EDITORIAL

Retail genetics

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General practitioners are increasingly encountering patients who have paid for a genetic profile.[1,2] These direct-to-consumer tests are promoted through community pharmacies or other retailers, by mail order or via the internet. They usually involve the collection of cellular material from cheek swabs or saliva which is sent to a laboratory that analyses the DNA using chip array-based genotyping.[3] These differ from the clinical genetic services that GPs can refer patients to.

Direct-to-consumer tests usually have no involvement of a medical practitioner when they are ordered and limited or no counselling is provided. Companies promoting direct-to-consumer genetic tests usually claim they are for consumer information rather than medical decision making. However, the breadth of the genetic profiles produced, particularly by predictive or pre-symptomatic genetic tests, may impact on family members, potential employment and life insurance.

Preventive care is fundamentally about risk assessment and management of a condition with a patient's family history playing a role. This is one area where, with the appropriate training of health professionals, genetic profiles have the possibility to inform care. Despite this, direct-to-consumer genetic test reports are difficult to interpret. In 2012 only 7% of Australian genetic specialists reported they would be confident to interpret and explain the results of these tests.[4]

Some companies specialise in pharmacogenomic tests that suggest how an individual's genetic make-up may affect their response to certain drugs. One company pays pharmacists to collect the test and interpret the result for the consumer. The results are also sent to the patient's GP.[3] Pharmacogenomic tests can sometimes be a useful alternative to selecting drugs by trial and error, especially if a patient has experienced a poor response to treatment or unexpected adverse effects. However, a 'normal' pharmacogenomic test does not mean the patient is not at risk of drug-related adverse effects, or of not responding to a drug. Current tests only capture known variants of known genes. In addition, even if the test shows gene variants that impact on a certain drug's metabolism, this is only one of many factors that influence how patients respond to drug therapy. Other factors include age, weight, drug interactions, allergies, renal and liver function, and psychosocial characteristics such as impaired cognition and health literacy.

Some GPs have expressed disquiet at receiving test results they have not ordered and the interpretation may be difficult. While knowledge in this area is increasing, in many specific clinical situations more work is required to ensure that test results will be meaningfully translated into clinical practice in order to achieve best outcomes for the patient.[5]

The Australian Competition and Consumer Commission (ACCC) has been concerned that, in one case, some statements about genetic testing (in pharmacy catalogues, television infomercials, in-store brochures and other promotional materials) 'risked conveying a false or misleading impression regarding the usefulness of the test and the consumers for whom testing may be appropriate'. Consequently, following ACCC intervention, the promotional materials containing statements of concern were withdrawn.[6]

Some companies risk over-enthusiastic promotion. For example, testing for the AMY1 gene is claimed to reveal how well the body can metabolise starch carbohydrates. This test is said to assist with a range of weight management and other health issues. One company recommends its own preferred practitioners who offer 'nutrigenomics' advice, based on the test result, for a variety of health conditions.[7]

There are also overseas companies that promote their tests in Australia via the internet. One offers genetic tests for 31 disease conditions, 53 carrier status conditions, 12 drug response genes, 6 wellness tests, 11 traits and 11 addictions.[8] These claims appear to go well beyond the evidence base underlying the tests and do not come under the jurisdiction of Australian regulators.

Direct-to-consumer genetic profiling tests provided by Australian companies or laboratories for self-testing are classified as Class 3 in vitro diagnostic medical devices by the Therapeutic Goods Administration (TGA). Until 2010, the level of regulation in Australia was very limited. A new regulatory framework began on 1 July 2010 to ensure that all such tests undergo a level of regulatory scrutiny commensurate with their risks. Commercial medical device manufacturers must now seek a conformity assessment certificate from the TGA if they want to supply such products in Australia.

From July 2017 local laboratories who develop medical devices 'in-house' must maintain their accreditation by the National Association of Testing

Authorities, Australia (NATA). Their tests must also meet National Pathology Accreditation Advisory Council performance standards.

It remains unclear what the potential impact of genetic profiling may be on purchasing various types of insurance, particularly life insurance. While private health insurance companies do not require consumers to undertake tests to assess the risk of disease, and premiums are not affected by the genetic test results, you are required to disclose information that may impact your insurability. Underwritten life insurance products, including cover for life, trauma, disability and income protection which may be required for business and bank loans, could be impacted by a genetic test result.

In conclusion, health professionals and consumers need to be aware that genetic tests developed in-house will not undergo regulatory scrutiny by the TGA until July 2017. In addition, promotional claims may exceed the evidence underlying the test. Furthermore, their cost is not covered by Medicare or private health insurance rebates, except for some tests, such as those that can guide cancer treatment. Health professionals should advise their patients not to purchase these tests from overseas. Patients should also discuss the usefulness of locally promoted tests with their doctor before paying for a test.

There needs to be ongoing education of all health professionals about the appropriateness and changing role of these tests as more knowledge becomes available. The education should be in keeping with useful information provided by the National Health and Medical Research Council for both consumers and medical practitioners.[9] This ongoing education should be independent of the companies promoting the test. <

Conflict of interest: none declared

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FURTHER READING

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