The Frontiers of DNA Regulation: Developing a National Policy Framework Encouraging Transparency, Security, and Cost-efficiency of Genetic Technology and Data

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Executive Summary: Genetic sequencing informs research, policy, and regulatory decisions that impact national priorities like agriculture, forestry, and human health. Emerging high-throughput sequencing (HTS) technologies are disrupting these sectors by providing precise information more quickly, thus raising concerns regarding responsible adoption by governments. The challenges of HTS include a lack of infrastructure, guidelines for data stewardship, and standardization of methods. Poor HTS practices can lead to more than bad data; without a policy framework, governments face safety, security, and quality risks. Without controls, increasing use and application of HTS could lead to privacy breaches, genetic discrimination, and disadvantageously high-cost models. Despite the proliferation of HTS in public and private sectors worldwide, we were unable to identify any national policy frameworks regulating its adoption or use. International networks are developing guidelines in specific areas (e.g. plant health diagnostics and precision medicine). However, these recommendations lack implementation policies. In Canada, used here as a case study, few government departments and agencies (henceforth 'DAs') have policies on genetic sequencing. Since the development of national HTS policy frameworks may offer substantial benefits and mitigate risks, we present the following policy options:

(1) Centralized: funding government housed HTS infrastructure while developing a national policy framework for genetic sequencing
(2) Semi-centralized: supporting DA's in co-developing policies and infrastructure for HTS technology and genetic sequencing
(3) Decentralized: relying on programs within DAs to determine and meet their HTS infrastructure and policy needs

Given the identified risks, we recommend that national governments consider centralized (1) or semi-centralized (2) options. The former is preferable to ensure the development of cohesive policies across government bodies; however, the latter may be more immediately actionable.

I. Issue Statement

Genetic sequencing supports government programs and regulations worldwide also impacting healthcare and driving economic improvements in agriculture, forestry, and other sectors (e.g. Rothschild and Plastow 2008, Goldberg et al. 2015, Olmos et al. 2018). HTS can accomplish in months (Maree et al. 2018) what took conventional methods years to complete (Rott et al. 2017), thus disrupting sectors and industries that rely on genetic sequencing. We examine the potential impacts of HTS and make recommendations to guide national policies.

In this memo, we focused on Canada as a case study. Canada has invested in the adoption of HTS in some DAs but has not yet developed comprehensive national policy frameworks for its adoption and regulation.

In Canada, the federal government provides the most support for genetics research and its applications for public use (Genomics R&D Initiative: Participating Departments and Agencies in Canada, 2020) through in-house genetic sequencing services (DNA Sequencing, Genotyping and Bioinformatics 2020; Genome Canada's Strategic Vision, Annual Report 2018) to fund academic, industry, and non-profit organizations (Genomics at the Canadian Forest Service Publications 2013). Currently, there is a lack of any formal Canadian DA policies or guidelines for HTS technology procurement (including pricing expectations), use, reporting, data privacy, and security. Without coherent regulatory frameworks, governments could face issues of reliability, reproducibility, data breaches, technological misuse, and/or inconsistent application and stewardship of data.

II. Potential benefits of HTS to nations

HTS may enhance research outcomes and the delivery of government programs (Progress Tracker for the Third Biennial Plan to the Open Government Partnership n.d.). Genomics-derived data may be used for the following applications: meeting legal and program requirements, facilitating research, identifying epidemics (Va et al. 2018), food safety (Mair-Jenkins et al. 2017; Ronholm et al. 2016), clinical microbiology (Gargis, Kalman, and Lubin 2016), forestry (Neale et al. 2013), pest control (Beef Genomic Prediction Trial 2018), and livestock outputs (NRC Researchers Help Crack the Wheat Genome Code 2020; Advances in Genomics Technologies Create Opportunities—and Some Challenges 2020).

Key benefits include pathogen testing applications for agriculture (crops/livestock), forestry, and precision medicine. HTS provides much quicker and more comprehensive results compared to conventional methods for agriculture and forestry (Pecman et al. 2017; Rott et al. 2017; Tremblay et al. 2018; Adams et al. 2018) and patient diagnostics (Meldrum, Doyle, and Tothill 2011; Smith 2017; Kamps et al. 2017; Di Resta et al. 2018). Portable HTS further enhances the accuracy (Eichmeier et al. 2016) and speed of plant pest diagnostics, including on-site sequencing in the field (e.g. Chalupowicz et al. 2019). In the clinic, on-site HTS enables testing for diseases linked to genetic markers such as cystic fibrosis, sickle-cell anemia, hemophilia, Huntington's disease, and other rare neonatal diseases (Daoud et al. 2016; Inaba et al. 2017; Lucarelli et al. 2017; Bahlo et al. 2018; Kubikova et al. 2018).

III. Barriers to widespread adoption of HTS and the government's role

Widespread adoption of HTS has not yet occurred in the public sector in Canada nor globally. Several practical barriers remain; despite increasing affordability, the costs of instruments, labor, quality control, and assurance, and information technology management remain high (Goldberg et al. 2015; Muir et al. 2016; Olmos et al. 2018). Furthermore, substantial digital infrastructure is required to manage large datasets (Kulkarni and Frommolt 2017; Massart et al. 2017; Messner et al. 2017).
Although the collection, interpretation, and reporting of clinical, biological, or environmental sequencing data differs by discipline and organism (Goldberg et al. 2015; Olmos et al. 2018), the standardization of methods is critical for the incorporation of HTS in regulatory and diagnostic decisions (Messner et al. 2017; Massart et al. 2017). This has not yet been achieved in most fields where HTS is used (Matthijs et al. 2016; Massart et al. 2017; Messner et al. 2017; Isabel et al. 2019).

Serious concerns also remain regarding data reliability and significance (Olmos et al. 2018;

Massart et al. 2017), privacy and security (Triplet and Butler 2013; Muir et al. 2016; Hubaux, Katzenbeisser, and Malin 2017), and ownership (Foster and Sharp 2008). For example, while the popularity of 'do-it-yourself' genetic tests using HTS from companies including LifeLabs, 23andMe, and Ancestry.com is growing (Schmidt 2016), little is known about how results are stored and whether they can be sold by holding corporations (Sándor 2018). Even completely anonymized DNA data can be traced (Alser et al. 2015), and broader risks could emerge from 'genome hacking', such as the creation of bioweapons (Perkel 2017).

IV. Policy options

Widespread implementation and adoption of HTS by governments can improve the delivery of regulatory programs and support research involving genetic sequencing. Canada has several federal science and technology policies (e.g. open data and science provisions via the Open Government Commitment of Canada) that require DAs to uphold principles of rigor, transparency, safety, and privacy (Findlay S. Model 2018; An Integrated Platform for Genome Sequencing & Analysis 2019). These same principles can be applied to a policy framework for HTS. We propose the following three options for nations developing policy frameworks for HTS.

i. Centralized: fund national HTS infrastructure while concurrently developing a national policy framework for genetic sequencing

Nations could fund public HTS-specific laboratories or laboratory networks and concurrently develop national policy frameworks and regulations to govern the adoption and implementation of HTS. Policy frameworks and regulations could be developed by leveraging existing frameworks for precision medicine (Policy Statement on The Collection, Use and Disclosure of Genetic Test Results n.d.; Immigration, Refugees and Citizenship Canada 2019) and the use and protection of genetic data (Canada's Genetic Non-Discrimination Act, 2017). While these examples focus on personal information, they could serve as models for national HTS policies focused on animal and plant health.

The advantages of this approach include the ability to nationally address concerns relating to privacy, regulations, transparency, and safety while reaping potential long-term cost savings associated with a centralized public provider. A strategic vision could facilitate the forecasting and adoption of future emerging technologies. However, national frameworks may be too broad to adequately meet the needs of individual DAs. Also, there are significant up-front costs associated with establishing national HTS infrastructure.

ii. Semi-centralized: support DAs to develop guidance and policies for the adoption of HTS

Nations can instruct relevant DAs to develop their own policy frameworks, which may include relying on existing initiatives (e.g. in Canada: Genomics R&D Initiatives, Genome Canada, private providers) or developing technology and expertise in-house. Each DA would tailor their policy frameworks to their specific needs with a strategic vision to leverage technologies for new initiatives or emerging problems. From a whole-of-government perspective, this approach likely has a lower initial cost than Option 1. However, splitting funding across DAs to meet their HTS needs may incur greater long-term costs than a centralized approach, particularly if DAs without access to intramural HTS infrastructure must contract from private providers at market rates. There is also a risk of incongruous strategies being developed across DAs; a cohesive approach to addressing privacy, regulations, transparency, and safety is preferable.

iii. Decentralized: individual programs within DAs determine and meet their HTS infrastructure and policy needs

Each individual program would determine their specific HTS strategy. Advantages include the ability to tailor policies and technologies to individual program needs at little additional cost. However, this approach lacks strategic vision. Without coordinated governance, nations may face barriers in forecasting and leveraging new technologies at the sectoral or national levels. There is also a high probability of incongruent strategies to address concerns related to privacy, regulations, transparency, and safety. Long-term costs may also be higher due to reliance on extramural providers of HTS technologies and creating silos within and across agencies and departments.

V. Existing models

Centralized policy frameworks for the adoption and regulation of HTS technologies in Canada or internationally were unable to be identified. The most centralized aspects of HTS adoption in Canada are data warehousing and funding for both government and non-government researchers (Genomics at the Canadian Forest Service Publications 2013; Advances in Genomics Technologies Create Opportunities—and Some Challenges 2020). The Canadian government hosts or funds repositories for data related to salmonella (Yoshida et al. 2016) and human genome sequencing (An Integrated Platform for Genome Sequencing & Analysis 2019). Policies for the regulation of genetic testing in Canada tend to address specific issues (e.g. use of genetic information) (Policy Statement on The Collection, Use and Disclosure of Genetic Test Results n.d.; Immigration, Refugees and Citizenship Canada 2019). This is also true of other countries; the U.S. has developed regulations and policies for subjects such as direct-to-consumer genetic testing (NIH Regulation of Genetic Tests 2019) and HTS in plant protection (Plant Protection and Quarantine 2017). LawSeq, funded by the US National Institutes of Health, studied the legal foundations for genomic translations, implementations, and validations into clinical applications. However, there has been no clear governmental uptake (Genomics R&D Initiative: Participating Departments and Agencies in Canada 2020). Other countries that use HTS in support of plant health (e.g. New Zealand) also lack national policies.

Globally, there are attempts to centralize genetic sequencing policies by topic. The Global Alliance for Genomics and Health aims to set global policies and technical standards for responsible sharing of genetic data related to human health (Wolf, Clayton, and Lawrenz 2019.). The International Plant Protection Convention has drafted recommendations for HTS in plant health (Enabling responsible genomic data sharing for the benefit of human health Current consultations for CPM Recommendations n.d.). Other international working groups (e.g. *Euphresco strategic research agenda 2017-2022* n.d.) and the Plant Health Quadrilaterals Group on HTS (USDA, APHIS 2019) are analyzing HTS and regulatory issues relating to plant health in the agriculture and forestry sectors.

VI. Policy recommendations

In the age of HTS and big data, we must consider the potential consequences of these technologies and think proactively about regulations. Therefore, we propose two recommendations for nations intending to develop policy frameworks for adopting and regulating HTS.

i. Nations could fund public HTS infrastructure while simultaneously developing pan-governmental policy frameworks on genetic sequencing

Canada and other nations could leverage global models to inform national health genomics policy frameworks and implementation plans (Australia's Implementation Plan by the National Health Genomics Policy Framework 2018; USA's Genetic Information Non-discrimination Act 2008; France Médecine Génomique 2016; Denmark's National Strategy for Personalised Medicine 2017; Improving Health through the Use of Genomic Data 2017; Boccia et al. 2017.; Qatar's Genome Program Guides 2020). Initial attempts can guide the development of policies on HTS technologies and data pertaining to human, plant, and animal health. Countries could leverage infrastructure programs similar to Canada's Federal Science and Technology Infrastructure Initiative (The Associated Press 2018) to fund public HTS laboratories. To implement such policies, committees of parliamentarians or representatives can study the issue. Such committees could assess existing regulations and legal frameworks governing current and potential future sequencing technologies and recommend development or amendment of legislation or policies as warranted.

ii. Nations could instruct relevant DAs to develop strategies on the adoption of and policy for HTS

This process could be coordinated by the government's lead scientific body. This approach was recently followed in Canada, where the Office of the Chief Science Advisor developed a model policy on scientific integrity and subsequently coordinated and helped DAs adopt and implement their own versions (Findlay S. Model 2018).

Although both policy recommendations will require substantial investment, the risks of inaction are high. Private HTS providers are proliferating worldwide (USDA, APHIS 2019), and serious concerns about the quality, privacy, and safety of these providers remain (Wang et al. 2017). The use of HTS in plant and animal policies may also affect international trade (Massart et al. 2017). Adopting national policies can help nations improve the delivery of their programs that rely on genetic sequencing while mitigating risks from unregulated market players and DAs implementing policies without coordination.

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