

Public Health Surveillance of Awareness and Use of Direct to Consumer Genetic Testing
Katrina A.B. Goddard, Ph.D.

DR. TUCKSON: Outstanding. Thank you all very much.

We have one important presentation left, and we will turn to that right away. We have a presentation from the CDC about the public's awareness and the use of direct-to-consumer genetic testing. We have been concerned for some time about DTC marketing of genetic tests and its impact on public health. I remember Francis Collins many meetings ago bringing that Nutraceuticals for the Millennium deal forward, a slide that I use regularly in talking about this issue. Several years ago we recommended that further efforts be made to gather data on the issue. We have been encouraged by CDC's responsiveness and are pleased that Dr. Katrina Goddard is here today. We're glad that Katrina is here to tell us more about what CDC has learned in the past year.

Katrina is a geneticist from Case Western University. She's currently serving in a fellowship at the National Office of Public Health Genomics at CDC.

Dr. G., we are so thankful that you joined us.

(Laughter.)

DR. GODDARD: Well, thank you very much, and thank you to everyone for staying until the very end for my talk.

Direct-to-consumer genetic tests have recently exploded onto the market. In 2003, Golost and co-workers reported that there were 14 companies that offered direct-to-consumer health-related genetic tests. Through our work, we have identified 27 companies that are currently offering these tests, between 1 and 16 tests from each company. Although there are non-health-related direct-to-consumer genetic tests such as paternity testing or ancestry testing, our work is really focused on the health-related tests such as nutrigenetics, predictions of fetal gender and tests that we're more familiar with, from clinical testing such as BRCA1 and 2 testing, hereditary hemochromatosis and CF carrier testing. The Internet gives nearly everyone immediate access to these tests.

Concerns have been raised in a variety of contexts surrounding these tests, including a GAO report last summer on nutrigenetic testing, and one of the main concerns that is raised is that the test may be misleading, unsubstantiated, and may make ambiguous predictions.

I'm not going to go through this because Marc Williams already gave a very nice talk this morning on the regulatory and oversight issues of genetic testing in general, which would apply to direct-to-consumer genetic testing as well.

So the CDC has undertaken a variety of tasks in the last year to look at surveillance about direct-to-consumer tests, and our main goal was to provide some baseline information on public demand and interest in nutrigenomic tests, and also to assess provider knowledge and experience with direct-to-consumer genetic tests. As this information is collected over time, we could be able to assess the impact of changes in policies and any public or provider education programs that occur and how that impacts awareness and use of these tests. We can also look at the evolution of the availability of the tests and how that might change the demand for these tests.

So there have been two national surveys that were conducted in the past year. The first is called the HealthStyles Survey, and that included 5,250 consumers from around the nation, and then the DocStyles Survey was an online survey of physicians that included 1,250 respondents.

There are also several state programs in public health genomics, including Oregon, Michigan and Utah that added questions about direct-to-consumer genetic testing on the Behavioral Risk Factors Surveillance System, or BRFSS surveys the past year. These surveys are considered to be more representative of the population because they use random digit dialing to recruit the participants in the studies.

So I just wanted to go through this quickly so you can see that although the different sites discussed the questions ahead of time, the final content of the questions was different for most of the surveys. So in red, you can see that Oregon and Utah and the national surveys specifically mention the words "genetic" and "DNA," whereas the Michigan survey used simpler language and said "a sample from the inside of your cheek," which could also be a little bit more restricting and not include types of genetic tests that are not from a cheek swab. In green, you can see that all the surveys mentioned that the test could be ordered directly, but the national survey did not mention that health care providers were not involved in the testing. In blue, you can see that the Michigan survey restricted the time period only to the past 12 months, whereas the other surveys were more general. In yellow, you can see the differences in what the intended benefits were of the tests.

So quickly going through the results of the different surveys, there was variation in the awareness of direct-to-consumer genetic tests, with the highest rate in Oregon of 24.4 percent and the lowest rate in Michigan of 7.6 percent. The Michigan survey may have a lower rate because of some of those differences in how the questions were worded.

Another issue that we need to address is that the characteristics of the populations may be different in these different sites, and using U.S. Census data the Oregon, Michigan and national distributions for important characteristics are actually very similar, but the Utah population tends to be younger, more affluent and more educated than the other populations. So that could have led to a higher rate for that state than for the others.

In terms of the use of direct-to-consumer tests, they all had reported a very low rate, less than 1 percent, and that was similar across the surveys.

All of the surveys identified the same characteristics of age, household income and education level as being important predictors of awareness of direct-to-consumer genetic tests. For age, you can see that the rate of awareness increases as the age increases, except for the oldest age category, where you see a drop in awareness for that group. Those with the highest household income and the highest level of education were also more likely to be aware of the genetic tests.

In terms of where consumers hear or read about these tests, they're most likely to find out about these tests through the media such as television, magazines and newspapers, but we found it very interesting that for the 29 respondents of this survey who had used a direct-to-consumer genetic tests, over 60 percent of them had heard about it from a health professional, and we did not distinguish between physicians or other types of health professionals. So that would be a question that would be interesting to address in the future.

Looking at the results for the survey of physicians, slightly less than half of the physicians were aware of direct-to-consumer genetic tests, and none of the factors or characteristics that we

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looked at were very different between those who were aware and those who were not aware of these tests, except that males were more likely to be aware of the direct-to-consumer genetic tests.

Only looking at those physicians who were aware of direct-to-consumer genetic tests, about 75 percent of physicians had less than 1 percent of their patients ask them questions about these tests, and over 90 percent of physicians had fewer than 1 percent of their patients discuss results of a direct-to-consumer test with them. So these tests, if patients are taking the tests, it's not really coming back into a practice with a physician.

Then turning towards physician sources of information, we asked several questions about this topic. On the Y axis of this graph you can see the results from the first question where we asked physicians to identify up to five of their most trusted sources of information on patient health-related topics. So journal articles was the most trusted source, government agencies, et cetera. So they're ranked from most trusted to less trusted. In Panel A you can see that physicians reported that they used the more trusted sources more frequently. However, for direct-to-consumer genetic testing in Panel B, you can see that the media was the most likely source for physicians on this topic, which was one of the least trusted sources.

So overall, we found that only a small percentage of the U.S. population is aware of or has used direct-to-consumer genetic tests, and that the media is the most frequent source of information for both consumers and physicians, suggesting that other venues for learning about these tests such as through professional organizations or government agencies might be useful, and that there are several limitations of the existing surveys, including the small number of respondents who used a direct-to-consumer genetic test, so we weren't really able to characterize that population very well. Also, there may have been some confusion over wording of the questions and the differences in the questions between the surveys, and we did not assess any health outcomes as a result of having the testing done. So we weren't able to assess what happened to people once they had taken a test.

Then I'd just like to acknowledge all the co-workers from the CDC and also from the Oregon, Michigan and Utah state health departments who contributed to this work. Thanks.

(Applause.)

DR. TUCKSON: Can we have a round of applause for the speaker? Oh, we already did that part.

Are you going to keep doing this? Is this one shot and out, or is CDC in this for the long run?

DR. GODDARD: We have questions on next year's survey at the national level, and I don't think it's entirely up to the CDC whether it will be put on the BRFSS surveys.

DR. TUCKSON: The CDC doesn't have any juice to get it on there? Muin, is it a powerless organization?

(Laughter.)

DR. KHOURY: It's too late in the day to respond to you.

(Laughter.)

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DR. TUCKSON: One quick question, rushing for time. Slide number 11, what do I take on the proportion, like 0.6? Does that mean basically almost nobody has seen anything?

DR. GODDARD: Sixty percent of the people who had used a direct-to-consumer genetic test heard about it from a health professional.

DR. TUCKSON: So that's just only the people who have seen it.

DR. GODDARD: No.

DR. TUCKSON: Who have done it, who have gotten it, have sorted through that. So there's no survey that says how many people actually have received these things.

DR. GODDARD: The black bars refer to people who say that they have used a direct-to-consumer genetic test, and the green bars are for people who have heard about them.

DR. TUCKSON: Okay, so that is a significant penetration. So these are common. Okay, thank you.

Questions?

DR. McLEAN: With that slide right there, do you have any sense of what kind of genetic tests were being mentioned by the physicians but allowed to be sort of negotiated entirely by the patients themselves? Was it BRCA or paternity testing?

DR. GODDARD: Well, the way that the question was worded, we were asking about tests that analyze DNA, diet and lifestyle for potential health risks. So that was a very generic question and we weren't able to ask about specific tests, but we're hoping that that is referring to health-related tests versus the non-health-related tests such as paternity testing.

DR. TUCKSON: Thank you very much.

DR. GODDARD: All right. You're welcome.

DR. TUCKSON: So we'll look forward to seeing other results of that.