The right to benefit from science and data sharing

A HUMAN RIGHTS APPROACH

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On September 24, 2018, Dr. Bartha Maria Knoppers from the Centre of Genomics and Policy at McGill University, presented a keynote address on the Right to Benefit from Science. She proposes a human rights approach for the next decade of science in the area of research and personalized medicine. We present highlights from her presentation:

It was during the creation of the Global Alliance for Genomics and Health (GA4GH) in 2013 that I thought about the possibility of an international consortium founded on something complementary to the usual models of either bioethics principles or legal frameworks. The idea would be to use a human rights approach for the next decade of policy making in this area of data-intensive science, so as to foster collaboration and data sharing.

WHAT IS THIS RIGHT?

The 1948 Universal Declaration of Human Rights states, in article 27.1: "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." Article 27.2 then states: "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." These are rights that go together.

Since 1966, the right to science and to attribution (or recognition) are anchored in "actionable" human rights conventions. Indeed, even the 1952 United Nations Educational, Scientific and Cultural Organization (UNESCO) Resolution on the right to participate in cultural life made specific reference to participation in science, emphasizing that "Such participation goes well beyond merely passively receiving the benefits—such as knowledge, technology, therapies and so on—generated by scientific advances made by professional scientists. Differently put, it treats participation in the scientific enterprise as one of the benefits of science to which we all have a right."

The human rights approach has the benefit of reaching beyond the laws and policies of any given country, which is especially important in a globalized world of collaborative research. It is complementary to bioethics, but has political and legal dimensions that go beyond the moral appeal of bioethics to change the philosophy, from a presumption that research may harm people, to showing how it benefits. It also has legal force, with the International Covenant on Economic, Social and Cultural Rights signed in 1966 by 168 states and ratified in 1976, and imposes positive duties on governments and private actors.[1] The right to science is therefore "actionable," meaning that citizens can hold their governments accountable for protecting that right.

This is a promising basis on which to build the next decade of laws, frameworks and policies. Nevertheless, it took some time for it to gain much attention and recognition.

Largely dormant since 1966, current interest in the human right to science started with the UNESCO Venice Statement of 2009, which identified the roles of States, the private sector, and the scientific community. The Venice Statement describes the right to science as:

1. access by everyone, without discrimination, to the benefits of science and its applications;
2. opportunities for all to contribute to the scientific enterprise;
3. the freedom indispensable for scientific research;
4. participation of individuals and communities in decisionmaking;
5. conservation, development and diffusion of science and technology.

In 2010, the American Association for the Advancement of Science (AAAS) picked up on the Venice Statement and proposed that the scientific community had a duty to nurture awareness of the social and human rights implications that come with the right to science.

In 2014 the GA4GH developed a Framework for Responsible Sharing of Genomic and Health-Related Data, as well as the policies and tools to activate the right to science.

This was followed by the Science and Human Rights Coalition of the AAAS survey of 2016, asking what government actions were required to give meaning to the right to science.[2] The 5 most frequently selected were:

1. Increase funding for scientific infrastructure and research.
2. Provide adequate science education to the general public.
3. Promote a positive view of science and scientists among the public.
4. Ensure open access to scientific information.
5. Promote and protect academic freedom.

Access to the applications of science was most often mentioned by respondents from South American and the Caribbean, while access to scientific knowledge, information and literature predominated in North America and Europe.

A review conducted by a researcher at Cambridge and me looked at the reports of state actions taken to implement the United Nations (UN) International Covenant on Economic, Social and Cultural Rights of 1966.[3] We found that 139 of the 168 States submitted regular reports to the UN on activities arising from the Covenant: 76 adopted legislative provisions to incorporate this right in their domestic laws, and 83 states reported taking concrete measures to promote the dissemination of science. Since 1990, the creation of databases was the most commonly adopted measure, which coincides with the rise of the Internet. A growing number of

states recognize an obligation to give everyone access to scientific information, including provisions that State-funded research be open-access. There is a sharper developed-developing countries divide regarding approaches to upholding the right to access the applications of science, with more developed states emphasizing the transfer from academia to industry, and developing states focusing on international technology transfer.[3]

In 2017, the UNESCO Recommendation on Science and Scientific Researchers used language that starts to interpret this right. Article 27.1 mentions the significant value of science as a common good, and stresses that open communication of results and hypotheses provides the strongest guarantee of accuracy and objectivity of scientific results. The Recommendation emphasizes sharing of science between researchers, and with policy-makers and the public, considering that states should "establish and facilitate mechanisms for collaborative open science and facilitate sharing of scientific knowledge while ensuring other rights are respected."[4]

Finally, citizen science has picked up on this language. Citizen science is where patient groups and advocacy organizations actually get involved in creating scientific resources. Citizen science is defined as "any form of active nonprofessional participation in science that goes beyond human subject research conducted by professional researchers."[5] An actionable agenda would include practical means of addressing the funding, oversight and regulation of citizen science, and the allocation and specification of property rights.

With international collaboration increasing at a dramatic rate, data transfer becomes increasingly prevalent. The 2017 Organisation for Economic Co-operation and Development (OECD) Recommendations on Health Data Governance[6] include government support for trans-border cooperation in health data and research that "serve the public interest," subject to safeguards.

DATA AND LEARNING HEALTH SYSTEMS

It should be noted that the American College of Medical Genetics and Genomics in 2017 considered that "the vast amount of data now being generated by genomic testing and genetic diseases will offer the opportunity to develop the framework for a national learning healthcare system, because the shared experiences of those caring for these patients continually contribute to improvements in delivering services to this population. A learning healthcare system that facilitates access to diagnostic, treatment and outcomes data to inform the care of today's patients requires a paradigm shift in how we share data to be used in research and clinical practice."[7]

The genomics community, over time, has built a culture of sharing data. Now we're trying to bridge that with the clinical community and get them to put their data in the public domain (of course with patient consent) in order to build a learning health system. And data refers to many different types of data, not just genomic data, but also demographic, economic and environmental data that contribute to personalized healthcare and precision medicine. There has been a dramatic expansion of data sharing among scientists globally through a multitude of networks and publications, far ahead of laws and frameworks to govern this sharing.

MOVING TOWARD A LEARNING HEALTH SYSTEM

There has been a shift over the past 3 decades, from a static approach before 2000, to a complex systems approach in the first decade of the 2000s, to a learning health system hopefully to be based on artificial intelligence (AI).

The static approach saw binary relationships between physician, patient and researcher, and research was subject to specific laws around the treatment of genetic information. Discussions are still going on today that exceptionalize genetics, rather than seeing it as a normal part of the human condition, like all medical information. It may be sensitive, like psychiatric or reproductive information, or even cancer information that used to be "sensitive": until 1981, physicians in Quebec had a therapeutic privilege not to tell a person or their family if a diagnosis was cancer. Sensitive information is not a new challenge, and strategies have been developed; there may not be a need for laws. There was a more paternalistic/maternalistic approach around what providers thought the patient needed to know. That has developed over time to now regard what a reasonable person in those specific circumstances and context would consider "material."

The medical model is gradually shifting toward consensual shared responsibility, though most of the laws today still dwell on the autonomy and rights of the individual. Individual interests will always take precedence over the interests of society, and ethics boards filter this approach through into research. But this decade also saw the emergence of probably the biggest success in public health: newborn screening programs that enable diagnosis of asymptomatic newborns who can then be identified and treated.

What is most remarkable is that the first decade of the 2000s saw the emergence of networks in genomics (and in the cancer field, which is always a prototype), with the recognition of the relationships between different diseases. This led to changes in consent to broaden out potential investigations, i.e. to a disease and "related conditions," and paralleled the emergence of a more "commons"-oriented language in policy, with references to "public good" and "community resources," and the emergence of open clinical trials registries. As well, citizens began to participate in biobanks, not for their disease or family, but to build a resource for others.

Just around 2010, the interest in rare diseases increased as researchers began to consider the potential role of these alleles in common diseases. Whole-genome and exome sequencing ushered in the era of big data, whether we were ready or not. The amount of data was vast, leading to questions about how it could be securely stored and accessed. The cloud appeared as a solution, but came with service agreements that had no sensitivity to medical data or genetic data.

That brings us to the learning health system emerging in

the present decade. The challenge is to make sure a patient receives better care because of the patient who came before them, and contributes to the care of future patients. Ongoing research should be fed into the clinic, and clinical samples should continue to feed back into research under a systems approach. The UK is already making efforts to redraw the social contract between patients and the healthcare system. Samples from patients treated in public hospitals are being used for research, and patients are being asked to consent to use of their medical records for research. Liquid biopsies enable a person to become their own control group over time. Apps can also trace people and accumulate information over time. Problems emerge as consent and access are usually highly individualistic and time-specific, and we have not yet achieved a systems level of interoperability. As well, people now want to self-recruit, find researchers and send in their samples to where the research is underway. It is difficult to see where the ethics review, consent and laws governing this international research are located. At the same time, international efforts are essential to inject diversity of "sources" into our learning systems. In Canada, 32% of the population comes from other countries.

The patient's relationship will increasingly be with this learning healthcare system (via the patient-physician relationship within that) and will be more participatory. The implementation of machine-learning systems will therefore require a reimagining of confidentiality and other core tenets of professional ethics.[8] Potential challenges with machine learning and AI are already evident, as biases may be introduced into algorithms from databases that are imperfectly generalizable.

MAKING A LEARNING HEALTH SYSTEMS APPROACH ACTIONABLE: ANTICIPATORY GOVERNANCE

As the central relationship in clinical medicine becomes that between a patient and a healthcare system, the meaning of fiduciary obligations may become strained, and notions of personal responsibility lost.[8] This contrasts with a traditional medical model of individual responsibility from physician to patient, and the privacy of medical data. We need to look to other disciplines and other models to find ways to proactively govern a future that is not yet clear. Ethical guidelines can be created to catch up with the age of machine learning and artificial intelligence that is already upon us.

The notion of anticipatory governance is especially relevant to reconciling data-driven learning health systems with a human right to science. Anticipatory governance is defined as "a broad-based capacity extended through society that can act on a variety of inputs to manage emerging knowledge-based technologies while such management is still possible."[9]

The possibility for anticipatory governance relies on continuous evolution, where the discovery engine is governed by policies for complex collective innovation, and the negotiation of codesigned innovation futures informed by earlier foresight generated with the inclusion of knowledge generators, end users and evidence (including uncertainty) to imagine the possible multiplex futures for innovations.[10]

Current efforts emphasize the need for international, independent, multi-stakeholder processes of consultation on AI and data ethics, to steer AI "fully towards promoting the public good"[11] and employ trust-building techniques to "skirt the zero-sum game of data privacy versus data utility."[12] There is a shift underway, from protecting people's data, to giving people a degree of control over what is done with their data. Four paradigm shifts are likely to occur in the big data era: a shift from disease orientation to health; from therapy to prevention; from health to lifestyle counseling; and from the role of the patient to the role of the user, customer or digital citizen. In other words, information will be the treatment.

The goal of this novel human rights approach to science and big data is to "reorient our conversation from policing science to governing society and would shift our focus from avoiding risks to protecting opportunities."[13]

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