
Genetic Services Policy Project

Type 2 Diabetes: A Vignette

Vignette 1: Patient perspective

Marjorie Jones is a 55-year old woman who lives in southern Alabama. She was recently diagnosed with diabetes after a routine check-up with her doctor. Her blood sugar had been somewhat high in the past, but not in the diabetes range. With a history of hypertension and high cholesterol, the doctor was particularly concerned about her cardiovascular health. He recommended diet and exercise, weight loss, and started her on a small dose of metformin, an oral hypoglycemic, in addition to her blood pressure and cholesterol medications. He gave her information on the disease with a list of recommended follow-up lab tests and exams, including eye exams, foot exams, and cardiac testing. He also suggested that she attend a diabetes education class offered at the medical center.

Marjorie's father, who also had diabetes, died several years ago from complications of the disease. He had had difficulty controlling his blood sugar, and eventually lost his eyesight. He suffered from depression for a number of years. Given her father's experience, the news that she also had the disease was quite distressing for Marjorie. Would her diabetes follow the same course as her father? She had heard about diabetes being a familial disease so she worried that her own kids, three sons and a daughter, would be doomed to the getting the disease as well. According to an article she read in a recent newspaper, there was a new genetic test for diabetes that could predict whether someone would get the disease. She decided to ask her diabetes class instructor about the test.

Vignette 2: Educator perspective

Sam Baker is a diabetes nurse educator at a large medical center in southern Alabama. Sam teaches self-management classes for individuals with diabetes and prevention classes for pre-diabetics. He also speaks frequently to community groups about diabetes risks and prevention. Alabama has one of the highest rates of Type 2 diabetes in the nation as well as high rates of obesity. Nearly 10 percent of adults in the state have diabetes, and 62 percent are at risk of diabetes because of being overweight or obese. Diabetes prevention and management are top public health priorities.

As an educator, Sam stays abreast of current research in diabetes and attends national diabetes meetings. Several years ago he read a review article about diabetes and genetics that discussed numerous possible gene-disease associations, but not much in the way of practical application. In his classes, Sam talks about the familial nature of diabetes, but focuses on the importance of healthy lifestyle for everyone, not just people with a family history of diabetes.

Sam was surprised when a genetic test for diabetes risk became available earlier this year (2007). He remembered the media reports last year when a group from Iceland discovered a major gene for diabetes and that there was a lot of hype about the importance of this discovery. He suspected that it would just be another in the long list of genes that had been associated with the condition, but wouldn't be particularly useful. Now the same group had come out with a clinical test for the risk gene.

At one of Sam's recent classes, a client asked him about the new genetic test. She was recently diagnosed with diabetes and was worried about her sons and daughter. Her father had also been diabetic. The client, an overweight woman in her 50s, thought this test might be helpful to see if her children would get the disease. Sam decided to do more research on the genetic test.

Sam checked out the company's website and learned the following information:

- The name of the test is deCODE T2™.
- The DNA-based test looks for a high-risk variant in the TCF7L2 gene.
- According to the company, a positive test (two copies of the high-risk gene variant) will increase motivation to change behavior (diet and exercise) and may suggest prophylactic medication (e.g., metformin) as a preventive strategy.
- Studies estimate that 7 percent of the population has two copies of the risk gene, and that having two copies nearly doubles one's risk of developing diabetes.
- The test is marketed as an important tool for diabetes prevention.
- Consumers can get the test directly through a web-based genetic testing service for \$300, or physicians can order it from the company in Iceland.

Sam, an avid computer user, explored a number of online resources, including several blogs, about the test. In one blog, a nurse described her experience with the test. She had already been diagnosed with diabetes and had a family history of the disease, but was interested in having the test because of potential implications for her children. Her test turned out to be negative. Was this information useful? Were her children any less at risk for diabetes? As it turns out, she was tested for free, so the cost wasn't an issue.

After reading about the test and finding no studies to support the use of the test in clinical care, Sam was pretty skeptical. He was sure insurance companies would not cover the cost of testing without more evidence of utility. Knowing how challenging it has been to get people to change their behavior, he wondered whether a genetic test that only examines one of many genes would be helpful. Could genetic testing actually have a negative effect? For instance, if the test is negative (meaning that an individual does not have two copies of the risk gene), people with pre-diabetes may think that their risk of developing diabetes is low and they may be less motivated to exercise and change their diet. And on the other hand, if the test is positive, people may think they are destined to get diabetes and not bother with making lifestyle changes. Pre-diabetics with the gene variant may opt for drugs like metformin over diet and exercise, adding to costs of care. Would a test that looks at multiple genes and gene variants be more useful, or only confuse things more?

The web-based testing service that offers the genetic test has an online survey to gauge interest and determine if people think the test will increase their own motivation to make lifestyle changes. From Sam's experience, even if people think something will increase their motivation, it may not translate into action. He has encountered numerous people who spend \$500 or more annually on a health club membership as an incentive to exercise, but never use it.

In considering his client and her family, Sam doesn't think the new genetic test will be helpful and the cost would likely be prohibitive for many people anyway. He thinks the client's family is at risk for diabetes whether or not they have the high-risk gene and should make the lifestyle changes needed to protect themselves. Sam decides to write about the test in his monthly diabetes e-newsletter.

Case Issues for Discussion:

1. In what situations might genetic testing for diabetes be indicated?
2. Would you spend \$300 on the deCODE T2™ genetic test for diabetes? Why or why not?
 - a. If you had a family history?
 - b. If you didn't have a family history?
 - c. If you had pre-diabetes?
3. What factors influence consumer demand for such a test?
4. What is the role of the media and online community (consumers and experts) in shaping demand?
 - a. Print media
 - b. Blogs
 - c. Message boards
 - d. Advertising
5. Do you think genetic tests will be helpful in getting people to change their behavior? Why or why not?
6. Should there be a requirement for genetic tests to demonstrate clinical utility prior to coming to market? Why or why not?
7. deCode, Inc. quickly turned their gene discovery into a gene test. What are the implications for other biotechnology companies? How might consumer demand for deCode's test impact the industry?
8. Communicating risk is a complicated process. What factors impact risk perception? What is the role of risk perception in genetic testing?

What genetic services delivery issues does this scenario raise?

- Public and health care provider awareness and understanding of benefits and limitations of genetic technology
- Challenges associated with communicating genetic risk, variability in risk perception
- Availability of tests that have not demonstrated clinical utility, but have potential usefulness
- Need for clinical studies
- Direct-to-consumer and direct-to-provider marketing of genetic tests
- Role of media in providing information, influencing consumer behavior
- High costs of genetic technology, compared to other tests and services

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