Physicians as guardians of genetic knowledge

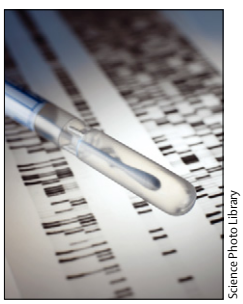
The genetic revolution in medicine, envisaged since the completion of the draft sequence of the human genome over a decade ago, is moving forward at a painfully slow pace. Although truly personalised care is, perhaps, still decades away, private companies have been quick to exploit the genetic information that has become available from the Human Genome Project. The past 5 years have seen a proliferation of personal genetic tests, which promise to predict risk for an array of complex conditions such as type 2 diabetes and Parkinson's disease, determine drug or food metabolism, or uncover carrier status for inherited diseases. And although the predictive power of some of these tests is questionable, they have been offered directly to consumers, who send off a swab of saliva or a blood sample (and US$200–$2000, depending on the test) in return for their genetic risk profile. Last week saw a new development in the regulation of these tests in the USA. An expert advisory panel of the US Food and Drug Administration (FDA) recommended that direct-to-consumer (DTC) genetic tests be subject to medical supervision; interpreted, and possibly also ordered by doctors, rather than by the lay public. The FDA has so far indicated that it might require physicians' involvement for some, but not all, types of genetic test.

The advice of the advisory panel is wise and will be welcomed by many health professionals concerned about the effect of such tests on consumers, as well as the dubious claims made by some manufacturers. Last year, an undercover investigation by the US Government Accountability Office (GAO) found examples of "deceptive marketing" by companies selling DTC tests, including claims made by four companies that consumers' DNA could be used to create personalised supplements to treat diseases. The clinical validity of some tests has also proven problematic. The GAO's investigation showed that disease risk predictions varied across companies for identical DNA samples. One DNA donor, for example, was told that he had below average, average, and above average risk for prostate cancer and hypertension by different companies. Whether doctors become the guardians of genetic tests or not, tighter federal regulation will be needed to ensure companies that do market products are making clinically valid claims. A registry for genetic tests that is being developed by the US National Institutes of Health should help towards this goal.

There are also question marks over the clinical utility of some DTC tests. For example, can anything useful be done with the information gleaned from disease susceptibility tests? After all, most of the interventions for reducing the risk of complex diseases are the same as those that physicians will recommend to all patients—eg, maintain a healthy weight, eat healthily, exercise, and refrain from drinking excessively and smoking. There is also some evidence to suggest that knowledge of disease risk might not hold much extra sway with patients in terms of leading a healthy lifestyle. A paper in the *New England Journal of Medicine* published in January showed that there were no short-term measurable changes in diet or exercise or use of screening tests in a selected group who underwent DTC genome-wide profiling. Some have argued, however, that it could take many years to show improved health outcomes for genetic tests intended to assist in the prevention and treatment of chronic diseases. In view of this situation, the American Heart Association has urged the FDA "to allow tests with clear clinical validity to be marketed even if their use has not been shown to result in improved clinical outcomes".

In the future, full genome sequencing might prove a valuable adjunct to clinical care, especially in tailoring drug treatment, as reported in an Article by Euan Ashley and colleagues published in *The Lancet* last year. Some companies already offer near full or full genome sequencing for consumers but at a prohibitively high price for the general public ($10 000–40 000). However, the costs are expected to come down considerably in the next 5 years to around $1000.

Are doctors prepared for the increasing use of genetics in clinical care? Some evidence suggests not. A 2009 survey of more than 10 000 US physicians by the American Medical Association showed that only 26% had any type of education in the use of genetic testing to guide treatment decisions. And only 10% felt they had the necessary training and knowledge to put pharmacogenetic testing to good use when treating patients. Medical schools and professional organisations will have an important part to play in improving this situation. Doctors will have to become increasingly adept at not only using genetic tests in clinical care but also at explaining their results and, importantly, their limitations to patients. ■ *The Lancet*



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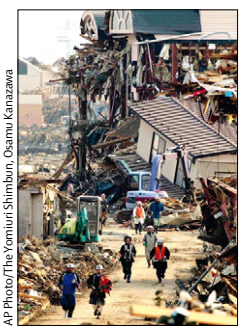
For the **GAO report** see http://www.gao.gov/new.items/d10847t.pdf

For the **paper on the effects of DTC genome-wide profiling** see *N Engl J Med* 2011; **364:** 524–34

Japan: health after the earthquake



AP Photo/The Yomiuri Shimbun, Osamu Kanazawa

The magnitude 9·0 earthquake that hit the northeast coast of Honshu at 2·46 pm on March 11 has shocked TV viewers worldwide. The unstoppable force of the tsunami that followed was a hitherto rarely seen spectacle—and tragedy. Estimates suggest that as many as 10 000 people may have died. Half a million people have been made homeless and the country has been plunged into a state of emergency. The Japanese Government has responded calmly and carefully to the catastrophe. But the very real danger of radiation exposure now represents a sinister further complication facing Japan's political leaders.

Although the earthquake caused huge structural damage, fires now seem largely under control and most hospitals are fully operational. Over 1 million households are still without electricity or running water, but those numbers are falling fast. The government acted quickly by establishing an emergency management committee, led by the Prime Minister. A disaster medical assistance team activated 120 field units, with a further 119 on standby. Food, water, blankets, and portable latrines have been widely distributed to those affected. The international response has also been impressive, with at least ten countries sending additional rescue teams.

The disaster is bad enough. But the multiple explosions at the Fukushima Daiichi Nuclear Power Station have caused temporary increases in radiation outside the affected reactor units. WHO immediately sought help from its Radiation Emergency Medical Preparedness and Assistance Network—40 specialist institutions expert in radiation emergency medicine. WHO's task in this situation is to assess the public health risk and provide technical guidance and assistance. It has done so, reporting that although the public health risk is small, conditions could change. What happens over the next few days depends on whether further radiation is released, as well as the weather.

In the coming weeks, Japan will inevitably enter a period of profound mourning and reflection. WHO might consider convening experts to review the consequences for human safety of nuclear energy, and the wider lessons to be learned from recent earthquakes. The mounting anxiety about events in Japan demands a calm but considered international, as well as national, response. ■ *The Lancet*

The end of the one-child policy in China?

Reuters

For the **two-child policy discussion in the annual plenary sessions of Chinese People's Political Consultative Conference and the National People's Congress** see http://english.peopledaily.com.cn/90001/90776/90882/7310975.html

For the **2008 survey** see http://pewglobal.org/2008/07/22/the-chinese-celebrate-their-roaring-economy-as-they-struggle-with-its-costs/

China's one-child policy, introduced in 1979, was a controversial social decision not only for the country, but also for the rest of the world. The policy was launched at the beginning of China's economic reforms, when the country was home to a quarter of the world's population. The Chinese Government at that time saw population containment as an essential component to alleviate its social, economic, and environmental predicaments. In 2007, Chinese authorities claimed the policy had helped prevent 400 million births. They also justified their coercive social experiment by arguing that it had contributed greatly to economic growth. In a survey undertaken in 2008, 76% of the Chinese population apparently supported the policy.

However, the one-child policy has been criticised within and outside the country as a serious violation of the right to reproductive freedom. It has led to forced abortions and sterilisations, maternal deaths among women with pregnancies outside of family planning, female infanticide, and child abandonment.

Last week, in the plenary sessions of the annual Chinese People's Political Consultative Conference and the National People's Congress, a two-child policy was proposed, to start in 2015. Experts have suggested that the one-child policy has resulted in an increase in older people and a decrease in younger workers, as well as a sex-ratio imbalance, which might threaten China's economic growth.

The debate around China's policy on the number of children allowed by a family deserves greater global scrutiny. The issue should not be one of economics. Instead, it should be about fully realising the right of each woman to determine her own reproductive health and exercise her own choices over the number of children she and her family have. China's economic success has delivered huge benefits to her people. But one benefit yet to be achieved, essential to China's sustainable future, is the expansion of freedoms to enable each individual's life path to be pursued without state coercion. Reproductive health is a vital, and neglected, dimension of those freedoms. ■ *The Lancet*

Shared innovations in measurement and evaluation

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Now more than ever, those engaged in measuring health and evaluating impact to improve health need to come together to share knowledge. The current economic environment, in conjunction with increasing demands for accountability, requires intensified efforts to innovate and borrow from other disciplines to ensure that methods and tools take advantage of the latest science and provide valid, reliable, and comparable measurements for wide implementation.

What has been missing from the global health calendar is a cross-cutting forum that unites the myriad disciplines that have something to contribute to an enhanced collective capacity for global health measurement and evaluation. In sponsoring the conference—Global Health Metrics & Evaluation: Controversies, Innovation, Accountability—we hope to build the field and provide a space to share new ideas about the growing body of evidence about what works in global health.

Our call for Abstracts in the autumn of 2010 yielded 433 submissions covering a range of topics (panel), from nearly every country in the world. After a rigorous peer-review process organised by *The Lancet,* 22 Abstracts were selected for oral presentation and 101 Abstracts for poster sessions. The results can be found in this booklet. The Abstracts are an interesting sample of worldwide work on health metrics and evaluation. The topics with the largest number of Abstracts submitted included non-communicable diseases, malaria, priority setting, and health inequalities, as well as a category that was hard to classify into any one area. The preponderance of work in these areas might have represented the interests of those who read the call for Abstracts, or might accurately reflect the growing field of health metrics and evaluation.

The Abstracts selected represent a wide array of work; a few examples illustrate this diversity. A new simulation and optimisation tool for priority setting in the health sector, created by Jake Marcus and colleagues,[1] promises to help policy makers to understand the trade-offs between expanding health-system capacities and investing in specific technologies. Households have suffered acutely in the current economic crisis, and rising health-care costs add additional strain. Highlighting one emerging method, Rodrigo Moreno-Serra and Peter Smith[2] argue for a new set of indicators to better capture the impact of financial barriers on health-care access. In a similar vein, Oona Campbell and Sabine Gabrysch[3] argue that health-system outputs have been overlooked as a rich data source for better measurement of maternal mortality.

The paucity of data in some countries requires increasing the availability of high-quality primary data. To generate these data, more countries are developing integrated surveillance systems, and Ramesh Sethi and Bhaskar Mishra[4] provide details about an ambitious programme to provide India with critical data to track the effect of recent health reforms. Stéphane Verguet and co-workers[5] address the vital topic of efficiency in health-service delivery by examining the determinants of the cost of providing antiretroviral therapy to people who are infected with HIV. When data are missing, researchers need to make the best use of available sources by cross-checking similar data from different sources and using multiple sources to fill in gaps. Adam Bennett and colleagues[6] have examined trends in malaria in Zambia by triangulation of data on vector-control coverage, climate variability, and the spatial distribution of malaria.

Health inequalities—between and within countries—are a key concern for policy makers. Miriam Alvarado and co-workers[7] build on an interesting study[8] from 2010 which showed the sizeable contribution of maternal education to the downward trend in child mortality, and reveal the extent to which disparities within populations contribute to divergent mortality trends. We also see deep disparities within the burden

For the **Abstracts booklet** see webappendix

***Panel:* Range of topics for the submitted abstracts**

- New quantitative tools for priority setting
- Emerging methods
- Latest approaches to measuring maternal mortality
- Integrated surveillance systems
- Next generation of metrics for health-system performance
- Controversies in burden of malaria
- Trends in health inequalities
- Transitions in non-communicable diseases in rich and poor countries
- Responsible data-sharing and strengthening country capacity for analysis

of non-communicable diseases. Felicia Knaul and colleagues[9] describe the gap in cancer survival between low-income and middle-income countries. Tara Nutley and colleagues[10] show how, even in a country with the fiscal challenges of Madagascar, a programme can be successfully implemented, and measured, if local health workers are empowered and local data-ownership is strengthened.

This conference will be a success if participants and readers of the Abstracts learn of new approaches that they could apply in their work, or are exposed to results that change the way they formulate or analyse health. Interdisciplinary meetings such as this one are always a risky venture. Cross-pollination requires enough common vocabulary and understanding for frameworks, methods, and results to be understood, challenged, and absorbed. Reading the Abstracts, we believe there is the potential to build enough common understanding to make this conference a fruitful venture.

The Abstracts also show several important trends in the way work on metrics and evaluation is done. There is an increasing number of systematic analyses that build on the concept of systematic reviews of the published literature, but put increasing emphasis on capturing the data and information in the huge volume of national and local surveys and data systems for health-service encounters. Many Abstracts illustrate the increasingly complex but potentially powerful analytical toolkit that has been spawned by low-cost computational power and the diverse array of statistical methods on offer. The Abstracts also provide multiple examples of various national and local data-collection systems that have been implemented to answer specific monitoring questions, and the scope for making use of them to answer broader questions.

We expect the conference will provide an opportunity not only to discuss specific topics, general trends in data-collection platforms, new methods, and analytical approaches, but also to reflect on opportunities for more integrated or synergistic approaches to health metrics and evaluation.

After reading the findings here, we are certain that you will be as intrigued as we were. There is much work still to be done, and we hope that you will engage in this ongoing discussion about how to build a better science for measuring population health, for tracking the performance of health systems, and for maximising the impact of policies and programmes.

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