Direct-to-Consumer Marketing of Genetic Tests

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Background

The International Society of Nurses in Genetics (ISONG) promulgates this statement to present critical factors to consider regarding direct-to-consumer (DTC) marketing of genetic tests. The intent is to inform patients, nurses and other healthcare providers, healthcare policymakers, and the general public.

In 1997 Holtzman and Watson (1997) defined genetic testing as "the analysis of DNA, RNA, chromosomes, and proteins to detect heritable disease-related DNA alterations" (Holtzman & Watson, 1997). This definition reflects the use of genetic testing by health care providers to diagnose disease, to identify predisposition to disease, to determine implications for future offspring, and to inform therapy decisions (Hudson, Javitt, Wylie & Byers, 1997). However, over the past few years numerous companies have emerged in the private sector that market to a variety of genetic tests directly to the public. In addition to health-related tests, such as BRCA identification, genetic information for legal use, such as paternity identification, and recreational use, such as ancestry investigation are also offered (Kaye, 2008). Enhancement genetic tests, such as nutrigenomic testing and dermagenetic testing, are also being offered by companies that sell dietary supplements and skin products purportedly based on one's genetic make-up (Hogarth, Javitt, & Melzer, 2008; ACOG, 2008). Therefore, in this statement genetic testing is understood to include "the analysis of DNA, RNA, chromosomes, and proteins" for any purpose.

Direct-to-consumer marketing is defined here as marketing, advertising, selling or otherwise providing to a consumer a genetic test without the supervision, guidance, and counseling of a licensed, independent health provider. Although DTC companies differ in their approaches to physician mediation, genetic counseling arrangements, and methods to provide

information the DTC marketing environment shifts the driving force behind accessing personal genetic information from the health care professional to the consumer (ACOG, 2008). Established safeguards developed within the healthcare and research arenas may not be in place in a consumer-driven marketplace. At this time there is neither consensus nor research to validate statements of benefit or harm. However, there are potential benefits and risks to be identified, reviewed and communicated. These benefits and risks must be balanced to maintain safe, effective and ethical means of engaging the public in understanding the genetic components of their health

Identified Benefits

Individuals are being asked to assume increasing responsibility for their own health care and lifestyle choices. DTC marketing of genetic tests may empower consumers to make autonomous decisions about their health, provide opportunities for educating the public about health risks and the part that genes and environment play in managing risks, and allow the public to more fully benefit from the work on the Human Genome Project (Hudson, Javitt, Wylie & Byers, 1997; Hogarth, Javitt, & Melzer, 2008; Gray, 2003). Along with increased autonomy may come increased privacy and control of personal health information (Hudson, Javitt, Wylie & Byers, 1997; Wolfberg, 2006).

Identified Risks

Simplistic or misleading claims associated with advertising of certain tests are contrary to informed consent (Hudson, Javitt, Wylie & Byers, 1997; Hogarth, Javitt, & Melzer, 2008; Gray, 2003; HGC, 2003; ACOG, 2008; Goddard, Robitaille, Dowling, Fishman, Bradley, More, et al., 2009), and may promote consumer anxiety (Wolfberg, 2006). Although the understanding of the relationship of specific genetic variants and certain diseases is evolving as new scientific data continues to emerge, the complexities of some information may elude the consumer. Full disclosure of risks and benefits, and accurate statements regarding the information derived from genetic test results may not be available. Online information is sometimes incomplete and may not agree with professional recommendations.

The value of genetic counseling, both prior to and after testing, has been viewed as a critical component of the genetic testing process (Hudson, Javitt, Wylie & Byers, 1997; Kaye, 2008; ACMG, 2008; ACOG, 2008). Information about genetic test results delivered without the advice of a licensed, independent health provider may create risks to the recipient. These risks include misinterpretation of information or distortion of its consequence to the overall health of the person tested due to the complexity of analytical finding implications and the vocabulary use itself. Misinterpretation of results may also lead to the failure to engage in preventive behaviors because the risk is not adequately presented (Hogarth, Javitt, & Melzer, 2008). Access to appropriate genetic counseling is of particular concern for those seeking genetic testing to inform critical health decisions. Genetic counseling can also assure that consumer anxiety is not exploited (Wolfberg, 2006). Furthermore, consumers who order a genetic test with no independent/unbiased professional healthcare guidance regarding the test's

rigor, context, reliability, validity or applicability to their health may risk poor outcomes as the result of conclusions made from the testing results.

Documentation and regulation of security measures for the protection of the privacy of consumers submitting test samples is critical (Hogarth, Javitt, & Melzer, 2008; ACOG, 2008). DTC advertising for genetic tests that lack independent professional oversight raises troubling questions about appropriate use and interpretation of these tests by consumers and carries implications for the standards of patient care (Geransar, & Einsiedel, 2008; ACOG, 2008).

The testing company's practices regarding disposal of tested samples, reuse of samples for research, laboratory method standards and information security are additional critical issues in ISONG's concern for the welfare of consumers (Hogarth, Javitt, & Melzer, 2008; HGC, 2003).

The Role of Nurses in Direct-to-Consumer Genetic Testing

The nursing roles as they relate to direct-to-consumer genetic testing are that of caregiver, patient advocate, researcher, educator, and counselor. Each respective nursing role includes standards of genetic competency.

The DTC marketing phenomenon in genetic tests raises questions for nursing inquiry. For example, research needs to explore the associations of cost differentials, privacy issues, and access as they impact the drive the demand for consumer-marketed tests. As patient advocates, nurses must understand patient perspectives regarding direct to consumer genetic tests and evaluate their rationales.

Additionally, the educator and counselor nursing roles are relevant in fostering communication with the public and with patients regarding concerns generated by the DTC genetic testing environment. The DTC genetic testing reminds nurses of their responsibility to promote risk reduction by recommending consultations with professionals trained in understanding where and when genetic tests are appropriate and how to communicate the results.

Nurse educators must recognize that genetic testing is gaining public attention and add essential genetics content to basic and advanced curricula. Understanding the benefits and risks of DTC genetic tests from the consumer/patient's perspective is also paramount to all nursing practice. Nurses must use their expertise to empower individuals to understand the genetic components of their individual and family's health through education about the role of genes and environment in health and disease and through appreciation of their personal family health history. Nurses should encourage open communication between consumers and their healthcare providers to promote consumer understanding of the benefits and risks of the process selected to ascertain genetic information.

Therefore, it is the position of the ISONG that utilization of DTC genetic testing be undertaken once the consumer has considered, independently, or with the help of a professional, the following;

1. The privacy mechanisms in place to ensure confidentiality of genetic information;
2. The purpose of the test and how the results will be used;
3. The clinical value of the test, or if and how the results can inform choices with regard to health care, behaviors, and lifestyle;
4. The additional concerns posed in the testing of minors;
5. The ability of the test results to provide scientifically based information relevant to the reason the test was requested;
6. The reputation of the company offering the testing in light of the fact that, depending on geographic location and the specific test, companies may be functioning with little, if any, regulatory oversight;
7. The quality/reputation of the laboratory performing the testing to assure the accuracy of the test and whether one can ascertain this information;
8. The accuracy and adequacy of the interpretation of the results;
9. The fate of the genetic material (destroyed, stored or used for research) after the test is complete. The use of genetic material for research purposes should be transparent and permission obtained; and
10. The potential benefits derived from genetic counseling prior to and after genetic testing to determine the appropriateness of the test and to explore the meaning of the results for the individual and the family.

References

American College of Medical Genetics (ACMG) (2008). *ACMG Statement on Direct-to-Consumer Genetic Testing*.

The American College of Obstetricians and Gynecologists Committee on Genetics & Committee on Ethics (ACOG) (2008). Direct-to-consumer marketing of genetic testing. *Obstetrics & Gynecology*, 111(6), 14931494. Geransar, R., & Einsiedel, E.(2008). Evaluating Online Direct-to-Consumer Marketing of Genetic Tests: Informed Choices or Buyers Beware? *Genetic Testing*, 12 (1), 13-24.

Goddard, K.A.B., Robitaille, J., Dowling, N.R., Fishman, J., Bradley, L.A., More, C.A., & Khoury, M.J. (2009). Health-Related Direct-to-Consumer Genetic Tests: A Public Health Assessment and Analysis of Practices Related to Internet-Based Tests for Risk of Thrombosis. *Public Health Genomics*, 12, 92-104.

Gray, S. (2003). Direct-to-Consumer Marketing of Genetic Tests for Cancer: buyer Beware. *Journal of Clinical Oncology*, 21(17), 3191-3193.

Hogarth, S., Javitt, G., & Melzer, D. (2008). The current landscape for direct-to-consumer genetic testing: Legal, ethical, and policy issues. *Annual Review: Genomics Human Genetics*, 9, 161-182.

Holtzman, N.A. & Watson, M.S. (1997). Promoting safe and effective genetic testing in the United States: final report of the Task Force on Genetic Testing, Retrieved March 25, 2009, from http://www.genome.gov/10001733.

Hudson, K., Javitt, G., Wylie, B., & Byers, P. with the ASHG Social Issues Committee. (2007). ASHG Statement on Direct-to-Consumer Genetic Testing in the United States. *Obstetrics & Gynecology*, 110(6), 1392-1395.

Kaye, J. (2008). The regulation of direct-to-consumer genetic tests. *Human Molecular Genetics*, 17, R180-R183.

Wolfberg, A.J. (2006). Genes on the web-Direct to consumer marketing of genetic testing. *New England Journal of Medicine*, 355, 543-545.