

Direct-to-consumer genetic tests: flawed and unethical

23andme, the winner of *Time* magazine's best invention of 2008 award, is the latest in a new wave of genetic tests that are advertised directly to consumers amidst claims of—among other things—allowing individuals to assess the risks they face of developing a number of diseases. These tests provide genome-wide assessments of multiple single nucleotide polymorphisms (SNPs) to reveal information about a person's traits, health, and risk of disease. However, although there might be an indication for relatives of individuals with a heritable disease to be tested for specific mutations related to that condition, the availability of genetic tests that allow an individual to fish through their genetic make up looking for variants that might predispose them to cancer or other diseases raises several concerns: do these tests have any clinical value and scientific validity, or do they simply prey on people's vulnerabilities and insecurities?

Of chief concern is the availability of complex genetic information without appropriate safeguards. Before providing samples of their DNA, consumers must be fully apprised of what the test in question can or cannot tell them about their health. Indeed, although certain mutations are linked to a higher risk of developing certain cancers, this risk is not absolute. To interpret the results of genetic testing as black or white is naive at best; will the general public be able to grasp the complexities involved in order to reach a balanced assessment of their risk? Access to genetic counselling, or at least sound advice from well-informed health-care providers, to assist users in interpreting the results of their tests in light of familial and personal history is essential. One must also bear in mind that our knowledge of genetics is far from complete. Life has spent eons evolving to its current state, in the process developing multiple levels of regulation, alternate pathways, and many subtle nuances that we have yet to fully grasp. Most sporadic cancers arise not as a result of a single mutation or a discrete number of SNPs, but rather as a number of insults—both environmental and genetic—accrued over time. We are almost certain to discover further mutations and SNPs that are involved in the development of cancer. Thus, a negative or inconclusive result from a genetic test does not imply that one is free of the risk of developing disease on genetic grounds, nor does it imply that individuals can assume that they are immune and thus able to adopt a high-risk lifestyle.

Due consideration must also be given to what consumers can do with the results of genetic testing. The findings of these genetic tests are not a diagnosis per se, and although diet and lifestyle can be modified, and more regular, earlier screening implemented in many cases, there is often no clearly prescribed course of action to be taken, either prophylactically or curatively. In such settings, should these tests be available to the general public at all—is the availability of such information, when nothing can be done, even ethical? The long-term psychological ramifications of such knowledge are as yet unknown.

Other concerns also remain. Who will bear the brunt of the additional health-care costs that are associated with doing the tests themselves, and in dealing with the consequences of their findings? The privacy of patients is also of paramount importance—how can we safeguard their genetic information against exploitation by individuals and corporations? And while insurance companies are generally restricted from accessing data on genetic predispositions to disease, privacy remains a grey area. In the future, will individuals who report a genetic predisposition to a disease, based on these tests, find themselves ineligible for life insurance or other long-term agreements?

While the choice to undergo genetic testing is obviously down to the individual, they must be fully informed of the inherent risks, and their rights and privacy protected and respected. The statement on direct-to-consumer genetic testing issued earlier this year by the American College of Medical Genetics is a welcome attempt to put forward coherent minimum requirements for genetic testing protocols, although companies developing and marketing such tests are not legally bound to follow these recommendations. Tighter regulation of this burgeoning industry is essential, and it is heartening to learn that the US National Human Genome Research Institute, part of the US National Institutes of Health, have recently commissioned studies to examine in detail the direct-to-consumer testing industry. In the meantime, regulatory agencies must adopt a more proactive role; the marketing of tests should be restricted to health professionals, rather than the lay public, and only accessed through health-care providers on the basis of their advice. ■ *The Lancet Oncology*



Tek Image/Science Photo Library

See [Reflection and Reaction](#) page 1121

For the statement from the American College of Medical Genetics see http://www.acmg.net/AM/Template.cfm?Section=Policy_Statements&Template=/CM/ContentDisplay.cfm&ContentID=2975