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What Do the British and Chinese Governing Visions on Human Genomic Research Tell Us about Biosovereignty?

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Abstract: Genomic research lies at the core of national bioeconomies and is a strategic area for national scientific competitiveness. Drawing on the UK's latest national vision on genomic research and my participation in one of China's policy consultations on its implementing rules on human genetic resources, this paper demonstrates how China's conception of 'biosovereignty' may be counterproductive, both to its scientific competitiveness and to the health of its people. The key argument is that 'biosovereignty' is not a property of an individual, a community, or an institution. Rather it is a powerful assemblage of ideals, infrastructures and network of capitals that steers our collective future. It is simultaneously a social contract and a social construct, both of which are evolving with socio-technical realities. The paper provokes reflections on the role of the state in promoting equitable genomic research and the question on what 'biosovereignty' means and how it should be represented.
Keywords: China, CRISPR genome editing, ethics, genomics

Introduction

With the discovery of the sequencing technique of DNA in the 1970s, the world has witnessed a fast-evolving genomic revolution. Yet with anticipated applications in precision medicine, population genetics, virus surveillance breakthrough of diagnosis, prevention and treatment, it seems that scientists, investors and the public alike are only at the beginning of grasping genomic research's full potential (Green et al, 2020; Neufeld, 2021; Mills 2022). Genomic research lies at the core of national bioeconomies and is a strategic area for national scientific competitiveness. The past few years saw the launch of national strategies for genomic research, such as the France Genomic Medicine Plan 2025, Germany's genomeDE strategy (2019), Genome UK (2020), and EU's 1+ Million Genomes initiative (2020). However, human genomic research has also been Western-centric, both in terms of the focus of its study (e.g. 86% of existing genomics studies are focused on people of European descent) and in terms of its professional power dynamic (Schwartz-Marín and Restrepo, 2013; Xiong, 2021; Fatumo et al, 2022).

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China presents a unique case. On the one hand, similar to many developing countries, bioprospecting and exploitative medical research remains a not-so-distant memory for Chinese society (Keim, 2003; Xiong, 2021). On the other hand, China is one of the few Global South countries that has the capacity and resources to reshape global genomic research. Following its first formal national legislation on human genetic resources in 2019 (State Council, 2019), China's *Biosecurity Law* promulgated in October 2020 further elevated the importance of human genetic resource governance as a matter of national security. Article 53 of the *Biosecurity Law* further claimed the governance of human genetic resources as part of China's national sovereignty (Standing Committee of the National People's Congress, 2020). This 'biosovereignty' framing, along with its securitisation of human genetic data, has generated much debate (Mallapaty, 2022; Sharma, 2022). More importantly, as this paper argues, China's decolonial invocation of biosovereignty may paradoxically alienate Chinese bioscience from global genetic research and thus reinforce a colonial power disparity. This is more evident when juxtaposing it with the global trend towards democratic governance over data-sharing (Fatumo et al, 2022; Hilberg, 2022).

Drawing on my familiarity with the UK's latest national vision on genomic research and my participation in one of China's policy consultations on its implementing rules on human genetic resources, this paper demonstrates how China's conception of 'biosovereignty' may be counterproductive, both to its scientific competitiveness and to the health of its people. The key argument is that 'biosovereignty' is not a property of an individual, a community, or an institution. Rather it is a powerful assemblage of ideals, infrastructures and network of capitals that steers our collective future. It is simultaneously a social contract and a social construct, both of which are evolving with socio-technical realities. The paper provokes reflections on the role of the state in promoting equitable genomic research and the question on what 'biosovereignty' means and how it should be represented.

Biosovereignty as a Modern Concept

Sovereignty is one of those core concepts whose meaning seems to be apparent to all while simultaneously being hard to pin down. For precisely because of its centrality to socio-political life, its meaning evolves and multiplies. For example, despite China's recent emphasis on biosovereignty, its definition seems to be taken for granted, as Chinese laws have not considered it necessary to give a specific definition. However, in this paper, sovereignty refers to the authority of a state in modern politics which is exercised through representative bodies, rather than the power of a monarchy (such as the British Crown) (Philpott, 2020). Broadly defined, the global

conception of biosovereignty can be traced to the UN's 1993 adoption of the Convention on Biological Diversity (CBD). Article 3 of the convention stipulates that 'states have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction'. In other words, while the Convention is premised on the recognition that the conservation of biodiversity is a common concern of humankind, it also affirms the right to control genetic resources and associated traditional knowledge as part of 'national sovereignty'. It must be noted that the Convention on Biological Diversity is primarily an instrument for environmental protection, thus human genetic resources is not covered by the Convention. In the mid-2000s, Indonesia was at the epicentre of an avian influenza outbreak. Samples collected from patients were initially sent to international laboratories affiliated with the World Health Organization's Global Influenza Surveillance Network (GISN). However, after detecting that some pharmaceutical companies in developed countries were profiteering from these specimens by developing treatments and vaccines which developing countries may not be able to afford, the then Indonesian Health Minister Siti Fadilah Supari announced that the viruses isolated from within Indonesian jurisdiction as sovereign property and refused further sample sharing. While since this controversy, sovereign rights were extended to viral genetic resources, there remains no explicit global agreement on ownership regimes over human genetic resources (Rhodes, 2016; Hong, 2018).

However, it is safe to say that CBD forms the foundations of the modern conception of biosovereignty. In relation to the discussion of this paper, there are two features that I want to highlight. One, the primary aim of asserting sovereignty was to ensure 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources' (CBD Article 01). The assertion of biosovereignty is to counteract what Juan Camilo Cajigas termed as the 'biocoloniality of power', an exploitation of genetic resources under Western-dominant capitalist logic (Cajigas 2007 in Schwartz-Marín and Restrepo, 2013, p. 994). As such, the proposition of sovereignty over genetic resources is to promote common prosperity. It is not intrinsically against the usage of biomaterials or against its global exchange. Rather it underlines the recognition that how genetic resources are used has a significant consequence for the public good. Knowledge and biomaterial flow from the Global South to the Global North are not necessarily controversial or exploitative, but there has always been a struggle of 'epistemological advocacy' in the matrix of global geopolitics (Hayden, 2003, p. 31; Hilberg,

2022). For example, Cori Hayden's ethnography in Mexico demonstrates, bioprospecting, the 'distinctly late-twentieth-century practice' in which corporate interests exploit biomaterial or traditional knowledge from less-developed biodiversity-rich regions, originally received moderate support from some Mexican ethnobotanists, chemists, and pharmacologists. This is because these local professionals considered 'the project of "translating" traditional or folk medicine into chemical compounds as a mode of advocacy itself' and is 'instrumental to the production of the "credibility" of (and now, dividends for) traditional knowledge' (Hayden, 2003, p. 32). It was only when multinational corporations turned such knowledge translation into a lucrative industry that a wave of exploitation was ushered in (Fredriksson, 2021). Thus, sovereignty claims in the modern age particularly resonate with decolonisation projects, which recognise the right to self-determination of all people (Williams, 2007, p. 6 original emphasis).

Relatedly, a second point that I want to draw attention to is the fact that national 'sovereignty' over genetic resources, or biosovereignty, was not conceived as an exclusive entitlement to usage or benefits, but a prerogative to set the terms of accessing biological resources within their jurisdiction. To put it in another way, sovereignty over genetic resources is constructed both as a sovereign right (i.e. the authority over resources) and as a sovereign duty (i.e. to act in the interest of the people) (Cotula, 2018). As biomedical science has become a data-intensive science (Dunn and Bourne, 2017; Altman and Levitt, 2018), the governance of human genetic resources is also related to a more general issue of data sovereignty, which, echoing the definition of biosovereignty, refers to 'the control of data flows via national jurisdiction' (Hummel et al, 2021, p. 1). In fact, in relation to genomic research, data access and data sharing at scale are critical to generate clinical meaning and verifying hypotheses (McGuire et al, 2021). 'Harvesting data then not making good use of them is not morally neutral' and does not constitute a trustworthy stewardship (Horton and Lucassen, 2022, p. 5)

Sovereignty is not absolute autonomy in the absence of external interferences or domestic conflicts. In fact, sovereignty is always contextual. It is conditioned by international relations and by domestic infrastructure (Williams, 2007; Hummel et al, 2021). More importantly, it is also conditioned by meaningful negotiation and collaboration between multiple agents who may have reasonable claims to data sovereignty (Fredriksson, 2021; Hummel et al, 2021; Hilberg, 2022). While not all countries have explicitly claimed national sovereignty in human genetic resources, all countries have exercised de facto biosovereignty through their biogovernance regimes on biomedical research, clinical application and biobanking. In the sections below, I analyse current governance regimes on human genomes in the UK and in China. Particular attention will be

given to the different national outlooks on how human genetic resources and associated data should be shared and how its governing conditions can be met.

Genome UK: Seizing the Future By Facilitating Access

In September 2020, the UK released the long-term plan Genome UK: The Future of Health Care, setting out the blueprint for the next decade of genetic research in the UK. The long-term plan underlined the importance of tapping into the innovative power of social enterprise, strengthening collaboration between public and private bodies, and facilitating the translation of genome data into clinical applications. Genome UK is to enable the vision of 'mak[ing] the UK the best location globally to start and scale new genomics healthcare companies and innovations' (Department of Health and Social Care, 2020, p. 56).

The most prominent aspect of Genome UK is that widening data access and enhancing the usage of the UK's genomic datasets are key to future global competitiveness. It is a nationwide effort that involves incentivising engagement from the scientific community and also from the general public. Not only is 'readily accessible and well curated' datasets to researchers recognised as 'necessary to maximise the benefits of research', but also patients and the public were ensured 'access to their own genomic and health information and [to] have an appropriate voice in the use of their data for research' (Department of Health and Social Care, 2020, 12, 31). Furthermore, an easily accessible high quality genomic dataset is seen as a way to reinforce UK's global presence and influence. UK Biobank provides 'non-preferential access' to researchers in different countries, undertaking health-related research that is for the public good (Department of Health and Social Care, 2020, p. 36). In fact, as of 2020, UK Biobank has approved over 12,000 registrations from researchers based in over 1,500 institutes in 68 countries (Department of Health and Social Care, 2020, p. 36). In fact, 80% of data access applications it receives come from outside the UK (www.ukbiobank.ac.uk).

The socio-economic rationale behind 'mak[ing] the UK the best place in the world to access genomic data for research' is not difficult to comprehend (Department of Health and Social Care, 2020, p. 7). In addition to taking advantage of its well-curated database to attract financial and intellectual capital globally, if the UK's genomic dataset becomes the core of the world's cutting-edge life sciences, then the British people will naturally be the most direct beneficiaries of the subsequent medical knowledge and clinical application. It will also help to establish a new norm where 'new genomics-based treatments to be sold globally from a UK base' (Department of Health and Social Care et al, 2022, p. 58).

The visions embedded in Genome UK highlighted a radical transformation in how 'value' is identified and realised in genomic materials. It is a good example of a paradigm change in how bioeconomy policies are conceived. For example, a conventional impression is that it is a common practice for Global North researchers to outsource clinical trials to Global South communities for advantages such as cutting costs, speedy recruitment and weak overseas governance structure (see Cooper, 2008; Kamat, 2014; Spielman, 2015). However, in 2020, the UK was already one of the top three bases for early clinical trials of cell therapy and gene therapy in the world. Although the UK has only 0.87% of the world's population, it hosts 12% of the above-mentioned early clinical trial treatments in the world (Department of Health and Social Care et al, 2022). It is worth noting that while UK Biobank is a world-leading database with comprehensive data of 500,000 volunteer participants, 89% of the participants are from England. If its data are used as the blueprint for scientific research and innovation, the direct beneficiaries of future biomedical innovations are self-evident. Moreover, the UK also hopes to further expand its share in the world in order to become a genetic diagnosis and treatment for both common and rare diseases innovation base. The strategy was to 'support a 50% increase in the number of clinical trials over the next five years 'with a particular focus on 'grow[ing] the proportion of "change of practice' trials and trials with novel methodology over the next five years' (Department of Health and Social Care et al, 2020, p. 43). The ambition was further reinforced by two subsequent policy papers: Genome UK: 2021 to 2022 Implementation Plan published in May 202, and Genome UK: Shared Commitments for UK-Wide Implementation 2022 to 2025 published in March 2022. In addition, the UK's Department of Health and Social Security further released policy paper, Data Saves Lives: Reshaping Health and Social Care with Data in June 2022. The emphasis was not limited to expanding and diversifying datasets, but also on how to facilitate the sharing and circulation of biological information.

Genome UK and associated government policies strongly indicate that as biomedical research has become more akin to information science (Nakai, 2019), physical possession of biological material itself no longer constitutes scientific capital. For example, in 2020, the UK's Parliamentary Office of Science and Technology's briefing noted the rapid growth of the digital sequence information (DSI) of genetic resources has reduced the demand for physical genetic resources and new governance challenges and opportunities created by the disembodiment of property and knowledge (Parliamentary Office of Science and Technology, UK, 2020). In other words, the manifestation of biovalue becomes more reliant on its circulation and in its utility. The scope and frequency of a particular type of genetic

information is used critically to shape future medical knowledge, clinical norms and even priorities. Racial disparities in stem cell bank samples, for example, means that patients from Black, Asian and minority ethnic backgrounds have a significantly lower chance of finding a living-saving donors than patients with northern European backgrounds. Health inequality created by this data disparity was so immense that the issue is seen as 'Silent Crisis' in the UK (see Shepherd and Zhang in this issue). How a lack of female data has created serious limitations of medical knowledge with real-world health impact is not only well-acknowledged in the academia but is increasingly of public knowledge (see Jackson, 2019; Kadambi, 2021).

To be sure, the value of biological materials cells, genes, and tissues have never been purely limited to being in and of themselves. However, with emerging trends in biomedical research, 'biovalue' has taken on a much expanded and versatile form that is beyond data extraction and is embedded in how bio-information is interpreted, compared, synthesised, designed and generated.

The heightened strategic importance of sharing and circulation of data has accentuated rather than decreased the demand for competent exercise of biosovereignty. Balancing easy access with safeguard issues such as privacy rights, benefit sharing, genetic discrimination, and public concerns about biological surveillance called attention to the significance of having a corresponding governing capacity.

In comparison with China, there are two main themes of capacity building that are worth highlighting. One is the investment in 'hardware' innovation and upgrade. To maintain the security and fair use of biological information, in addition to the well-established access approval and ethics review procedures, the UK has also introduced new governing tools and structures. Most notable is the UK Health Data Research Alliance's (2020) development of a TREs (Trusted Research Environment) platform since 2017 to enable barrier-free large-scale parallel sharing of health-related data. In simple terms, TREs provides a firewall-protected operating environment in which different scientific teams can conduct remote analysis of anonymised health information simultaneously. This helps to reduce the risk of data leaks or abuse. If a conventional logic of controlling biological information is to rely heavily on gatekeeping through user restriction, and requires tracking and responding to risks along the whole chain of data transmission (as exemplified by the Chinese rationale discussed in the next section), then TREs demonstrates an alternative 'safe havens' approach in which health data can be accessed and analysed in a secured environment monitored by the data provider (www.hdruk.ac.uk). The TREs model has its limits, such as it cannot be applied to the needs of 'wet labs', which requires access to physical biomaterials, not just informatised data. However, the

point here is that new data sharing imperatives demand not only regulations and guidelines dictating how data 'should' be used or by whom, but also require structural and technical support to enable safe and responsible data sharing and data processing. In other words, biosovereignty is not only a prerogative that needs to be recognised, but it embodies a systematic set of rights and responsibilities that need to be safeguarded through appropriate technical and structural support.

A second theme worth highlighting is the UK's emphasis on cultivating public confidence and a sense of public partnership. Of the five governance themes stated in the implementation plan of Genome UK, the first two were on 'ethics and maintaining trust' and 'engagement and dialogue with patients and the public' (Department of Health and Social Care et al, 2022). Public access to their own data, their participation in related ethical debates and engagement efforts from the research communities are all seen as important to maintain public trust. Society's exposure to both the potential benefits and potential negative impacts of genomic research is key for better societal understanding and support. The need to correct ethnic bias historically formed in most large genetic datasets through targeted minority recruitment was also recognised, although its challenge, as Shepherd and Zhang's article in this volume demonstrates, still remains. But what is clear is an effort towards government-society partnership to further bolster the UK's dominance as a global genetic data provider. In parallel, the nationwide project 'Our Future Health' was also launched. This project strives to expand the UK biological sampling scope through the collection of biomaterial and health information of millions of volunteers, in the hope of accelerating diagnostic and treatment discoveries (ourfuturehealth.org.uk).

At the time of writing, the Genome UK initiative still has another two years ahead. It is too early to assess its success or failure, especially given that Brexit and the COVID pandemic have introduced new scenarios into bioeconomy and bioresearch, not least in the UK but globally. However, it is safe to say that the new visions set out by the UK correspond to emerging norms of how biomaterial and related information are used in cutting-edge biomedical research and the new roles biodata play in defining new horizons of medical investigations. Would the rationale exemplified by Genome UK lead to new forms of biocoloniality in which new biomedical knowledge and innovations are effectively 'enclosed' by UK-based genome data? Only if there are few alternative datasets. National dominance aside, a more likely form of bio-disparity is the chronic problem of lack of racial diversity within a national dataset.

China: Securitising Data Access as Correction to Historical Injustice

Despite leading the world's scientific output both by quantity and quality and being a major player in global genomic research (NISTEP, 2022),

China remains in a catching-up position when it comes to governing human genetic materials. It took two decades of deliberation before China established its current national regulation on human genetic resources in 2019. As demonstrated below, while there have been several rounds of nominal consultations, the making of the legislation appeared to be driven mostly by public servants with limited coordination with scientific, social and legal studies experts. As a result, the orientation of the regulations is mainly rooted in biopiracy and bioprospecting concerns, with minimal reflection on the changing roles of biomaterial and biodata in contemporary biomedical research and in bioeconomy. China remains overly reliant on punitive administrative measures that restrict data access. While its intention is to protect China-based innovation, its narrow understanding of biosovereignty has paradoxically become a new barrier for securing future research competitiveness and future health benefits for its population.

Similar to many other biodiverse countries in the Global South, such as Brazil, India and South Africa, China has long struggled to institutionalise effective rules on biopiracy and bioprospecting. China's earliest regulation was the 1998 Interim Measures for the Administration of Human Genetic Resources (hereafter Interim Measures) jointly promulgated by China's Ministry of Science and Technology and the Ministry of Health, in response to a series of exploitative Western medical research conducted in China in the 1990s, which came to be known as the 'Gene War of the Century' (Shou, 1997; Xiong, 2021). One most cited scandals concerned Harvard Professor Xiping Xu who led a local Chinese research team and collected tens of thousands of blood samples from illiterate peasants in Anhui province without proper informed consent (Keim, 2003). In the years to come, Chinese bioethicists often referred to this episode of exploitative bioprospecting as emblematic of the 'Wild West', a rebuttal to developed countries' 'Wild East' derision of China's early regulatory vacuum in the life sciences (Zhai et al, 2019). While the 1998 Interim Measures have set out general principles of promoting 'equal and mutually beneficial international collaborations and exchange' (article1) and have mandated that only China-based partners can apply for government approvals on genetic data usage and sharing in international collaborations, the regulations were relatively sketchy. In the decades that followed, China's legislation over human genetic resources has moved slowly (see Table 1 for the list of key milestones). It was not until two decades later, in 2019, that the State Council (China's highest executive body) approved the *Regulation of the People's Republic of China on the Administration of Human Genetic Resources*. It took another three years for China's Ministry of Science and Technology (MOST) to publish *Detailed Implementing Rules for Regulation on Administration of Human Genetic Resources* (hereafter Detailed Implementing Rules) for public consultation.

Table 1: Summary of Key Milestones in China's National Regulations on Human Genetic Resources

Year	Legislation
1998	Interim Measures for the Management of Human Genetic Resources
2005	Draft Regulations on the Management of Human Genetic Resources
2012	Regulations on the Management of Human Genetic Resources (Draft for Public Comment)
2019	Regulation of the People's Republic of China on the Administration of Human Genetic Resources
2022	Detailed Implementing Rules for Regulation on Administration of Human Genetic Resources (Draft for Public Comment)

Source: Author on Compilation

According to a report produced by Deloitte, between 2016 and 2020, while the number of international studies with a China component and corresponding human genetic resource applications have steadily increased, the approval rate has steadily declined (Xie, Qian and Dong, 2021). The *Detailed Implementing Rules* publicised by the Ministry of Science and Technology in 2022 was widely regarded as China's further tightening its control over the sharing and usage of genetic data (Mallapaty, 2022). China's nationalist paper *Global Times* (2022) interpreted this as an effective 'ban' on using Chinese human genetic resources abroad. This is because *Detailed Implementing Rules* stipulates that only Chinese research institutions can collect, store and process Chinese human genetic resources. Overseas organisations and individuals, including institutions in which foreign stakeholders have financial control or 'major' administrative influence (Article 12) are no longer allowed to collect or store Chinese human genetic resources.

In addition, the *Detailed Implementing Rules* have made more specific requirements in the filing and handling of data and set specific conditions for benefit sharing. While the original intention is to protect China's biomedical research interest and secure Chinese researchers more

leverage in international collaborations, many researchers considered the new stipulations in fact restricts Chinese scientists' international outreach and disincentivise collaborations. For example, Shuhua Xu, a geneticist at Shanghai told *Nature* that the new requirement for 'security reviews' of datasets involving more than 500 samples is a relatively small number for genetic research (Mallapaty, 2022). In addition, applying for permission from MOST is complex and time-consuming with no clear criteria publicised. It also significantly restricted Chinese scientists' capacity to deposit genetic data on global publicly accessible repositories, and their desire to join international research initiatives due to worries of a potential violation of this new data sharing legislation (Sharma, 2022).

The perverse effect of China's recent regulations on human genetic resources is mainly rooted in two inter-related issues. One is Chinese policy-makers' lack of engagement with the research community and society in general. The other is an over-fixation of a historical loss to biopiracy, which has blinded Chinese regulators from recognising the changing landscape of global biomedical research. I explain both points in turn through my policy consultation experience.

In April 2022, I had the privilege of being the only foreign national among the 22 experts invited to a policy consultation on the *Detailed Implementing Rules*, co-organised by Huazhong University of Science and Technology, the host of two main national major research projects on life science governance, and by the Bioethics Expert Committee of the Chinese Society for Dialectics of Nature. The panel consists of academics from the fields of bioethics, philosophy, law, sociology, stem cell research, cancer research and biobanking. The outcome was a 40 pages of recommended revisions (Lei et al, 2022). In the meeting, I proposed eight specific recommendations, evolving around promoting accountable data sharing internationally and establishing better government-society partnership to boost public confidence and public support. These were all included in the recommended revisions (Lei et al, 2022).

In contrast to Genome UK's comprehensive agenda of engaging with the public and mobilising their interest and participation, the *Detailed Implementing Rules* resembled more of a top-down government-led gatekeeping. The very limited input from wider scientific or legal communities in the drafting of the *Detailed Implementing Rules* was also reflected in its wording: a number of the scientific terminologies used were quickly identified as inaccurate or too general to be operational by the panel (Lei et al, 2022, 36). There were also a few places where legal experts pointed out a lack of precision or a conflict with other regulations. There was no mention of public access to their health data, nor an indication of involvement of professional associations or social enterprise (Lei et al,

2022, 5-8, 17-18). Another striking absence is a commitment to research infrastructure upgrades. Article 19 on 'information system building' was mainly on building a reporting system where it facilitates administrative tasks 'such as registration, administrative approval and record creation'. Article 20 on 'foundational platform and databank building' is mainly focused on standardisation and professionalisation of biobanks, with no guidance on data management, such as internet security, cross-institution sharing, etc.

It seems the primary consideration of *Detailed Implementing Rules* was not about better management of bio-data or bio-material per se, but about concentrating powers to manage people. Chinese authorities seem to consider 'biosovereignty' as a 'thing' that could be preserved by limiting contact. They fail to see 'biosovereignty' as a bundle of rights and prerogatives whose actualisation necessitates corresponding technical support, as well as the coordination of and contribution from various stakeholders at multiple levels. Relatedly, safeguarding biosovereignty was effectively reduced to guarding against foreign access and to economic calculations of benefit sharing. *Detailed Implementing Rules* was more successful in mapping out a vision of administrative surveillance carried out by (national level) authorities than a vision on the future of biomedical research.

Legal experts at the consultation pointed out that the *Detailed Implementing Rules* had an imbalanced emphasis on punitive measures for wrongful sharing, at the cost of overlooking specifying the service or training that regulatory institutions can provide to enable and facilitate consistent compliance (Lei et al, 2022, p. 37). In fact, almost 1/3 of Chapter 6 of the *Detailed Implementing Rules* was focused on penalties. This debilitating effect of red tape around the access and circulation of data was raised by both scientists and social scientists. In the meeting I pointed out that current draft rules indicate an ethos of 'safekeeping' of genetic resources rather than responsible usage of them. A number of panelists echoed my view that biovalue is embedded in the frequency of biomaterials and bioinformation being put to use and in the scope of their circulations. Directors of regional biobanks in China were particularly worried that the safekeeping ethos would further aggravate the segregation of local biobanks, which are already battling with low willingness for data sharing, duplication of investments and low sample utilities which all negate a key function of human genetic biobanks which is to serve the needs of health research (Lei *et al,* 2022, p. 37).

Perhaps a more telling example of Chinese regulators' lagging behind the contemporary research landscape was the mandatory benefit sharing clause, which generated much controversy among scientists and industry practitioners in China. It is useful to be reminded that, as noted at the beginning of this section, China's regulation on human genetic resources

was reactionary to the 'Gene War of the Century'. China's policy gap left its society exposed to biopiracy and bioprospecting was a recent memory. Consistent with various interim measures and the eventual 2019 national legislation, there was an evident post-colonial sentiment in the Detailed Implementing Rules' articles on mandatory benefit sharing.

For example, Article 16 of *Detailed Implementing Rules* dictates that any patent rights as a result of research based on Chinese human genetic resources should be co-owned by Chinese and foreign collaborators. Article 17 further stated that when benefit sharing with international collaborators cannot be agreed upon on the basis of research contributions, the benefits should be 'equally' split between Chinese and non-Chinese partners. While both articles were to give Chinese researchers legal backing to their negotiation with foreign counterparts, scientists at the consultation meeting noted that such clauses oversimplified the complexity of research collaborations, in which interests are often much more diverse and entangled than intellectual property rights or immediate economic benefits. Anecdotally, one legal scholar also pointed to examples where Chinese research teams would not honour the mandated benefit sharing with collaborators in other developing countries. Explicit mandates of an absolute equal split (such as Article 17) would not protect Chinese scientists' interests but only isolate them from the global human genetics community, a view also expressed through media (see Mallapaty, 2022).

At the time of writing, China has yet to publish revised *Detailed Implementing Rules* following its public consultation period. Similar to many other non-Western countries, China was also once a victim of biopiracy and bioprospecting. Thus, a national human genetic resource regulation was a much anticipated legislation that could defend the Chinese scientific community and its society from future injustice. It was expected to promote a bioeconomy not for the few but for the common good. However, the practice and norms of biomedical research have drastically changed over the past few decades. China's 2019 and 2022 legislation on human genetic resources raise an interesting pair of questions for the nation-states: Can the protection of biosovereignty be delivered through administrative decisions and be detached from the state of bioscientific research? Conversely, policy makers also need to consider to what extent is enabling national bioscientific research capacity a constitutive element of conducting biosovereignty, and whether that capacity-building can be restricted by a 'nationalist' lens.

Given the interruption caused by the COVID pandemic, the full effects of these new regulations on the global presence of Chinese biomedical science and global studies on Chinese human genetic data are yet to be seen. As researchers and biomedical enterprises both inside and outside of China have shown concerns over the impact of China's restriction over data sharing, it may not be far-fetched to ask: Would Chinese authorities'

efforts to correct historical injustice over issues of narrow biosovereignty paradoxically create a secondary epistemic injustice for Chinese life science communities?

Biosovereignty Reconsidered

Sovereignty is a slippery concept, for it 'is a mingled compound of idea, reality and goals' that is subject to continuous 'modification arising from changing goals or changing factual requirements' (Lee, 2009). Biosovereignty, which incorporates both the sovereign authorities over genetic materials (e.g. genetic sovereignty) and related information (e.g. data sovereignty), is and should always be a concept-in-the-making, defined contextually and continent to socio-technical changes. However, recent British and Chinese national regulations on human genomic resources remain informative on how biosovereignty could and should be conceived.

Firstly, biosovereignty is not a property or a privilege reserved for the state. At its core, sovereignty is a 'supreme authority within a territory' (Philpott, 2020). Yet as both the UK and China cases have shown, the realm of genetic research is where geopolitical, epistemic, economic, cultural and personal priorities intersect and overlap. The supreme authority within one territory may unavoidably compete or be in conflict with the authority of another (e.g. the need to align individual authority over their personal data with biobank's authority over data usage, or China's authority over data sharing was seen as in potential conflict with scientists' authority over where to publish). This reinforces rather than contradicts Hobbes' (1651) point in Leviathan that sovereignty is a social contract built on the consensus of the governed.

Secondly, expanding on the above point, biosovereignty, as an aggregated authority from an assembly of territories (or social spheres), represents a fundamental balance of consensus. This is why having diverse publics involved and continuously seeking their confidence and support matters in national visions of genomic research. This is also why human genetic regulations oblivious of myriad societal power relations would generate concerns and would resemble more of a practice of autocracy than an exercise of biosovereignty.

China's invocation of sovereignty over human genetic materials recalls the Global South's struggle against the biocoloniality of power. However, China's 2019 Regulation and associated 2022 Detailed Implementing Rules seem to weaken Chinese human genetic research community's global influence and dim the prospect of public health benefits. In contrast, by overturning the logic of data possession to data circulation, the UK seems to be enroute to secure future financial and health advantages by capitalising on its genomic data.

An assertion of biosovereignty was originally conceived as a way to counterbalance the colonial legacy of a West-Rest power dynamic. This also helps us to comprehend what, countries such as China and Indonesia are really demanding when they invoke the language of 'biosovereignty': At its core, the struggle for biosovereignty is about securing a nation's collective self-determination over the use of biomaterials and over the development and application of associated science and technology. However, power-imbalances and political hegemonies also exist within a nation-state. Not all voices are equally recognised as part of a national collective. Thus, exercising biosovereignty may not necessarily be an act of epistemological advocacy. It is perhaps more accurate to say that biosovereignty, as an assemblage of ideals, infrastructures and network of capitals, could challenge, alter or reinforce existing political or epistemic hegemonies. This precariousness in biosovereignty's effect lies in the fact that it requires a simultaneous assumption of a right and a duty: the right to set the conditions for the use of biomaterials and associated data, and the duty to ensure that those conditions are intelligible and sensible to the political audience. It also lies in the fact that biosovereignty itself is not static, but its meaning is contingent, primarily upon the evolving and expanding roles genetic materials play in biomedical science and upon the role of biomedical science in society.

References

Alliance Nationale pour les Sciences de la Vie et de la Sante (Aviesan) France. 2016. Genomic Medicine France 2025. Paris: Aviasan

Altman, Russ B and Levitt, Michael (2018) 'What is Biomedical Data Science and Do We Need an Annual Review of It?' Annual Review of Biomedical Data Science, 1, i-iii. https://doi.org/10.1146/annurev-bd-01-041718-100001

Cooper, Melinda (2008) 'Experimental Labour—Offshoring Clinical Trials to China'. East Asian Science 2, 73–92. https://doi.org/10.1007/s12280-008-9040-y

Cotula, Lorenzo (2019) 'Reconsidering sovereignty, ownership and consent in natural resource contracts: From connects to practice'. European Yearbook of International Economic Law 2018, Volume 9. DOI: 10.1007/8165_2018_23

Department of Health and Social Care (2022) Data saves lives: reshaping health and social care with data, 15 June. https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data

Department of Health and Social Care, Department for Business, Energy & Industrial Strategy, Office for Life Sciences, and Lord Bethell of Romford (2020) Genome UK: the future of healthcare. 26 September https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare

Department of Health and Social Care, Department for Business, Energy & Industrial Strategy, Office for Life Sciences, Welsh Government, The Scottish Government, and

Department of Health (Northern Ireland) (2022) Genome UK: shared commitments for UK-wide implementation 2022 to 2025, 18 March. https://www.gov.uk/government/publications/genome-uk-shared-commitments-for-uk-wide-implementation-2022-to-2025/genome-uk-shared-commitments-for-uk-wide-implementation-2022-to-2025

Dunn, Michelle C, Bourne Philip E (2017) Building the biomedical data science workforce. PLoS Biol 15(7): e2003082. https://doi.org/10.1371/journal.pbio.2003082

Fatumo, S., Chikowore, T., Choudhury, A. et al. (2022) A roadmap to increase diversity in genomic studies. Nat Med 28, 243–250 (2022). https://doi.org/10.1038/s41591-021-01672-4

Fredriksson, Martin (2021) Dilemmas of protection: decolonising the regulation of genetic resources as cultural heritage, International Journal of Heritage Studies, 27:7, 720-733, DOI: 10.1080/13527258.2020.1852295

Global Times (2022) 'Chinese human genetic resources to be banned for use abroad: Ministry of Science and Technology'. Global Times, 23 March. Online access: https://www.globaltimes.cn/page/202203/1256572.shtml

Green, E.D., Gunter, C., Biesecker, L.G. et al. (2020) Strategic vision for improving human health at The Forefront of Genomics. Nature 586, 683–692. https://doi.org/10.1038/s41586-020-2817-4

Hayden, C. (2003) When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico. Princeton: Princeton University Press.

Hilberg Eva (2022) Molecular sovereignties: patients, genomes, and the enduring biocoloniality of intellectual property. Biosocieties. 7(4):695-712. doi: 10.1057/s41292-021-00237-5. Epub 2021 Jul 3. PMID: 34249139; PMCID: PMC8254056.

Hong, Avery (2018) 'Viral Sovereignty: Equity and Global Health Risk Controversy', Global Health Forum. Georgetown University. Online access: https://globalhealth.georgetown.edu/posts/viral-sovereignty-equity-and-global-health-risk-controversy

Horton, Rachel and Lucassen, Anneke (2022) 'Ethical considerations in research with genomic data', The New Bioethics, 1-15 doi: 10.1080/20502877.2022.2060590.

Hummel, Patrik; Braun, Matthias; Retter, Max and Dabrock, Peter (2021) 'Data sovereignty: A review', Big Data & Society, January-June:1-17. https://doi.org/10.1177/2053951720982012

Jackson, Gabrielle (2019) 'The female problem: how male bias in medical trials ruined women's health' The Guardian (UK), 13 November. Online access: https://www.theguardian.com/lifeandstyle/2019/nov/13/the-female-problem-male-bias-in-medical-trials

Kadambi, Achuta (2021) 'Achieving fairness in medical devices', Science, 372 (6537), 30-31 https://www.science.org/doi/10.1126/science.abe9195

Kamat, Vinay R. (2014) 'Fast, cheap, and out of control? Speculations and ethical concerns in the conduct of outsourced clinical trials in India,' Social Science & Medicine, 104, 48-55.

Keim, B. (2003) Out of Sight, Out of Mind: How Harvard University Exploited Rural Chinese Villagers for Their DNA. Genewatch, 16, 10-11

Lee, Leo-Felix (2009) ‘Sovereignty over, ownership of, and access to natural resources’, in A. Dan Tarlock and John C. Dernbach ed. Environmental Laws and Their Enforcement. Oxford: Eolss Publishers

Lei, R., Jiao, H., Liu, H., Shi, J., Zhang, J. Y., Zhang, H., Yao, P., Wu, C., Zhang, D., Wang, Y. and others. (2022) Policy Recommendations for China’s ’Implementing Rules for Human Genetic Resources Management’. HUST Center for Bioethics.

Mallapaty, Smriti (2022) China expands control over genetic data used in scientific research, Nature 605, 405. doi: https://doi.org/10.1038/d41586-022-01230-z

McGuire, A.L., Gabriel, S., Tishkoff, S.A. et al. The road ahead in genetics and genomics. Nat Rev Genet 21, 581–596 (2020). https://doi.org/10.1038/s41576-020-0272-6

Mills, Demaris (2022) ‘Igniting A New Genomics Revolution’. Forbes, Online access: https://www.forbes.com/sites/forbestechcouncil/2022/04/29/igniting-a-new-genomics-revolution/?sh=ac3c7672a3ba

Ministry of Science and Technology, China (2022) Detailed Implementing Rules for Regulation on Administration of Human Genetic Resources (Draft for Public Comment). Beijing: Ministry of Science and Technology of the People’s Republic of China

Ministry of Science and Technology and the Ministry of Health, China (1998) Interim Measures for the Administration of Human Genetic Resources. Beijing: Ministry of Science and Technology and the Ministry of Health,

National Institute of Science and Technology Policy (NISTEP) (2022).Japnaese Science and Technology Indicators 2022. NISTEP Research Material No 318. Tokyo: National Institute of Science and Technology Policy https://doi.org/10.15108/rm318e

Nakai, Kenta (2019) ‘Information Science Should Take a Lead in Future Biomedical Research’,

Engineering, 5(6), 1155-1158,

Neufeld, Dorothy (2021) ‘The Genomic Revolution: Why Investors Are Paying Attention’, Visual Capitalist. Online access: https://www.visualcapitalist.com/sp/the-genomic-revolution-why-investors-are-paying-attention/

Parliamentary Office of Science and Technology, UK (2020) POSTNOTE 630 September 2020 Digital Sequence Information. London: Parliamentary Office of Science and Technology

Philpott, Daniel (2020) ‘Sovereignty’, in Edward N. Zalta ed, The Stanford Encyclopedia of Philosophy. Online access: https://plato.stanford.edu/archives/fall2020/entries/sovereignty/

Rhodes, Catherine (2016) Potential International Approaches to Ownership/Control of Human Genetic Resources. Health Care Anal (2016) 24:260–277

DOI 10.1007/s10728-015-0300-4

Schwartz-Marín, Ernesto and Restrepo, Eduardo. (2013) Biocoloniality, Governance, and the Protection of ‘Genetic Identities’ in Mexico and Colombia. Sociology. 47(5):993–1010. doi: 10.1177/0038038513494506.

Sharma, Yojana (2022) ‘New genetic research rules: What impact on collaboration?’ University World News, 7 April, https://www.universityworldnews.com/post.php?story=20220407145532404

Shou, P. and Li, H. (2001) Huge dispute over China-US collaboration, heated gene ethics debate at Hangzhou conference. Southern Weekly, 6 April. http://www.china.com.cn/txt/2001-04/06/content_5027995.htm.

Standing Committee of the National People's Congress, China (2020) Biosecurity Law of the People's Republic of China. 17 October 2020. Beijing: Standing Committee of the National People's Congress

State Council, China (2019) Regulation of the People's Republic of China on the Administration of Human Genetic Resources. Beijing: State Council of the People's Republic of China

Spielman, Bethany (2015) 'Nonconsensual Clinical Trials: A Foreseeable Risk of Offshoring Under Global Corporatism'. Bioethical Inquiry 12, 101–106 (2015). https://doi.org/10.1007/s11673-014-9596-2

UK Health Data Research Alliance (2020) Trusted Research Environments (TRE)

A strategy to build public trust and meet changing health data science needs. 30 April https://ukhealthdata.org/wp-content/uploads/2020/04/200430-TRE-Green-Paper-v1.pdf

Williams, David (2006) 'Ownership, sovereignty and global governance' Global Economic Governance Programme Working Paper No 2006/22. Oxford: University of Oxford.

Xie, David; Qian, Megan and Dong, Kylie (2021) Safeguarding Biopharma R&D: New Heights in China's Human Genetic Resources Management. Deloitte Touche Tohmatsu Limited

Xiong, L. (2021). Xiong Lei | Investigate Harvard's Poaching of Chinese Genes, Experience the Contest with Capital. Netease News 3 January. https://www.163.com/dy/article/FVDE23IC0514C63D.html.

Zhai, X., Lei, R., Zhu, W. and Qiu, R. (2019) Chinese Bioethicists Respond to the Case of He Jiankui. The Hastings Centre, 7 February. https://www.thehastingscenter.org/chinese-bioethicists-respond-case-jiankui/.

Websites:

UK Biobank: www.ukbiobank.ac.uk

Trusted Research Environments (TREs): https://www.hdruk.ac.uk/access-to-health-data/trusted-research-environments/

Germany, genomeDE strategy: https://www.bundesgesundheitsministerium.de/en/en/international/european-health-policy/genomde-en.html

The European Union's '1+ Million Genomes' Initiative: https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes