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RESEARCH ARTICLE

Trends and Gaps in Awareness of Direct-to-Consumer Genetic Tests From 2007 to 2014

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Introduction: Direct-to-consumer genetic tests for inherited disease risks have gained recent approvals from the Food and Drug Administration, and interest in these tests has continued to grow. Broad use of these tests coupled with planning and discussion with health providers regarding genetic risks and potential protective behavior changes have been proposed as preventive tools to reduce health disparities and improve equity in health outcomes. However, awareness of direct-to-consumer genetic testing has historically demonstrated differences by education, income, and race; these disparities could jeopardize potential benefits by limiting access and use.

Methods: The national survey data from the Health Information National Trends Survey was analyzed to understand how overall awareness of direct-to-consumer genetic testing and disparities in awareness across sociodemographic groups have changed since 2007.

Results: The findings showed persistent disparities, as well as a widening gap in awareness between Hispanics and non-Hispanic whites ($OR_{2007} = 1.52$, $OR_{2014} = 0.58$, $p_{change} = 0.0056$), despite overall increases in awareness over time.

Conclusions: Given these findings, policies regulating direct-to-consumer genetic tests should prioritize equitable distribution of benefits by including provisions that counteract prevailing disparities in awareness.

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INTRODUCTION

Clinical genetic testing interest has grown significantly over the past three decades. The ability to identify inherited disease risks can help patients discuss and plan for genetic risks with providers and allows for targeted clinical therapies should diseases develop. In parallel, costs for genetic tests available directly to individuals have declined to less than \$200, making some genetic screening relatively inexpensive.[1] After several years of regulatory challenges, the Food and Drug Administration (FDA) recently approved marketing to the general public of tests for ten diseases that have genetic risk factors.[1,2] The market for direct-to-consumer genetic testing (DTC-GT) is projected to reach \$340 million by 2022 in the U.S. alone.[3]

DTC-GT services have been criticized because of their limited clinical utility (e.g., lack of direct relevance to clinical decisions), concerns about patient and family members' privacy, and mixed findings related to patients' abilities to interpret results accurately.[4–9] Additionally, there are concerns that racial disparities in genetic risk education and social factors influencing the understanding of familial risk could exacerbate inequities in clinical

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genetic testing, counseling, and treatment.[10] Given that familial risk and family health history are of particular importance to black customers of DTC-GT services when compared with whites,[11] DTC-GT can play a role in mitigating these potential inequities. Moreover, there are other inequities to be considered, including low minority representation in genetics research and relatively low clinical genetic testing awareness among minority groups, in particular non-white Hispanic populations compared with those of Northern European ancestry.[12–14] Thus, awareness and literacy of both clinical genetic testing and DTC-GT are important areas of study and logical prerequisites for equitable access to disease risk screening, therapeutic interventions, and more general benefits of engaging health providers in discussions regarding genetic risks.

Awareness of DTC-GTs has been measured regularly since 2007 using the Health Information National Trends Survey (HINTS). As of 2013, just less than 50% of the U.S. population reported awareness of DTC-GT services.[15,16] Disparities in awareness have been found across income levels, education levels, population density, and reported Internet use.[15–17] Older studies also identified racial and ethnic disparities in awareness, although the differences between whites and blacks were mediated in one analysis that included a proxy for numeracy.[13,18] Other data have shown racial, educational, and income disparities in awareness and use of clinical genetic tests for cancer screening.[18–21] Collectively, these studies provide evidence of disparities in both DTC-GT and clinical genetic testing awareness across income, education, some racial and ethnic groups, and numeracy levels. However, no studies have examined how disparities in awareness among demographic groups have changed over time. A longitudinal assessment of consumer awareness is particularly important to policymakers and researchers interested in promoting equitable access and effective use of increasingly available DTC-GT products.

The purpose of this study is two-fold. First, HINTS data from 2007 through 2014 were used to estimate recent and historical levels of DTC-GT awareness among demographic subgroups. Second, changes in awareness disparities are examined between demographic groups over time. In particular, testing focused on whether disparities found in earlier cross-sectional studies[15,17] have changed over time. The findings presented provide insight for organizations like clinical genetics professional societies and nonprofit organizations. These groups often translate evidence on genetic testing and related services into policies, recommendations, or statements on proposed legislation and regulations. This study demonstrates a widening racial gap in awareness associated with DTC-GT and supports the claim that there is an increasing disparity of awareness. Also, this study supplies health providers and researchers with knowledge regarding groups of patients more likely to discuss genetic testing with health providers. Analogous to the effect DTC pharmaceutical advertising has had on discussions about drugs, groups with higher DTC-GT awareness may be more likely to engage providers in discussions related to genetic risk or pursuing screening.[22] Whether this potential effect has positive or negative consequences is not the subject of the current study, but providers can benefit from this evidence on DTC-GT awareness.

METHODS

Study Population

The HINTS survey is sponsored by the National Cancer Institute and focuses on cancer-related information with the intent to understand and improve health-related communication. This study uses fives waves of HINTS data with identical survey items related to DTC-GT awareness. There were 15,826 survey responses examined using the approach outlined by Finney Rutten and colleagues[17] in 2012. In 2007, responses were collected via both random-digit dialing and mailed surveys, which had response rates of 24.2% and 31.0%, respectively. In subsequent survey years, response rates were 37.9% (2011), 40.0% (2012), 35.2% (2013), and 34.4% (2014).[23] The 2007 data were analyzed to identify the presence of response bias across the two survey methodologies.[24] Mailed surveys demonstrated significant ($p<0.01$) differences in responses to some variables based on the mode of survey administration and were excluded from the analysis. Consequently, only the random-digit dialing-based data from HINTS 2007 were analyzed. In all other survey years, HINTS used only mailed surveys to collect responses.

Measures

The key dependent variable was a binary measure of DTC-GT awareness: *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?*

Sociodemographic variables of interest were age (18–34, 35–49, 50–64, 65–74, and ≥75 years), education (less than high school, high school, some college, and college graduate), annual income (<$35,000; $35,000 to <$75,000; and ≥$75,000), and race/ethnicity (Hispanic, non-Hispanic white, non-Hispanic black, and other non-Hispanic).

Health insurance status and regular source of health care served as measures of healthcare access. Respondents were asked to identify their type of health insurance coverage, or to indicate if they did not have health insurance. Respondents were also asked to respond *yes/no* regarding whether or not they have a particular doctor or other health professional that they see most often.

Participants reported on their Internet use with a yes/no answer to whether or not they ever go online to browse or use e-mail. Additionally, a binary measure defined as rural-urban designation