Realising the promise of genomics: exploring governance

Elizabeth Dowdeswell,* Abdallah S. Daar, Tara Acharya and Peter A. Singer

Canadian Program on Genomics and Global Health,
Joint Centre for Bioethics,
University of Toronto,
88 College Street,
Toronto, Ontario, Canada M5G 1L4
E-mail: edowdeswell@nwmo.ca E-mail: a.daar@utoronto.ca
E-mail: tara_acharya@yahoo.com
E-mail: peter.singer@utoronto.ca
*Corresponding author

Abstract: The tremendous potential of genomics to contribute to significant healthcare innovations in the developing world will not be realised without attention to governance. Governments, industries and citizens will encounter numerous ethical issues in achieving a balance between risk management and the promotion of the benefits of genomics. We need a governance mechanism that maintains a balance between the global public goods characteristics of genomics knowledge and the private goods nature of its application. Networks may well be an appropriate way of preventing a bleak future of increasing disparities between industrialised and developing countries. An informed debate that attempts to exchange the politics of polarisation with a truly participatory process would be worth pursuing. Consequently, this paper proposes a Global Genomics Initiative (GGI) that would provide such a forum.

Keywords: genomics; governance models; global public goods; Global Genomics Initiative (GGI); biotechnologies.

Reference to this paper should be made as follows: Dowdeswell, E., Daar, A.S., Acharya, T. and Singer, P.A. (2006) 'Realising the promise of genomics: exploring governance', *Int. J. Biotechnology*, Vol. 8, Nos. 1/2, pp.132–141.

Biographical notes: Elizabeth Dowdeswell is a Visiting Professor of the Joint Centre for Bioethics at the University of Toronto and the President and CEO of the Nuclear Waste Management Organization. She has served as a Under Secretary General of the United Nations and as an Executive Director of the United Nations Environment Programme from 1993 to 1998. She received her MSc in Behavioural Sciences and is the recipient of 10 honourary degrees and a Pierre Elliott Trudeau Foundation mentorship.

Dr. Abdallah S. Daar is a Professor of Public Health Sciences and Surgery at the University of Toronto, where he is also a Co-Director of the Canadian Program on Genomics and Global Health, and a Director of Ethics and Policy at the McLaughlin Centre for Molecular Medicine. He was awarded the 2005 UNESCO Avicenna Prize for the Ethics of Science and he is currently a member of the High Level Africa Biotechnology Panel appointed by the African Union.

Tara Acharya is currently consulting to the Bill & Melinda Gates Foundation's Global Health Policy program, where she is helping to develop strategy for engaging the growing R&D capacity in developing countries to contribute to the development of global health products for communicable diseases. She is also a consultant to the Rockefeller Foundation's Health Equity program, exploring new directions for their global health strategy with a focus on emerging systems of innovation of scientifically -advanced developing countries. She has also worked in the biotechnology industry as a scientist with Celera Genomics and Genaissance Pharmaceuticals. She received her PhD in Biochemistry and Master's degree in Public Health from Yale University.Previously, she was a Research Associate at the University of Toronto Joint Centre for Bioethics. Her key projects include coordinating the analysis of over 1000 research abstracts for the Bill and Melinda Gates Foundation's Grand Challenges in Global Health initiative and co-authoring a report on 'Biotechnology and the Millennium Development Goals' for the United Nations Millennium Project's Science and Technology Task Force.

Dr. Peter A. Singer is the Sun Life Financial Chair in Bioethics and a Co-Director of the Canadian Program on Genomics and Global Health. He directs the University of Toronto Joint Centre for Bioethics and the World Health Organization (WHO) Collaborating Centre for Bioethics at the University of Toronto. He is a Professor of Medicine at the University of Toronto and University Health Network and a Distinguished Investigator of the Canadian Institutes of Health Research.

1 Introduction

World leaders have developed a collective agenda to address threats to global stability – the Millennium Development Goals. Targets have been set that would eradicate extreme poverty and hunger, combat disease, reduce child mortality and ensure environmental sustainability. But, by all accounts progress in meeting these commitments are slow and the gap between aspiration and action too wide (World Economic Forum, 2005).

For the optimists among us, a century of innovation in science and technology points to attractive possibilities. The InterAcademy Council report on "Inventing a Better Future: A Strategy for Building Worldwide Capacities in Science and Technology", concurs but stresses the necessity and the urgency of building capacity as the world rushes to reward knowledge-based economies (InterAcademy Council, 2004). UN Secretary General Kofi Annan noted that

> "if every nation gains full access to [the] broader world community of science and has the opportunity to develop an independent science capability, its public can engage in a candid dialogue about the benefits and risks of new technologies, such as genetically engineered organisms or nanotechnology, so that informed decisions can be made about their introduction into our lives" (Annan, 2003).

2 The specific case of genomics

Genomics – that powerful new wave of health-related life sciences energised by the human genome project and the knowledge and tools it is spawning – illustrates the tremendous potential. This knowledge can be directed to significant healthcare

innovations with the development of new diagnostic technologies, treatments and preventative programmes and thus reduce stark health disparities (World Health Organization, 2002). In 2002, the University of Toronto published a study in which an international panel of scientists – half of them from developing countries – identified the ten biotechnologies most likely to improve the health of people in the developing world in the next 5–10 years (Daar et al., 2002). The team then mapped these biotechnologies onto the UN Millennium Development Goals to illustrate their potential contribution towards the development solutions (University of Toronto, 2004).

Although there are examples of successful application of these technologies to health problems in developing countries, their health and accompanying economic benefits are not guaranteed. Whether or not the potential is fully realised may well depend on bridging an emerging genomics divide through a conscious world effort to develop common understanding, set a strategic direction and mobilise commitment. This is governance in the best sense of the word.

3 Genomics and governance

Governments, industries and citizens in both developed and developing countries will encounter numerous ethical issues in achieving a balance between risk management and the promotion of the benefits of genomics. Can these technologies be used responsibly? What should be the balance between private and public sector interests? What health needs should be given priority? How can capacity to develop an appropriate regulatory regime be built? What policies and measures are needed to transfer and accumulate technologies to the communities of greatest need? The power and promise of emerging technologies has both a bright side and a dark side. Through the lens of human security, a companion piece in this journal suggest an initiative to explore the forms of the governance that could help us to control the potential misuse of genomics, while at the same time keep in sight the all-important promotion of genomics for global health equity. Traditional governance models that only focus on risk and advocate restrictions on use may not be helpful in energising industries and governments to create environments of innovation.

4 Through the lens of global public goods

Governance for genomics is a challenge not just because of the complexity of ethical, social and legal issues involved, but also because of the rapid evolution of the science. Globalisation increases this complexity. So do the significant global public goods characteristics of genomics knowledge. The benefits of a public good can be enjoyed by all (non-excludable); and its consumption by one individual does not deplete the good (non-rivalrous). Global public goods exhibit a significant degree of ‘publicness’ across national boundaries. A healthy ozone layer is an example. It should protect all of us, regardless of national boundaries and should not be depleted through individual ‘use’. Externalities caused by other activities can have an impact on both quality and quantity of public goods (e.g. the production and use of chlorofluorocarbons, designed for a worthy purpose but with an unintended consequence of depleting the ozone layer). Public goods require some form of governance to maintain them, typically one that transcends nation-states.

Genomics is fundamentally about knowledge, which, according to Stiglitz (1999), is the archetypal public good. Genomics knowledge (sequences and databases) is in the public domain and is potentially non-excludable and non-rivalrous. But the translation of it into a marketable product (such as, for instance, a diagnostic tool for malaria) has characteristics of a private good (see Box 1). We need a governance mechanism that maintains a balance between the global public goods characteristics of genomics knowledge and the private goods nature of its application. The market is already the major driving force for human health – most goods and services, and therefore most research and development in health, are geared to the needs of the developed world. If this continues, there is a real danger that the majority of the world's 6 billion people – who do not present profitable market opportunities – will not see the benefits of genomics. We need new mechanisms to address such market failures, perhaps some form of stewardship to maintain the global public goods characteristics of genomics.

Box 1 Public and private aspects of the SARS genome

The recent worldwide Severe Acute Respiratory Syndrome (SARS) outbreak aptly illustrates both the global public goods nature of genomics and its private aspects. In April 2003, Canadian scientists at the Michael Smith Genome Sciences Centre of the British Columbia Cancer Agency sequenced the genome of the SARS virus (which belongs to the family of coronaviruses) for the first time. The sequence of the 30,000 bp genome was shared immediately with scientists all over the world via the internet. These scientists were able to download and analyse the data directly and apply it towards their epidemiological investigations in situ, highlighting the importance of sharing the information globally towards local solutions. (This unprecedented achievement points to another critical factor: the convergence of genomics and information technology in the interest of global public health). Going a step further into the realm of private goods, the California-based biotechnology company Affymetrix Inc. was able to use the public genome to create a marketable product – a SARS gene chip for diagnostics. This example points to the continuum of characteristics that genomics possesses, with public input at one end of the spectrum and private goods emerging at the other. In this stepwise process, the public genome provides the basis for the private sector to create a specialised, value-added product.

The global public goods characteristics of genomics knowledge inevitably raise issues about access to this emerging resource. This will surely test our skills in the evolution and management of international relations, foreign policy, regulation and intellectual property rights (Daar et al., 2003). A governance mechanism that can successfully harness these global public goods characteristics could be highly effective in promoting genomics for global health.

In the absence of a concerted effort, genomics-based tools may not be diffused and widely implemented in developing countries. The barriers are significant: the lack of financial resources and an appropriate investment model; a non-receptive policy environment; lack of human resources to develop policies, institutions and infrastructure (scientific, legal and financial); few incentives for entrepreneurial activities, insufficient investment in the research and development, limited public education and dialogue that would lead to effective and accepted public policy. All these can reduce the ability of developing countries to absorb and apply new technologies. In addition to this the failure of the developed world to ensure the distribution of benefits of new technologies that can

address developing countries' needs and you have a recipe for inequity. Arguably inattention to the governance whereby these complex issues are understood and integrative actions taken may be the fundamental reason why new technologies are not implemented effectively.

5 Exploring governance models

This genomic technological revolution will almost certainly bring social, economic and political changes. In an interconnected world, a global dialogue that would raise awareness, perhaps build consensus and set the agenda for action is essential. This public policy issue is first and foremost about society's understanding, acceptance and management of risk. Consequently, an informed debate that attempts to exchange the politics of polarisation with a truly participatory process would be worth pursuing.

5.1 Commissions

Governments have developed numerous mechanisms to provide exposure to certain issues, undertake research, elicit opinion and develop recommendations for action. Specifically, international commissions have provided for catalysing change supported by a public consensus. The best have built trust and confidence and integrated diverse points of view and expertise. A forthcoming book published under the aegis of the United Nations University examines the influence of international commissions focusing on the power of their ideas (the 'mind of global governance') rather than the creation of institutions (Thakur et al., 2005). Among their conclusions is a caution that big ideas which are often the subject under study by commissions rarely translate well into practice. Commissions must strive for a balance between idealism and realism. Our own earlier examination of a proposal for a commission on genomics and global health identified other structural and conceptual barriers. It pointed to resulting agreements that were negotiated at the lowest common denominator and the absence of a bias for action (Dowdeswell et al., 2003). Significantly, the missing link may be the absence of 'normal' agencies for implementation.

5.2 Treaties

Other global public goods that exhibit challenging governance characteristics have turned to the negotiation of formal treaties. Depletion of the ozone layer was the impetus for the Montreal Protocol. The Convention on Biological Diversity aims to conserve biodiversity while using it sustainably and sharing the benefits in a fair and equitable manner. Genomics has similar needs – the option value of enormous potential benefits to global health, as well as the potential misuse of genomics knowledge. Table 1 displays certain similarities and trends among these global public goods. A global governance mechanism for genomics could borrow elements from both the relatively successful Montreal agreement (where most countries acknowledged the disadvantages of the thinning ozone layer and agreed on measures to reverse the trend) and the relatively complex Convention on Biological Diversity (where there were differences in national-level priorities and incentives were not so clear).

Table 1 Global public goods and corresponding interventions

Global public good	*Driving force for governance*	*Priority*	*Governance structures*
Ozone	Thinning of the layer – effect on human health	Reduction of chlorofluorocarbons	Public–private partnerships; global convention
Biodiversity	Loss of biological diversity; potential use and sharing of benefits	Species and ecosystem conservation	Public–private partnerships; global convention
Genomics	Potential use; risk of misuse (ethical considerations)	Improving global health	Public–private partnerships; a Global Genomics Initiative (GGI)?

However, as a recent analysis demonstrates, many intergovernmental agreements do not perform well as problem-solving mechanisms (Simmons et al., 2001). Some have too vague a mandate, become too easily outdated, are undercut by other agreements or limited by inadequate incentives or enforcement authority. Treaties and conventions are slow to negotiate and suffer from poor adherence. They may well be poorly suited to the urgent issue of benefit-sharing in science and technology, particularly for rapidly evolving sciences such as genomics.

5.3 Networks

In the past decade, a considerable attention has been directed to the examination of networks as a response to fast-paced change, complex issues and global interdependence. In commenting upon A-M. Slaughter's recent book, *A New World Order* (2004), Joseph Nye notes "Global interdependence requires governance, but we properly fear global government." Slaughter describes a world of networks, each with specific objectives and activities, membership and history. Some expand regulatory reach while others build trust and establish relationships. Most exchange information about their own activities, develop databases of best practices and offer technical assistance and professional socialisation to members from less developed countries.

Slaughter makes a distinction between government networks and global policy networks. The former involve national government officials, either appointed by elected officials or directly elected themselves who perform legislative, administrative and adjudicative functions of a world government. The latter – global policy networks – may not possess the same legitimacy as it is never clear who is exercising power on behalf of whom. Nevertheless, Rischard (2001) summarises their potential:

> "On our increasingly small and interconnected planet…global problems cannot be solved within any one nationstate. They call for collective and collaborative action – something that the nations of the world have never been good at….The current international system is simply not effective enough – or at least fast enough – to solve these problems."

Recent useful initiatives, such as the G8 Digital Opportunity Task Force, illustrate however that reducing global inequity may not be achieved by such an exclusive club restricted to certain countries and generally not open to participation from civil society or industry. It would be useful to examine networks that work well to examine their applicability to the field of genomics.

6 A global genomics initiative

The Joint Centre for Bioethics at the University of Toronto has examined the idea of a GGI to promote and facilitate broad-based, informed and ethical decision-making about the use of genomic technologies to contribute to global health equity. Our intent was to meet three broad objectives: to inform and shape institutional decisions and public policy; to provide a forum for an exchange of views about issues and policy options among the public and experts; and, to raise public awareness and understanding.

On balance, we are convinced that a global network with inclusivity and agility is an appropriate model to promote and institutionalise cooperation. We envisage a network underpinned by governments to have legitimacy and accountability but expanded to include other networks of international organisations, non-governmental organisations, corporations and other interested actors. These could be bilateral, plurilateral, regional or global. Building on the work of Slaughter (2004), this model recognises that states are not the only actor, but are important; that states will continue to have distinct interests; that networks can exist alongside more traditional international organisations. We believe this network of networks could address issues, seize opportunities and resolve problems as genomics and global health becomes a global concern.

Specifically, a GGI could:

- *Promote genomics as a global public good*. The GGI would try to ensure rapid and reliable global access to the world's expanding genomics knowledge and resources.
- *Encourage equitable participation*. The GGI would represent a dedicated effort to hear all voices in the genomics debate. Participation rooted in the right to be involved would be essential for building consensus and avoiding knee-jerk reactions to the technology.
- *Strengthen capacity in biotechnology*. Participation in the GGI would promote international and intersectoral exchange of knowledge and encourage partnerships between countries (especially developing ones) to build their genomics research and development capacity and to undertake rigorous assessment of policies in the research and development investment and human resources.
- *Prioritise needs and foresight activities*. The GGI would undertake surveys or need assessments, as well as anticipatory evaluations of emerging genomics technologies and respond collectively to a new technology or policy initiatives as they arise.
- *Design financing alternatives*. GGI partners could explore and evaluate alternative financing options to fund public and private biotechnology applications for developing countries.
- *Examine intellectual property rights and other ethical and legal considerations*. The GGI could examine different models of intellectual property protection to optimise social utility while maintaining necessary incentives for discovery.
- *Inspire appropriate regulation*. The GGI could also help draft and promote norms and principles for the global harmonisation of ethical standards applied to genomic technology research, with benefit-sharing and risk minimisation.

Although a network may not decide to tackle all these activities, such a network would thus help to set the agenda and stimulate thoughtful debate, finding common ground and generating reasoned solutions. It would serve as a catalyst for action and could become a neutral, trusted, authoritative broker and disseminator of information. A major role would be to safeguard genomics knowledge, make it openly accessible and promoting its application by developing countries, while minimising the risk of misuse.

The GGI would foster international dialogue for access to and sharing of genomics knowledge. It could coordinate the assortment of existing alliances, partnerships, agreements into a global governance network, and help bridge the gap between bilateral partnerships, public–private partnerships and alliances at one level and the higher-level governance structures and international organisations such as the UN and the World Health Organization.

Existing public–private partnerships, alliances, networks and coalitions in the arena of genomics and health (such as NEPAD, BIOPAD, the Malaysia-MIT biotechnology partnership) could contribute significantly to this network. There is considerable advantage for these partnerships in forging links within a global network – access to knowledge, expansion of partnerships and the creation of new scientific capacity through shared resources that are obviously beneficial.

The power of such a network is in a design that would maximise participation and inclusion. This loose collaboration among multiple sectors would provide a forum for discussion of goals and needs to create an environment in which the valid but differing views of participants would be recognised while striving to build consensus. The focus would be on cooperation. The diverse membership could influence constructively many governing institutions at the local level. Inclusivity means that developing countries could initiate and assume leadership in driving the agenda for health equity. Networks could also be launched quickly and with minimum bureaucracy and hierarchy could remain agile and responsive to rapidly-evolving issues.

Although institutional development would take several years and significant resources, a process like the GGI is likely to yield both short- and mid-term benefits in support of global health. Box 2 shows a concrete example of the type of project for which the network could be responsible.

Box 2 The potential efficacy of partnerships – removing arsenic from groundwater in Bangladesh

Naturally occurring arsenic in groundwater in Bangladesh has created a public health problem of enormous proportions. A number of sub-surface microbes have been identified to promote the movement of insoluble arsenic deposits underground into a soluble form that enters drinking water aquifers, which are tapped by tube-wells. In recent years, scientists have discovered bacteria that do the opposite: they can convert dissolved arsenic into a less soluble form, providing a possible solution to this problem which has put 50 million people at risk in Bangladesh. A worthwhile project might scan the genomes of the two different types of microorganisms to identify differences and apply that knowledge for solving the problem of arsenic contamination in Bangladesh. A global partnership such as the GGI could mobilise resources and partners that are necessary to make this happen – a collaboration between, for example, Bangladeshi and Australian microbiologists, geneticists and water engineers, public health officials, foreign funding agencies, government and local officials and non-governmental organisations.

7 From concept to reality

A GGI is still on the drawing board. If it is to be credible and legitimate it must be built collaboratively. The GGI could establish legitimacy on a global level. The key to this is strong leadership and inclusive membership. There must be champions for such a dialogue within the government, industry and civil society, willing to provide both leadership and funding. The GGI could initiate truly global and inclusive dialogue on genomics. A flexible network could minimise the complexity and promote equal participation and partnership within the global network, while ensuring that individual countries are provided the opportunity to prioritise their own health goals. But dialogue must proceed with enough urgency to provide real value to policymakers given the pace of technological developments in genomics. A GGI must learn about transparency, inclusiveness and accountability from other multi-stakeholder initiatives.

The relative lack of participation by most of the developing world in the Information and Communication Technology revolution contributed to the digital divide. The genomics divide between North and South is growing and the nanotechnology divide is on the horizon. Technologies advance at a faster pace than ever before, threatening to widen the gaps between the developed and developing world. International participation in global governance networks like a GGI could help prevent a bleak future of even greater disparities between the industrialised and developing countries.

An interconnected and interdependent world in which the greatest majority has limited access to the healthcare while the quality of life of the minority expands is a recipe for social confrontation. Avoiding a genomics divide is well within human capacities. A network could be instrumental in developing common understandings among governments and their citizens, setting a strategic direction and mobilising commitment to a healthier, more equitable world.

Acknowledgements

The Canadian Program on Genomics and Global Health is primarily supported by Genome Canada through the Ontario Genomics Institute and the Ontario Research and Development Challenge Fund. Matching partners are listed at http://www.geneticsethics.net. ASD is supported by the McLaughlin Centre for Molecular Medicine. PAS is supported by Canadian Institutes of Health Research Distinguished Investigator award.

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