

Online Direct-To-Consumer Genetic Testing in Australia

Concerns, Regulation and Recommendations

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Direct-To-Consumer (DTC) genetic testing is here defined as any DNA test offered directly to the public for a medical or non-medical trait, available without a medical referral and outside of the health system. Many DTC genetic tests are now offered online via overseas companies without any Australian accreditation or approval, and are growing in popularity. These online DTC tests vary substantially in quality, validity and price. Some DTC genetic tests are supported by scientific evidence, such as ancestry tests. However others are completely unsubstantiated by evidence¹ and would be in clear breach of TGA regulations if sold by an Australian company. Yet these products are still being accessed online by Australians via the internet, in some cases causing serious harm.

In general, consumer fascination and interest in genetic testing is growing. In some cases, demand for cheaper online genetic tests is also fuelled by a lack of patient access to approved local genetic testing products. Challenges exist for the TGA or other authorities to regulate online genetic testing. Here we outline our concerns with this kind of online DTC testing, summarize current Australian regulations, and offer recommendations for how to address this emerging health issue.

Unaccredited online Direct-To-Consumer (DTC) genetic tests raise a number of public health concerns². Below we highlight some of the most pressing, related to regulation, medical issues, ethics and privacy.

Table 1: Concerns with unaccredited online DTC genetic testing

Regulation / Quality Control	
<i>Difficulty in regulating through local authorities</i>	TGA and other authorities are not empowered to prevent access to or regulate the validity and quality of online, offshore DTC products
<i>Lack of informed consent</i>	Informed consent is overlooked by most online DTC companies, which provide no genetic counselling or medical advice prior to testing
<i>Return of genetic findings not supported by evidence</i>	Online DTC companies are not held to any standards regarding provision of evidence for medical risk information, compared with approved clinical tests
Medical	
<i>Burden on local health services</i>	Patients with results from online DTC tests are presenting at Australian GPs and genetic services seeking support and interpretation
<i>Damaging to the reputation of medical genomics</i>	'Promoting tests with little or no scientific backing runs the risk of inflating customer expectations and ultimately undermining consumer confidence in genuinely clinically useful genetic tests' ³
Ethical	
<i>Recreational intent vs. discovery of genetic risk</i>	Consumers may purchase online DTC products out of curiosity or for recreational purposes, but subsequently can be made aware of serious medical risk factors, non-paternity or other unexpected information ⁴
<i>Disclosure of genetic risk variants for non-treatable conditions</i>	Some DTC tests return genetic risk information for conditions with no treatment or clinical actionability (e.g. APOEε4 for Alzheimer's disease) which is considered by many to be unethical ⁴
<i>Return of pathogenic variants without genetic counselling</i>	Some online DTC tests can return significant genetic risk information of medical and psychological gravity (e.g. BRCA mutations), without any genetic counselling or medical support ⁴
Privacy	
<i>Retention of consumer DNA samples</i>	Many online DTC companies retain DNA samples indefinitely. Some consumers have reported difficulties in having DNA samples destroyed upon request ⁵
<i>Access to genetic data from third parties</i>	Some online DTC companies have been accused of selling access to their databases of genetic information to third parties, potentially without the knowledge of donors ⁵

¹ Genetic tests promised to help me achieve peak fitness. What I got was a fiasco. STAT. Rebecca Robbins.

² Retail Genetics. Aust Prescr 2017;40:86-71 Jun 2017. Harvey & Diug

³ A DNA App Store Is Here, but Proceed with Caution. MIT Technology Review. Daniel MacArthur (quoted).

⁴ PERSONAL GENOMIC TESTING, GENETIC INHERITANCE, AND UNCERTAINTY. BioEthical Inquiry. Paul Mason.

⁵ The Privacy Delusions Of Genetic Testing. Forbes. Peter Pitts.

Current Australian Regulation

Under current Australian regulation, the TGA does not purport to control or police the quality of online genetic tests from overseas companies. This means that, unlike testing offered through Australian laboratories, offshore tests:

- do not need to be registered with the TGA or entered onto the Australian Register of Therapeutic Goods;
- need not comply with the TGA's Essential Principles and Conformity Assessment Procedures; and
- can be sold direct to consumers, even if they disclose medical findings, through TGA's "self-importation" mechanism (which purports to prohibit individuals from ordering tests for others and restricts individuals to only ordering tests for themselves or immediate family members).

Unlike the rigid requirements for Australian clinical tests, there is insufficient regulation for online, offshore DTC genetic testing with regard to accreditation and quality control issues. The interpretation and return of genetic findings and the level of evidence required to categorize genetic findings as meaningful is also not regulated.

From 1 July 2017, any Australian laboratory offering testing using in vitro diagnostic medical devices (IVDs) must be accredited, register the device on the ARTG and comply with the Essential Principles checklist and Conformity Assessment Procedures. However, there is no such regulation of the quality control of overseas DTC genetic tests, hence they are "slipping through the cracks".

Future

Unless further measures are undertaken by the government, it is likely Australian consumers will continue to have difficulty distinguishing between quality (locally accredited) and non-quality (unaccredited) genetic testing products online. Due to the growing fascination with genetic testing in our society, Australians will continue to access DTC genetic testing of questionable quality. In some cases, the demand will be further fueled by the lack of access to and cost of locally accredited clinical genetic testing through the Australian medical system.

Recommendations

With respect to the sale of unaccredited, online Direct-To-Consumer genetic tests in Australia; authorities could consider taking the following actions:

1. Amend regulations so that personal importation of devices for genetic testing is not allowed.
2. Publicise warnings in prominent and widely accessed media about risks of unaccredited DTC tests.
3. Publicly endorse Australian companies who meet local accreditation standards.
4. Prohibit internet advertising of non-accredited overseas tests, and engage with overseas regulators regarding strategies for regulating advertising of and access to online tests.