knowledge-based economy, and to harnessing life-sciences research for health and economic development. Although the relevant policies are in place, what remains to be seen is to what extent they will be translated into concrete support for research, development and delivery of products and services in the human genomics field. Identifying the needs, encouraging local collaborations and helping to form R&D networks will go a long way towards establishing South Africa in this field.

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FURTHER INFORMATION
African Genome Education Institute (AGEI): http://www.africagenome.com
African Institute of Biomedical Science and Technology (AiBST): http://www.aibst.com
African Society of Human Genetics (AfSHG): http://www.afshg.org
Biodiversity Act: http://www.info.gov.za/gazette/acts/2004/a10-04.pdf
Burden of Disease Research Unit FAQs, Medical Research Council: http://www.mrc.ac.za/bod/faqdeath.htm
Centre for Proteomic and Genomic Research (CPGR): http://www.cpgr.org.za
Freedom to Innovate report by the African Union High Level Panel on Modern Biotechnology: http://www.nepadst.org/doclibrary/pdfs/biotech_africa_2007.pdf
Gknowmix: http://www.gknowmix.com
Lifelabs: http://www.lifelab.co.za
McLaughlin–Rotman Centre for Global Health: http://www.mrcglobal.org
National Institute of Genomic Medicine (INMEGEN), Mexico: http://www.inmegen.gob.mx
The Division of Human Genetics, University of Cape Town: http://web.uct.ac.za/depts/genetics
The Living History Project: http://www.africagenome.com/index.php?option=com_content&task=category&sectionid=4&id=13&Itemid=43
The Public Understanding of Biotechnology programme: http://www.pub.ac.za
The Skin Colour Education Project: http://www.africagenome.com/index.php?option=com_content&task=view&id=17&Itemid=39
The World Health Organisation's South Africa overview: http://www.who.int/countries/zaf/en

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SCIENCE AND SOCIETY

The next steps for genomic medicine: challenges and opportunities for the developing world

Billie-Jo Hardy, Béatrice Séguin, Federico Goodsaid, Gerardo Jimenez-Sanchez, Peter A. Singer, and Abdallah S. Daar

Abstract | This is a historical moment on the path to genomic medicine — the point at which theory is about to be translated into practice. We have previously described human genome variation studies taking place in Mexico, India, Thailand, and South Africa. Such investments into science and technology will enable these countries to embark on the path to the medical and health applications of genomics, and to benefit economically. Here we provide a perspective on the challenges and opportunities facing these and other countries in the developing world as they begin to harness genomics for the benefit of their populations.

Thanks to rapid economic development, two-thirds of the entire global economic growth last year was from the so-called emerging economies, which are predicted to grow at an average of 6.7% in 2008 compared with 1.3% in the United States, Japan and European Union[1]. In addition, emerging economies in the developing world, such as India, China and Brazil, are investing heavily in innovative science and technology (S&T) and making significant progress in the life-sciences arena, where they are increasingly protecting the subsequent intellectual property[2–4]. The situation in the poorer parts of the developing world, especially in sub-Saharan Africa, has so far been different. The proportion of gross domestic product (GPD) spent on research and development (R&D) is extremely low in sub-Saharan Africa[5], and health expenditure is less than

US$30 per capita annually[6] compared with more than $6,000 in the United States[7]. However, in terms of understanding the value of S&T for development, of investing in S&T, and of realizing the need to spend more on health, the situation might be changing. For example, African Union countries have endorsed the call to spend 1% of their GDP on S&T and have undertaken to spend more on health[8,9].

We have described several case studies in Mexico, India, Thailand and South Africa, which demonstrate how emerging economies in the developing world are investing in large-scale human genomic variation studies[10–13]. The most comprehensive programme is Mexico's National Institute for Genomic Medicine (INMEGEN), which has described in a recent publication a nine-point strategy for the adoption of genomic medicine, including: building an innovative organizational design; establishing the initial infrastructure; initiating nationwide strategic alliances; conducting R&D in genomic medicine; applying genomic technology to common health problems; reaching excellence in teaching and training programmes; supporting academic programmes in genomic medicine; addressing ethical, social and legal issues; and translating genomic knowledge into products and services[14]. For these countries that have already embarked on major genomics initiatives, establishing research institutes and conducting the research are the first steps on the path to genomic medicine. For them the major question now is how they will go from this early-phase investment towards the hoped-for health-oriented applications, and the economic benefits. For other countries that have not started genomics initiatives, the question is: what are the potential entry points? And for all developing countries, with or without current genomics initiatives, the question is: what are the challenges and opportunities along the way to the adoption of genomic medicine and to deriving economic benefit from genomics? Some challenges are common to all countries, whether economically developed or developing. Other challenges will be more specific to developing countries. Here we present a perspective on the challenges and opportunities associated with the adoption of genomic medicine, particularly in the developing world, and the need to understand the interdependent nature of efforts to develop genomic medicine globally.

Projects in the developing world

The large-scale human genomic variation projects that we have described are not the only projects of their kind taking place in emerging economies and the developing world. China was the only developing country that participated in the sequencing of the human genome. Several years later, it has a number of important initiatives related to genomics. For example, China's Beijing Institute of Genomics plans to sequence the entire genome of 100 Chinese individuals. Some relatively wealthy countries, previously unknown for their involvement in human genomics, are also investing in this field. Researchers in the Al-Mulla molecular pathology laboratory at the University of Kuwait, for example, are using haplotype mapping to study the Arab genome and to identify genomic sites linked to colorectal cancer and type II diabetes. Iran has initiated the Human Genome Diversity Project of Iran (HGDPI), with the main objective of documenting genomic diversity in the populations of Iran for anthropological purposes, and generating a database towards furthering the understanding of disease predisposition. Finally, sub-Saharan African countries other than South Africa are also investing in this field. In the year 2000, a national DNA data bank was initiated in The Gambia containing samples from ~57,000 West Africans[15,16]. More recently, a biobank and pharmacogenetics database was established in Harare, Zimbabwe, containing 1,488 samples from several ethnic sub-Saharan African populations (Nigeria, Kenya, Tanzania, Zimbabwe and South Africa)[17].

Finally, the Pharmacogenetics for Every Nation Initiative (PGENI) is also worth noting in this context as its goals include: enhancing the understanding of pharmacogenetics; building local infrastructure for pharmacogenetic studies; providing guidelines for medical prioritization; and promoting the integration of genetic information in the developing world.

Exploring potential opportunities

Countries in the developed world, such as the United Kingdom, the United States and Japan have made tremendous investments in R&D towards genomic medicine[18,19] (the UK Biobank and the US National Office of Public Health Genomics, for example). Emerging economies in the developing world that have made a similar commitment will need to consider how best to identify their next steps into genomic medicine. Thinking of these next steps might also help them identify unique niches that would give them commercial advantages. For other countries that have not yet started genomics initiatives, their entry points will depend, to some degree, on their respective life-sciences innovation infrastructure. Such entry points (see below) would need to be appropriate for their level of investment in genomics R&D and their existing health-care delivery systems.

The current trend in terms of both next steps and entry points is for countries in the developing world to collaborate in R&D with more developed nations (north–south collaborations). The Human Genome Organisation (HUGO) Pan-Asian SNP Consortium provides an example of a recent north–south R&D collaboration between Asian countries[20,21]. Lessons learned from such collaborations have contributed to the further development of international ethical guidelines for benefit sharing, ownership and R&D capacity building in human genomic research. However, increasingly there is a trend towards south–south collaborations[22], in which developing countries pool their limited resources, help each other and learn from each other's experience. For example, Mexico's significant investment in genomic research infrastructure provides other Latin-American countries lacking genomic R&D capacity the opportunity to pool their resources with Mexico, as opposed to the United States or Europe, towards the development of genomic medicine and innovative genomic medicine products for this region.

Next steps and entry points will need to be cost effective. Pharmacogenomic approaches, including diagnostics, can reduce adverse drug reactions in countries that can least afford to waste money on drugs that might not have the expected therapeutic effect. Diagnostics might be easier to develop than new drugs and vaccines, as they bypass the costly clinical trial stage and tend to have a shorter regulatory review schedule. In this respect, once the cost drops significantly, pharmacogenomic diagnostics might be an early next step or even an entry point for some developing countries. Given their access to large populations exposed to multiple infections (for example, HIV/AIDS, malaria and tuberculosis), another viable option for developing countries could be to focus genomics R&D on the host–pathogen responses for these infections.

Bioinformatics provides another potential option. The South African National Bioinformatics Institute (SANBI), for example, has developed eVOC — a software program that unifies gene expression data by facilitating a link between the genome sequence and expression phenotype information[23]. The World Health Organization-based Special Program on Tropical Diseases Research and Training runs training

programmes on bioinformatics for scientists in the developing world[24].

National genotyping projects are useful for establishing base-line profiles, which might have great benefit for subsequent studies. For example, INMEGEN has revealed significant ancestral components between populations from different regions of Mexico. Moreover, identification of unique SNPs and significant differences of functional variations related to drug metabolism suggest the need for regional approaches for the study and applications of genomic medicine in Mexico. The Indian Genome Variation (IGV) consortium recently uncovered high levels of genetic divergence between groups of Indian populations that cluster largely on the basis of ethnicity and language[25]. The study of such population groups will be useful for addressing stratification and complex study design issues[25]. Here, large collaborative efforts on R&D in fields such as pharmacogenomics, vaccinogenomics and toxicogenomics could serve as entry points for developing countries. Examples include pharmacovigilance programmes and detailed analyses of data from vaccine trials in which some but not all the human subjects respond to a particular vaccine. A well known example demonstrating that genetic factors can have a strong effect on the immune response to certain vaccines is the response to hepatitis B surface antigen (HBsAg). Up to 10% of people do not respond to HBsAg vaccination. Recent evidence suggests that although genes encoded within the major histocompatibility complex are important for this immune unresponsiveness, more than half the heritability is determined outside of this complex. Identification of these genes will help us to understand regulation of immune responses to viral proteins[26].

A potential to improve the understanding of genomics and traditional medicines through fields such as nutrigenomics provides another possible entry point that offers these countries an intellectual property advantage. Traditional medicine is well established in China and India, where a memorandum has recently been signed to further the understanding of their respective traditional medicine sectors[27]. Whether genomics can add any value to such endeavours remains to be seen.

Although limited, private sector firms in developing countries have also begun to leverage the opportunities in genomic medicine, identifying possible entry points and using unique resources. Avesthagen Ltd, an Indian-owned life-sciences company, has a large-scale genotyping project of the Parsi population in India[28]. They predict an initial market in translational medicine, such as genomic medicine, with an eventual foray into early diagnosis, pre-symptomatic and life-long treatment through a combined offering of wellness products (for example, nutrigenomics) and personalized health care. In other countries, such as South Africa and Thailand, a few innovative firms are considering targeting the medical tourism market[12,13].

Finally, additional possible entry points might involve anthropology or human history and migration studies, as part of establishing a base-line of data for possible health applications. This, for example, was the original impetus for the HUGO Pan-Asian SNP Consortium[20,21]. Other countries might become involved as a result of participating in the HapMap project, as did Nigeria[29,30].

Challenges

Genomic research platforms in emerging economies and developing countries will be faced by a number of similar challenges as they become established and proceed towards the adoption of genomic medicine in their respective countries. These challenges are: the current lack of skilled human resources; ensuring sustainable funding and political will; sourcing alternative funding; improving collaboration within the public research sector as well as between the public research sector and the private sector; developing opportunities for south–south and north–south collaboration; improving the commercialization infrastructure in both the public and private sector; developing and improving the existing regulatory infrastructure; developing a health-care infrastructure that can address access and delivery issues of genomic medicine; training health-care workers; and engaging with the public to improve awareness and participation[10–14]. A number of these challenges are local and can be addressed as such by and in individual countries. Others, such as establishing international R&D collaborations in genomics research and the need to address the lack of harmonized regulatory infrastructure for genomic medicine, require collaborative efforts on an international scale to address them.

Internationally, issues that rapidly need to be addressed for productive and equitable collaborations include data and sample sharing, research capacity building in developing countries, and rules and guidelines for building and using international repositories containing long-term treatment outcomes in both developed and developing nations. These issues are often not straightforward to address. For example, data and sample sharing in many developed countries have traditionally focused upon consent and the concerns associated with privacy and confidentiality[31]. But in international collaborations, in addition to these concerns, considerations will also have to be given to the sovereign nature of the data and of samples sourced in emerging economies and developing countries[32]. The Public Population Project in Genomics (P3G), an international consortium that aims to build the necessary collaborative infrastructure between institutes in order to foster interoperability on the research level[33], provides one example of how international consortia can contribute to addressing these challenges. It is important to think about such issues early because the need for large-scale collaborative research is becoming more pressing as R&D in genomic medicine advances. These studies will require data comparisons and validation in large sample sets across different populations[34], which is one reason the European Science Foundation has recommended that European biobanking initiatives harmonize their efforts to achieve maximal benefit[35].

Collaborative efforts will also be necessary to address policy issues related to translation of genomic research and applications for population health. An example is the Genome-based Research and Population Health International Network (GRaPH-Int), a global collaborative network that fosters dialogue, research, education and training, and communication and stakeholder engagement, with the aim of establishing public policies, programmes and services in public health genomics. These types of consortia will be necessary for integrating approaches to genomic medicine and accelerating global consensus-building towards the development of international standards, the regulation of genetic testing and consumer genomics, and accessibility of genetic data and associated information.

Broader issues that require consideration include the integration of genetic information into public health decision-making, guidelines for medical prioritization, intellectual property regimes, and the association between regulatory bodies and health technology assessment bodies. For instance, forward-looking intellectual property regimes will need to be developed that can be used by countries, depending on the stage of economic and scientific development, to facilitate access to health products, scientific capacity building or economic profit. There is also a great need to build capacity in

technology transfer in many developing countries.

One of the major challenges in the application of genomic medicine in emerging economies and developing countries involves the limited, or even absent, regulatory infrastructure. Some of these countries may have limited capacity to regulate traditional drugs and diagnostics, and will need to build capacity for these and for emerging genomic medicine products. Furthermore, regulatory capacity in many developing countries will need to encompass the work of ministries of health, science and technology, industry, commerce, natural resources, the judiciary and legislative bodies, as well as of drug licensing agencies. Developing countries might benefit from the experience of developed countries that are currently drafting the necessary guidelines to address unique emerging issues associated with the regulation of genomic medicine products[36]. In the developed world, these issues are being addressed on a national scale by their regulatory agencies and on an international scale through the International Conference on Harmonization (ICH)[37]. The inclusion of emerging or developing countries in the ICH harmonization of guidelines associated with genomic medicine, as well as in other consortia that can help to improve regulatory capacity, will provide a concrete opportunity to improve the application of genomic medicine to global health.

Genomic medicine is redefining how both developed and developing countries need to work together in the application of new knowledge to improve public health. The intrinsic value of information in the human genome is associated less with national boundaries and income than with how comprehensive this information is, and is strongly dependent on the information from many individual genomes and from many individual countries. Data acquired from the genotyping and sequencing projects in emerging and developing countries summarized above help to bridge the gaps in the application of genomic medicine between developing and developed countries. Access to these data throughout the world will be crucial for the identification of novel biomarkers of drug safety and efficacy. Whereas the generation of information from the human genome requires a global effort, its application will require development of therapeutic, diagnostic and other applications and products aimed at sub-populations and individuals. The most important benefits will probably be in the use of genomics knowledge to prevent diseases and promote health. At an individual level, and perhaps a sub-population level, the benefits will depend on how genomics is integrated in health systems. To achieve these aims of genomic medicine on a larger scale, public health systems in countries throughout the world will need to integrate pharmacogenomic data from their citizens and will need to use these data effectively for the optimal allocation of diagnostic and therapeutic resources, to improve health education of their publics. This will help their public to change their health-related behaviour, to educate health professionals, and to re-engineer health-care systems more towards prevention and health promotion.

In terms of the benefits of S&T generally, the current trend to develop knowledge, skills and products in the economically and scientifically more developed countries and then struggle to make these available to the less scientifically developed and poorer countries is not sustainable in the long run. This is why so many developing countries, especially the emerging economies, are focusing more on local innovation, invention and commercialization to break the cycle of dependency. To go 'from the lab to the village' through discovery to product development to commercialization by, and in, developing countries will require that science, business and capital be brought together creatively. One proposal involves creating 'convergence centres', which are an evolution beyond science parks and incubators, aimed specifically at enhancing opportunities for knowledge sharing and rapid innovation, and have a focus on product development and commercialization[38].

Conclusions

The existing initiatives in emerging economies in the developing world, which range from databases run by research networks to comprehensive national institutes with public health mandates, serve as models for how to invest in innovative S&T towards development. Such initiatives can strengthen local research infrastructure and local intellectual property regimes, address local health needs and reduce health-care costs, thus improving local health equity. How these countries choose to capture these benefits early on will depend, in part, on the type of entry points they opt for, which in turn will depend on the level of development of their research and health infrastructure. There is much to be learnt from the experience and examples of India, Mexico, Thailand and South Africa.

There are, however, significant challenges to be addressed before the adoption of genomic medicine, and although these are for the most part being experienced by all countries, the challenges are more pronounced for developing countries. There is therefore a need to strengthen existing collaborative efforts, especially south–south collaborations, which in the long run might be more sustainable. Current and future initiatives and investments in R&D capacity will further enable countries in the developing world to participate as equal R&D partners with more developed countries, instead of merely facilitating access to local biological resources.

In terms of international collaborations that would add value to all countries, at a recent workshop in Mexico City (see Emerging Regulatory Issues in Genomic Medicine conference overview) experts in the emerging issues in genomic medicine from both the developed and developing world discussed a number of ways forward. They included the creation of an information clearing-house, a virtual network of interested parties, phenotypic and genotypic databases associated with drug development, an international consortium for biomarker development with real involvement of emerging economies and developing countries, and methods of international harmonization of genomic product regulation. Many in the developing world are excited with the prospects of genomic medicine. We are at the crossroads between theory and practice. It is important now that we all think seriously about the challenges and opportunities lying ahead.

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FURTHER INFORMATION

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eVOC software program: http://www.evocontology.org
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International Conference on Harmonization (ICH): http://www.ich.org/cache/compo/276-254-1.html
McLaughlin–Rotman Centre for Global Health: http://www.mrcglobal.org
National Institute for Genomic Medicine (INMEGEN), Mexico: http://www.inmegen.gob.mx
Pharmacogenetics for Every Nation Initiative (PGENI): http://pgeni.unc.edu
South African National Bioinformatics Institute (SANBI): http://www.sanbi.ac.za
The Public Population Project in Genomics (P3G): http://www.p3gconsortium.org
UK Biobank: http://www.ukbiobank.ac.uk
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