Basta con il biolaw: What about knowledge and trust?

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Lasciate ogne speranza, voi ch'intrate
Abandon all hope, ye who enter here

Canto I, Inferno, Dante Alighieri

1. Introduction*

One could be forgiven for surveying the current landscape of norms that regulate genetic data and having the first line of Dante's *Inferno* in the back of one's mind. The terrain is complex and is full of unsightly scenes. And unlike the mellifluous *terza rima* of the magnum opus, the going is tough and there is no guarantee that one will emerge to see again the stars.

The COVID-19 pandemic exists within this universe of norms. The crisis has brought into sharp relief the heterogeneous nature of the public interest rationale in our normative systems. The public interest is what grounds (justifiably) draconian measures such as enforced isolation, mandated wearing of masks in public, and other such incidents that are now part of our new normal. Yet, social life will only again be recognizable through advances in basic and translational science.

COVID-19 host genetics research, whereby the genome of the person infected with COVID-19 is sequenced and analyzed, holds much potential to further our understanding of the variability in response to SARS-CoV-2 and, in turn, to improve clinical care. Following a spring 2020 call for international COVID-19 data sharing and solidarity from the World Health Organization, Wellcome, the European Commission, and others, where is the much-needed international data?

Drawing from recent biolaw events, both pandemic and non-pandemic, we will highlight some of the traps of genetic exceptionalism (1) and knots of data protection (2) that genomics currently faces. We then turn to a creation of a ladder of knowledge and trust to possibly deliver us from the status quo (3).

2. Traps of genetic exceptionalism

One key, ongoing issue as regards the ethico-legal dimensions of genetic data relates to genetic exceptionalism. At its core, genetic exceptionalism posits that genetic data merits different treatment in law and ethics by the very fact that the information is genetic. It has been called into question by others. Genetic exceptionalism is a powerful social, political, legal, and ethical idea that can fuel the propagation of norms. By way of illustration, the Supreme Court of Canada recently upheld the constitutionality of the federal *Genetic Non-Discrimination Act* in part because the "potential for genetic test results to reveal highly personal information about the individual tested and their relatives is immense"[1] and

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[1] *Reference re Genetic Non-Discrimination Act* 2020 SCC 17 per Abella, Karakatsanis, and Martin JJ at para 88.

because genetic information is "uniquely elemental to identity, and uniquely vulnerable to abuse".[2] The intensity of language that the members of the Court employ raises eyebrows and underscores genetic exceptionalism.

Indeed, nowhere is genetic exceptionalism more evident than in the past 25 years of legislation prohibiting "genetic" discrimination. Such legislation seeks to protect access to health, life, and disability insurance and prevent discrimination by employers. Yet, the only evidence we have thus far of genetic discrimination having a material effect on people's lives is in the realm of life insurance. Individuals with a family history of genetic illnesses will forego essential presymptomatic testing for fear of being denied life insurance.[3] The fear that genetic discrimination inspires may lead to overbroad laws that essentialize genetic information and which do not serve their purported policy objectives.

Singling out genetics under law can actually create additional problems of justice and fairness as discrimination based on physical and mental disabilities has already been long prohibited under human rights law and could well be an avenue for any genetically based injustice. Genetic exceptionalism may further exacerbate the social stigma and perceived "abnormality" of genetic conditions as distinct from other medical conditions. Singling out genetics over other health information may also give a false sense of security. With the -omics revolution, other unique, probabilistic insights can be drawn about individuals, such as with polygenic risk scores, and on which important individual-level decisions may be made. Current approaches to genetic discrimination tend not to have sufficient flexibility to protect against multi-faceted informational and discriminatory harms.

This biolaw trend of singling out genetic data has had a spillover effect beyond the domain of genetic discrimination. Explicit participant consent is typically required to examine the role of genetic factors in research. For prospective studies, this is not an issue. Where, however, important retrospective data analysis is carried out in the public interest, issues may arise. For example, host genetic data from COVID-19 patients is missing from the early months of the first wave of the pandemic. Samples and data collected prior to the creation and ethics approval of multi-site research endeavours had no possibility of prospective participant consent. Although still too early to take stock of the effects the inaccessibility of this data has caused, a postmortem is in order when we are on the other side of the pandemic.

3. Knots of data protection

Related to genetic exceptionalism, the normative claims of data protection over genetic and health-related data have the scientific community in a bind. We have plenty of biolaws, but few, if any, aim to *promote* international collaboration in a way that strikes a proportionate balance between the fundamental data protection and privacy interests of individuals and the collective interest of humanity in the fruits of scientific research. Gone is the age where scientific advancement is the brainchild of a handful of individuals whose data scarcely left their lab notebooks. Instead, insights are drawn through intense, international collaboration where the broad sharing of data is needed.

[2] *Ibid.* per Abella, Karakatsanis, and Martin JJ at para 92.

[3] M. ROTHSTEIN, *Can Genetic Nondiscrimination Laws Save Lives?*, in *Hastings Center Report*, 51, 1, 2021.

Instead of biolaw that supports collaboration, we witness the imposition of cumbersome legal processes on data sharing between institutions and countries, due to the already existing data silos and legal drawbridges. Data linkages need to be robust and secure, but also efficient and low-cost. Genetic and familial medical records and administrative health data should be further linked. While after a decade, national resources such as biobanks have succeeded in lowering some of the legal drawbridges, the same is not true for the transfer of medical and genetic data across jurisdictions.

Consider the European Data Protection Board (EDPB)'s statement on COVID-19 research. The EDPB merely states that international cooperation is "probably" required and that international data transfers "may" be implied.[4] (To say nothing of the complexities genetic and health-related research faces for international transfers following the *Schrems II* decision.) The EDPB's guidelines "lack both any sense of urgency and any consideration of the public good, and fail to take into account other fundamental rights, societal interests, and scientific considerations".[5] By and large, current approaches to the *General Data Protection Regulation* have lost sight of its recitals, which are meant to guide its interpretation and emphasize the need to strike a proportionate balance of fundamental rights and to promote the welfare of citizens.

4. A ladder out: prioritizing knowledge and trust

Policy making requires a strong social nexus. Generalized social sensitivity to genetic data can give rise to a "prohibition reflex", whereby with certain advances, the public swiftly demand a law against "it".[6] Yet, despite these pressures, there is little empirical data regarding the public's attitudes about the sharing of genetic data and of their genetic data literacy. A first-of-its-kind global survey of 36,268 individuals across 22 countries (and in 15 languages) indicated that those individuals who had greater knowledge of genetics and trusted the users asking to use their genetic data were more likely to be in favour of donating data.[7] This suggests that knowledge and trust are central to delivering on the promise of genetics. Both are fiercely difficult to establish. A simple prohibition does not serve the former and only serves the latter when the prohibition is tailored to preventing behaviour that is repugnant to social expectations.

Promoting knowledge calls for a reasoned look at genetic data to take stock of its features and implications. *Any* data type has its own distinguishing characteristics. Indeed, a taxonomy of data would not be possible without recognizing such characteristics. Rather than saying *simpliciter* that genetic data is different, we can look at the ways in which it is functionally different. Yes, genetic data can give us probabilistic insights about one's future health status. But, so does one's postal code (as a proxy for both

[4] European Data Protection Board, *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak*.

[5] J. Bovenberg et al., *How to fix the GDPR's frustration of global biomedical research*, in *Science*, 370/6512, 2020, 41.

[6] B.M. Knoppers, *Scientific Breakthroughs: The Prohibition Reflex (From IVF to AI)*, 2019 Friesen Lecture at the University of Ottawa, available at https://www.youtube.com/watch?v=TnA6f4Jr2FI. See also B.M. Knoppers, *Does policy grow on trees?*, in *BMC Medical Ethics*, 15, 87, 2014.

[7] A. Middleton et al., *Global Public Perceptions of Genomic Data Sharing: What Shapes the Willingness to Donate DNA and Health Data?*, in *The American Journal of Human Genetics*, 107, 2020, 743-752.

environmental and socio-economic factors). Indeed, even conditions with significant familial aggregation, such as type-2 diabetes and obesity, are increasingly understood as the result of complex relationships between and among genetic, epigenetic, and environmental factors.

Further reflecting on the relational aspects of genetic data, familial implications emphasize the importance of examining the ambit of the (expanding) duty of care that clinicians owe not only to patients but also to family members. Potential ways to mediate among competing priorities such as the right not to know and the duty to warn must also be considered and translated into appropriate contexts through tools such as familial consent clauses. Perhaps, however, such work is better contextualized within a broader debate that patients need to be in dialogue with their genetic relatives and relevant healthcare professionals regarding the implications of any diagnosis or risk factor for others.

Increasing scientific literary, and genetic literacy in particular, requires broad coordination between the State and civil society in providing both accurate, accessible information and the creation of education opportunities for children, adolescents, and adults alike. Indeed, awakening the human right to science implicates better scientific education. Beyond prohibitions, trust requires that what actually happens with genetic data accords with the expectations of interested individuals and groups. One hopes that, in the *longue durée*, the dialectic between knowledge and trust will create evidence-based policy that supports international collaboration.

5. Conclusion

Genetic testing is no longer only for individuals with rare diseases, nor for research purposes alone. With the development of clinical genomics services, the importance and relevance of genetic information for medical diagnoses and care is greater than ever. Stewardship of this area of biomedicine calls for policy that supports knowledge and trust of actual and future patients and citizens alike.

We have come a long way from the 1996 Bermuda Principles, which mandated the rapid, open release of genetic sequences for the benefit of humanity. In the intervening years, we have become an information society with acute concerns about unscrupulous uses of personal data. Concerns about informational harms, discrimination and stigmatization, combined with notions of genetic exceptionalism, have largely caused policy discussions to lose sight of the need to secure benefits alongside reducing the likelihood of harms.

Any biolaw, then, must have this concern of proportionately balancing risks and benefits at its heart. Autonomy and privacy must be furthered alongside strong, open science. Long ago, scholars identified that genetic data implicated the interests of multiple groups such as the proband, their genetic family, healthcare professionals, researchers, the State, insurance companies, and others. The proband's prerogatives will be the starting point, but they alone cannot determine the course of policy making. Rather, any sensible normative framework must balance these varied interests in a way that is sensitive to context and to a society's core values and principles.

The limitations of (statutory) law should also be recognized. Positions may crystallize in a way that is increasingly in tension with contemporary scientific knowledge. Do not let overly simplistic accounts of genetic exceptionalism fool you. Complexity must be embraced in conjunction with normative flexibility in the face of such a rapidly progressing domain.

We encourage lawmakers and policymakers alike to seize upon the entire normative toolkit

at their disposal: policies, standards, memoranda of understanding, regulations, international declarations, codes of ethics, and, if appropriate, primary legislation (statutes). These norms should not claim the entire decisional space. There must be room for transparent, professional discretion combined with effective mechanisms of accountability. If anything, the COVID-19 pandemic highlights the urgency to ensure that clear pathways exist for the invocation of the public interest by trusted experts who are accountable to the public.