Genetic Testing for Cancer Risk Doesn't Change Consumer Behavior, PGen Study Finds

Dec 12, 2016 | Elizabeth Newbern

Premium

This article has been updated from a previous version to clarify the nature of the action the FDA took against 23andMe.

NEW YORK (GenomeWeb) – Members of the Impact of Personal Genomics (PGen) study have published their first research findings exploring how patients using direct-to-consumer (DTC) genomic testing for cancer risk change their health behaviors.

Published today in the Journal of Clinical Oncology, the study evaluated 1,042 patients who received cancer risk estimates for breast (women only), prostate (men only), and colorectal cancer. The patients were surveyed at baseline and six months after they received their test results to determine whether they had made any changes to their diet, exercise, vitamin and supplement intake, or cancer screening behaviors.

The researchers found that while men who received an elevated risk estimate for prostate cancer did change their vitamin and supplement use more than those with an average or reduced risk, most adults who received elevated risk estimates for cancer did not significantly change health behaviors.

This study was the most recent of more than a dozen that the PGen researchers have published in peer-reviewed journals — including studies published earlier this year in Genetics in Medicine and the Annals of Internal Medicine — and there are still more scheduled for publication in coming months. All of them analyze different concerns primary care physicians and researchers have expressed concerning DTC genetic testing's effect on consumers' health. Shortly after DTC genetic testing became available, researchers and clinicians began wondering if it could cause consumers undue anxiety, spur them to change their prescriptions, or confuse them.

There have been a number of legitimate concerns regarding whether consumers misunderstand and consequently mismanage their health as a result of DTC genetic testing, Robert Green, director of the Genomes 2 People Research Program in the Division of Genetics at Brigham and Women's Hospital, Broad Institute, and Harvard Medical School, and co-principal investigator on the PGen study, told GenomeWeb.

However, all the publications to date have shown there is no strong indication that DTC genetic testing has had a negative impact on consumers. "[The PGen study results also show] there is a potential for misunderstanding, but it's rather modest," Green said.

Funded by the National Institutes of Health in 2010, the PGen study surveyed consumers of two US companies — 23andMe and Pathway Genomics — which at the time both provided DTC genetic testing services.

In 2013, the US Food and Drug Administration told 23andMe to stop offering health reports as part of its personal genome service due to unanswered questions about "its intended use in the diagnosis of disease." The FDA considered the service in the same class as a medical device, which requires some kind of input by a physician or genetics counselor that at the time was not included in consumer services. The ban was preceded by a number of letters sent to 23andMe and other companies providing genetic testing services. As a result, 23andMe worked closely with the FDA to modify its services to better fit within health guidelines, and Pathway Genomics no longer offers those services.

The overarching goal of PGen was to collect data on how consumers were using the information they learned after receiving genetic testing results. The researchers evaluated 1,648 consumers at baseline. Of those initially evaluated, 1,046 of them participated in the two-week follow-up survey and 1,042 of them participated in a six-month follow-up.

After collecting all of the follow-up data, the PGen researchers spent subsequent years analyzing it and begin to piece together what the actual health impacts for consumers were across different areas of interest, such as changed health behaviors.

"People do seek out medical follow-up, but less than we would have expected," Green said. "People aren't changing prescriptions without permissions of their doctors based on pharmacogenomic [results]."

"I think [these] findings are similar to other studies that have looked at the impact of genetic testing in general," Cinnamon Bloss, professor of psychiatry, family medicine, and public health at the University of California, San Diego's Division of Health Policy, told GenomeWeb.

Earlier in her career, Bloss, who was not involved in the PGen research, worked on a large prospective longitudinal study called the Scripps Genomics Health Initiative. It began recruitment in 2008, also well before the FDA shut down many DTC genetic testing services. It used a similar model to the PGen study, but looked at and regularly followed up on over 2,000 consumers of tests from Navigenics, a DTC genomics testing company acquired by Life Technologies in 2012. After data analysis, the Scripps initiative published between 12 and 15 papers.

"The study that received the most attention was one we published in 2011 in the New England Journal of Medicine," Bloss said. "In that study we looked at changes in anxiety, changes in diet, and exercise behaviors, and also propensity to seek follow-up screening tests like a colonoscopy or something of that nature. We didn't see any adverse impacts. [But] we found absolutely no evidence of a positive [health] effect either."

"A theme we've seen is that there is not a lot of adverse impact in providing people with this information

and in most cases people have a little bit of a ho hum response to [testing results]," she added.

"I agree that the PGen study has generally indicated satisfaction and a lack of negative consequences for consumers," Wylie Burke, a professor of bioethics and humanities at the University of Washington who also was not involved in the study, told GenomeWeb in an email. "The study also suggests that consumers assume their DTC genetic results have value for their health and health care, when in fact most DTC results have little value for guiding health care or predicting risk. Thus the study suggests that consumers of DTC testing may overestimate the value of this product."

Burke noted that one of the findings in PGen study published this year in the Annals of Internal Medicine in study was some consumers feeling dissatisfaction with doctors who do not engage with their patients regarding DTC results.

"This result suggests to me that one potential harm of DTC results is that they may contribute to misunderstanding or discord between patients and doctors," she said.

While these are valid points, Green said, he also believes that rather than creating misunderstandings it can be a great "teachable moment" for physicians to explain the differences between genetic and lifestyle factors that can impact a patient's health.

Green also noted that there are some important caveats to the PGen study. "As always in survey research we only hear from the people who like to talk to us," he said. "We might not be hearing from the people who are more confused or more anxious."

"Even when we hear from people, we get [whatever information] they want to tell us. Not necessarily what they are [actually] doing," Green added.

Filed Under Cancer Sequencing DTC genetic testing