

Ethical aspects of genetic analyses; The Sale of Genetic Information

Ástríður Stefánsdóttir, 14.
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The Sale of Genetic Information Direct-To-Consumer (DTC)

- A client sends a DNA sample to a company, which analyzes the sample
- The customer receives a readout of his or her levels of risk for specific conditions.
- This is done without any association between a health worker and the person from whom the specimen is obtained.

Exciting innovation ?

- This service is apt to bolster the freedom of the individual.
- Empowering; it can enhance the self-awareness of the client.
- It is easier to defend the privacy of the individual.

Ethical concerns

- Uncertain results
- Health information?
- Negative effect on the health system
- Gaining health information without the health professional
- Consumerism and commercialism

Uncertain results:

Analytical validity

- **“At present, both the testing processes and the results from DTC genetic tests leave room for inaccuracy and misunderstanding. Collecting biological samples at home might or might not maximize the reliability of results, as individuals may not follow the protocols sufficiently closely. In addition, it would be difficult to verify to whom the sample belongs and there could be a danger that an individual would send in another person’s biological sample, for example, that of a child or spouse (with or without that person’s knowledge of the genetic testing). The laboratories themselves may or may not be certified under the Clinical Laboratory Improvement Amendments (CLIA), which strengthened federal oversight to assure the reliability and accuracy of test results, and the processes used to conduct the genetic analyses and glean results are not transparent, making assessment of reliability and validity difficult. Standards of sample collection and their processing may vary and lead to misinformation or mal-information, which could be harmful in itself and/or if people act on it.”**

• Katherine Wasson et al., Direct-to-consumer online genetic testing and the four principles: an analysis of the ethical issues, *Ethics & Medicine*, 22/2 (Summer 2006): p.84

Uncertain results:

Clinical validity

- **“Most of the diseases listed by the direct-to-consumer testing companies (e.g., diabetes, various cancers, and heart diseases) are so-called complex diseases thought to be caused by multiple gene variants, interactions among these variants, and interactions between variants and environmental factors. Thus, a full accounting of disease susceptibility awaits the identification of these multiple variants and their interactions in well-designed studies. What we have now is recognition of a limited number of variants associated with relative risks of diseases on the order of 1.5 or lower. Risk factors with this level of relative risk clearly do a poor job of distinguishing people who will develop these diseases from those who will not“**
- Hunter DJ, Khoury MJ, Drazen JM. Letting the genome out of the bottle; will we get our wish? *N Engl J Med*. 2008

Uncertain results:

Clinical utility

- **“Many DTC companies offer genetic testing for the purposes of dietary management (Afman and Muller 2006) and may include a report of recommended health behaviours to decrease risk for heart disease. However, there is little evidence for the hypothesis that genetic susceptibility information will result in significant behavior change (Audrian et al. 1997; McBride et al., 2002; Lipkus et al., 2004) . As importantly, the behaviour recommendations that companies are promoting to reduce risk of cardiovascular diseases are general recommendations for those at increased risk for any reason (diet, family history, medical history) and are not clearly related to the genetic test result per se. Therefore, the preventive health recommendations would likely be the same, and possibly just as useful, in the absence of a genetic test. Finally, the test result may add little to the risk information that other well-established risk assessment tools such as age, smoking habits, weight, blood pressure, and lipid profiles provide. (Sheridan et al., 2003)”**
- Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): p.287

Health information?

- Consumers responsibility
- Doctors responsibility

Effect on the health system.

- Might cause the limited funds within the service to be prioritised in an apparently arbitrary way.
- Increased expense to the public health service.
- It is unlikely that this would deliver results in terms of better health for the individual.

Gaining health information without the health professional

- **In the current environment, consumers are at risk of harm from DTC testing if testing is performed by laboratories that are not of high quality, if tests lack adequate analytic or clinical validity, if claims made about tests are false or misleading, and if inadequate information and counselling are provided to permit the consumer to make an informed decision about whether testing is appropriate and about what actions to take on the basis of test results.**
- Kathy Hudson et al., ASHG Statement on direct-to-consumer genetic testing in the United States, *The American Journal of Human Genetics*, 81/3 (September 2007):p.637.

Challenge to professionalism

- **“It is important, indeed imperative, for doctors to recognize that what they have is not just a market relationship or a trade union deal with the rest of society, but a very special moral contract. If this contract is blemished or broken, not only is public confidence in, and common esteem for, the medical profession sapped, but it will also infect and consume the self-esteem and moral habitus of the practitioners themselves.”**
- Hernes G. The medical profession and health care reform- friend or foe? (editorial) *Soc Sci Med* 2001; 52: 175-7.