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Brigham and Women's, Univ. of Michigan Team with 23andMe and Pathway to Study Consumer Genomics

By Matt Jones

NEW YORK (GenomeWeb News) – Researchers at Brigham and Women's Hospital and the University of Michigan School of Public Health will work with consumer genetics companies 23andMe and Pathway Genomics to study how consumers view, and are affected by, genetic tests and their results.

Funded by the National Human Genome Research Institute, the partners in the Impact of Personal Genomics (PGen) Study will survey personal genomics consumers to learn about their motivations, expectations, and attitudes, and how they respond to learning about their genetic disease risk, carrier status, and drug response results.

The three-year, $1.1 million PGen project will enroll 1,000 participants, including 500 customers from Pathway Genomics and 500 from 23andMe, Brigham and Women's Hospital said yesterday.

The PGen partners hope to find out more about who seeks personal genomic testing and why, the psychological impacts the test results have on consumers, and how consumers use their genetic information, such as making changes in their behaviors or insurance policies.

"There's a lot of controversy about direct-to-consumer genetic testing," Robert Green, a joint principal investigator on the project and a researcher at Brigham and Women's Hospital and Harvard Medical School, told *GenomeWeb Daily News* on Monday. "We're interested in all of the things that make this controversial.

He said the partners will be looking for answers to questions, such as, "Do people have a realistic sense of what they are asking for? Do they have a realistic sense of what they have received? What do they do with the information? Do they do something good, something positive for their health? Are they falsely reassured? Do they take it to their physician, and if so, does their physician order up a bunch of tests, or tell them to forget about it and go home?"

"There has been considerable speculation, but not a lot of data, to inform the debate about the possible benefits and harms of personal genomics services," joint PI J. Scott Roberts, of the University of Michigan School of Public Health, said in a statement. "We hope that our study will help to bridge this evidence gap."

The research team includes an interdisciplinary group with specialties in genetics, genetic testing policy and practice, genetic counseling, bioethics, health law and psychology, and web survey design.

The project will involve three surveys, one that will be administered to the 1,000 participants before they have received their test results, another just after they received the results, and another around six months later.

The researchers also will have consent from the participants and the companies to look at the same genomic results that the participants received before they administer the second survey.

The partners hope that examining the consumers' attitudes and opinions alongside the results of their genomic tests will enable them to study how well the participants understood the meaning of the genetic information that the companies provided them.

One of the concerns looming over the consumer genetics field has been the question of how well the public and physicians comprehend the meanings of genetic data, which often may be highly scientific, open to interpretation, subject to change based on new research, and based on nuanced statistical data.

Green told *GWDN* that this study will be able to address those questions about whether people understand or misunderstand the genetic information, because "we can compare what they say they understand to the actual report."

From a psychological standpoint, having the actual genomic data to compare with the surveys will enable the researchers to compare people's "actual risk" for disease versus their "perceived risk," Roberts told GWDN in a separate interview. "Are people's perceptions accurate in terms of what their actual genetic test results say? That will give us some insight into the psychological experience of receiving the information, and also about their comprehension of the education materials that they are provided.

"If we see a lot of discrepancy between their perceived risk versus their objective risk it might call into question just how well they understand the results that they were told," he said.

Roberts also said that the study will aim to assess if this information has any negative psychological consequences among the participants. He said that the partners do not expect to see the results lead to much distress.

Previous research into genetic testing information for disease risk has suggested that "people tend to cope pretty well with that kind of information," Roberts said. "I think what we are more interested in from a psychological perspective is how does it change the way people think about their risk of disease. … Did they feel more empowered to do anything about their health risks, because it is conceivable that the information might prompt them to gain additional information or seek out resources that could be valuable?"

Another part of the study involves assessing how participants may use this genetic information in their medical care.

"In theory, you could imagine that if someone learns they are at higher risk for something they might press for more frequent tests that could add extra and potentially unnecessary costs to the healthcare system," Roberts said.

"These are not necessarily things that would be very significant at an individual level, but if they were multiplied out by hundreds of thousands of people they could have real public health impact," Green added.

Green said that the PGen partners have an agreement in place with 23andMe and Pathway Genomics that gives them complete academic freedom.

The plan between the academic and industry partners was outlined in a recent issue of *Genetics in Medicine*, in which Green and other authors explained that the agreement required addressing the "dual priorities of maintaining scientific rigor and objectivity while respecting the concerns of the industry being studied. Academic investigators and industry scientists had to develop solutions that would satisfy both partners," Green said.

One important component of the partnership is the involvement of a third party web survey specialty company that has experience in handing sensitive healthcare data and which will handle most of the communication with the participants. The partners also agreed that each company will receive the survey data provided by their own customers, they will have some limited input into the analysis, and they can request additional analysis on topics of special interest.

Green said that the two genetic testing companies are seen as scientific collaborators in the project, who "have a say, not the final say, but a say in how the data are presented."

He also pointed out that although companies naturally are sensitive about their information being shared with other corporate partners, as well as how they may be perceived depending on what the study uncovers, the process has been "transparent" and the partners have been "extremely open" to the project.