

Direct-to-Consumer Genomic Testing Offers Little Clinical Utility but Appears to Cause Minimal Harm

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Direct-to-consumer genomic testing is available to anyone willing to pay for it. We investigated the reliability and reproducibility of such testing by sending DNA samples to 2 popular companies and by reviewing current literature on this topic. The concerns that were initially raised about direct-to-consumer genomic testing still seem valid.

With direct-to-consumer (DTC) genomic testing, an individual can send off a DNA sample, order tests, and receive results without an independent health care provider serving as an intermediary [1]. Some have hailed the availability of DTC genomic testing as a positive step that allows individuals to take charge of their health care; others point out that such testing can be unreliable, that the results can be misleading, and that such testing may cause more harm than good.

Since 2008, when *Time* magazine hailed 23andMe's DTC genomic testing as the invention of the year [2], this industry has expanded significantly. For \$99, 23andMe now promises to deliver information regarding risk markers for 120 diseases; carrier status for 50 genetic disorders; 24 drug responses; and 60 traits, ranging from eye color and earwax type to muscle performance and reading ability [3].

Proponents of DTC genomic testing tout its potential to motivate lifestyle change and to increase vigilance for health conditions. Skeptics point out that existing data do not suggest that providing this kind of genetic risk information meaningfully affects a patient's lifestyle, and they note that increased vigilance is of questionable value when dealing with diseases that cannot be prevented.

In the early days of DTC genomic testing, there were concerns that the advertisements for such testing overstated the value of the testing, inappropriately suggested a deterministic relationship between genes and disease, and/or reinforced invalid notions about the relationships between diseases and ethnic groups [4]. As the cost of the services offered by these companies declines and the claims regarding these services increase, it seems reasonable to investigate what consumers may actually gain from such information. It also seems prudent to ask whether DTC genomic testing has provided the health care revolution that was predicted.

In 2008, we compared the results of DTC genomic tests provided by 23andMe and DeCODEme, which were 2 of the leading commercial suppliers of such testing at that time (S.D.A. and J.P.E., unpublished data). We purchased 2 kits from each company. DNA samples from 2 individuals were sent to both commercial laboratories for analysis, allowing direct comparison of 2 sets of results for the same DNA sample. No phenotypic information was provided to the companies. The DNA samples used were acquired by the International HapMap Project, which was launched in 2002 to identify "common patterns of DNA sequence variation in the human genome" (haplotypes) and to provide public access to that information [5]. HapMap samples are publicly available through the nonprofit Coriell Institute for Medical Research [6].

There were 14 health conditions for which both companies reported relative risk information. For 5 of these 14 health conditions—colorectal cancer, Crohn disease, heart attack, prostate cancer, and restless leg syndrome—one of the companies reported an increase in relative risk and the other company reported a decrease in relative risk (Table 1). The significance of relative risk changes was overemphasized, given that they were associated with very small changes in absolute risk. For example, one of the companies told both patients that their test results indicated a relative risk of 0.47 for celiac disease. With an absolute risk of 0.08%, however, this translates to an absolute risk reduction of approximately 0.04%. Even for conditions posing larger absolute risks, such as heart attack, the modest changes in risk represented by the 2 companies' relative risk estimates (0.83 and 1.18 for one patient in this analysis) were not meaningful enough to affect medical management.

We concluded that, although customers might find their risk profiles interesting, this information provides no guidance for physicians trying to make informed clinical deci-

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TABLE 1.
Estimates of Relative Risk From 2 Companies Performing Genomic Testing on DNA Samples From the Same 2 Individuals

Condition	Relative Risk			
	DNA sample 1		DNA sample 2	
	23andMe	deCODEme	23andMe	deCODEme
Age-related macular degeneration	0.62	0.25	0.62	0.25
Breast cancer	1.13	1.16	0.87	0.96
Celiac disease	0.47	0.38	0.47	0.24
Colorectal cancer	0.99	1.15	1.02	1.16
Crohn disease	0.91	2.29	0.56	0.88
Heart attack	0.99	0.87	1.18	0.83
Multiple sclerosis	1.37	1.52	2.69	2.41
Obesity	1.02	1.05	1.17	1.37
Prostate cancer	1.03	0.85	1.53	2.39
Restless leg syndrome	0.75	1.60	0.75	1.06
Rheumatoid arthritis	1.38	2.32	0.41	0.49
Type 1 diabetes	0.56	0.46	0.04	0.01
Type 2 diabetes	0.81	0.76	0.62	0.58
Venous thromboembolism	0.98	0.88	0.98	0.88

Note. Relative risk was reported to be increased by 1 company and reported to be decreased by the other company for 5 of the 14 health conditions for which both companies reported such information: colorectal cancer, Crohn disease, heart attack, prostate cancer, and restless leg syndrome. One sample had 4 discordant results and the other sample had 2 discordant results; the discordant relative risk values are in boldface type.

sions. The insubstantial magnitude of the risk information raised doubts about clinical validity. Moreover, there were sometimes substantial differences between the 2 companies in the level of risk reported, which calls into serious question the analytic validity of the findings.

A possible limitation of our findings is that these analyses were performed in 2008. However, the US Government Accountability Office (GAO) conducted a more extensive study in 2010, results of which were reported in testimony before members of the House of Representatives [7]. This study found similarly disturbing mismatches among the risk results provided by different leading DTC companies when identical samples were analyzed (Table 2).

Critics of DTC genomic testing have argued that companies' claims are misleading and could cause patients unnecessary worry or harm. The GAO study, which analyzed the results of 10 tests from 4 different companies, was particu-

larly critical of the DTC genomic testing industry [7]. The following major concerns were raised in the GAO report: Some predictions of risk conflicted with the patient's known medical conditions (eg, a subject with irregular heartbeat was told that he was at decreased risk for developing such a condition); different companies made contradictory risk predictions for the same condition in the same patient (Table 2); the companies made misleading claims (eg, none of the companies was able to provide African American or Asian individuals with complete test results, although this limitation was not explicitly disclosed prior to purchase); and good-quality expert advice was lacking (follow-up consultations failed to provide the expert advice that had been promised) [7].

Furthermore, the GAO study found "10 egregious examples of deceptive marketing" [7], including claims that a consumer's DNA could be used to create a personalized supplement to cure diseases, claims that a company's supplements could "repair damaged DNA" or cure disease, and claims that testing could predict what sports a child would excel in. Finally, the report states,

Perhaps most disturbing, one company told a donor that an above average risk prediction for breast cancer meant she was "in the high risk of pretty much getting" the disease, a statement that experts found to be "horrifying" because it implies the test is diagnostic.

Authors of a recent update on cardiovascular genomics concluded that "currently there are no clinically recommended genetic tests for many common forms of [cardiovascular disease] even though direct-to-consumer

TABLE 2.
Contradictory Risk Predictions for Prostate Cancer and Hypertension Provided by 4 Different Companies Using DNA Samples From a 48-Year-Old Male Donor

Condition	Risk prediction			
	Company 1	Company 2	Company 3	Company 4
Prostate cancer	Average	Average	Below average	Above average
Hypertension	Average	Below average	Above average	Not tested

Source: This table is adapted from a report of a study by the US Government Accountability Office [8].

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

Monica Gulisano

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

genetic tests are being marketed to healthcare providers and the general public" [8].

In 2011, a survey showed that DTC genomic testing companies were offering testing for a host of mental health-related conditions—including alcohol dependence/abuse, autism, depression, nicotine dependence, schizophrenia, and smoking [9]—despite evidence that the markers being measured contribute only a small proportion of the genetic contribution to these conditions [10]. Although there seems to be strong public interest in testing for susceptibility to psychiatric disorders, little is known about the impact on individuals of receiving the results of such genetic tests [11]. Moreover, the low predictive power and uncertain clinical validity of DTC genomic testing for psychiatric disorders leads to significant difficulty interpreting such test results.

Further contributing to the potential for confusion among consumers are claims made by companies on their Web sites and in their marketing materials. The 23andMe Web site (<https://www.23andme.com/>) currently displays a link to a "life-changing story" about a woman who suffered from

gastrointestinal symptoms for years before her doctor suggested DTC genomic testing, which revealed an elevated risk of celiac disease. This prompted her physician to obtain standard clinical testing, leading to a diagnosis of celiac disease in both the patient and her daughter. Such claims conflate marginally elevated risk assessment with diagnostic testing, the former being no substitute for appropriate clinical assessment and diagnostic evaluation.

Critics have worried that the confusion created by complicated risk profiles in the absence of proper genetic counseling may provoke unnecessary fear and worry in consumers. Current data, however, have not shown this to be a significant cause for concern. In a 2011 study, patients expressed no significant worries [12]. A more recent study showed that most consumers of DTC genomic testing services showed no difference in anxiety after long-term follow-up, compared with baseline, and 98.6% of respondents reported no test-related distress [13].

Nevertheless, geneticists are becoming aware of anecdotal incidents suggesting that some consumers may be

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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suffering as a result of DTC genomic testing, and there is certainly a potential for serious untoward incidents. 23andMe is now testing for the *APOE4* variant associated with increased risk for Alzheimer disease, as well as for several *BRCA1* and *BRCA2* mutations, which are associated with risk of breast and ovarian cancer. Reports of these test results are "locked," and there is genetic counseling information provided on the Web site, but all it takes to unlock these results is the click of a button. The Web site forums reveal that a number of individuals are concerned after learning that they are homozygous for the *APOE4* allele.

Positive outcomes from DTC genomic testing have also been reported. A small study carried out by 23andMe included 11 women and 14 men who had received an unexpected test result—the finding of a *BRCA1* or *BRCA2* mutation—and none of them reported more than transient moderate anxiety [14]. Furthermore, most of these individuals sought medical advice that resulted in confirmatory testing, risk-reducing procedures, screening of at least 30 relatives, and identification of 13 additional mutation carriers.

A major claim made by proponents of DTC testing is that simply knowing whether one is at increased risk for a particular condition may be enough to motivate significant lifestyle change. Some studies of DTC genomic testing customers have shown a trend toward both intended and actual behavior changes in individuals who learn that they may have a greater risk for conditions such as colon cancer [12, 15]. However, it is important to keep in mind that early adopters of DTC genomic testing services are likely to be among those most motivated to make health-related changes.

Those who work in primary care know that changes in patient behavior require more than just information, such as knowledge of cardiovascular disease risk factors or statistics regarding the impact of cigarette smoking on common health conditions. Although the notion of using genomic data to encourage preventive health strategies is appealing, early studies suggested that only a minority of consumers act on this information [16-20]. Furthermore, a primary care visit often includes collection of a family health history that identifies relatives with early heart disease or type 2 diabetes,

which will provide much more relevant data regarding relative risk for these genetically complex, multifactorial conditions than data obtained through current DTC genomic testing. A 2012 study [21] compared individuals who had been recently diagnosed with familial hypercholesterolemia through DNA testing with individuals who had no known genetic predisposition to cardiovascular disease (CVD) but who had a positive CVD-risk profile based on family history, cholesterol levels, and blood pressure. Those with positive findings on DNA testing had a higher perceived risk of CVD, but the 2 groups did not differ in the degree to which they attributed their risk to lifestyle or in their preventive behaviors [21].

The DTC genomic testing industry may expand in the future, but so far neither the benefits nor the risks have been as great as were initially predicted. In the future, North Carolina physicians will see more patients who want help deciding whether to pursue DTC genomic testing services, as well as patients who want advice regarding how to interpret their test results. At the present time, these results can generally be regarded as being largely of entertainment value. Only in rare cases will DTC genomic testing provide relevant health information to consumers, and it often produces data of uncertain validity. In our opinion, patients are currently better off spending their money on a gym membership (and then using it!) rather than parsing their genetic risks through DTC genomic testing.

The need for physician education is also a salient issue [22]. A survey of academic family physicians in the United States and Canada showed that a majority felt they were not knowledgeable about available genetic tests [23].

In summary, concerns regarding DTC genomic testing include both analytic validity and clinical validity. Currently, analytic validity is highly problematic—as illustrated by the fact that risk estimates from different companies for the same individual vary significantly, and the companies sometimes provide contradictory recommendations—which highlights the fact that no one yet understands how to validly interpret genomic data [24]. Clinical validity is also an area of concern, because the “risks” being reported are frequently insignificant, especially compared with the risk information that a physician can obtain by collecting a good medical and family history.

A central axiom of medicine is the admonition *primum non nocere* (first, do no harm). The wisdom of this insight remains instructive today, reminding us to remain cautious and vigilant in our treatment and testing, regardless of how superficially attractive DTC genomic testing may appear. NCMJ

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