

Leapfrogging with Genomic Data Workshop

October 2019

Introduction

The Leapfrogging with Precision Medicine Project, which is part of the Precision Medicine Portfolio of the World Economic Forum, focuses on co-designing and piloting policy and governance frameworks that enable healthcare leaders in emerging economies to prepare for and integrate precision medicine approaches into their health ecosystems.

Leapfrogging with Genomic Data Policy is one workstream within this project. Genomic data is an especially sensitive form of health data, and its collection and use support scientific research, improved diagnosis and disease treatments that underscore precision medicine. Genomic data collection is accelerating, including in low- and middle-income countries (LMICs)¹, to fill critical gaps in the understanding of populations not traditionally included in genomics and precision medicine. Without future-looking

policies that address genomic data collection, countries face two main risks: 1) their genomic data does not inform scientific research that may lead to more population-relevant diagnostics and treatments; or 2) their genomic data may be used by and benefit primarily outside parties.

This workstream aims to address this issue by developing and testing elements of genomic data policies and a corresponding ethical framework from a “future of healthcare” and patient-centric perspective. The areas of focus for the workstream are four foundational categories for genomic data collection and use: consent, data privacy, data access and benefit sharing. Since genomic data is the most sensitive form of data, the development of sound policy approaches here will enable and inform approaches to all other types of sensitive data.

Leapfrogging with Genomic Data Framing

Consent

Data Privacy

Data Access

Benefit
Sharing

Ethics

Context: Low- and middle-income countries
Patient-centric perspective
Forward-looking uses of data

Workshop objectives and structure

The Precision Medicine team convened the Leapfrogging with Genomic Data Workshop on 18 July 2019 at the World Economic Forum's Centre for the Fourth Industrial Revolution in San Francisco, California. Approximately 30 experts in policy, industry, genomics, research, bioethics, academia and civil society from Africa, Middle East, Latin America, South-East Asia and North America participated.

Objectives

As the first workshop in the Leapfrogging with Genomic Data workstream, the purpose of the workshop was to identify the tangible policy challenges and ethical tensions that need to be addressed within the categories of consent, data privacy, data access and benefit sharing. Specific objectives were:

- Validate the focus on the four categories in the framework
- Identify the key issues or tensions within these categories from both a policy and ethical perspective that stand in the way of attending to them
- Begin brainstorming solutions to these issues or tensions, such as governance questions and learnings from real world examples
- Build a community of practice to participate in co-designing, testing, refining and scaling the genomic data policy and ethics framework and collaborate in sharing knowledge and experiences with each other

By the conclusion of the workshop, participants identified priority policy barriers and gaps germane to the opportunities and risks faced by LMICs, exposed the ethical underpinnings of these issues that must be considered for effective policy development and posited possible approaches to addressing the identified gaps and barriers.

Structure

The focus of the workshop required participants to step out of their current context and travel into the near future to discuss highly complex, politically charged and emotionally sensitive issues related to genomic data collection and use in an LMIC context. This was achieved using hypothesized vignettes or short scenarios. The vignettes, while fictionalized, are based on real situations that have or may cause points of conflict but do not yet have solutions.

Each vignette focused on one of the four foundational elements of genomic data policy and presented fictionalized short stories oriented five to 10 years in the future. The vignettes had two main personas, often representing perspectives of the Global North and South. The personas helped illuminate the ethical tensions underpinning each policy issue. Desk research and expert interviews on existing or emerging tensions informed each vignette.

Participants worked through these vignettes in small groups, with each group adopting one of the personas as they identified the cause of the conflict, underlying considerations and possible solutions. Groups then returned to plenary to address the group that adopted the counter persona. These presentations offered an opportunity to question and discuss conflicts from a solution-oriented perspective, when possible.

The full vignettes are linked in the Appendix.

Workshop agenda

08.30 – 09.00

Registration and Breakfast

09.00 – 09.10

Welcome to the World Economic Forum and Precision Medicine Portfolio Overview, **Genya Dana, Head of Precision Medicine**

09.10 – 09.35

Interactive "Where Do You Stand?" Exercise and Introductions, **Genya Dana and Elissa Prichep, Precision Medicine Lead**

- Participants will discuss their perspective on the trajectory of genomic data, providing context for the rest of the day

09.35 – 10.20

Opening Panel: Promises and Challenges of Genomic Data

- A conversation on the practical and ethical issues raised by the advancements in genomics and digital data with:
 - **Catalina Lopez-Correa**, Chief Scientific Officer and Vice-President Sectors, Genome British Columbia, and Co-Chair, Global Genomic Medicine Collaborative
 - **Jennifer Maroa**, Clinical Assistant Professor, University of Washington and Program Manager, African Academy of Sciences
 - **Pelu Tran**, Chief Executive Officer, Ferrum Health
 - **Alicia Zhou**, Vice-President of Research and Scientific Affairs, Color Genomics

10.20 – 10.35

Break

10.35 – 10.45

Project Overview and Workshop Objectives, **Elissa Prichep**

10.45 – 11.45

Diving Into the Future: Breakout Scenario 1

- Designed to facilitate an exploration of a future 10 years from now where genomic data has affected norms on data privacy and how we engage with patients through consent processes

11.45 – 12.05

Plenary: Popcorn Share

- Members of each breakout group share how they approached their future situation

12.05 – 13.00

Lunch

13.00 – 14.00

Diving into the Future: Breakout Scenario 2

- Designed to facilitate an exploration of a future 10 years from now where genomic data has affected norms on data access and benefit sharing from research

14.00 – 14.45

Diving into the Future: Pitch

- Exploration of the key factors and consequences that emerged in your scenario and how your group recommends addressing those from "your" assigned perspective
- Counterpoints offered by group assigned an alternative perspective

14.45 – 15.00

Break

15.00 – 15.45

Diving into the Future: Common Ground

- Participants are re-combined into four new groups to develop common group and solution-oriented recommendations

15.45 – 16.45

Plenary: Share and Discussion

- Members of each breakout group share how they reconciled their future situation and all participants engage in a discussion on key themes and what they learned

16.45 – 17.00

Postcard to Self, Commitments and Closing remarks, **Genya Dana and Elissa Prichep**

- Each participant addresses a postcard to themselves, sharing a key learning and how they want to be involved in this work in the future
- Reflections on the day and next steps for the Leapfrogging with Genomic Data workstream

17.00 – 18.00

Reception



Vignette-based discussions and insights

The following section provides an overview of each fictionalized vignette and key considerations and potential solutions related to each of the conflicts presented.

It must be noted that the topics raised by each vignette are inextricably linked. Consent, data privacy, data access and benefit sharing are informed in their inception by ethical norms and they tactically inform each other in their implementation. As such, common considerations and potential solutions emerged across vignettes. Instead of discussing them under multiple vignettes, the three main cross-cutting insights are pulled out and introduced below.

1. Identify the roles and responsibilities of those engaged in research. Several conflicts emerged from lack of clarity on genomic data ownership, responsibility and accountability at each stage of the research process. In the absence of clarity, assumptions are made that often create conflict or leave important gaps. Key questions to consider in establishing roles and responsibilities on genomic data include:

Who owns the data?
Who has access to the data?
Who benefits from the data and how?
Who is responsible for safeguarding the data?
Who is accountable for upholding requirements?

Do these roles and responsibilities shift at certain points throughout the lifecycle of the data?

2. Inclusion is critical. Across the vignettes, those conducting research or setting policy often did not include affected parties in the planning, execution or evaluation processes. This often left blind spots from which conflict arose. Inclusion of research participants or potential third-party collaborators in the design of genomic data research or policy should both minimize potential points of conflict and strengthen the research studies and policy approaches.

3. Governance, governance, governance. Lack of inclusion is often due to lack of mechanisms to include other groups. Developing governance approaches to ensure inclusion, and also to address key questions such as those raised above, is a critical mechanism to reducing potential points of conflict. Governance is also critical in fostering collaborative efforts between parties that lack trust, as further explored in the ethics section of this report.

Vignette 1: Consent

Vignette summary

In a future where the cost of whole genome sequencing has fallen dramatically, a country in east Africa forms a collaboration with a major US corporation that enables new-born baby screening for all babies born in a hospital. The Vice-President of Genomic Research for the corporation and the Director of the National Ethics Review Committee in the Ministry of Health discuss what model of parental consent is appropriate – broad or tiered – and implications for when the infants who provided the data become adults. (The full vignette is available in Appendix C.)

Consent is the critically important step of gaining permission from research participants to collect and use their data in the manner to which they agree. Constituents suggested a thoughtful communication approach is critical to ensure meaningful informed consent.

One element of meaningful consent is ensuring that the consent document contains the necessary content. The document should address key topics such as the purpose of the research, the ownership of the data, the risks and benefits to the participant and the accessibility of the data to other researchers.

A second critical element of meaningful consent is ensuring that the participant understands what they are consenting to and also has time to think about this information. Providing the consent form with a verbal explanation at an accessible genomic literacy level, allowing for discussion, addressing questions and having the signer explain (teach-back) the key elements of the consent document back to the researcher are essential steps in ensuring a participant is providing meaningful consent.

Participants also suggest beginning the consent conversations as early as possible and with a focus on the research issue or health issue at hand. In the case of this vignette, the discussion of consent for new-born baby screening could have started early in the pregnancy with a conversation about the definition and purpose of new-born baby screening. The approach not only creates awareness and understanding but also gives people an opportunity to consider their options over time and in non-stressful situations.

Privacy vignette

A researcher receives broad consent to collect genomic data from an indigenous tribe in a secluded region of the Andes as part of a study on the tribe's ability to thrive at such high altitude. The study does not provide any insights but uncovers new details about the tribe's ancestry which, if published, could challenge its identity and reignite territorial tensions with another nearby indigenous population. The researcher and the tribal elders meet in this exploration of the balance between maintaining privacy and advancing knowledge, and the responsibilities of researchers to their participants. (The full vignette is available in Appendix C.)

This vignette exposed a series of system failures and misaligned incentives that enabled a researcher to begin with a narrowly defined study and end with the opportunity to publish detrimental information on a population. Such systemic failures, though uncommon, have devastating and far-reaching implications for populations and the research community. Smaller failures, those that are noticed and addressed, are still detrimental and likely occur regularly in a global context.

Increasing governance at various steps in the research process would reduce such risks. While the researcher in the vignette did have approval from her university's institutional review board (IRB), this only ensured that the university's interests were represented and the original research approach was sound. There remained gaps in community involvement, research transparency and oversight that additional governance could have filled. Such governance models could include the development of a community IRB or inclusion of community members in the university IRB, a framework for user-centred study design that enables community input on the research question, approach and endpoints, as well as inclusion of stakeholders at appropriate points during and after the research study. While the researcher in this vignette spent time with the native community, it appears that she did not fully understand the community structure or values, nor did she include the community's insights in the development of her research proposal. It was also unclear whether the researcher was involving the right people from the community in conversations prior to research and in attempting to resolve the publishing dilemma.

Privacy is inextricably linked to consent. While the vignette did not provide details on the consent process, the presumed disparity in knowledge between the researcher and the research participants regarding genomic data applications placed the onus on the researcher to ensure an understanding of the risks and implications of research participation. The university faculty overseeing the research should have helped the researcher elucidate these potential benefits and harms and ensured that they were disclosed to the members of the indigenous community in a meaningful consent process.

Ultimately, workshop participants felt the researcher stepped beyond her research mandate and recommended that, in such scenarios, a researcher should default to the originally planned project. That would mean not publishing ancestry findings.

Data access vignette



Researchers in Nigeria and France are planning to share genomic data as part of their collaboration to identify cancer biomarkers unique to certain African populations. However, the new Global Health and Genomic Treaty Organization (GTO) has developed an enforceable framework that governs health data transfers and access between all member countries. Countries or institutions outside the GTO must show they have met certain “adequacy standards” on data collection, privacy, use and security prior to receiving data from GTO member nations through consortiums, federated data systems, or other data access models. France is a GTO member nation; Nigeria is not. A series of events ultimately lead to the Minister of Health of Nigeria contacting the GTO Head of Adequacy Standards. The Minister of Health accuses the GTO Head of institutionalizing a uni-directional flow of information, benefiting only the Global North and further increasing global healthcare disparities. The GTO Head defends his organization’s mission to protect and secure genomic information in an age of increasing cyber-terrorism, data hacks and genomic espionage. Both agree that the current situation stands in the way of research intended to improve health and longevity and they seek to find a resolution. (The full vignette is available in Appendix C.)

This vignette presents two complex situations: How could the GTO have acted to prevent this situation from arising; and how can both parties develop opportunities for beneficial collaborations across the Global North and South?

The situation described in the vignette may have been averted if the GTO leadership was more inclusive of LMICs. Prior to launching the framework, the GTO should have been inclusive through creating awareness of this initiative and in the development of the health data framework and adequacy standards. That is not to say data security standards should be lessened, but they should be developed with insight into existing gaps in data infrastructure and approaches to address those gaps.

Now that the framework is live, workshop participants recommended the GTO should be inclusive by working with LMICs to create onramps, or defined pathways that offer accelerated opportunities to achieve GTO membership or meet adequacy standards. To be sure, the development of onramps is not easy or straightforward. As such, participants recommended development of use cases that both test approaches to onramps and address the concerns of the GTO as well as non-member states.

While cybersecurity is currently out of scope for this workstream, genomic data is highly valuable and sensitive information, which makes it a target for hackers. Participants agreed that increased inclusion and collaboration in genomic data research needs to be achieved without sacrificing data security. As such, onramp solutions must account for and potentially include support for meeting data security standards. LMIC participation with the GTO will likely require resources that support capacity building, infrastructure development and workforce training. The GTO should consider these resource implications and establish approaches to enable access to grants or funding that support LMICs in their onramp process.

Benefit-sharing vignette

The Head of Research at a European organization contacts his counterpart at a leading South Pacific research organization seeking access to genomic information on several native groups. He is thrilled to learn this data has already been collected, digitized and put into the cloud. While the two organizations have a long-standing benefit-sharing agreement that includes capacity building and training when research must be conducted in person and involves physical sample collection, this is new territory. There is no framework for benefit sharing related to digital samples – data – and they express different opinions on how to move forward. How might they maintain the research benefits of digitalization such as reduced cost and increased speed of data access without increasing disparities in capabilities between Global North and South? How might each person think about the value of this genomic information now that it is digitized? (The full vignette is available in Appendix C.)

The ability to share genomic data raises new questions about how to value this data in relation to physical samples as well as how to maintain the benefits of capacity building and workforce development driven by in-person collaborations. Some believe “information is information” and should be valued the same regardless of form, while others believe data enables cost savings over physical samples and that should be reflected in a lower valuation. Others suggest that much more research can be achieved with data, so it is more valuable than physical samples.

Without answers, research collaborations are stalling. Participants suggested that existing benefit-sharing models should be a starting point to these conversations, with benefits remaining similar to those already established between organizations. These can be tested and iterated in pilot projects that are fit for purpose before being more firmly established. The approaches can also be developed into scalable templates, as many researchers are eager for models on which to base their agreements.

To be sure, the power dynamics between organizations can strain these conversations. Entities with less power often feel pressured to form relationships, engaging in less optimal benefit-sharing agreements for fear of losing access to research opportunities. It is also possible that groups with less power may seek to leverage the perceived value of their data set and feel more empowered than ever to request increased benefits.

Situations of bilateral benefit-sharing negotiations may also strain regional relationships as, for example, two countries

with similar population profiles may find themselves “negotiating” against each other for opportunities with research partners. As such, participants advocated that countries establish regional or global benefit sharing frameworks.

Ethical tensions and underpinnings

In the latter part of the workshop, participants discussed the layers of ethical concerns that their vignette personas attempted to satisfy in resolving the conflicts presented. Reflecting on these, participants noted that policy solutions developed in the workshop did not address the underlying ethical issues their personas faced. This blind spot guaranteed their policy ideas were temporary fixes at best.

Several ethical tensions emerged through discussion at the workshop. The following three cut across all vignettes and reflect the desire to respect individual needs without stifling research and its possibilities to improve health.

The tension between individual privacy and societal benefits

Several countries guarantee privacy as a fundamental or legally implied right and hold privacy as a societal tenet. Since an individual’s genomic information is both immutable and deeply revealing, individuals are justly concerned about harms that may result from their loss of genomic privacy as information is disclosed. However, benefits to society of medical advancement are lost by keeping individual genomic information isolated. Peter Mills and Jennifer Miller describe this tension in [Why We Need a New Social Contract for Data in Healthcare](#): “The effectiveness with which we can treat any one person depends upon the quantity, quality and variety of data we can obtain from a great number of other people.”

Further clouding this tension is the misleading use of “privacy” and “confidentiality” as interchangeable, which sets up expectations on data stewardship that are not necessarily reflected in practice. Privacy refers to the freedom from observation whereas confidentiality refers to keeping information secret.² People may expect that all of their information is kept from observation, although, in practice, their information is shared with identifying aspects kept confidential.

The tension between individual privacy and societal benefit are perhaps most visible in different approaches to consent: should consent be broad, tiered or specific; should consent prioritize researchers or individual data contributors as decision makers; should consent be static or dynamic; should consented data be identifiable, anonymous or deidentified? There is no universal solution and the balance shifts based on legal, scientific, social and cultural beliefs.

The tension between open information access and restricted information access

The onus of safeguarding genomic information shared by individuals falls to a custodian – such as a government, a research institution, a university, a private company – that is again faced with a decision on whether it is better to restrict data access or open data access. In a world of increasing cyber-terrorism and data theft, as well as a world in which collected data repositories carry value, restricted data access may offer security and a path to increased benefits. However,

too much restriction limits scientific research and discovery that can support health goals as well as limits the ability to materialize the value within a data repository.

Further complicating this tension is the self-perception of the custodian and the potential for bilateral or multilateral data access arrangements. Does the custodian view themselves as a data provider, a data seeker, or both? Does the custodian seek to engage in multi-party consortiums? For example, a government custodian in a country with a history of experienced exploitation may err towards overprotection of data. This approach fits a one-way dynamic where information is most likely requested from the country by an organization based elsewhere. However, if the government custodian is in a position of also receiving data to drive their own research, or seeks to set up a multi-country data repository, overprotective policy will limit opportunities. Time, technological safeguards and governance approaches may shift how data custodians balance the ethical tensions here.

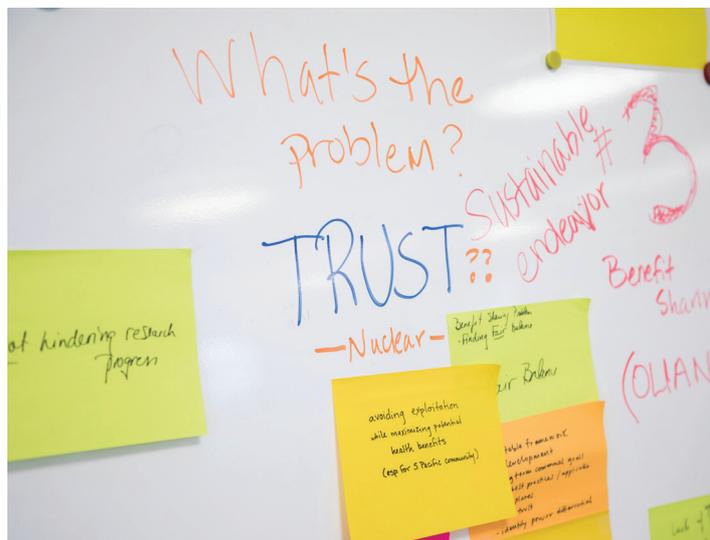
The tension between altruistic donation of genomic data and receiving benefits

There is a traditional view that people altruistically donate genomic information that will lead to health discoveries that benefit society. To pay for such information would undermine societal norms and potentially lead to new ethical dilemmas such as valuing people differently based on the rarity of their genomic information. However, this long-held belief in altruistic donation has historically fuelled the exploitation of several populations whose data is used for healthcare improvements they never experience. It must not be carried into the age of genomic medicine.

Limiting research until benefit-sharing questions are addressed risks undermining what altruism seeks to provide – rapidly advancing research to provide improved health outcomes. Finding an initial balance between altruism and benefits may, as suggested by workshop participants, lie in existing models of benefit sharing.

To be sure, access to genomic data presents unique challenges from, for example, pathogen sharing addressed in existing models such as the [Nagoya Protocol](#). Genomic data may lead to diagnostics and therapeutics that take much longer and are more expensive to develop, have longer utility and profitability in the marketplace, have high potential uptake in other geographies, and provide incidental findings that are also valuable. The extent of these potential outcomes may not be known at the time of genomic data collection. Further complicating this tension is the level at which benefits should be applied – individual, community or nation – and the international cooperation needed to ensure that benefits are applied equitably and justly across countries.

On trust



The workshop participants explored trust as one component of a solution to bridge ethical tensions between parties. The history of exploitation and discrimination in LMICs, combined with existing global healthcare disparities and the lack – real or perceived – of policies, rules, procedures, regulations and accountability mechanisms governing genomic data collection and use make trust a tenuous topic.

Trust is built, in large part, on the trustworthiness of people or institutions as demonstrated through numerous interactions. Where trustworthiness has some foundations, trust can be built further through collective approaches. Two such approaches are for groups to jointly develop 1) a transactional model where fair compensation is agreed on and payment is made in exchange for providing a service or item of value; and 2) a collaborative model that includes and benefits participants and enables them to resolve issues together. The second option, while more complicated to develop, is the better approach when building long-term relationships and addressing complex, evolving issues such as genomic data collection and use.

Where trustworthiness is absent, a trustworthy system becomes imperative. Laws, governance models, regulatory standards and accountability mechanisms must be relied on to compel and enforce certain behaviours. For genomic data and related items of perceived value, these rules must identify ownership of genomic data and related items of perceived value, state when and how that ownership transfers, delineate clear responsibilities for the custodians of those items and enforce accountability among involved parties. Additionally, elements of a system intended to engender trust must include frameworks that support equitable distribution of benefits.

Endnotes

1. While this document refers to LMICs, it is important to note that this project scope also includes high-income countries such as those in the Middle East, whose populations have not traditionally been included in genomic research and who are advancing their health ecosystems to include precision and genomic medicine.
2. Oxford English Dictionary

Workshop participants emphasized that, whether pursuing collaborative approaches or system-strengthening approaches, components must be designed inclusive of all parties involved in genomic data collection and use. The workshop highlighted the general issue that research participants are rarely consulted in the design, ethical review, findings or implications of research projects. Inclusion of research participants or community representatives from the planning stage, and throughout research, would likely prevent numerous conflicts and enable better research outcomes.

Next steps

The key deliverable of the Leapfrogging with Genomic Data workstream is a high-level, forward-looking, scalable policy and ethics framework for genomic data. This document will be published in December 2019.

Elements of the framework will be piloted with several government partners in their own contexts, providing a “sandbox” for addressing policy and ethical issues related to genomic data. Testing the framework through real-world applications with geographically diverse government partners will enable revision and refinement of the framework. Learnings from these pilots will be incorporated into the framework and shared with the intent of scaling approaches to additional government partners.

Conclusion

Using policy and ethics frameworks to balance the promise and opportunities of genomic data with the real-world practicalities of implementing such initiatives provides a path forward for countries. Leapfrogging is possible. The international and national level frameworks from this workstream will eventually lead to standards and guidelines that will inform policies and regulations. It is the hope of this community that such work supports the goal that genomic data from LMICs will lead to diagnostics and treatment developed with, tailored and accessible to those populations, improving health outcomes globally.

Appendix

Appendix A: [Click for genomic data policy resource list](#)

Appendix B: [Click for agenda and list of participating organizations](#)

Appendix C: [Click for vignettes](#)

For more information on the Leapfrogging with Genomic Data Workstream, contact Elissa Prichep at elissa.prichep@weforum.org