

Direct-to-Consumer Genetic Testing (DTC GT) for Health Purposes

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Doctors of BC Position

- In the interest of patient safety and upholding quality patient care, Doctors of BC calls for:
 - Federal regulation of marketing and health-related claims in connection with DTC GT, similar to regulation of direct-to-consumer advertising of prescription drugs in Canada;
 - The development of national standards for reliability and validity of DTC GT; and
 - Public education initiatives aimed at increasing patient awareness of potential implications of DTC GT for health purposes.
- With increased use of DTC GT by the public, physicians (particularly family physicians), will be increasingly presented with DTC GT results. To support physicians, Doctors of BC commits to working with stakeholders to:
 - Develop clinical guidance for physicians working with patients who are interested in or who have obtained DTC GT; and
 - Increase education and training on physician responsibility and liabilities regarding medically significant genetic testing.

Background

Medical genetic testing in humans involves examining an individual's genetic information to identify their predisposition to illness, prognosis of disease, and potential response to certain medications.

As genetic testing technology has become more sophisticated, it can now be done at cost and in time similar to other screening and diagnostic tests. DTC GT refers to testing sold directly to consumers via the Internet, television, or other marketing avenues without the involvement of health professionals.[1]

This policy statement only refers to DTC GT for the purpose of providing health information; however, it is noted that companies also promote DNA ancestry services that trace customer lineage.

DTC GT services are available directly to the Canadian consumer. For instance, for \$199 customers can order a personal testing kit and return a saliva sample to obtain personalized information about their DNA. Test results include reports for over 100 health conditions and traits and information about inherited risk factors

and response to certain medications. Each customer's results include individualized risk assessments for single-gene disorders, like cystic fibrosis, as well as complex multifactorial diseases like cardiovascular disease. Risk is assessed by comparing an individual's genetic make-up against population data.

Customers report using DTC GT to complement traditional health care, to satisfy curiosity, or to learn about potential future disease.[1] Publicized benefits of DTC GT include wider testing availability, without geographical limitations, as well as patient autonomy and empowerment through increased health literacy.[2]

Analysis

The popularity of DTC GT suggests that the service is fulfilling a consumer need. However, introducing a health-related decision-making tool outside of the usual testing protocols presents unique challenges.

If the privacy of DTC GT results is not adequately maintained, potential consumer harms include

discrimination and stigmatization.[3] Some DTC GT providers are able to offer sequencing services below cost because it facilitates data collection at the individual and population-level, which may be used and sold for direct-to-consumer marketing of health products including vitamins and dietary supplements.[4]

Canadian DTC GT customers may also be unaware that potential insurers can request the results. The Canadian Life and Health Insurance Association has stated that applicants will not have to undergo genetic testing but could be asked if they have already undergone testing and, if so, to share the results.[5] The Office of the Privacy Commissioner of Canada has requested insurers “refrain from requesting access to existing genetic test results until such time as they can be shown to be demonstrably necessary and effective.”[6]

In the US, the Food and Drug Administration has raised concerns regarding the reliability and validity of DTC GT and its potential to adversely affect a patient’s health.[7]

In Canada, there is regulation for clinically initiated genetic tests used for diagnostic purposes, patient management, and clinical trials because of the potential for the results to affect patient safety.[8] However, genetic tests marketed and sold directly to consumers are not regulated, despite the fact that they also provide diagnostic information and data about medication response.[8] Given the potential for harm, federal marketing and health-claim related regulations should be implemented to protect patients from potential harms associated with the rapid development and promotion of DTC GT.

Health Canada has regulated direct-to-consumer prescription drug advertising and should place similar restrictions on the marketing and use of health claims by the for-profit private industry of DTC GT. Ultimately, direct-to-consumer marketing has been shown to lead to an inappropriate use of and demand for other health products or services.[4]

Family physicians are appropriately a frequent first point of contact for patients with health-related questions. Given the health-focus of DTC GT, patients will most likely bring results to their family physicians. There is potential for this to impact the health care system in the following ways:

Family physicians lack adequate experience interpreting DTC genetic test results, knowledge of where to refer these patients, or training in genetic counselling. Currently there is a lack of guidelines outlining physician responsibility or liability in the use of DTC GT results.

The use of DTC GT results also raises concerns over access.[9] It is unclear whether services related to DTC GT should be publicly funded. There are costs associated with physician review of results as well as potential costs associated with additional testing to confirm results.

Finally, there is potential for consumers to use results from DTC GT to make decisions without the advice of a health care provider, which could lead to more serious health problems later, at significant cost to the health care system.

It is essential that policy and legislative frameworks be established to support physicians and patients in the responsible use of DTC GT. Doctors of BC commits to working with stakeholders to increase education and training for physicians regarding clinically significant genetic testing. Additionally, federal public education initiatives aimed at increasing patient awareness of potential implications of DTC GT should be developed.

References

1. Su P. Direct-to-consumer genetic testing: a comprehensive view. *Yale J Biol Med* 2013;86:359-365.
2. Hudson K, et al. ASHG statement on direct-to-consumer genetic testing in the United States. *Am J Hum Genet* 2007;81:635-637.
3. Hogarth S, Javitt G, Melzer D. The current landscape for direct-to-consumer genetic testing: Legal, ethical, and policy issues. *Annu Rev Genomics Hum Genet* 2008; 9:161-182.
4. European Society of Human Genetics. Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes. *Eur J Hum Genet* 2010;18:1271-1273.

FOR FURTHER INFORMATION

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POLICY STATEMENT

5. Canadian Life and Health Insurance Association. CLHIA position statement on genetic testing. 2003.
6. Government of Canada. Statement on the use of genetic test results by life and health insurance companies. Office of the Privacy Commissioner of Canada. 2014.
7. United States Food and Drug Administration. Direct-to-consumer genetic testing and the consequences to the public. July 2010.
8. Webster PC. Regulation of genetic tests unnecessary, government says. CMAJ 2010;182:1715-1716.
9. Canadian Medical Association. Regulatory framework for direct-to-consumer clinical genetic tests. May 2010.

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