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Diffusion of ethical governance policy on sharing of biological materials and related data for biomedical research [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

This paper considers how ethical norms on sharing of human biological materials and related data in international policy documents diffuse from global forums to national policies and practices. With focus on the domestic policies of four countries (i.e. Guinea, Argentina, India and Malawi), this paper seeks to explain policy diffusion by broadly applying an analytical framework wherein policy learning is one of four theories used to explain how countries learn policy norms from expert epistemic communities and international organizations. While the governance structures of all four countries broadly incorporate key ethical provisions in international policy documents on sharing of biological materials and related data for biomedical research, relative emphasis on certain provisions differ among them. In three of these countries (i.e. Guinea, Argentina and India), international ethical norms have had direct influence over their domestic governance policies. Their impact has been greatest for Guinea and Argentina, whose governance policies had to be adapted in response to the Ebola virus epidemic in West Africa and the Zika virus epidemic in Latin America. In both countries, sharing of biological materials and related data with international organizations increased significantly to meet therapeutic and research needs during the outbreaks. International organisations have had a comparatively greater role in bringing about policy change in Guinea when compared with Argentina, mainly due to the fragility of the
health system in Guinea in 2014. In contrast, policy in India and in Malawi occurred under less strenuous conditions. This may account for the relatively greater emphasis on control and limits to cross-border transferability in their policies when compared with those of Guinea and Argentina. While all four countries have made significant progress in establishing accountable governance arrangements, still more needs to be done to ensure that the ethical goal of equitable sharing of benefits is realised.

**Keywords**
Policy Diffusion, Policy Learning, Biological Materials, Guinea, Argentina, India, Malawi

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Background

International ethical policy on the sharing of human biological materials and related data has made significant advancements due in part to two epidemics that occurred in close succession from 2014 to 2016, and to biomedical research initiatives, particularly those relating to ‘Big Data’ and Precision Medicine. By international ethical policy, we mean the provisions that apply to the sharing of human biological materials and related data in the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS Guidelines)1 and the Guidance for Managing Ethical Issues in Infectious Diseases Outbreaks (WHO Guidance)2. For the purposes of this paper, we focus on the provisions relating to governance, which the CIOMS Guidelines explain as follows3:

Institutions in which biological material and related data are archived after collection for research purposes or as “left-overs” from clinical diagnosis or treatment must have a governance structure in place in which at least the following items are regulated:

- to which legal entity the material is entrusted;
- how authorization from the donor is obtained;
- how the donor can retract this authorization;
- in which circumstances donors need to be recontacted;
- a procedure for determining whether unsolicited findings should be disclosed, and if so, how they should be managed;
- how the quality of the material is controlled;
- how confidentiality of the link between biological specimens and personal identifiers of the donors is maintained;
- who may have access to the materials for future research, and under what circumstances;
- which body may review research proposals for future use of the material;
- appropriate mechanisms for keeping donors informed of research outcomes;
- how participatory engagement with patient groups or the wider community is organized;

- to which other sources of personal information the results of analyses on biological materials may be linked;
- in broad terms, which types of research will be pursued;
- which types of research will be excluded or included only after recontacting the donor for consent;
- to whom any benefits from the research are expected to accrue;
- appropriate mechanisms for keeping participants informed of research outcomes; and
- how the rights and welfare of individuals from whom the materials were collected are not adversely affected.

The provisions relating to governance in the WHO Guidance do not differ substantively from those of the CIOMS Guidelines, but give emphasis to a number of requirements that are more pertinent to an infectious disease outbreak. In the light of this international policy, we consider how its provisions on governance have contributed to change in related domestic policies in four countries (i.e. Guinea, Argentina, India and Malawi) through policy learning. In this respect, we broadly apply the analytical framework developed by Frank Dobbin et al.,4 where policy learning is one of four theories used to explain how countries learn policy norms from expert epis- temic communities and international organizations, who define (in the context of this paper) what responsible scientific progress and good governance should be like. In more recent studies, such an analytical framework has been applied to explain the spread of healthy public policy in Canada5, the transfer of knowledge relating to medical specialization (with focus on emergency medicine) in India6, the uptake of the United Nations Convention on the Rights of the Child in Africa7, and on policy changes more generally8.

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1 CIOMS Guidelines, Guideline 11: Collection, Storage and Use of Biological Materials and Related Data, pp. 42-43.
2 World Health Organization. 2016. Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. Geneva, World Health Organization. Available at: https://www.who.int/blueprint/what/research-development/guidance_for_managing_ethical_issues.pdf?ua=1.
3 CIOMS Guidelines, Guideline 11: Collection, Storage and Use of Biological Materials and Related Data, pp. 42-43.
4 Dobbin, Frank, Beth Simmons, and Geoffrey Garrett. 2007. The Global Diffusion of Public Policies: Social Construction, Coercion, Competition, or Learning? Annual Review of Sociology 33: 449-72. https://doi.org/10.1146/annurev.soc.33.090106.142507.
5 Politis, Christopher E., Michelle H. Halligan, Deb Keen, and Jon F. Kerner. 2014. Supporting the diffusion of healthy public policy in Canada: the Prevention Policies Directory. Online Journal of Public Health Informatics 6 (2): e117. https://doi.org/10.5210/ojphi.v6i2.5372.
6 Sriram, Veena, Asha George, Rama Baru, and Sara Bennett. 2018. Socialization, legitimation and the transfer for biomedical knowledge to low- and middle-income countries: analysing the case of emergency medicine in India. International Journal for Equity in Health 17: 142. https://doi.org/10.1186/s12939-018-0824-y.
7 Mbise, Amana Talula. 2017. The diffusion of the United Nations Convention on the Rights of the Child (UNCRC) more than the African Charter on the Rights and Welfare of the Child (ACRWC) in Africa: The influence of coercion and emulation. International Social Work 60 (5): 1233-1243. https://doi.org/10.1177/0020878516639370.
8 Shearer, Jessica C., Julia Abelson, Bocar Kouyaté, John N. Lavis, and Gill Walt. 2016. Why do policies change? Institutions, interests, ideas and networks in three cases of policy reform. Health Policy and Planning 31 (9): 1200-1211. https://doi.org/10.1093/heapol/czw052.
The governance structures that apply to the sharing of biological materials and related data for biomedical research in all four countries comprise provisions on all of the items set out in the CIOMS Guidelines, although relative emphasis on certain provisions differ among them. In three of these countries (i.e. Guinea, Argentina and India), the CIOMS Guidelines have had direct influence over their domestic governance policies on the subject. Its impact was greatest for Guinea and Argentina, whose governance policies had to be adapted in response to the Ebola virus epidemic in West Africa and the Zika virus epidemic in Latin America. In both countries, sharing of biological materials and related data with international organisations increased significantly to meet therapeutic and research needs during the outbreaks. International organisations have had a comparatively greater role in bringing about policy change in Guinea when compared with Argentina, mainly due to the fragility of the health system in Guinea in 2014. In contrast, policy in India and in Malawi occurred under less strenuous conditions. This may account for the relatively greater emphasis on control and limits to cross-border transferability in their policies when compared with those of Guinea and Argentina.

In spite of situational differences, there are a number of common emphases in the domestic policies of all four countries. Consistent with the position in the CIOMS Guidelines, the governance policies of these countries adopt the principle of accountability and require good stewardship of stored biological materials and related data. However, there appears to be less clarity over how accountability and good stewardship should be expressed in terms of operating procedures, processes and institutional mechanisms. Unlike provisions in the CIOMS Guidelines, there is uniformly insufficient emphasis on public engagement and outreach or education, as the case may be. As each of the case studies (below) show, governance policies need to be clearer about involving interested stakeholders (especially the donors) in ways that are meaningful and engender trust. Equitable sharing of benefits remains a difficult ethical goal to realise, even as training and capacity building could count as benefit from a systemic point of view. Each of the four case studies are prepared by contributing authors who have been closely involved in policy development in their respective countries. These case studies highlight important recent developments and offer insights on how existing policies could be better aligned with recommendations of the international ethical policy on sharing of biological materials and related data for biomedical research.

Case study 1: Ebola virus epidemic in Guinea

Although Article 15 of the Constitution of the Republic of Guinea stipulates that health is a fundamental right\textsuperscript{9}, its health and biomedical research infrastructures are among the weakest in the West African sub-region. In 2014, poorly equipped health facilities and inadequate laboratory systems precluded the early detection of the Ebola disease outbreak, which, coupled with other systemic and organizational deficiencies, led to it being declared a Public Health Emergency of International Concern (PHEIC) by the WHO\textsuperscript{10}. Prior to this outbreak, little work has been done on the ethical dimensions of conducting clinical and behavioural research, especially in the context of public health emergencies in the region. Where the sharing of biological materials and related data is concerned, the 2014 Ebola disease outbreak clearly demonstrated the need of an efficient and effective governance framework. Since the outbreak ended in 2016, there is an ongoing initiative to establish and sustain a platform to share the biological materials and related data obtained from Guinea, Sierra Leone and Liberia during the outbreak. Discussions involving policy makers and key stakeholders helped to define the means of compiling a mass of disparate data within a single and harmonized database, practical modalities for implementing such a platform with Ministries of Health in the affected countries, secure storage mechanisms and data protection measures, and appropriate conditions of access that would be needed\textsuperscript{11}. While the data sharing system seeks to be responsive to research and training needs, it also attempts to prioritize the informational needs of Ebola-affected communities according to pre-established principles and conditions. Key ethical goals of an integrated platform to access biological samples and related data have early-on in the discussions been identified as protection of human rights and transparency, equitable service delivery and reduction of the information gap within the scientific and medical communities.

It is with these goals in mind that the theme of the 3\textsuperscript{rd} Sub-Regional Conference of West Africa in 2017 was dedicated to strengthening post-Ebola health systems\textsuperscript{12}. The conference was held in Conakry, and attended by members of the health communities of three countries (Guinea, Sierra Leone and Liberia) that were most affected by the Ebola outbreak, to discuss the establishment of a post-Ebola crisis biological materials and data-sharing platform\textsuperscript{13}. The platform, which will involve international cooperation, has the objective of consolidating and systematizing all the clinical, epidemiological and laboratory data obtained from patients with Ebola haemorrhagic fever in the affected communities in West Africa. This data will be made

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\textsuperscript{9} Constitution of the Republic of Guinea, 2010 ed. Available at: https://www.constituteproject.org/constitution/Guinea_2010.pdf?lang=en; see also: http://ddata.over-blog.com/1/35/48/78/Guinee/constitution-Guinee-2010.pdf.

\textsuperscript{10} US Centers for Disease Control and Prevention. 2019. 2014-2016 Ebola Outbreak in West Africa. Last reviewed 8 March 2019. Available at: https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html.

\textsuperscript{11} Cori, Anne, Christel A. Donnelly, Iaria Dorigatti, Neil M. Ferguson, Christophe Fraser, Tini Garske, Thibaut Jombart, Gemma Nedjati-Gilani, Pierre Nouvellet, Steven Riley, Maria D. Van Kerkhove, Harriet L. Mills, and Isobel M. Blake. 2017. Key data for outbreak evaluation: building on the Ebola experience. Philosophical Transactions of the Royal Society B 372 (1721): 20160371. https://doi.org/10.1098/rstb.2016.0371.

\textsuperscript{12} Advancing Partners & Communities, West African Consortium Hosts Conference on Post-Ebola Health Challenges, 10 October 2017. Available at: https://www.advancingpartners.org/about-us/news/2017/10/post-african-consortium-hosts-conference-post-ebola-health-challenges.

\textsuperscript{13} Abramowitz, Sharon, Tamara Giles-Vernick, Jim Webb, Jennifer Tappan, Elanah Uretsky, Jorge Varanda-Ferreira, Katharine Mason, Molly Beyer, Claire Collin, and Amadou Sall. 2018. Data Sharing in Public Health Emergencies: Anthropological and Historical Perspectives on Data Sharing during the 2014-2016 Ebola Epidemic and the 2016 Yellow Fever Epidemic, 26 November 2018. Available at: http://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-in-public-health-emergencies-yellow-fever-and-ebola.pdf.
available to the public and to scientific and medical humanitarian communities to disseminate knowledge about the disease, support the expansion of research in West Africa, and improve patient care and future response to an outbreak.

The requirements on access to biological materials and related data are determined by the Steering Committee of this platform. The Minister of Health in each of the West African country involved has an appointed representative on the Steering Committee. The presence of these representatives is essential to ensure that these countries have the opportunity to define the goals, development trajectory and governance of the platform together with the international partners, which have led the initiative. These appointments are also intended to maximize the impact of the platform, to respond to the needs of Ebola-affected communities, and to support the training of scientists in the most affected West African countries. Other representatives on the Steering Committee include individuals appointed by the following organizations: the West African Health Organization; World Health Organization; West Africa Group for the Control of Emerging and Re-emerging Infectious Diseases (or ‘WATER’); Médecins Sans Frontières; the Wellcome Trust; International Medical Corps; and Oxford University Charitable Scientific Organization. Steering Committee members contribute their expertise to directing the policies, strategies and management of the platform. Operationally, the Steering Committee meets face-to-face twice a year and holds conference calls every three months. The members of the Steering Committee sit for a three-year term, and is renewable once.

Discussions at the conference in Conakry highlighted the need for greater integration of data, data security, and data sharing through the establishment of a searchable database. Strategic directions and policy commitments were also emphasized as essential. For example, the need for compilation, secure storage and accessibility of Ebola data was demonstrated with the technical and financial support of the partners. A group of national experts (from Oxford University and elsewhere) and foreign researchers have been appointed to pilot the project for the three countries. Data collected during the Ebola epidemic was carried out by the Coordination Cell Unit, together with supervisors of health facilities operating at different levels, and with the support of international partners like WHO and CDC, among others. In the post-epidemic context, all data has been stored at the Urgency Operation Center where governance practices and principles are aligned with recommendations in international ethical policies, particularly the CIOMS Guidelines.

Critical reflection

Open stakeholders’ discussions have helped to allay fears, and have facilitated the establishment of an effective partnership for the sharing of biological materials and related data at regional and international levels. The scope, pace and scale of implementation of the platform point to the strong political commitments for this initiative so far. However, ethical issues are complex and difficult to address, due in part to the varied stakeholders and interests to which they relate. These include healthcare providers and patients, researchers and participants, public health practitioners and affected communities, as well as opinion leaders and the public. A major challenge with sample and data sharing for research purposes arise from the difficulties in balancing the rights and interests of affected individuals on the one hand, and the interests of researchers and society more broadly to promote scientific and technological advancement.

The concerns of the former are recurrent and persistent, and relate to a range of ethical considerations, particularly confidentiality, anonymity, security and well-being. There is also a lack of information about the values and preferences of affected individuals and their families, their communities and health care providers, even though patient-centred care is increasingly being emphasized. This development coincides with a new initiative that has been introduced to improve community health services. Individuals and communities are now realizing the need to establish themselves as responsible actors for their health and well-being. In addition, advances in information and communication technology gives them the means to achieve this. Overall, it is reasonable to argue that an efficient approach to health system strengthening could be through advancing data sharing mechanisms, platforms and practices, which will then help to empower individuals as patients or research participants. For researchers and policy makers, they recognise the importance of improving transparency, accountability and sustainability. The governance of data practices relates to organizational, managerial and ethical capacities, while specific regulations highlight the tools, principles and ethical values relating to the production and management of data for decision-making and action. Thus, to better understand the underlying issues, three critical points need to be considered: interest in the data, contextual requirements and sharing of real-time health data and related guidelines. It should be emphasized that the sharing of real-time health data includes surveillance data and scientifically validated data, both of which can be demanding (in terms of time and resources) to generate if they are to be scientifically robust and ethically sound. Regarding recommended practices in international ethical policy documents, these are not sufficiently disseminated or internalized, hence gaps still exist in relation to best practices and critical aspects of data practices. To address this challenge, it is not only essential to disseminate and promote these policies, but to also adapt them to the contexts and situations where they are applicable through training and capacity building.

14 World Health Organization. 2016. Recovery Toolkit: Supporting countries to achieve health service resilience. Geneva: World Health Organization. Available at: https://apps.who.int/iris/bitstream/handle/10665/205944/WHO_HIS_SDS_2016.2_eng.pdf?sequence=1.

15 Goldacre, Ben, Sian Harrison, Kamal R. Mahtani, and Carl Heneghan. 2015. WHO consultation on Data and Results Sharing During Public Health Emergencies: Background Briefing. Oxford: Centre for Evidence-Based Medicine. Available at: https://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf.
Case study 2: Development of a governance framework in Argentina

With increasing overseas research collaborations involving scientists in Argentina, biobanking and the secondary research use of biological materials and data have raised ethical and regulatory concerns. A number of these concerns became prominent during the Zika virus epidemic, which was declared a PHEIC by the WHO in February 2016. The research governance framework in Argentina is defined by the Ethical Guidelines in Biomedical Research Involving Human Subjects (AEGBR)\(^\text{16}\) and the national regulation on Good Clinical Practices for Clinical Trials (AGCP)\(^\text{17}\). The AEGBR was promulgated by the National Ministry of Health of Argentina (NMHA) to provide general guidance for conducting biomedical and health related research, based on the recommendations and standards set out by international organisations like the World Medical Association and CIOMS. It also gives directions on review standards for research ethics committees, as well as requirements on composition and functions. The AGCP is a regulation of the National Administration of Drugs, Food and Medical Technology, which prescribes standards in accordance with those of the Guideline for Good Clinical Practice of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The requirements in the AGCP are mandatory for any clinical trial that is conducted in Argentina. However, there is no legislation or guidelines specifically on biobanking, or the sharing of biological materials and related data for research purposes.

In the absence of legal or regulatory guidance, researchers and research ethics committees have been left with the responsibility of taking decisions on their own. This situation carries the risk of different standards being applied and inadequate safeguards for the rights and welfare of research participants. For this reason, researchers have called for clearer regulatory guidance on sample and data sharing, especially those working in the field of genomics. In response, the NMHA convened a technical commission (ATC) composed of interested stakeholders, including public biobanks, representatives of the Ministry of Science and Technology and the National Institute of Cancer, bioethicists, lawyers and researchers\(^\text{18}\).

The ATC has identified several concerns that have arisen from the lack of a governance framework for biobanking and related activities. One concern relates to the meaning of “biobanking” and related activities that should fall within regulatory oversight.

Many public and private biobanks have emerged in Argentina\(^\text{19}\). There are even institutions with collections of biological materials that may not be recognised or treated as biobanks. There is also a current initiative of establishing a population biobank\(^\text{20}\). However, these biobanks are either being developed or operated without appropriate oversight. Existing biobanks do not operate within a governance system that ensure ethical and regulatory requirements are observed. These requirements include those relating to informed consent, future use of biological materials and keeping donors informed of future studies, return of results of unanticipated findings and confidentiality.

Where data and samples are transferred overseas, it is unclear if this is pursuant to an appropriately drafted material transfer agreement (MTA), as there is currently no legal requirement to that effect. In international collaborations, an agreement may be imposed on local researchers with no possibility of negotiating favourable terms on confidentiality, intellectual property rights, return of results and benefit sharing.

Hence, the ATC recognizes the need to develop a governance framework for biobanking and data/sample sharing that fall outside the scope of clinical trials. For this purpose, the revised and updated CIOMS Guidelines serve as a helpful reference in the drafting of a new regulation on biobanking and related data, particularly Guideline 11 (on Collection, storage and use of biological materials and related data), and Guideline 12 (on Collection, storage and use of data in health-related research)\(^\text{21}\). These guidelines helped to identify the key concerns that the new regulation will address, which include:

1. What needs to be governed: All existing collections of biological materials should be subject to appropriate governance; hence, the term ‘biobank’ will be broadly defined to include both large population biobanks and small biorepositories consisting of bio-specimens in laboratories;

2. Specification of roles and responsibilities: As custodians of biological materials and related data, biobanks will have clearly specified roles and responsibilities, which will include ensuring the quality of the materials and data collected, and that donors’ rights (such as rights to privacy and confidentiality, access to information and feedback) are respected;

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\(\text{16}\) República Argentina. Ministerio de Salud. Resolución Nº 1480/2011. Guía para Investigaciones con Seres Humanos. Available from: http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/187206/norma.htm. Accessed 1 June 2019.

\(\text{17}\) República Argentina. Ministerio de Salud de la Nación. ANMAT Disposición 6677/2010. Available from: http://www.anmat.gov.ar/comunicados/disco_6677-10.pdf. Accessed 1 June 2019.

\(\text{18}\) República Argentina. Ministerio de Salud. Resolución Nº 1002/2016. Available from: http://servicios.infoleg.gob.ar/infolegInternet/anexos/260000-264999/263682/norma.htm. Accessed 27 September 2018.
(3) Regulatory environment: Appropriate mechanisms will be introduced to protect donors’ rights and achieve harmonization in biobanking operations;

(4) Future use of biological materials and related data: The use of broad consent is permissible for unspecified future research use, provided that ethics review and approval ensure that certain requirements are satisfied; and

(5) Transfer of materials and data: Key provisions of an MTA will be enumerated to allow researchers and institutions to negotiate fair terms relating to secondary uses, return of results and benefit sharing.

Critical Reflection

The development of a biobanking governance framework is important to support the advancement of biobanking in Argentina, and the CIOMS guidelines have been helpful in setting out the key ethical issues. However, some further actions are required in order to promote local and international collaboration, as well as to protect the rights of participants and local researchers. Infrastructure and specialized personnel are required for more effective and ethically responsible data and sample management. Training for researchers is also needed to promote the benefits of data and sample sharing and in ensuring that ethical requirements, such as informed consent, withdrawal of consent, and confidentiality, are observed. Training should include members of ethics committees who are involved in the review of studies that use stored materials or data, and the consent procedures entailed. Unless ethics committees are properly trained, they are likely to be overly cautious in their review of studies with broad consent and sample/data sharing for future uses. This is primarily because broad consent may conflict with current national guidance. Ideally, international research collaboration that involves the sharing of biological materials and data should contribute to capacity building, which includes the capability of an ethics committee to support ethically sound arrangements that engender credibility and trust.

Also, community engagement needs to be enhanced to promote public trust in biobanking. Research is required to better understand public views and attitudes towards biobanking studies and sample/data sharing. To address this gap, several strategies such as community consultation, surveys and interviews, are required. In addition, educational materials should be developed to support the comprehension of these studies in order to allow free and informed choice to be exercised through a broad consent process.

Case study 3: India’s national guidelines on biobanking and data sharing

In India, clinical trials for new therapies and new medical devices are regulated by the Drug Controller General of India through its Central Drugs Standard Control Organisation, under the Ministry of Health and Family Welfare. All clinical trials are required to be registered at the Clinical Trials Registry - India and have to comply with the regulations of Schedule Y of the Drugs & Cosmetics Act 1940 and its recent amendments and follow the Indian Good Clinical Practice Guidelines (2001). Adherence to ethical standards in the conduct of clinical trials and medical research is regulated by the Indian Council of Medical Research (ICMR) through its National Ethical Guidelines for Biomedical and Health Research involving human participants (ICMR Guidelines), first formulated in 1980, then revised in 2000, 2006, and most recently in 2017. The 2006 Guidelines, consistent with the provisions in Schedule Y 2005 Amendments, primarily focussed on the regulation of clinical trials and the requirements and responsibilities of Institutional Ethics Committees (IECs) and researcher.

The 2006 ICMR Guidelines had limited coverage of biobanking, which was addressed under the chapter on Human Genetics and Genomics. This focus on genetics may have been a response to Article 20 of the UNESCO Draft Declaration on Human Genetic Data, which urges that:

States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multi-disciplinarity, pluralism and transparency, as well as the principles set out in Declaration…

It also required regulatory agencies to broaden the definition of a ‘researcher’ to include a molecular biologist and basic science researcher, and to widen the scope of research ethics from that pertaining to clinical trials to include new and emerging science and technologies. There has been relatively little attention on potential bioethical issues relating specifically to biobanking until around 2013. During this period, biobanking initiatives involving the establishment of biobanks (mostly of stem cells, cord blood and surgical leftover ‘waste’ tissue) and the conduct of biobanking research have been popular with private sector entities, particularly private hospitals and diagnostic companies. However, no formal registration with a regulatory

22 Emanuel, Ezekiel J., David Wendler, J. Killen, and Christine Grady. 2004. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *Journal of Infectious Diseases* 189 (5): 930–937.

23 UNESCO, Bioethics Committee. 2003. International Declaration on Human Genetic Data.

24 St.s, K.L., P. Jha, P. Mony, A. Kurpad, V. Lakshmi, and N.K. Ganguly. 2007. Public health. Biobanks in developing countries: needs and feasibility. *Science* 318: 1074–5; Shankar, S., and U. Yamananda. 2011. Biobanking: Basic concepts and role in rheumatology. *Indian Journal of Rheumatology* 6: 129–137. https://doi.org/10.1016/S0973-3698(11)60075-7.

25 Limaye, Nimita. 2013. Pharmacogenomics, Theranostics and Personalized Medicine – The Complexities of Clinical Trials: Challenges in the Developing World. *Applied & Translational Genomics* 2: 17-21. https://doi.org/10.1016/j.atg.2013.05.002; Chaturvedi, S., K.R. Srinivas, and V. Muthuswamy. 2016. Biobanking and Privacy in India. *Journal of Law, Medicine & Ethics* 44 (1): 45-57. https://doi.org/10.1177/1073110516644198.
authority is required and hence no official data is available on the number of biobanks in India or their location\textsuperscript{27}. It was also unclear under the 2006 Guidelines, if stored biological samples used for research constituted human subject research and if the collection of residual samples from clinical trials or diagnostic studies constitutes a biobank\textsuperscript{28}. The 2017 ICMR Guidelines addressed this gap in a new section on biological materials, biobanking and datasets\textsuperscript{29}. The ICMR used review articles, international guidelines and multiple consultations to formulate and refine the provisions in this section, that are primarily directed at researchers on the one hand, and those that relate to the donors of biological materials and related data on the other. Provisions that are directed at researchers include definitions of biological materials, biobanking and data sets; requirements concerning storage, such as safety requirements and quality maintenance; sample typology based on identity linkage and related confidentiality concerns; waiver of consent and consent requirements in relation to vulnerable populations (e.g. children). The provisions that relate to the donors include different consent-taking approaches (e.g. re-consent and multi-tiered consent) and supporting documentation (e.g. multiple forms) to account for different research conditions, such as the time-lag between the collection of the biological sample and the actual research, and the secondary or extended use of biological materials and related data. In addition, the consent form is presented as an instrument in which issues of access to data-linked samples, return of incidental and end-of-research findings to donors, sharing of samples and data with researchers/ national or international institutions, potential collaborations and commercialisation, and benefit sharing could be addressed. Other recommendations set out in the 2017 ICMR Guidelines include:

1) Ownership, which is retained by the donor, who has the right to withdraw her/his biological material and related data from the biobank or repository. The biobank or the institution responsible for the tissue and/or data repository acts as a custodian or trustee of the biological materials and data;

2) Transfer of samples should be pursuant to a MTA and regulatory clearances (with appropriate Memoranda of Understandings, where applicable), as well as from the Directorate-General of Foreign Trade for inter-institutional, inter-country and commercial transfers.

3) On benefit sharing, researchers are encouraged to commit to sharing with the donors, their families and/or their communities the potential commercial value of the biological sample or data, even if such a benefit is not known at the time of the start of the research. This could be in the form of access to the products, tests or discoveries resulting from the research.

The 2017 ICMR Guidelines indicate that an IEC, whether of the institution housing the stored samples or of an independent biorepository, has a key role in the oversight and use of the biological material and data repositories for research. Biobanks should have well-structured SOPs for collection, coding, anonymization, storage, access, retrieval and sharing of biospecimens and data. It is also recommended that a governance structure be put in place, comprising members with expertise in science and ethics. An entity (which may assume the name of ‘Technical Authorization Committee’) within this governance structure is expected to oversee material and data transfer agreements, in tandem with an IEC. If a data repository is to be used for a specific research purpose or for commercialisation, ethical review is required. Data mining, access control, and data usage for research must be approved by an IEC. Data privacy, data accuracy, data security and the possibility of legal liability are to be taken into consideration when data is outsourced or sold. Specific provisions apply to health datasets that are to be exploited for commercial purposes. Above all, measures to protect privacy and confidentiality of individuals must be in place.

**Critical Reflection**

In India, there is a real-risk of the consent-taking process being reduced to a mere formality, due to the low level of scientific literacy on the part of donors of biological materials and related data, medical paternalism and therapeutic misconception. For this reason, broad consent tends to be interpreted as a means to protect the interests of researchers and research institutions, rather than giving effect to the ethical requirement of respect for persons\textsuperscript{30}. In addition, recommendations of multi-tiered consent and re-consent may sound sensible, but is in reality difficult or impossible to implement. In a study done by one of the authors (MV), it was found that donors want researchers to remain accountable to them, but not through means like repeated consent-taking\textsuperscript{31}. For these donors, accountability and respect are better expressed through the sharing of research outcomes with the donors, either through a newsletter, an email or through their healthcare institution\textsuperscript{32}. Returning individual results to donors may be difficult to do for a number

\textsuperscript{27} There is however, a legislative bill that has been tabled in the Indian parliament in 2019 that seeks to implement accreditation for all DNA Data Banks and DNA laboratories. See: Ministry of Science and Technology and Earth Sciences, Government of India. The DNA Technology (Use and Application) Regulation Bill, 2019. Available from: http://prsindia.org/billtrack/dna-technology-use-and-application-regulation-bill-2019.

\textsuperscript{28} Vaz, Manjulika, Mario Vaz, and K. Srinivasan. 2014. Ethical challenges in Biobanking: Moving the agenda forward in India. *Indian Journal of Medical Ethics* 11 (2): 79-88. https://doi.org/10.20529/IJME.2014.022.

\textsuperscript{29} Indian Council of Medical Research. 2017. *National Ethical Guidelines for Biomedical and Health Research involving Human Participants*. New Delhi: ICMR. Available from: https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf.

\textsuperscript{30} Vaz, Manjulika, Mario Vaz, and K. Srinivasan. 2015. Listening to the Voices of the General Public in India on Biomedical Research – An Exploratory Study. *Indian Journal of Medical Ethics* 12 (2): 68-77. https://doi.org/10.20529/IJME.2015.024.

\textsuperscript{31} Ibid.

\textsuperscript{32} Ibid.
of reasons, including the lack of access by researchers to the donors (e.g. due to de-identification), and lack of resources (both financial and operational) and expertise (e.g. in counseling needed with the disclosure of sensitive and/or complex results). The situation becomes more complex where the results are likely to be of clinical significance, as there is arguably an ethical obligation on the part of researchers to inform the donors or participants concerned.

While the provisions in the 2017 ICMR Guidelines represent a step in the right direction, certain aspects remain under-developed. Although benefit-sharing is encouraged, commercialisation through acquisition of intellectual property rights is encouraged33, along with consent forms being written up in such a way that prevents the donors or research participants from having any claims over such benefits arising from the research34. In this respect, there is a need to develop tools and mechanisms to ensure fair and equitable sharing of benefits. The 2017 ICMR Guidelines also fail to recognise that certain concerns may need stronger safeguards. For instance, privacy concerns that arise from certain types of biobanking research may need strong legal protection35. Finally, the need for community engagement to promote public trust has not been given due attention. For instance, encouraging biobanks to set up community advisory boards may be a helpful way to engage with communities, maintain transparency and address practical difficulties of access and communication.

**Case study 4: Precluded future research use of human biological materials in Malawi**

The Government of Malawi through its National Commission for Science and Technology (NCST) has established a relatively comprehensive governance framework on accessing, collecting, storing and using human biological specimens for research. This framework is a composite of ethical requirements on use of human specimens and data from various guidelines produced by NCST and the National Health Sciences Research Committee. This framework is summarized in a document published by the NCST titled “What is the National Regulatory Requirement and Position on Accessing, Collection, Storage and Use of Human Biological Specimens for Research in Malawi?” This document states that researchers are allowed to access, collect, store and use human biological specimens and related data. However, this is only for approved research protocols that have met certain requirements, including obtaining informed consent. Regulatory requirements do not allow researchers to collect biological specimens that are not required to address their immediate study objectives. Malawian guidelines on informed consent have provisions on individuals without decision-making capacity to participate or contribute to research. Similarly, no provision is made on research involving future unspecified use of human biological specimens obtained from such individuals.

Furthermore, for specimens collected for a presently approved study, “tests on biological specimens should only be as described in the approved proposal; specimens collected for a particular purpose should not be used for other purposes”. When specimens are collected, they may be stored for an initial period of five years. In the event that tests/analyses are incomplete, investigators can request approval to store specimens for a further 5-year period from the research ethics committee. If no approval is given, the specimens must be safely discarded or destroyed, though no mechanism exists to confirm safe disposal of specimens. Tests/analyses of stored specimens must be carried out in Malawi unless there are exceptional circumstances preventing this. Such circumstances include, lack of technology to conduct the tests, need for further tests to confirm results, and for quality control and validation of results. In these cases, investigators can request approval to export the specimens. This should be done pursuant to a MTA. Current MTA documents do not have provision for proof of specimen destruction.

**Critical reflection**

Not giving participants the option for subsequent use of their human biological materials after the completion of a research project is inconsistent with the principle of autonomy. In addition, it could compromise the social value of the research and thereby violate the principle of justice36. The principle of respect for persons as outlined in the Belmont report is applied in the informed consent process. According to 2014 NCST document, researchers are not allowed to use stored biological specimens for future unspecified research. Potential participants are denied the right to make informed choices about the use of their biological materials in potentially beneficial future research. It is neither stated nor explained why participants are not allowed to provide consent for subsequent research use. The ethical guidelines do not state whether participants may be re-contacted for further consent. It is also not stated whether a waiver of consent would be provided for such future research use. Denying potential participants this right unduly limits their exercise of autonomous decision-making.

Emerging technological advancements allow for potentially greater and as-yet-unknown research applications of stored specimens. In addition, human resources, materials and capital are expended during collection, transport and storage of these specimens. Discarding or destroying specimens would therefore lead to loss of scientific and economic benefit, from the failure to maximize benefit derivable from these already collected specimens, while potentially wasting more precious resources having to collect them again. In many regulatory systems, specimens that are anonymized need not be destroyed. However,

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33 Vaz, Manjulika, Sridhar T.S., and Sanjay A. Pai. 2016. The ethics of research on stored biological samples: outcomes of a workshop. *Indian Journal of Medical Ethics* 1 (2): 118-22. [https://doi.org/10.20529/IJME.2016.032](https://doi.org/10.20529/IJME.2016.032).

34 Vaz, Manjulika, Mario Vaz, and K. Srinivasan. 2017. The views of ethics committee members and medical researchers on the return of individual research results and incidental findings, ownership issues and benefit sharing in biobanking research in a South Indian city. *Developing World Bioethics* 18 (4): 321-330. [https://doi.org/10.1111/dewb.12143](https://doi.org/10.1111/dewb.12143).

35 Chaturvedi, Sachin, Krishna Ravi Srinivas, and Vasantha Muthuswamy. 2016. Biobanking and Privacy in India. *Journal of Law, Medicine & Ethics* 44 (1): 45-57. [https://doi.org/10.1177/107310516644198](https://doi.org/10.1177/107310516644198).

36 Lutge, Elizabeth, Catherine Slack, and Douglas Wassenaar. 2017. Defining and Negotiating the Social Value of Research in Public Health Facilities: Perceptions of Stakeholders in a Research-Active Province of South Africa. *Bioethics* 31 (2): 128–135. [https://doi.org/10.1111/bioe.12323](https://doi.org/10.1111/bioe.12323).
this is this not provided for in the current guidelines and so diminishes potential value to communities that provided them. As research on human biological specimens becomes more prominent in Malawi, there is a need for clearer guiding policy in order to maintain the delicate balance between necessary oversight, and promoting robust and beneficial research on stored human biological specimens. We therefore recommend allowing donors to provide broad consent for future research use in a manner that is consistent with the CIOMS Guidelines. We also recommend a consultative process to produce guidelines to protect vulnerable individuals whilst allowing them to contribute to socially valuable research.

### Discussion and conclusion

Policymakers in Guinea experienced a steep learning curve following the onset of the Ebola virus epidemic in 2014, where rapid sharing of biological materials and data was a necessary response. The involvement of international partners was critical as the epidemic shed light on systemic deficiencies that prevented Guinea from mounting an effective response on its own. During the period of public health crisis, learning was primarily through emulation, as the establishment of a specimen and data-sharing platform was led by the international organisations, many of which were involved in the provision of medical and humanitarian assistance. Experiences with this sharing platform and the challenges of putting in place an appropriate governance regime for it have been constructive, and is a good example of learning through international collaboration. Post-crisis, the learning has continued although it now has a more collaborative character where policymakers and key local stakeholders have taken on more active roles, alongside these international organisations as partners. Lessons learnt are being applied towards capacity building, including the use of data on an evidentiary basis to address policy and healthcare concerns. In order to support continuing meaningful and effective sharing of biological materials and data, further evaluation of ongoing reforms in Guinea (and West Africa more generally) is needed. Data governance needs to be revisited and adapted to meet new challenges (to data security for instance) and local needs in ways that help build trust.

In Argentina, policy learning on the sharing of biological materials and related data was under similarly strenuous conditions, with the outbreak of the Zika virus epidemic in early 2015. A governance approach that was centred around clinical trials did not adequately address the ethical, legal and social concerns that arise from international sharing of biological materials and related data. Post-crisis, a specific governance framework for biobanking has been developed in Argentina to balance between promotion of responsible research and sharing of samples and related data on one hand, and the protection of donors and community interests and rights on the other. Biobanking challenges the old ways of doing research in the country and its traditional regulation and ethical standards. Continuous future and unspecified studies with biological samples and related data, broad consent and its implications, a more complex process of data protection, genomic research and data-sharing through the cloud, data and sample sharing among many countries in international collaborative works and for public health emergencies – such as Ebola and Zika outbreaks – are just examples of new aspects to understand and govern. Developing a biobanking regulation has presented policymakers and key stakeholders in Argentina an opportunity to rethink research as a dynamic process where boundaries are not clear and rigid, instead of a more conventional and static perception of a specific study. This development has also brought attention to the need of cultural changes, and the importance of training for researchers, biobank operators and members of research ethics committees, among others. Perhaps most important of the changes to be introduced is the incorporation of community engagement in the governance process. Public education and engagement on benefits (and potential risks) and other ethical issues are required to promote public participation and to ensure that biobanking arrangements continue to be inclusive and equitable.

Policy diffusion occurred under less strenuous conditions in India and in Malawi. Perhaps because policy learning and development occurred in ‘peacetime’, greater significance has been attached to specific interests, such as sustaining scientific progress (in India) and safeguarding individual rights (in Malawi). While these interests are important, it has been argued that certain aspects of biobanking governance in India and Malawi need to be reconsidered in the light of more recent developments in international governance policies on biobanking. In India, greater emphasis on public engagement is needed to ensure that altruistic donors of biological samples and health data are sufficiently empowered and to build trust in the system. Public understanding can be stoked through engaged deliberation, and the practical aspects of re-consent and return of results can be meaningfully discussed. More clearly spell out mechanisms for return of incidental (but beneficial) individual or group findings and other forms of benefit need to be developed. While existing guidance prioritises appropriate and elaborate consent documentation, studies have shown that greater reciprocity and distributive justice are needed to ensure that public trust is sustained in biobanking research. Ethical focus on ‘common good’, reciprocity (‘two-way altruism’) and collective values need to be entrenched in biobanking policies and furthered through ongoing public engagement in order for science to flourish as a public institution in India.

Malawi has a comprehensive framework that governs research on stored human biological specimens. However, some ethical requirements are narrow and restrictive and may unnecessarily hinder research that is of social value. Malawian citizens who wish to donate their biological materials for future unspecified research use are currently not allowed to do so. It has been argued that the requirement for re-consent to be obtained from these donors for future use of their donated materials and related data does not necessarily give effect to the ethical principles of respect for persons and justice. In addition, there is need for community engagement to assess the views of
donors and develop guidelines that are sensitive to the ethical, social, political and cultural context of Malawi. For instance, provisions on MTA may need to be updated to ensure that there is proof of destruction of biological specimen after the purposes of its gifting are exhausted. Public education is also required. Malawian society is not free of superstition. The social unrest and violence that accompanied rumours of vampirism (blood sucking and organ trafficking) are potent examples of the lack of public understanding of science. Increased awareness through education can dispel these beliefs and make research more acceptable to the public.

International ethical policy on sharing of biological materials and related data has been an important source of guidance for domestic countries, particularly during an infectious disease outbreak. The four case studies illustrate the different degrees of diffusion in governance standards, requirements and practices from international ethical / policy documents to national policies on the subject. While all four countries have made significant progress in establishing accountable governance arrangements for the responsible sharing of biological materials and related data, still more needs to be done in raising the level of public understanding and trust, and to ensure that the ethical goal of equitable sharing of benefits is realised. There is at the same time a need for researchers and those responsible for ethics review to be appropriately trained, and more generally, for health systems to be adequately capacitated to enable ethically sound research.

**Data availability**
No data are associated with this article.

**Authors contributions**
CH has been responsible for conceptualising the paper in consultation with all of the other authors of this paper. MV wrote the case study on India, AGP wrote the case study on Argentina, WN wrote the case study on Malawi and AAD wrote the case studies on Guinea, and CH reviewed and edited all four case studies. All authors reviewed the final draft of the paper in its entirety and contributed to its drafting. For this reason, authorship is shared equally among all the authors and not in the order of authorship.

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This paper provides four interesting case studies of the influence of international biobanking and health data policies and guidelines for national policy development. The four case studies are clearly described and the differences between the four cases analysed and discussed in the ‘Discussion and conclusion’ section. This a very good paper, but I think it could be strengthened in a number of ways which would make it an even more valuable contribution to the literature.

There are five areas where I think the analysis could be improved:

1. The authors state that they apply Dobbin et al.’s framework for analyzing the global diffusion of policies, but it is not clear that they really do that. Some of the case studies have elements that seem not to be straightforward examples of ‘policy learning’ but of some of Dobbin et al.’s other categories.

2. The authors relate their analysis to the CIOMS guidelines and WHO guidance, but give no argument for why these two sets of international guidelines have been chosen. Why not, for instance include the WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks. The WMA declaration is in some ways more restrictive than the CIOMS guidelines, but may by some be seen as more authoritative.

3. The authors mention that two of the case studies involve national policy change spurred by a significant international public health emergency where the countries in questions were affected by the emergency, and they label that ‘strenuous conditions’. But, that means that the countries in question may be in a situation where their bargaining position is weak. In order to receive the help they need they may have to agree to policies they would not otherwise have agreed to. This needs to be considered.

4. It is implied in the argument that adherence to the CIOMS guidelines by national policy is always a good thing. But, that is not obvious. Like all international guidelines the CIOMS
guidelines are political in the sense that the interests of important stakeholders play a role in their formulation. But, national interests and the interests of the public in a particular national context may not align with the interests of the stakeholders involved in guideline formulation. This point comes out in an interesting way in the Argentina case study where the authors on the one hand claim that ‘The use of broad consent is permissible for unspecified future research use’ and then a little later that ‘community engagement needs to be enhanced... Research is required to better understand public views’. But, what if the Argentinian public is not comfortable with broad consent for future unspecified research use? Should the international guideline, or the view of the Argentinian public then take precedence, and why?

5. In the Malawi case it is stated without reference that not being able to give broad consent to future use is inconsistent with the principle of autonomy. This is clearly a liberty infringement, but not all liberty infringements are infringements of the principle of respect for autonomy, so an argument or reference is needed for why we should conceptualise this particular liberty infringement as an autonomy problem.

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Research ethics, the ethics of biobanking

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
The manuscript “Diffusion of ethical governance policy on sharing of biological materials and related data for biomedical research” by Vaz et al. addresses the issue of how national policies on ethical governance of biobanking and the sharing of biological samples broadly defined have been shaped in four countries in recent years and how that reshaping has been influenced by pre-existing policies and infrastructures — or sometimes the lack thereof — in the individual target countries as well as internationally.

It references the work by Dobbins, Simmons and Garrett (2007)\(^1\) on four potential mechanisms underlying policy diffusion and claims to "apply" their analytical framework, but I found that methodological part rather weak, as it is not introduced in sufficient detail, nor used to frame, structure or analyze the case studies in detail.

For instance, Dobbins et al. distinguish "policy learning" from "social construction", "coercion" and "competition", none of which are commented on in the manuscript, although it could be argued that they might have played some role in the observed cases of policy diffusion.

Vaz et al. also observe that policy changes came about under "strenuous" conditions in two of the analyzed countries (Ghana and Argentina) in contrast to more "peacetime" conditions in the other two (India and Malawi), and no commentary is provided as to how that would fit with Dobbins et al.’s analytical framework.

The main value of Vaz et al.’s work is thus in providing:

- observations of policy diffusion regarding ethical governance of biobanking and the sharing of biological samples in the four countries.

- some details about the practical context of these observations rather than in elucidating the theoretical underpinnings. This is valuable as such but should be better reflected in the abstract and introduction.

There would also be good value in strengthening the theoretical part, though I could see that this might shift the nature of the manuscript too much, so I could imagine this to be handled in follow-up work.

What I would like to be considered for the theoretical part includes:

- adding an illustration of the diffusion of certain policy elements described in the text

- comparing the four national and reference policy frameworks with respect to how they would handle some standard epidemiological use cases like post-epidemic analyses of sera from long-term storage to
  - measure antibody levels before, during and after relevant outbreaks, e.g. as per
Sharma et al. (2017)²
○ perform genetic analyses of pathogens from individuals involved in the early phase of an epidemic, e.g. as per Worobey et al. (2016)³

○ discussing
  ○ how policies in the four countries and beyond can, do or should handle "research as a dynamic process" (as suggested in the Argentina case study)
  ○ how policy learning/diffusion frameworks can help address challenges commonly raised throughout the manuscript
    ○ training
    ○ community engagement
  ○ the balancing of specific interests (briefly mentioned as "scientific progress (in India) and safeguarding individual rights (in Malawi")"
  ○ differences in policy learning/diffusion for different types of biobanks (alluded to in the manuscript)
  ○ the effect of the availability (or not) of model policies or MTA templates
    ○ for instance, the availability of the Harvard model policy on open access did likely contribute to the broad adoption of similar policies around the globe
    ○ the role of open licensing of such model text, e.g. that Harvard model policy is available under the terms of the Creative Commons Attribution License 4.0
  ○ the FAIR principles for the sharing of scientific data and metadata (Wilkinson et al., 2016)⁴
    ○ along with the standardization of metadata and the sharing and aggregation thereof, e.g. through the use of persistent identifiers
      ○ that standardization could include
        ○ some test content, similar to how http://orcid.org/0000-0002-1825-0097 is used for testing and demoing ORCID-related matters
        ○ some showcase content, which could help with public engagement, e.g. as per Project H.M.
    ○ their applicability to epidemiological contexts, as discussed in Pisani, Ghatauer and Merson (2018)⁵ (especially their Table B) and also highlighted in the Zika case study in the report “Turning FAIR into reality”
      ○ that report also discusses machine-actionable policies, as do Miksa et al. (2018)⁶, which have a strong potential to modulate policy diffusion
  ○ data sovereignty - between countries, it is somewhat implied throughout the manuscript, albeit not explicitly mentioned, but there are also important policy considerations for data sovereignty of different communities within a country, e.g. as per the Good Data Practices for Indigenous Data Sovereignty and the CARE Principles for Indigenous Data Governance

While reading the manuscript, I annotated it using https://hypothes.is/; and these annotations — which include comments beyond classical peer review — can be found via https://hypothes.is/search?q=url%3Ahttps%3A%2F%2Fwellcomeopenresearch.org%2Farticles%2F4-170%2Fv1 and have been archived at http://web.archive.org/web/20191227174305/https://hypothes.is/search?q=url%3Ahttps%3A%2F%2Fwellcomeopenresearch.org%2Farticles%2F4-170%2Fv1. I also took some notes on my review process, which can be found at https://github.com/Daniel-Mietchen/ideas/issues/1263.
Some more comments on the questions from the review form:

- **Is the rationale for the Open Letter provided in sufficient detail?**
  - The authors provide a rationale for addressing the issue of policy diffusion with respect to biobanking. They provide no rationale as to whether an Open Letter is the most appropriate manuscript type for that, but upon checking the Guidelines for Open Letters, I find the choice appropriate.

- **Does the article adequately reference differing views and opinions?**
  - It does not cover differing views and opinions in much detail, but highlights issues where there is a practical need for reconciling them.

- **Are all factual statements correct, and are statements and arguments made adequately supported by citations?**
  - What is written appears correct and supported by suitable citations. Lots more could be added — see comments above and annotations.

- **Is the Open Letter written in accessible language?**
  - Yes. A few minor linguistic issues are pointed out in my annotations.

- **Where applicable, are recommendations and next steps explained clearly for others to follow?**
  - Here, I chose "partly" because this is sometimes unclear, as highlighted in my annotations, e.g. for the example from Ghana which does not provide sufficient details to find out whether the platform exists and where to find it.

This report is available under the terms of the CC0 1.0 Universal (CC0 1.0) Public Domain Dedication.

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6. Miksa T, Simms S, Mietchen D, Jones S: Ten principles for machine-actionable data management plans. *PLoS Comput Biol*. 15 (3): e1006750 PubMed Abstract | Publisher Full Text

**Is the rationale for the Open Letter provided in sufficient detail?**
Yes

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Data sharing policies and infrastructure

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.