development of these frameworks reflects regional groupings, as shown in the map on Figure 1. Western African countries have used the Economic Community of West African States (ECOWAS) forum as the central lever aiding the development of the data protection frameworks. This is not surprising as ECOWAS has been promoting common mechanisms across its fifteen member states in many fields of activity, including the economy and healthcare. One of the most prominent such activities of latter years has been the regional one health coordination mechanism. (39) Thus, this regional forum provides a fertile ground for coordinated regulatory emergence and harmonization and has the potential to strengthen further the regional biobanking activities, as for example through the ECOWAS biobank hosted in Côte d'Ivoire. (40)

It must be noted at this point that privacy, data protection and data localization are "borrowed concepts", i.e., Western notions that have been introduced into Africa, and not necessarily entirely aligned with local views. For example, the African Charter on Human and People's Right (African Charter) (41) did not include a privacy provision. Thus, there have been several academic and legal discussions as to how fundamental this right may be at the regional context (42). The Malabo Convention (43) was adopted in 2014 by the African Union (AU), as a first whole-continent attempt to harmonize data protection, driven by the need for enhanced cyber security. While the convention itself has only been partially adopted across the continent, it has had two significant impacts in the fields of health research and biobanking: firstly, it alludes to a privacy right, and secondly, it has allowed governments to reflect on data protection policies nationally, acting as a catalyst for their subsequent development. Specifically, Southern African countries have followed the early example of South Africa in terms of creating comprehensive frameworks, and in a similar manner, Eastern African countries are developing with Kenya and Tanzania currently having the more mature systems. The notable gap is in the central African section where there is a complete lack of such legislation, reflecting the disruptive and continuing political instability.

Research initiatives: An interesting point is the impact of the H3Africa initiative on the creation of regulatory frameworks for biobanking and data protection across the African continent, which was established in 2012 and has benefited by and interacted with the above-mentioned contexts. H3Africa highlighted the importance of establishing ethical guidelines and legal frameworks to govern the collection, storage, and sharing of genetic and health data in research settings early on through four sets of activities: i) it emphasized the necessity of upholding high ethical standards in genomic research, including obtaining informed consent, respecting privacy and confidentiality, and ensuring community

engagement and benefit sharing. These principles have indeed informed the development of regulatory frameworks for biobanking and data protection. ii) H3Africa prioritized capacity building in bioethics and regulatory affairs to strengthen the ability of African countries to develop and implement appropriate regulatory frameworks. This was done often in collaboration with national or other international initiatives, e.g., BCNet. iii) It fostered collaboration and knowledge exchange among African countries and international partners and iv) it advocated for the integration of ethical considerations into national policies and legislation governing biobanking and data protection.

The above activities had two consequences that are now visible through the emerging legislative frameworks: they led to an increased recognition of the importance of protecting research participants' rights and interests, as well as promoting trust and transparency in genomic research initiatives, and secondly, they have resulted to similarities that can be seen in these acts from different countries, though falling short of a harmonized landscape.

Cultural determinants, Trust and Transparency: Finally, another issue that was frequently highlighted by the literature as a reason for the creation of such legal frameworks was the mistrust that exists for the scientific cooperation with international partners. The negative history of past misguided attempts at using physical samples and associated healthcare data in some parts of the continent and has described previously (44, 45) is still resonating with legislating bodies. While this has a positive implication of perhaps accelerating the creation and implementation of these frameworks, at the same time it may also have a negative consequence for biobanking which requires partnership and data transfer in its core and may thus require some time to overcome the existing historical legacy.

Additionally, the cultural understanding of data privacy is an important parameter in the development of legal frameworks. Specifically, Ubuntu, is an African philosophy emphasizing community, interconnectedness, and mutual respect, offers a unique perspective on privacy. It views privacy not as an individual right but as a communal value, where personal information is respected and protected within the context of maintaining harmony and trust within the community. In Ubuntu, privacy is balanced with the collective well-being, ensuring that while individuals' dignity and personal boundaries are honored, the needs and health of the community are also considered. Thus, the legal frameworks developed in sub-Saharan Africa for biobanking should be viewed through this cultural lens (46, 47).

Limitations

In general, finding the acts in the sub-Saharan African context was a challenging task. Some acts could not be found online, some were not in the English language, and some were not publicly accessible. Despite efforts to comprehensively search for relevant studies, it is possible that some relevant regulations may be missed. In addition to this, while there was data describing these documents, in many cases no exact data can be found about the implementation of the acts. As such caution should be given to the interpretation of the national efforts, as they can be at very distinct phases of implementation, ranging from a consultation/preparatory phase to a formal regulatory framework that has been approved, yet its

status can range from being non-implemented to fully implemented. Moreover, regulations may exist in local languages that was thus difficult to identify with the current search methodology.

Conclusions

Our findings confirm that for health-related data protection frameworks in sub-Saharan African countries as they relate to biobanking continue to emerge and spread across the continent at different speeds, responding to the calls for stronger regulation to support research in this region. However, they are fragmented and largely in-development. Most of the acts in place are broad guidelines without extensive details, which then require an interpretative step to aid implementation. Notably the regional initiatives, such as the one championed by ECOWAS, have the potential for accelerating this process and can lead through an indirect harmonization towards feasible scientific co-operation among the countries in the region and further afield.

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Disclaimer:

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The health-related acts are listed in Table 1.

Country	Title	Implemented	Relevant section
Angola	Law 8/04 on HIV and AIDS (2004)		
Africa	Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa-2017		
Africa	H3Africa Guideline for Informed Consent-2017		
Africa	H3Africa Consortium Data Sharing, Access and Release Policy-2020		
Benin	Portant Code D'éthique Et De Déontologie Pour La Recherche En Santé En République Du Bénin.		
Botswana	Public Health Act 2007		
Ethiopia	National Health Research Ethics Review Guidelines	2014	Chapter 9
Gambia	Guidelines of the National DNA bank, 2001		Section 7
Global	UNAIDS - Considerations and Guidance for Countries Adopting National Health Identifiers	2014	
Kenya	The Health Act No. 21 of 2017	Yes	
Kenya	National Guidelines for Ethical Conduct of Research Involving Human Participants	2020	
Malawi	Policy Requirements, Procedure and Guidelines for the Conduct and Review of Human Genetic Research in Malawi-2012		
Mauritius	Ethical Guidelines for Biomedical Research Involving Human Subjects-2003		
Nigeria	Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (PS1.02013)-2013		
Nigeria	National Code of Health Research Ethics-2007		
Nigeria	Keeping Personal Health Information Safe and Secure: A Guide to Privacy and Data Security Laws in Nigeria	Oct-15	
Nigeria	HIV and AIDS (Anti-Discrimination) Act 2014		Section 13
Nigeria	National Health Act 2014	Oct-14	
Sierra Leone	GUIDELINES FOR CONDUCTING CLINICAL TRIALS OF MEDICINES, FOOD SUPPLEMENTS, VACCINES AND MEDICAL DEVICES IN SIERRA LEONE	2014	
South Africa	No. 61 of 2003: National Health Act	2004	Chapter 9
South Africa	Guidelines on Ethics for medical research, reproductive biology and genetic research		
South Africa	Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications - 2018		
South Africa	Ethics in Health Research - 2015	•	
Sudan	National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008)	^S x	
Tanzania	Human DNA Regulation Act, 2009 (Act No. 8 of 2009)		
Tanzania	THE HIV AND AIDS (PREVENTION AND CONTROL) ACT, 2008		Part 5
Fanzania	Guidelines Of Ethics For Health Research In Tanzania - 2009		
Uganda	HIV and AIDS Prevention and Control Act, 2014	Yes	Section 29-31
Uganda	National Guidelines for Research involving Humans as Research Participants-2014		
Zambia	The National Health Research Act, 2013	Yes	Section 26, 32, 47-53
Zimbabwe	HEALTH PROFESSIONS ACT Acts 6/2000, 22/2001,14/2002, 28/2004	2001	

The general data protection acts which have covered some health-related aspects are presented in Table 2.

Country	Title	Implemented	Relevant section
Botswana	The eHealth Strategy of Botswana (2020-2024) - 2020		
Botswana	Data protection act 2018		Section 23
Botswana	Data Protection Act 2021	15,Oct,2021	
Côte d'Ivoire	LAW No. 2013-450 dated June 19, 2013 on the protection of personal data	19-Jun-13	Chapter4-ar 21
Eswatini	The Data Protection Act - Act No.5 of 2022		
Gabon	Law No. 001/2011 on the Protection of Personal Data "the Law" - 2011		
Ghana	Data protection act, 2012	10, May, 2012	Section 62
Kenya	The Data Protection Act No. 24 of 2019	Yes	
Kenya	The Data Protection General Regulations 2021	Yes	Section 57
Malawi	The Data Protection Bill 2021		
Nigeria	NIGERIA DATA PROTECTION REGULATION 2019: IMPLEMENTATION FRAMEWORK	2020	
Nigeria	Nigeria Data Protection Bill, 2022	2023	Section 6-8
Rwanda	Law No. 058/2021 of 13 October 2021	2021	
Rwanda	STANDARD OPERATING PROCEDURES (SOPs)		Section 10,31,35
Senegal	Act No 2008-12 of 25 Jan 2008		
South Africa	The Protection of Personal Information Act (POPIA) Act no 4 of 2013	Nov.2013	Section 32
Tanzania	THE PERSONAL DATA PROTECTION ACT-13/6/2023		
Тодо	Charte du Comité de Bioéthique pour la Recherche en Santé-2009		
Тодо	Law No. 2019-014 (DPA Law)		Chapter 1
Uganda	Data Protection and Privacy Act of 2019	Yes	
Uganda	Data Protection and Privacy Regulations, 2021	May 2021	
Uganda	Personal Data Protection Office Website		Page 10
Zambia	Data Protection Act, No.3 of 2021 (Data Act)	Apr-21	
Zimbabwe	Data Protection Act 2021 (Act 5 of 2021)	NO	Part 5, Section 12
	Table 2 : General Data Protection Acts in Sub-Saharan African Could Image: Second S	ntries	17.





Figure 1: Health-Related Acts Regarding Data Protection in Sub-Saharan African Countries

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Supplementary information

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