REVIEW

Public health emergency preparedness and response in South Africa: A review of recommendations for legal reform relating to data and biological sample sharing

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COVID-19 exposed flaws in the law regulating the sharing of data and human biological material (HBM). This poses obstacles to the epidemic response, which needs accelerated public health research and, in turn, efficient and legitimate HBM and data sharing. Legal reform and development are needed to ensure that HBM and data are shared efficiently and lawfully. Academics have suggested important legal reforms. The first is the clarification of the susceptibility of HBM and HBM derivatives to ownership, including, inter alia, the promulgation of a revised version of the South African Material Transfer Agreement (SA MTA) by the Minister of Health. This would remove uncertainty regarding the current SA MTA's perpetual donor ownership clause. The second is the development of data trusts, the adoption of open access to research data, and the creation of an African 'data corridor'. This would ensure that data are protected while allowing for the efficient transfer of data between researchers for the collective good and in the interest of the public. The third is the amendment of the Space Affairs Act to extend the powers of the Council of Space Affairs to include the management of data collected through the utilisation of Earth observation and geographical information systems. This would ensure the protection of outer space data, legislating its use and sharing once it lands on Earth. The implementation of these legal reforms and developments will better prepare SA to face future epidemics from a health research perspective.

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The COVID-19 pandemic has highlighted the importance of public health emergency preparedness. To effectively respond to and manage such health epidemics, as well as natural disasters, it is imperative that governments and private institutions engage in public health research. In the context of the pandemic, public health research and innovation necessitates the collection and sharing of human biological material (HBM; such as saliva, cell samples or DNA), personal data (such as COVID-19 test results) and geospatial surveillance data (such as the proximity of houses in specific geographical areas). For research purposes, HBM and data are often shared between institutions and governments around the world. The pandemic has accelerated the need for such sharing – the pooling of resources is beneficial for producing meaningful research. The need for efficient collection and sharing of HBM and data emphasises the significance of effective regulation of these activities. Various scholars have investigated the South African (SA) legal scheme regulating the sharing of HBM and data, revealing certain pre-existing flaws that have been emphasised by the COVID-19 pandemic.[1-14] These flaws hinder SA's response to the current pandemic and to future public health emergencies and natural disasters. This article focuses on the regulation of the sharing of HBM, geospatial data and personal information in light of the current pandemic's acceleration of the need for researchers to rapidly share these resources in order to engage in important public health research. The article reviews and integrates the analyses, and presents the different legal recommendations for legal reform to improve SA's response to future pandemics and disasters.

Background

The COVID-19 pandemic has emphasised the need for expedient (and legitimate) sharing of HBM and, in turn, has revealed pre-existing inconsistencies and shortcomings in the law. One shortcoming is the lack of legal clarity regarding the susceptibility of HBM to ownership,[1,8] which in turn leads to uncertainty about many aspects of research, such as rights in inventions based on such HBM.[1] Legal uncertainty is detrimental. The Nuffield Council of Bioethics states that:

> 'the need to clarify the law is important insofar as its uncertainty may impede legitimate treatment, teaching, study or research or even, at worst, may encourage illegitimate uses of human tissue'.[15]

The clarification of the lawfulness of using and sharing HBM for research purposes[1] is important, not only because of the development of biobanks in many African countries,[9] but also owing to the need for rapid and efficient HBM sharing to facilitate crucial international collaborative research related to COVID-19 and future pandemics. In order to ensure that HBM is being collected, used and shared lawfully, the legal position on the susceptibility of HBM to ownership must be clarified.[1]

The COVID-19 pandemic has also highlighted the need to use technology to assist in disease detection and prevention through

predictive modelling and disease pattern and cluster tracking.[2] Geospatial and information technologies enable the mapping of disease outbreaks.[2] The ability to track and map the clustering and spreading patterns of a disease allows public health and policy decision-makers to 'timeously prepare for and effectively manage health emergencies and disasters in communities and across borders'.[2] For example, geographical information systems (GIS), geospatial analysis, dot density maps and choropleth maps were used to find correlations between the spread of COVID-19 and different meteorological and geographical factors.[2,16-18] GIS were used in Cape Town to determine the extent to which social distancing was possible in informal settlements, and to predict which areas may need special healthcare support.[2,19-21] GIS were also used to 'provide real-time data'[1] on the spread of COVID-19 in some of SA's most densely populated areas.

The SA government created a database to track the spread of COVID-19. This database had contact tracing potential; however, it was shut down as it collected people's names, identity and mobile numbers, and COVID-19 test results, without consent.[2,10] The SA government then created the COVID Alert App, which did not collect personal information, but, naturally, citizens are suspicious of it.[2,10] This demonstrates that the privacy rights of data subjects must always be adequately protected and considered – even in the context of public health research in the midst of a pandemic. If we are to rely on data-driven solutions to the pandemic, it is critical to build public trust through effective data protection.[3,4] For example, the analysis of health-related data such as heart rate and glucose levels has proven useful in the prediction and tracking of the spread of the COVID-19 virus.[3] However, the use, sharing and storage of health-related data poses a risk to privacy and the autonomy of data subjects.[3] These factors must be considered in balance with the need for 'rapid access to and sharing of data'[3] during the pandemic.[3-5,7]

Sharing of human biological material

As summarised above, there is legal uncertainty regarding whether HBM is susceptible of ownership. Before it can be established who owns donated HBM, it must be established whether HBM can be owned in the first place.

Can human biological material be owned?

HBM has historically been perceived as not susceptible of ownership. However, in their analysis of the common law, Thaldar and Shozi[1] point out that the fact that HBM has become useful to science is a deciding factor that – when applying established common law principles – makes HBM susceptible of ownership. The authors also highlight similar developments in the case law of comparative jurisdictions.[1] Finally, they analyse statute law, and suggest that although there is no express provision regarding the ownership of HBM in the National Health Act No. 61 of 2003[22] (NHA) or its regulations,[23-25] the fact that these statutes refer to the 'donation' of HBM is legally significant: donation is a legal-technical concept that entails that ownership is transferred.[1] This implies that the thing that is being donated must be susceptible of ownership (this is why one cannot donate a baby, or the sun – these are not entities that are susceptible of ownership.)[1]

Having established that HBM is susceptible of ownership, the question arises, who owns donated HBM – the HBM donor, or the person or institution collecting the HBM?

Who owns donated human biological material?

The use of the concept 'donation' in statute law has a further implication, namely that the transfer of ownership by a research participant to the research institution is peremptory.[1] There is no space for exceptions, such as that the research participant can choose to somehow retain ownership.[1,11]

This conclusion highlights a conflict between the NHA and the SA Material Transfer Agreement for Human Biological Materials (the SA MTA).[1,26] Despite the references to 'donation' in primary legislation and the SA MTA itself, paragraph 3.3 of the SA MTA states that 'the donor remains the owner of the material until such materials are destroyed.'[26] Clearly, this clause is in conflict with the NHA and therefore invalid.[1] We suggest that retaining the SA MTA's perpetual donor-ownership provision, which is evidently a legal impossibility, can only serve to confuse and create misleading expectations.[14] We therefore agree with Thaldar and Shozi[1] that the Minister of Health ought to promulgate a revised version of the SA MTA that rectifies the notion of perpetual donor ownership. In the interim, given that the SA MTA is only a 'framework',[26] parties are at liberty to change the substantive content of the SA MTA as they please – as long as they retain all its headings in some form or another.[1]

This speaks to the issue of trust by research participants in health research. While Mahomed and Staunton[4] acknowledge that trust is important, they maintain that the SA MTA 'is currently the only national template available which aims to protect institutions, researchers and participants when human material is transferred out of SA'. This ignores the fact that a group of law academics, after consultation with stakeholders, have developed and published a revised version of the SA MTA online (https://researchspace.ukzn.ac.za/handle/10413/19095) for anyone to use.[27] This revised version, or 'SA MTA 1.1', is intended to offer an agreement that is practically usable and in which the most egregious mistakes of SA MTA have been rectified (as mentioned above, given that the SA MTA refers to itself as a 'framework', its substantive content can be changed at will). Moreover, what is important from the perspective of trust is that the SA MTA in its original form undermines trust by creating the impression that research participants will retain ownership, while this is contrary to the express provisions of primary legislation – the NHA – and hence not legally possible. To preserve trust in research, research institutions entering into MTAs should take care not to include promises that are legal impossibilities. It follows that research institutions should therefore not include the SA MTA's perpetual donor-ownership provision. This has been rectified in SA MTA 1.1.[27]

Once HBM has been donated to a research institution, such an institution can transfer ownership of the HBM to another research institution, or simply transfer possession while retaining ownership.[1] This is the case irrespective of whether the receiving research institution is local or foreign. The SA MTA's provision that the providing institution retains custodianship does not affect the transfer of ownership, and is a substantive provision that is open to the parties to change at their pleasure.

While ownership provides a legal foundation for how research institutions deal with HBM, it would be advisable that material transfer agreements provide in detail for issues such as intellectual property rights based on research using the transferred HBM.

From human biological material to personal information

In genetics research, the focus is not so much on HBM as on the genetic code that can be acquired from such HBM. While HBM is regulated by the NHA and its regulations, personal information is most prominently (but of course not exclusively) regulated by SA's Protection of Personal Information Act No. 4 of 2013 (POPIA).[28] Certain personal information, such as health records, falls into the ambit of both the NHA and POPIA. A DNA sample is HBM, and therefore falls under the ambit of the NHA, but when the DNA is sequenced to obtain the genetic information contained in the DNA, and the genetic information is recorded, POPIA becomes applicable. Both Adams *et al.*[12] and Mahomed and Staunton[4] express the opinion that since DNA is innately identifiable, it may be difficult to define 'the exact point'[4,12] at which DNA 'become[s]' personal information.[4,12] Thaldar[13] expresses his reservations about the helpfulness of this choice of words, pointing out that while information can be gleaned from DNA by sequencing it, it does not mean that DNA *becomes* personal information. Furthermore, in order for genetic information to fall within the ambit of POPIA, it must be entered in a record.[13,28] In order to enter genetic information into a record, it must be sequenced. Thaldar[13] points out that DNA sequencing is 'not an instantaneous event, but rather a gradual digital accumulation of genetic information over a period of hours. As such, thinking in terms of an "exact point" may not be helpful.' Thus, entering of genetic information into a record in terms of POPIA is best conceived of as a process, rather than an exact point in time.

Sharing of data

Geographical information systems

The use of technologies such as geospatial analysis and GIS in public health research has been effective in the tracking and prediction of the pattern and spread of diseases such as COVID-19.[2] These technologies have been used to correlate factors such as population density, pollution and poverty with the spread of COVID-19, as well as to detect potential deficits of hospital beds and determine the accessibility of hospitals during the pandemic.[2] The use of GIS and geospatial surveillance demands consideration of many different laws, both national and international.[2] Since satellites orbit Earth, they 'do not and cannot respect territorial boundaries or political considerations,'[2] and therefore it is imperative to effectively govern the data that materialise from them, especially when those data include personal information.[2]

Outer space data from satellites are regulated by international space law and can be commercialised.[2] However, once the data reach land, they are regulated by national territorial privacy laws; in SA, this is POPIA.[28] POPIA does not regulate the commercialisation of personal data.[2,5,8] Thus, while Botes[2] recognises that the harmonisation of international instruments, national legislation and privacy rights would be a 'monumental task', she recommends the development of a code of conduct in terms of section 60 of POPIA to regulate 'the intersection between remotely sensed or outer space data and personal data when received on earth.' This would ensure that issues such as the commercialisation of outer space data once it reaches Earth can be regulated in a manner that respects data privacy rights and the need for efficient data sharing.

In terms of POPIA, the collection of personal information via GIS may only occur with the specific consent of the data subject.[28] However, in its recognition that the individual right to privacy may be limited when outbalanced by other rights, such as the right of access to and free flow of information, POPIA makes exceptions to this.[2] The data collector is relieved of the specific consent requirement in cases where:

- the collection and processing of the data is in the legitimate interests of the data subject,[28] such as in the interest of his or her health during a pandemic; or where
- the collection and processing are in the interests of the sensed or collecting country,[27] such as in the case of management of a pandemic or disaster.

POPIA includes an exemption from collecting data directly from the data subject. Data may be collected from another source if this will not prejudice a legitimate interest of the data subject or is in the interests of national security, or in the interests of the sensed or sensing country.[28] The collection of data for the purpose of pandemic or disaster management will be in the interests of both the sensed and sensing country.

The effective surveillance of COVID-19 depends on international collaboration and legal frameworks that allow open access to and sharing of data while adequately protecting privacy rights.[2] In this regard, Botes[2] recommends that data protection must be central, 'while still allowing for international harmonisation and data sharing for creating a global data picture of natural disasters, pandemics, or health emergencies'. Access to data is promoted in the Principles Relating to Remote Sensing of the Earth from Outer Space[29] and the Group Earth Observation System of Systems Data Sharing Principles.[30] These both provide that when data are produced that concern a specific territory, that territory should have access to them at minimal or reasonable costs. These principles are not, however, legally binding.

The Space Affairs Act No. 84 of 1993[31] defines 'space activity' as 'activities directly contributing to the launching of spacecraft and the operation of such craft in outer space'. This definition seems to exclude the collection of data through Earth observation satellites.[2] Thus, Botes[2] recommends the amendment of the Space Affairs Act to include provisions for the protection of data which are collected in outer space. The Council of Space Affairs, established in terms of the Space Affairs Act, licenses the launch and operation of spacecraft. Botes[2] recommends that the council should govern the collection and sharing of Earth observation data. This would allow the council to 'engage with and manage any earth-based data emanating from earth observation and geographical information systems'.[2] Such a change would require amendment of the Space Affairs Act to extend the council's powers.[2] We support this recommendation as a manner in which to promote both data subject rights and access to outer space data.

Botes[2] identifies a lacuna in SA law – there is no provision for the commercialisation of geospatial data by private institutions. This area must be regulated to ensure that stakeholders:

> 'act *bona fide* by ensuring that their remote sensing activities are aimed at the betterment of social mobilisation, to formulate appropriate scientific, policy, and social measures and provide accurate and valuable feedback to relevant countries, governments, public health officials or affected communities.[2]

Thus, Botes[2] recommends the amendment of the current legislation to clarify the position on collecting and commercialising geospatial data. We support this recommendation – clarity on the legality of commercialisation of geospatial data is especially critical during a pandemic, and amendments to provide such clarity would strengthen the response to future pandemics and disasters.

Data governance and cross-border transfers of personal information

The COVID-19 pandemic highlights the importance of the collection, use, analysis and sharing of personal information in health research.[3,4] It further highlights the fact that access to data is crucial.[2,3] Data must be shared between different institutions and countries.[3,4] In this way, the pandemic demonstrates the need for legal and ethical data stewardship.[3] Effective data protection measures build public trust, which is especially critical during a pandemic.[3,4] The pandemic 'has created a global emergency necessitating rapid access to and sharing of data,'[3] as the analysis of health-related data is useful in predicting and tracking the spread of COVID-19.[3] The sharing of data resources between researchers allows more effective research – large data sets allow for better analyses.[3,4] In the context of a pandemic, data sharing also assists in disease monitoring.[3,4] However, the use, storage and sharing of health-related data pose risks to the privacy and autonomy of data subjects.[3]

POPIA restricts the export of data by enforcing the requirement for the existence of a legal ground, or legal reason, for the transfer of personal information to a third party in another country.[3,28] For example, the data subject's consent is one legal ground for the lawful transfer, among other possible legal grounds as contained in section 72(1).[28] In addition to the necessity of a legal ground for the transfer of personal information, POPIA enforces an adequacy requirement in section 72(1)(a), which states that personal information may be transferred to a third party in a foreign country only if the third party 'is subject to a law, binding corporate rules or binding agreement which provide an adequate level of protection'.[28] Such law, binding corporate rule or agreement must contain provisions regulating the processing and transfer of the personal information that are 'substantially similar'[28] to the provisions of POPIA. This means that an adequacy assessment is required.[3] The data protection laws of the recipient country must be '"essentially equivalent" or "substantially similar"'[3] to the protection offered by POPIA. POPIA is similar to the European Union (EU)'s General Data Protection Regulation (GDPR) in that it 'provides a high-level principle-based approach'.[4,5] The GDPR has a similar adequacy requirement to that of POPIA, which states that transfers of personal data to third countries may only occur if the third country has an adequate level of protection.[32] Mahomed and Staunton[4] raise issues with completing an adequacy assessment in terms of POPIA. An adequacy assessment may take as long as 13 weeks, which does not promote rapid access to data.[4] The authors recommend that the information regulator publish guidelines clarifying the adequacy assessment process.[4] The guidelines, it is suggested by the authors, should include provision for expedited assessment in light of public health emergencies.[4] We support these recommendations.

Adequacy requirements can be fulfilled using standard contractual clauses in a data transfer agreement (DTA).[3,4] The DTA clauses would have to provide a similar level of protection to the legislation in the country from which the data are transferred.[3] However, no African countries have developed such standard clauses for data protection.[3] Mahomed and Staunton[4] recommend that a DTA should be required for all international transfers of data. However, this recommendation means that even if a recipient country did have adequacy in terms of POPIA, SA researchers would still be legally compelled to have a DTA for every transfer to that country. Although having agreements in place may be good scientific practice, using the force of law to compel adherence to good scientific practice would require good reasons. Unfortunately, Mahomed and Staunton offer none.

Developments in the EU will affect the way in which data can be transferred from the EU to SA. The transfer of personal data from EU member states to other countries must be done in compliance with the GDPR.[32] This is to protect the rights of data subjects and to ensure that authorities can pursue complaints and investigations relating to the use of such data outside of the EU.[32] In order for data to be transferred from the EU to a non-EU member state, the non-EU member state recipient must either have 'an adequate level of protection'[32] in its law, or, in lieu of an adequacy decision, 'appropriate safeguards'.[32] These safeguards can be contained in a legally binding instrument, binding corporate rules, standard data protection clauses, codes of conduct or an approved certification mechanism.[32] Thus, African countries receiving data from the EU will have to undergo an adequacy assessment and, failing that, may receive the transfer by enforcing appropriate safeguards through article 46.

The decision on adequacy is made by the European Commission (EC).[32] Article 45(2) lists the considerations to be taken into account by the EC when determining adequacy.[32] The EC publishes a list of the countries that have been granted adequacy.[32] The Court of Justice of the EU confirmed the requirement of an adequacy assessment to ensure that countries meet the adequacy requirement.[32,33] This assessment before data transfer will ensure that their data protection laws are essentially equivalent to EU data protection laws, ensuring the protection of data subjects.[33,34] An adequacy decision requires consideration of various factors, including determining the 'existence of effective judicial remedies and the enforcement process and regime governing such laws.'[3] Thus, the decision on the validity of standard contractual clauses depends not only on compliant legislation, but also on the possibility of ensuring compliance with EU data protection requirements.[3] In order to receive data from the EU, African countries will have to undergo adequacy assessments.[3] However, the EC has not yet granted adequacy to any African countries.[3]

The Organisation for Economic Co-operation and Development[35] has recommended the use of data trusts for data storage.[3] Data trusts allow data to be accessible while protecting data subject privacy. The establishment of data trusts could be a way forward for the protection of SA data subjects. Townsend[3] suggests that data trusts, open access to research data and the provisions of POPIA together could provide a SA solution for data protection, especially in the context of a pandemic. This would allow data to be protected by the data trust while being 'more freely accessible for research purposes for the collective good and in the public's interest.'[3] Townsend recommends the harmonisation of regional law to ensure streamlined data transfer within Africa, which would 'encourage research, investment and economic growth, by removing the

Table 1. Recommendations

Legal instrument	Suggested reform
POPIA[28]	Develop a SA Code of Conduct in terms of section 60 to regulate the receipt of sensed or outer space data that become personal data when reaching Earth[2]
SA Material Transfer Agreement for Human Biological Materials (SA MTA)	The Minister of Health should promulgate SA MTA 1.1 to repeal the existing version[1,24]
Space Affairs Act No. 84 of 1993[31]	Amend to extend the powers of the Council of Space Affairs to include the management and protection of outer space data[2]
Legal issue	**Suggested reform**
Need for efficient, lawful sharing of personal information and data	Consider creating an African 'data corridor' in terms of the AU Convention[3] Develop data trusts to protect data, while making them accessible[3] Introduce open access to siloed data for research purposes[3]
Need for guidelines on adequacy assessment process	Information regulator should publish a set of guidelines to clarify the process of an adequacy assessment in terms of POPIA[4]
Need for legal clarity regarding HBM's susceptibility of ownership	General legal recognition of HBM as susceptible of ownership[1]
Need for regulation of the private commercialisation of geospatial data	Develop legislation that will ensure that the aims of those collecting and commercialising geospatial data are *bona fide*[1]

SA = South Africa; AU = African Union; POPIA = Protection of Personal Information Act No. 4 of 2013; HBM = human biological material.

developmental obstacles caused by the juridical differences among the various African territories.'[3]

Townsend[3] further recommends the consideration of creating an African 'data corridor', to enable efficient and rapid data transfer between African countries and lawful transfer of personal information between African countries. She recommends that African countries within the data corridor must have national laws that comply with the principles of the African Union Convention for Cyber Security and Data Protection[36] and Convention 108+.[37] Both of these conventions contain principles for the protection of data subjects and access to data. We support the recommendations made by Townsend, which, if implemented, would improve SA's response to pandemics and disasters by promoting both access to data and data subject rights.

Conclusion

The COVID-19 pandemic has highlighted shortcomings in the legal scheme regarding data and HBM sharing, which, if amended, would improve SA's ability to respond to increased demand for health research during future pandemics. Recommendations for legal reform in the context of HBM, geospatial surveillance data and personal data sharing are listed in Table 1.

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