Direct-to-Consumer Nutrigenomic Testing:  
Is It Valuable in Spite of Its Limitations?

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Genetic testing is available for nearly 300 specific targeted mutations associated with various disorders [1]. Advances in genomic technology such as genome-wide association studies (GWAS) made possible the discovery of many such associations, and these advances have also ushered in an era of direct-to-consumer (DTC) genomic testing. Such testing is marketed directly to consumers, who can purchase it without any involvement on the part of their health care provider. There has been much discussion about regulation of such testing (and regulation of the marketing claims made regarding such testing), but DTC genomic testing is currently not regulated in the United States [2]. A 2008 survey [3] found that 23 companies were providing DTC genomic testing, and a 2012 review [2] found that 12 of those companies continued to offer such services.

Over the past decade, great advances have been made in discovering the genetic basis of monogenic diseases such as Tay-Sachs disease and cystic fibrosis, but finding meaningful associations between genetic variants and polygenic diseases such as diabetes, cancer, and cardiovascular disease is more difficult and will require more time. The clinical validity of currently available DTC nutrigenomic tests is limited, because the associations that have been discovered between gene variants and health conditions such as obesity and cancer are only small pieces of the puzzle; an individual’s risk of disease ultimately results from the interaction of many genetic and environmental factors, only some of which are understood [2].

The idea of receiving nutrition recommendations based on one’s unique genetic makeup is certainly attractive and can be perceived as empowering, especially in an age that calls for consumers to take charge of their own health. A recurrent marketing theme employed by companies that offer DTC genetic testing is to evoke a sense of empowerment in consumers by giving them genetic information; however, such marketing often fails to clearly disclose the lack of evidence for the tests’ claims and the limitations in their ability to predict risk [4].

One of the presumed benefits of genetic testing is its potential to motivate lifestyle changes, although the ability of such testing to encourage healthy behavior is disputable [2]. Current research suggests that consumers believe that they will change their health behavior once they know their genetic test results. However, studies of actual changes in behavior after people receive the results of genetic testing have come to mixed conclusions. In a randomized trial of the use of personalized genetic risk counseling to motivate diabetes prevention [5], subjects were randomly assigned to receive genetic testing or no genetic testing. Those who had been tested were then ranked from highest to lowest risk, and those in the top and bottom quartiles were enrolled in a diabetes prevention program along with untested control subjects. Few significant differences were found in motivation, program attendance, and weight loss when the lowest-risk and highest-risk groups were separately compared with the control group [5].

One of the concerns surrounding DTC genetic testing is that it could cause consumers undue psychological stress and anxiety. However, studies that have investigated whether or not this is the case have not found data
to substantiate that concern [6, 7]. This may be because consumers who purchase such tests tend to have high educational levels and knowledge of genetics [2].

Some companies claim to offer a genetically tailored diet plan and nutritional supplement recommendations that will protect against the diseases to which an individual is genetically predisposed and/or that will compensate for loss of function caused by a genetic variant. A study by the Government Accountability Office [8] failed to find support for these claims; instead, this study found that the advice offered usually consists of only standard sensible dietary suggestions and lifestyle recommendations.

The research community insists that current work in nutrigenomics is merely the tip of the iceberg and that it is still premature to determine the validity and utility of such testing. In the meantime, existing nutritional recommendations should be followed. For example, to decrease blood pressure and the risk of cardiovascular disease, diabetes, and certain cancers, patients should be encouraged to follow current evidence-based guidelines with regard to everyday eating and to consume a balanced diet—one containing a colorful and plentiful variety of vegetables and fruits; moderate amounts of lean animal and/or plant proteins, healthy fats, and whole grains; and appropriate calcium sources. Patients should also be encouraged to avoid consuming too many calories and to cultivate an emotionally healthy approach to eating. At the present time, personalized advice on how to accomplish these goals will be more helpful to patients than personalized genomic test results. NCMJ

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Acknowledgment

Potential conflicts of interest. M.G. has no relevant conflicts of interest.

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Electronically published November 19, 2013.

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