

Public Awareness and Use of Direct-to-Consumer Genetic Tests: Results From 3 State Population-Based Surveys, 2006

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We conducted population-based surveys on direct-to-consumer nutrigenomic testing in Michigan, Oregon, and Utah as part of the 2006 Behavioral Risk Factor Surveillance System. Awareness of the tests was highest in Oregon (24.4%) and lowest in Michigan (7.6%). Predictors of awareness were more education, higher income, and increasing age, except among those 65 years or older. Less than 1% had used a health-related direct-to-consumer genetic test. Public health systems should increase consumer and provider education and continue surveillance on direct-to-consumer genetic tests. (*Am J Public Health*. 2009;99:XXX-XXX. doi:10.2105/AJPH.2007.131631)

The increasing availability of direct-to-consumer nutrigenomic tests is an emerging public health issue.¹⁻⁷ Direct-to-consumer nutrigenomic testing entails combining information on diet and lifestyle with testing for genetic variants of mostly uncertain clinical significance⁸ to inform recommendations on changes in behaviors, diet, specific nutritional supplements, or some combination of the three. Direct-to-consumer nutrigenomic tests are ordered directly by consumers without the involvement of a health care provider, and the direct-to-consumer nutrigenomic testing

company provides the consumer with results and nutritional advice.

In July 2005, several established businesses began offering direct-to-consumer nutrigenomic tests in several retail outlets in Minnesota. The Minnesota Department of Health was invited by registered dietitians in the field to observe and provide technical support. After a highly critical report by the US Government Accountability Office⁹ was released in July 2006, however, retail sales of the nutrigenomic testing kits in Minnesota were discontinued. These events raised questions about the public health impact of nutrigenomic testing. To address this issue, public health researchers developed and administered questions via the 2006 Behavioral Risk Factor Surveillance Systems (BRFSS) in Michigan, Oregon, and Utah to assess the public's knowledge of and interest in direct-to-consumer nutrigenomic testing. These results were compared with a recent study¹⁰ of the HealthStyles national survey, conducted by Synovate Inc, which surveyed 5250 respondents about health-related topics.

METHODS

The BRFSS survey was conducted by telephone to track health conditions and risk behaviors in the United States.¹¹ In addition to the standardized core questions, each state health department had the opportunity to develop and add questions specific to the state's priorities. All state health departments used disproportionate stratified sampling techniques to yield random residential telephone numbers. Survey staff interviewed a randomly selected noninstitutionalized adult aged 18 years or older in each household. Response rates were 52.4% for Michigan, 51.7% for Oregon, and 63.4% for Utah.¹²

Awareness was measured in all 3 states with a single question that varied across states (Table 1). Use of direct-to-consumer nutrigenomic tests was measured only in Oregon and Michigan. Analyses were conducted with weights to adjust the observations for the probabilities of selection and to each state's population distribution. Co-authors from each state evaluated their own data separately with SAS version 9.1.3 service pack 4 (SAS Institute Inc, Cary, NC), STATA version 9.2 (StataCorp LP, College Station, TX), or SUDAAN version 9

(Research Triangle Institute, Research Triangle Park, NC), for Utah, Oregon, and Michigan, respectively. Statistical analyses included obtaining estimates and confidence intervals and performing the χ^2 test for univariate analyses of categorical variables. Our aim was to identify sociodemographic predictors of awareness and use that were significant at $\alpha=.05$. All reported *P* values are uncorrected for testing multiple covariates.

RESULTS

For the 3 states, estimates of awareness of direct-to-consumer nutrigenomic tests ranged from 7.6% in Michigan to 24.4% in Oregon (Table 1). Age, household income, and education level were consistently associated with awareness of direct-to-consumer nutrigenomic tests for all of the surveys (Table 2). Those who were more affluent and better educated were more likely to be aware of direct-to-consumer nutrigenomic tests. Other sociodemographic characteristics (e.g., gender, race, ethnicity) were not consistently associated with awareness of direct-to-consumer nutrigenomic tests.

The Oregon, Michigan, and national surveys were relatively consistent in the estimates of use of direct-to-consumer nutrigenomic tests, which were all less than 1% of the total population (Table 1). Because of the small sample size ($n=6, 29,$ and 52 for the Oregon, national, and Michigan surveys, respectively) and statistically insignificant findings, the characteristics of persons who had used direct-to-consumer nutrigenomic tests are not presented.

DISCUSSION

Our data provide population-based information on awareness and use of direct-to-consumer nutrigenomic tests. A limitation includes the differences in wording among surveys, and therefore, caution must be taken when comparing the state and national results. Another limitation is the sociodemographic composition of the survey populations. Michigan and Oregon populations are similar to the national distribution.¹³ The Utah population, however, was younger, better educated, and more affluent than the overall US population.

TABLE 1—Questions and Results of State Behavioral Risk Factor Surveillance System and National HealthStyles Surveys on Awareness and Use of Direct-to-Consumer Nutrigenomic Tests: 2006

	Awareness or Use, % Yes (95% CI)
Oregon (n = 1867)	
Some companies are offering genetic tests of your DNA that are advertised to improve your health and prevent disease. You can order these tests directly, without the involvement of a health care provider. Have you heard about these tests?	24.4 (22.2, 26.7)
Have you ever used any of these tests?	0.3
Michigan (n = 5499)	
Some companies are advertising new ways to improve your health by testing a sample from the inside of your cheek. This sample is mailed directly to the company without involving a doctor, nurse, or other health care professional. A few weeks later, the company provides you with a personal health profile and lifestyle recommendations based on their findings. In the past 12 months, have you heard or seen anything about this type of test?	7.6 (6.8, 8.4)
In the past 12 months, have you or anyone you know obtained this type of test?	0.9
Utah (n = 2441)	
Some companies are offering genetic tests of your DNA that are advertised to improve your health and prevent disease. You can order these tests directly, without the involvement of a health care provider. Have you heard about these tests?	19.7 (17.7, 22.0)
National ^a (n = 5250)	
Genetic tests that analyze your DNA, diet, and lifestyle for potential health risks are currently being marketed by companies directly to consumers. Have you heard or read about these genetic tests?	14 (12.7, 14.6)
Have you ever had a genetic test that analyzes your DNA, diet, and lifestyle for potential health risks?	0.6

Note. CI = confidence interval.

^aResults are from Goddard et al.,¹⁰ who reported unweighted estimates.

TABLE 2—Characteristics of Respondents Who Were Aware of Direct-to-Consumer Nutrigenomic Tests: State Behavioral Risk Factor Surveillance System and National HealthStyles Surveys, 2006

	Oregon		Michigan		Utah		National ^a	
	%	<i>p</i> ^b	%	<i>p</i> ^b	%	<i>p</i> ^b	%	<i>p</i> ^b
Total aware of direct-to-consumer nutrigenomic tests	24.4		7.6		19.7		14	
Gender		.660		.039		.055		.056
Men	24.9 ^c		6.7		17.3		13	
Women	23.9		8.4		21.6		14	
Race/ethnicity		.103		.794		.483		.066
White	25.0		7.7		19.6		14	
Black	NA		6.5		NA		11	
Hispanic	NA		8.6		20.2		13	
Other	16.4		6.9		14.1		18	
Age, y		<.001		.007		<.001		<.001
18-24	10.3		3.7		14.3		15	
25-34	20.3		7.6		15.3		17	
35-44	24.0		7.5		17.5		14	
45-54	27.8		9.7		26.9		15	
55-64	33.9		8.6		26.9		14	
≥ 65	26.8		7.2		21.4		9	

Continued

The uncertain analytic validity, clinical validity, and clinical utility of direct-to-consumer nutrigenomic tests may result in unnecessary interventions and costs.¹⁴ The paucity of federal oversight for direct-to-consumer nutrigenomic tests is of further concern.¹⁵⁻¹⁹ The need and opportunity exist to improve educational efforts, monitor potential benefits and harms that occur from existing direct-to-consumer genetic tests, and develop strategies to minimize the risks and maximize the benefits of direct-to-consumer genetic tests.²⁰⁻²²

Recently, the American College of Medical Genetics,²³ the National Society of Genetic Counselors²⁴ and the American Society of Human Genetics²⁵ released separate statements regarding direct-to-consumer genetic testing (which includes direct-to-consumer nutrigenomic testing). The National Society of Genetic Counselors' statement²⁴ includes questions for consumers to consider before undertaking a direct-to-consumer genetic test. The American Society of Human Genetics' statement²⁵ includes recommendations for companies that offer direct-to-consumer genetic tests, recommendations for

TABLE 2—Continued

Household income, ^d \$.031	<.001	.074	<.001
< 25 000	21.6	4.7	14.2	11	
25 000–49 999	21.4	6.6	18.8	13	
≥ 50 000	28.2	9.5	21.4	16	
Education level ^e		<.001	<.001	<.001	<.001
High school or less	16.3	5.2	13.1	9	
At least some college	25.4	6.9	18.1	15	
College graduate	33.0	11.6	28.6	19	

Note. NA = not applicable (because of small sample size).

^aResults from Goddard et al.¹³

^bP values were obtained from the unadjusted χ^2 test compared with respondents who were not aware of health-related direct-to-consumer nutrigenomic tests within the categorical levels.

^cPercentages refer to row percentages by state or national survey, e.g., 24.9% of men in Oregon were aware of health-related direct-to-consumer nutrigenomic tests, compared with 24.4% of the entire population in Oregon.

^dFor the national survey, the categories for household income were <\$25 000, \$25 000 to \$59 999, and ≥\$60 000.

^eFor the national survey, the categories for education level were high school or less, at least some college, and graduate or professional.

professional organizations to educate their members, and recommendations for relevant agencies of the federal government to take targeted regulatory actions to ensure the analytic and clinical validity of direct-to-consumer genetic tests. Like the National Society of Genetic Counselors, the American College of Medical Genetics, and the American Society of Human Genetics, the public health community and academic institutions should become active in educating consumers and policymakers about the risks and limitations of direct-to-consumer nutrigenomic testing. ■

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Contributors

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Human Participant Protection

The human research protection offices at the Centers for Disease Control and Prevention, Michigan Department of Health, Oregon Department of Human Services, and Utah Department of Health have determined that the Behavioral Risk Factor Surveillance System survey is exempt from institutional review.

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