

As personalized, genomic medicine takes off, four developing countries show the way for others

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Developing countries that want the benefits of cutting-edge health care possibilities based on the genetic variation of individual citizens and sub-populations need to foster the new science at home, says a major new Canadian study published today by Nature Publishing Group.

In a special six-paper supplement of the journal *Nature Reviews Genetics* (NRG), researchers from the McLaughlin-Rotman Centre for Global Health (MRC), Toronto, say four countries with emerging economies -- Mexico, India, Thailand and South Africa -- are showing the way for others in similar economic circumstances.

The study details how those four countries are actively establishing domestic capacity in genomic medicine – efforts that will improve national health, slash medical costs through better resource allocation, and bolster their economies.

The two-year study was undertaken by Dr. Béatrice Séguin, Billie-Jo Hardy, Dr. Peter A. Singer and Prof. Abdallah S. Daar of the MRC, part of Toronto's University Health Network and the University of Toronto.

Says project leader Dr. Séguin, who is also assistant professor at the Leslie Dan Faculty of Pharmacy: "Developing countries have much to gain from genomic medicine and can least afford to waste precious resources on ineffective therapies and diagnostics."

"Benefits of this emerging science cannot be an exclusive luxury reserved for wealthier industrialized countries," she says. "Instead, it must be universally advanced by developed and developing countries alike to prevent an increased widening of already huge difference in global health care quality."

Says Prof. Daar, the project's principal investigator, a professor of public health sciences at the University of Toronto and co-director of the MRC's Program on Life Sciences, Ethics and Policy: "The world has reached an historic moment on the path to genomic medicine – the point where theory is about to be translated into practice."

"Developing countries cannot rely on the altruism of western economic interests to address specific health needs of their populations," he adds. "And purchasing health products from the West will only contribute to continued dependency of developing countries on wealthier northern neighbours."

Knowledge of the genomic variation of individuals and sub-populations will usher in an era of personalized medicine, characterized by more accurate abilities to predict illness, prevent disease, promote health and allocate resources better at national levels.

It will also provide a better handle on disease susceptibility and on the likelihood of benefitting from drugs while avoiding harmful reactions to them.

For individuals, genomic medicine holds the promise of personalized therapies. Even today we have genetic tests for patients taking anti-HIV medication that can predict if they will have serious or even lethal reactions to those medications. Genomics knowledge, including knowledge of genomic sequences of pathogens and their vectors, will facilitate development of better drugs, vaccines and diagnostics

The case studies revealed six major cross-cutting themes underlying initiatives in all four countries studied: political will, institutional leadership, the goal of producing local health benefits, protecting genomic sovereignty, and promoting economic benefits.

The authors describe what motivated the four countries to undertake these genomics initiatives, the mechanisms being used to develop genomic medicine appropriate to their circumstances, the potential for commercializing research results, and how challenges are being addressed, including ethical, legal, social and cultural issues that have either arisen or may arise.

The authors say the insights chronicled will be of particular interest to developing world policy-makers (especially in science and technology, industry and commerce, and health ministries); legislators considering research funding; leaders of research institutions; individual scientists; investors and small and medium private sector enterprises in both industrialized and developing countries, and international organizations interested in the use of science and technology to accelerate global health equity, health security and economic development.

Mexico program most comprehensive

The most comprehensive genomic medicine program in an emerging economy is being spearheaded by Mexico's National Institute for Genomic Medicine (INMEGEN). It has genotyped over 1,200 people from different regions of Mexico, triggering a series of studies looking at possible relationships between genetic make-up and such health problems as macular degeneration, hypertension, obesity, infectious diseases, cancer, diabetes and cardiovascular diseases (the latter three representing Mexico's top causes of death).

Mexican experts estimate genomic medicine has the potential to reduce diabetes-related healthcare costs alone by 36% between 2010 and 2025.

Individual variation has resonance with traditional medicine in India

The case study of India (which included additional co-authors Dr. Mitali Mukerji of the Institute for Genomics and Integrative Biology, India, and Dr. Samir K. Brahmachari of the Council of Scientific and Industrial Research, India), says the idea of personalized therapeutics based on individual variation has existed for more than 4,000 years in India's traditional practice of Ayurveda medicine.

Four millennia later, a new national databank contains genetic samples from about 15,000 unrelated individuals from India's diverse geographic and linguistic subpopulations.

Meanwhile, an Indian life-sciences company, Avesthagen Ltd, has announced a five-year, \$32 million project to genotype the country's entire Parsi population -- about 69,000 people. The Parsis, thought to be genetically homogenous, are feared to be at risk owing to their religious prohibition of marriage outside of the community.

The aim is to determine linkages between genes, disease and environmental factors and develop new therapies and diagnostics, with a focus on chronic diseases, such as cancer and central nervous system disorders, that can be used to directly benefit the Parsi population, with an additional potential to be marketed globally where appropriate.

According to one interviewee in the Indian study, up to 13% of Northern India's population does not respond to up to 30 essential drugs. If the nonresponder cases can be explained by genomic variation, better

tailored treatments could potentially be devised, according to the paper.

Thai database grows

A new Thai database will help authorities look for gene-disease associations, including genetic susceptibility to malaria and dengue fever.

One project has collected 1,500 samples from patients and healthy Thais throughout the country; another is working with 3,000 samples from victims of the 2004 tsunami who experienced posttraumatic stress disorder (PTSD).

An example mentioned in the Thai case study is that of patients undergoing kidney transplantation who would benefit from pharmacogenetic testing to prevent adverse reactions to azathioprine, a commonly used drug to stop organ rejection.

South Africa – cradle of the human species, home to vast genetic diversity

Sub-Saharan Africa, where modern humans arose, is home to a wealth of human genetic, linguistic and cultural diversity, according to the South African case study, the authors of which included Dr. Raj Ramesar of the University of Cape Town.

South Africa, with its rich ethnic diversity and many isolated populations, has a unique research advantage and is beginning to apply genomics to address local health needs, including HIV and tuberculosis, two leading causes behind its low life expectancies – 50 for men and 53 for women – and its economic problems.

Researchers are studying human genomic diversity using biological samples from several indigenous tribes in Southern Africa – Zulu, Xhosa, Herero, San and Sotho-Tswana. Although this study does not look at disease genes per se, it will provide data on baseline variation across these populations.

The South African government is also considering a proposal for a national genomic medicine research programme with three components: characterization of human genomic variation within the South African populations, identification of the genomic basis of susceptibility to common diseases (both chronic and infectious) and pharmacogenomics.

"Genomic sovereignty"

Mexico recently enacted genomic sovereignty legislation in response to reports of foreign researchers attempting to obtain blood samples from Mexican subjects, including indigenous groups, without official approval. This "safari research" fuelled concerns that neither the research participants nor the general Mexican population would benefit from such research.

In India, guidelines restrict the export of human samples. They were created amid similar worries about foreign exploitation of India's large population resource, with its multi-generational endogamous families and well maintained genealogical records.

One fifth of the global population lives in India and thus a significant amount of human genomic variation can be found there among its various populations.

Many of those took part in the study noted the delicate balancing act required to protect genomic sovereignty while fostering international collaborations that can provide much needed financing and potentially

contribute to local scientific capacity building.

Challenges

The concluding paper in the series was co-authored by the MRC team and Dr. Federico Goodsaid, Associate Director for Operations in Genomics of the U.S. Food and Drug Administration, as well as Dr. Gerardo Jimenez-Sanchez, Director General of the National Institute of Genomic Medicine.

It looks at challenges and opportunities for developing countries and emerging economies as the era of genomic medicine and health approaches. It also identified potential next steps for those already on the journey, and potential entry points for those contemplating getting on board.

There are numerous challenges locally and globally, the latter requiring international collaborative efforts, both North-South and South-South, according to the authors.

The lack of regulatory regimes remains one of the main global challenges to the adoption of genomic medicine. Some regulatory agencies in the West are already preparing for the eventual implementation of genomic medicine in their respective countries.

Says co-author Billie-Jo Hardy: "The inclusion of developing countries, specifically those with emerging economies and existing investments, in the development and harmonization of these regulatory regimes, in concert with attempts to improve scientific capacity through collaborative opportunities, will provide a concrete opportunity to improve the application of genomic medicine to global health."

Next steps

Emerging economies and developing countries with investments in genomic initiatives will need to consider their next steps carefully.

Says Dr. Séguin: "These next steps will need to explore unique niches which can provide them with a competitive advantage, be cost-effective, and should reflect their existing science and technology innovation infrastructure, health needs and health delivery systems."

Among the paper's proposals: 'convergence centres' for science, business and capital -- an evolution beyond science parks and incubators -- aimed at enhancing opportunities for knowledge sharing, rapid innovation, and a focus on product development and commercialization.

Source: McLaughlin-Rotman Centre for Global Health

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