



USPTO Roundtable Written Commentary

In response to this committee's request for quantitative data, FORCE has gathered information from sources including healthcare providers, the hereditary breast and ovarian cancer (HBOC) patient community, and respected institutions such as the Cancer Legal Resource Center and the Michigan Department of Community Health.

Of the four key questions presented in Section 27 of the America Invents Act, we are best-qualified to address the issues surrounding the role that cost and insurance play in access to genetic testing; and the desire for confirmatory or second opinion testing in the patient and healthcare provider communities.

1) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

In 2005, the United States Preventive Services Task Force (USPSTF) released a Grade B Recommendation Statement entitled "Genetic Risk Assessment and *BRCA* Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement indicating that at least fair evidence was found that the service improves health outcomes and that the benefits outweigh the harms. That statement specifically states:



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“Women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes [should] be referred for genetic counseling and evaluation for *BRCA* testing.”

The National Comprehensive Cancer Network (NCCN) has published guidelines for *BRCA* counseling and testing for women and men with a personal history of breast cancer; women with a personal history of ovarian cancer; and, individuals with a relative with a known genetic mutation. It should also be noted that NCCN has guidelines for cancer risk management services for women who test positive for a *BRCA* mutation.

Unfortunately, based on data from the Michigan Department of Community Health, nearly half of health insurers don't follow the testing guidelines, and two-thirds have not adopted NCCN guidelines for risk management services. Our testimony to this committee in February 2012 noted that Tricare discontinued coverage of *BRCA* testing last January. Approximately 9 million people insured by Tricare didn't have access to this critical genetic test. Tricare reinstated coverage of *BRCA* genetic tests in August.

The Michigan Department of Community Health is a leader in the utilization of genetic information to provide statewide public health benefits. Its Cancer Genomics Program has done extensive work to increase the availability of cancer-related genetic information in order to decrease barriers to “risk-appropriate” services. After significant efforts to get insurers’



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written policies in alignment with national guidelines, only 14 out of 25 (an increase from 4 in 2009) major Michigan health plans have written policies aligned with USPSTF—which also require or strongly recommend genetic counseling prior to testing. Seven health plans aligned with NCCN recommendations for cancer risk management services for BRCA positive women.¹

Medicare only covers BRCA genetic testing for women who have had a cancer diagnosis. It doesn't cover any BRCA testing for men. Tens of thousands of high-risk people over age 65 cannot access BRCA testing through Medicare, and many can't afford to pay out-of-pocket for genetic testing. This has a significant impact on these individuals and their families in determining if there is a genetic mutation or which side of the family a mutation comes from.

Cost and health insurance coverage—or lack thereof—place a significant financial and health burden on the patient population. In a MDCH study conducted 2007-2011, of the 1,722 patients who had genetic counseling and did not have BRCA testing, nearly 15% cited inadequate insurance coverage as their reason for not receiving genetic testing. This data demonstrates the importance of inadequate insurance coverage as a barrier for many patients who would benefit from such testing.

In response to the request from the USPTO for more data, FORCE developed an online survey which we promoted to consumers and healthcare professionals. Over 500 people completed the survey. Of the 38 individuals who responded that they did not undergo genetic testing,



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26% indicated that health insurance denied coverage of genetic testing and they could not pay out of pocket; 5% stated that they were uninsured and unable to pay out-of-pocket as the reason they did not undergo testing.

Of those who did have genetic testing, 7% indicated that insurance initially denied coverage and they had to appeal to get the testing covered. Another 7% of respondents said that their health plan denied coverage of their testing completely, and 1.5% didn't have health insurance but were able to pay for genetic testing out-of-pocket. Given the cost of some genetic tests, this is a significant burden on the patient community.

We queried the healthcare community about their experiences with the impact of cost and health insurance on patients who meet nationally published guidelines for BRCA genetic testing. A summary of this information and more is provided for your review.

Of 116 healthcare providers who answered this question, 22% indicated that their patients often experience difficulty in getting health insurance to pay for genetic testing and 64% said occasionally. Over half of the healthcare providers indicated that at least 80% of their uninsured and underinsured patients are unable to access genetic testing through other means such as participation in research or via financial aid.



2) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

At least eleven states and Medicare currently mandate private insurance coverage for some form of second medical opinionsⁱⁱ. The majority of these laws allow for patients to visit a second physician. While they don't explicitly mention genetic test results, it is important to acknowledge that there is a trend to value second opinions as a cost-saving measure for insurance companies, and a right for patients before making life-changing medical decisions.

On the question of demand for second opinion testing, the FORCE survey indicated that 60% of healthcare professionals and 35% of patients who underwent testing for a gene mutation indicated that they would like the option of a 2nd opinion / verification genetic test.

Comprehensive information on the impact of insurance and cost on access to genetic counseling and testing, as well as information about desire for 2nd opinion testing is detailed in the attached summaries of our survey. Additionally, we have provided some personal accounts of the impact these issues have on the already over-burdened high-risk community and the healthcare providers who serve them.



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In closing, I would like to emphasize again that cost and health insurance coverage are key factors in patient access to genetic counseling, testing and preventive services. I also want to bring attention to the fact that Myriad's "comprehensive panel" is less than comprehensive. The BART rearrangement panel, offered at an additional cost of \$700, finds mutations missed by Myriad's comprehensive BRACAnalysis. Cost of this additional panel on top of the cost of full sequencing places a financial burden on populations that already face disparity. People of Hispanic ethnicity, for instance, are more likely to carry a BART rearrangement.

Thank you for the opportunity to submit commentary on this important topic.

ⁱ Michigan Department of Community Health, Genomics and Genetic Disorders Section

ⁱⁱ Cancer Legal Resource Center. California, Florida, Illinois, Indiana, Kentucky, Maryland, Missouri, New York (only in the case of cancer), Oregon, Washington, West Virginia, and Wisconsin require coverage of a second medical opinion.



USPTO Gene Patent Survey Comments January 2013

Select Survey Comments:

Healthcare Professionals

1. I have been a Board Certified Genetic Counselor specializing in cancer for over 20 years. Myriad's exclusive patent has prevented many of my patients from being able to access testing (due to the high cost - about triple what it is in Canada and Europe), and certainly has prevented the option of repeat confirmatory testing in another lab.

1/9/2013 2:45 PM
2. The issues I run into are policies that only allow up to a certain amount (typically \$300) for preventive services, including genetic testing, which leaves the patient with a large out-of-pocket expense. If the initial cost of BRCA testing weren't so high, it may be more feasible for these patients to pursue testing and handle the residual out-of-pocket expense.

1/9/2013 8:12 AM
3. Gene patenting can limit patient access to testing, which can significantly impact their health care options. Currently, there are genomic panels available that test for multiple genes involved in breast cancer risk, at a fraction of the cost of testing for each of these genes individually. If the BRCA genes were able to be included in these panels, that could significantly reduce the overall cost of genetic testing, and potentially provide important information not only regarding BRCA gene status, but also about how other genes involved in breast cancer risk may work in conjunction with the BRCA genes to further modify cancer risks, leading to a more personalized risk assessment / management discussion with each patient and their families.

1/8/2013 9:03 AM
4. My high risk clinic experiences substantial payor denials for reflex BART testing in appropriate clients. In my opinion, the current costs for multisite³, single site, comprehensive and BART testing are EXCESSIVE set by a purely profit-motivated company with no other alternatives available (globally). There is essentially no comparable testing permitted in the industry (because of patent protection) to provide price competition. I participate in the City of Hope Genetics Community of Practice and this opinion is shared by all members of that group.

1/8/2013 12:06 AM



Healthcare Professionals (continued)

5. While I trust Myriad's QA practices, my biggest concern is their refusal to share their data with the BIC and other BRCA databases, thereby restricting the clinician's ability to interpret a VUS for a patient.

1/8/2013 4:07 PM

6. My main issue with the BRCA gene patent, specifically, is that other laboratories offering the recently developed "panel" testing (comprehensive analysis of multiple genes using next generation sequencing techniques) cannot include these 2 genes in their panel. So if I see a patient with apparent hereditary breast cancer, s/he cannot be tested for a comprehensive panel of breast cancer genes with one test. We have to rule out BRCA first, for \$3400, and then order an additional \$3000-\$4000 worth of testing to rule out other genetic causes. It is time and cost prohibitive. It also does not make sense that full sequencing of a panel of 20 genes costs \$3000 but similar analysis of only 2 genes (BRCA1 and BRCA2) costs more! This will not go away given that whole exome and whole genome sequencing is coming. Furthermore, most insurance companies will not cover the additional panel testing because they have already covered BRCA testing and the CPT codes are the same. This problem does not exist for other hereditary cancers such as colon cancer, because you can order one comprehensive panel that includes all of the currently known colon cancer genes. As long as a lab who has the patent on a gene does not have to compete with another lab for business, these costs will never come down and our patients and our healthcare system will suffer.

1/7/2013 5:24 PM

7. I also believe the Medicare population is underserved by the guidelines established by CMS - they are not for prevention. Therefore, there are many unaffected and affected individuals with cancer who meet national guidelines for testing, but not Medicare criteria for coverage. The cost of testing is too prohibitive for them to pay out of pocket. Therefore, this can lead to less informative individuals in the family (such as daughters of a mother with bilateral breast cancer >50 yo) undergoing testing and having their insurance pay for testing. This can lead to wasted healthcare dollars when the most informative individual in the family cannot be tested due to insurance and cost limitations.

1/7/2013 9:39 PM

8. Big decisions are made based on these test results. It would be wonderful to have second opinion testing. Additionally, when results are unclear (low penetrance mutation, variant, etc.), it would be extremely useful to see how another lab categorizes this finding.

1/7/2013 3:40 PM



Healthcare Professionals (continued)

9. We are moving to gene panel testing for many families that do not appear to be straight forward BRCA families. We are able to look at 10-15 genes linked to breast cancer with one test that is approximately \$2500-\$3500 yet these panels cannot include BRCA1/2 due to the patent. We must then run a separate \$3400-4000 test to look at BRCA1/2. This is an unnecessary added expense that would not exist today if the patent were not in existence.

1/8/2013 11:09 AM

10. A drop in patent resulting in a drop in the cost of genetic testing would be a great relief to the patients, us as professionals, and also to the insurance companies. With that said, insurance companies have surprisingly covered a majority of BRCA1/2 sequencing, however the discrepancy between coverage of sequencing and BART is unfortunate and confusing for patients. They think they have tested negative completely, but then you mention there is a second available test that is not covered. While BART mutations are rarer, it is still a worthy test in necessary situations. We have seen better coverage of this test since adopted into the NCCN guidelines, however we are still waiting for additional larger companies, such as Aetna. Myriad states they are going to be incorporating this test under one title, thus the effect (if any) of this on insurance coverage for BART testing will be interesting to see.

1/7/2013 3:52 PM

11. Our biggest problem is patients with Medicare who meet family history guidelines for testing, but who have not had cancer themselves and are therefore not eligible for coverage. I understand this may be changing with the ACA, but in the meantime there are many patients who fall through this specific crack. Federal Employees generally do not have coverage for genetic testing, so this is another group that has issues with affordable coverage.

1/7/2013 8:58 PM

12. I have attended two international symposia on hereditary breast/ovarian cancer and been struck both times by the way that the patent situation has hampered progress in the realm of HBOC relative to Britain, Australia, Canada and many other countries. A monopoly, even by a relatively well-meaning company, is not healthy for our patients or those of us trying to learn more.

1/7/2013 3:58 PM

13. I do not like that Myriad does not offer a discount when the patient is paying out of pocket. It is also extremely frustrating that Medicaid will not pay for BRCA testing, because the largest part of my patient population has Medicaid. Perhaps if Myriad wasn't the only lab who offered this test, a lab within my state could offer this test and maybe it'd be covered.

1/7/2013 2:23 PM



Patients

1. Medicare would not pay for genetic testing because I am male. I have daughters and nieces for whom the test results could be very important.
1/7/2013 12:10 AM
2. I was tested for the BRCA 1 gene and the results came back positive so I then had prophylactic bilateral mastectomy and total hysterectomy. I have always wondered...what if the results were wrong? I would hate to think that I had all of this extreme surgery and I was not a carrier. That thought frightens me.
1/9/2013 6:25 PM
3. In my case it was important that my insurer judged my family history of cancer diagnoses to be enough reason alone to test me, before my own cancer diagnosis and without a known mutation in my family. There was some initial question about the usefulness of the test for me since the members of my family with diagnosed cancer refused genetic testing. My test was therefore a sort of fishing expedition for a possible mutation. I am very grateful that my doctors recommended it and my insurer covered it because I was obviously able to find out about my own risk but was also able to pass on the information to other members of my family, some of whom were then able to get insurance to pay for tests to search for the specific mutation.
1/9/2013 2:12 PM
4. I think that insurance companies, at least mine did not know enough about the proper care for my situation and the rights of women with the BRCA genes. They did not know the laws with reconstruction and doctor choices at the time, 2007, and I had to have a legal suit to pay for my surgery.
1/8/2013 6:52 PM
5. This information is vitally important for people who may be high-risk. Please do everything you can to ensure that the people who need the testing have reasonable access to it.
1/9/2013 11:59 AM
6. I needed an oncotype diagnostic test in order to inform treatment decisions. This test, and the very few others like it, are out of the price range of anyone who does not have comprehensive health care insurance. It was nearly denied to me on the basis of cost alone. I believe this cost derives from gene patenting resultant limitation on the availability of the technology. My treatment plan was highly impacted by the data that the oncotype diagnostic provided.
1/8/2013 2:40 PM



Patients (continued)

7. I would like to tell by descendants if I have the BRCA1 and/or BRCA2 mutations so they are aware. So far my insurance has refused to supply any criteria used in determining the need for the testing. The huge cost of the testing is beyond my ability to pay for the testing. It has been a very frustrating experience trying to get answers and/or responses from the various parties. My daughter went for genetic counseling about the matter and was told I should be tested based on the results of her tests.

1/8/2013 11:43 AM

8. Initially, BRCA 1 came back negative. After BART, I was POSITIVE for BRCA 1

1/8/2013 10:01 AM

9. I find it outrageous that my insurance company paid such a small portion of the cost of the test, considering that a relative of mine tested positive, so that in my mind, it was imperative that I find out. How in the world can people who cannot afford to pay for that possibly consider getting tested? It would be a huge debt burden. Also, I believe it is very important for the test results to be discussed with a genetic counselor in person, instead of over the phone. I know some medical centers practice this, but some do not. A face-to-face encounter is much more valuable and helpful.

1/7/2013 10:54 PM

10. Testing was extremely expensive and I have a large family. We all paid cash and this was a hardship. Some of us pitched in money to pay for those who couldn't afford it. I am concerned about how many women have gotten tested without any genetic counseling prior. They come to me (as a volunteer outreach person) with more anxiety, fear, and confusion than need be if they were properly prepared. Not everyone is properly informed about the importance of genetic counseling prior to testing. I think Myriad works to get primary care docs to test without counseling to increase their revenues. This is another ethical problem with Myriad's patent. Oh, and by the way...I own my genes. All of them. Even the mutated ones! Thank you.

1/7/2013 6:17 PM

11. I'm concerned that the BART panel which has been recommended by two different medical teams (following my recent breast cancer recurrence) is not going to be covered by my insurer, Aetna. The test is \$700 which is prohibitive for me right now. I think the BART should be included within the larger BRAC Analysis and it doesn't make sense to me why it is not.

1/7/2013 5:50 PM



Patients (continued)

12. I paid out of pocket for my genetic testing and was upset that the cost was so high & that there as not another lab available for use. Though I understand the need for patents, I disagree with monopolies & patenting genes where research is concerned.....kind of reminds me of countries bickering during the initial AIDS outbreak, perhaps BRCA carriers are not as important because we don't die as quickly. Also my insurance carrier would have made it difficult to obtain my initial genetic testing, but makes it easy to obtain authorizations for prophylactic surgeries. They still continue to make additional visits with genetic counselors and additional screenings required for BRCA as non-preventative which means more out of pocket costs.

1/7/2013 2:56 PM

13. Even with insurance, the test cost me \$600 out of pocket. My daughter is paying \$450 to only be test for BRCA2. I'm sure the cost puts the test out of reach for many who would benefit from it.

1/7/2013 2:13 PM

14. Genetic testing is prohibitively expensive for women without health insurance. I was lucky enough to get my genetic test covered by insurance - but many women in my family are not being tested because they cannot get this test covered, or they fear that BRCA+ results will mean that they have a pre-existing condition. Genetic testing needs to be affordable, it needs to be covered by insurance, and women shouldn't live in fear of getting BRCA+ results.

1/7/2013 1:41 PM

15. Given that we are recommended to take such drastic surgical and lifestyle-offering surgeries to reduce our risks of cancer, it would be comforting to know, unequivocally, that our mutation is present. With only Myriad to check and the high cost of the testing, it is prohibitive to do so.

1/7/2013 12:29 AM

16. Insurance would not pay for genetic testing or counseling although my father died from pancreatic cancer and I was told that I had breast cancer and was at risk of carrying the BRCA mutation . My genetic counselor was very helpful in my decision to have a hysterectomy as well as a mastectomy. I did test positive or BRCA2 and so my adult. children needed to be tested as well.

1/9/2013 12:13 PM

17. Despite the recommendation of 2 physicians, a positive test in my father, and a history, I was denied coverage

1/ 10/2013 4:52 AM



Patients (continued)

18. My insurance said genetic testing was covered, but it only applied to my deductible - so I paid for the testing myself.

1/8/2013 11:41 PM

19. Appealed three times before they paid

1/9/2013 8:19 AM

20. I did a second test and paid for it out of my pocket.

1/7/2013 7:41 PM

21. I would have liked to have had the option of a full panel test, b/c I also carry risk on my father's side and I worry that I am also at risk of carrying another genetic defect. However, since a mutation was found on my mother, I was only tested for that specific germline.

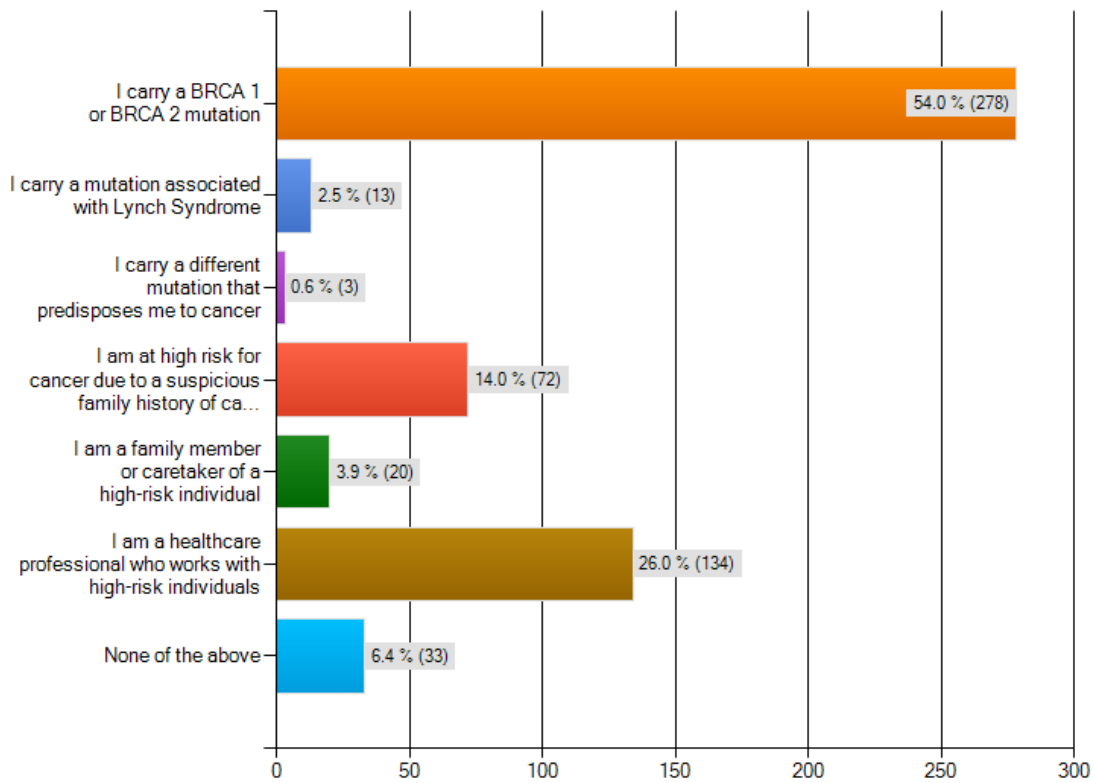
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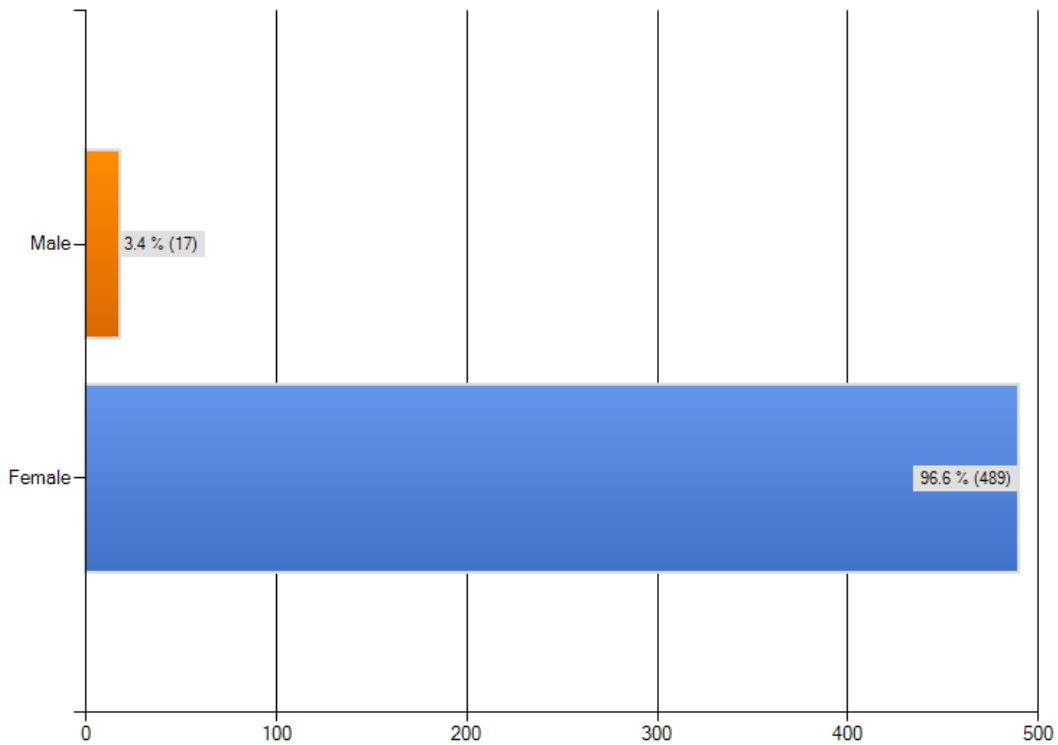
Patient Accounts from Cancer Legal Resource Center Helpline

1. 2011, Baltimore, MD - Recently Blue Cross Blue Shield Federal Insurance has changed the interpretation of the criteria they use to define "medically significant". They never have defined the term to providers like Myriad Lab, or genetic counselors or clients. I have just been diagnosed with breast cancer needing surgery, and according to my genetic counselor meet criteria for BRAC testing insurance to cover. Myriad Labs called me this week to tell me I would not meet my insurance's criteria and need to pay \$4000 out-of-pocket. After several calls between my genetic counselor, and Myriad and Blue Cross, it seems that the current criteria have not changed but Blue Cross interpretation of "medical significance" has changed. Blue Cross has been denying claims to Myriad that they were paying up to several months ago. According to my genetic counselor, I met the criteria for insurance to cover BRCA and she submitted a letter to Myriad along with necessary paperwork saying I met the criteria for testing and for medical significance. According to Myriad, had I submitted for BRAC testing months ago Blue Cross would have paid for it. Myriad has had so many new claims denied and eaten the cost that they figured out based on their denials what Blue Cross is no longer covering. Myriad has notes on the Blue Cross Federal "proposed new guidelines" for genetic testing. My blood is at Myriad. Now I need to agree to pay privately for testing before Dec. 31st to stay within the 2011 guidelines. If I pay Myriad \$4000 up front, Myriad will file through my insurance (which they are pretty sure will be denied based on recent history with Blue Cross). My option is to pay up front and file a useless appeal.
2. 2012, Clarksville, VA – Caller's insurance company denied genetic testing coverage. A \$3000 bill was sent to collections.

The following best describes me:

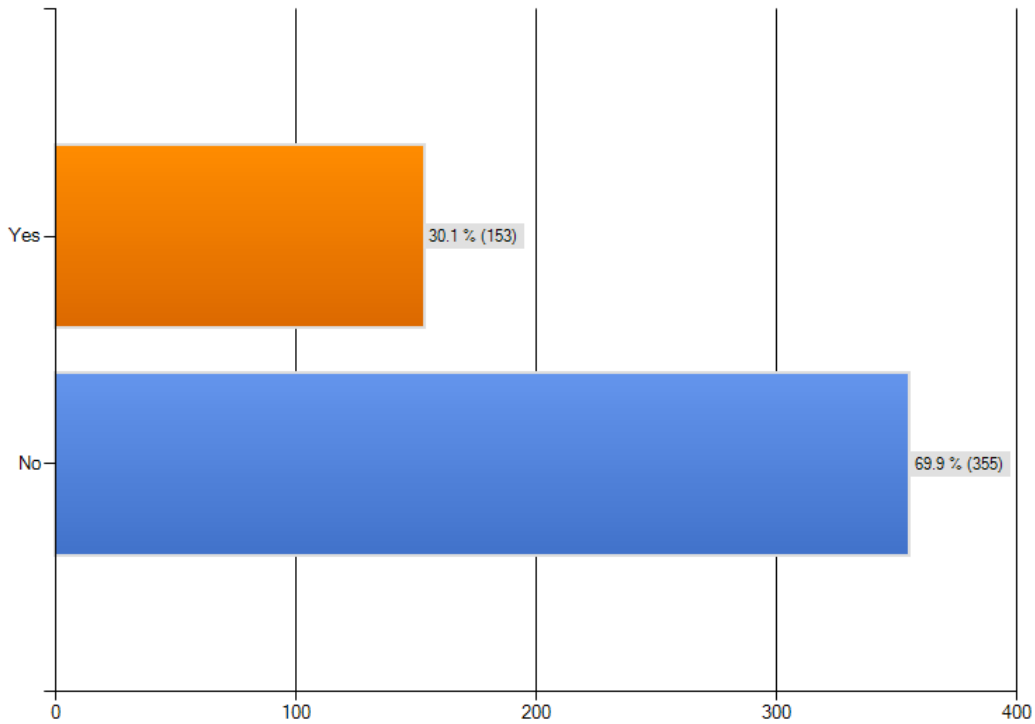


What is your gender?

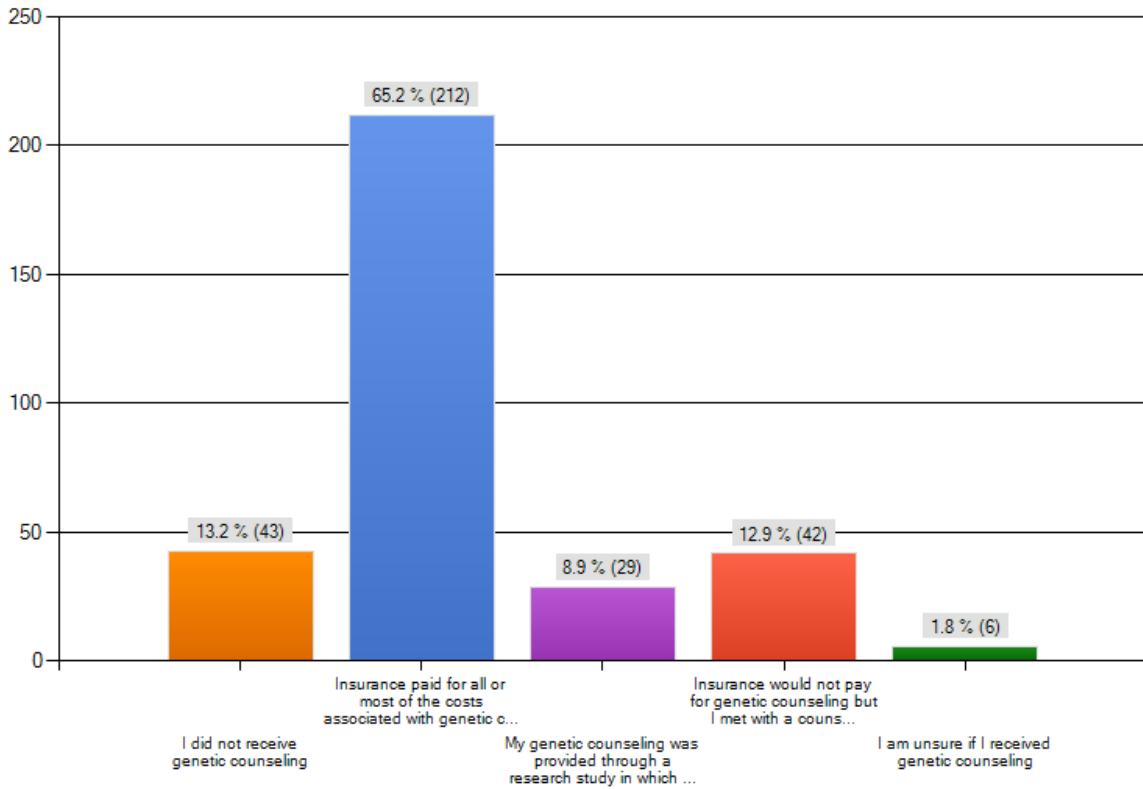


PATIENTS

Are you a cancer survivor?

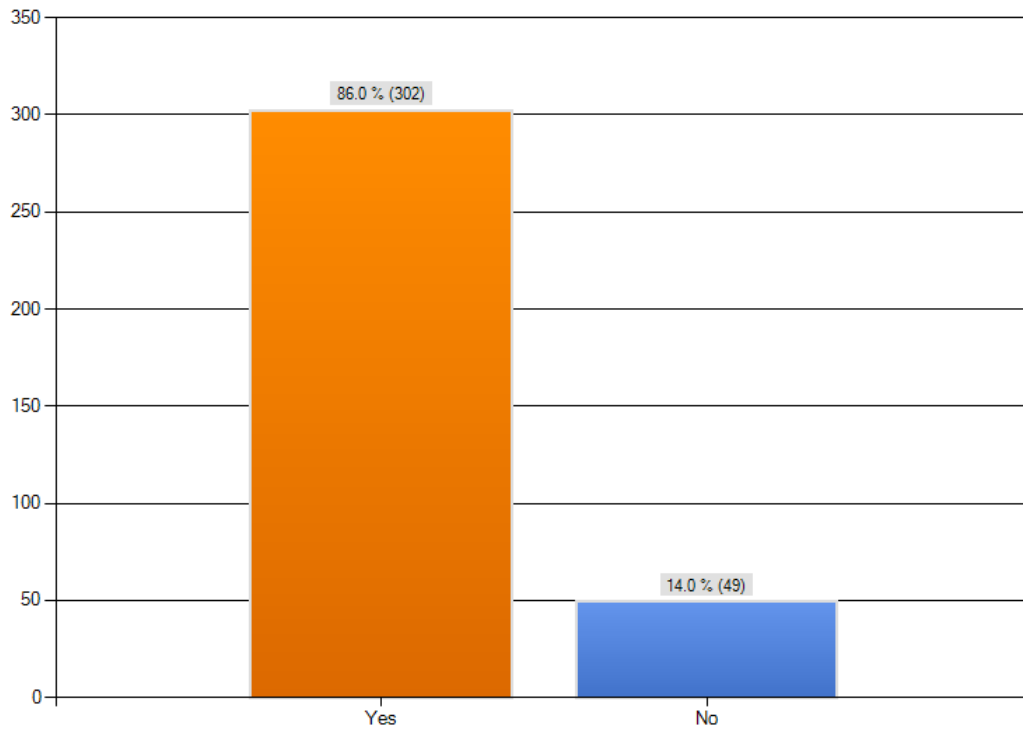


If you have had or considered testing for a genetic mutation, please tell us about your experience with genetic counseling (choose one):

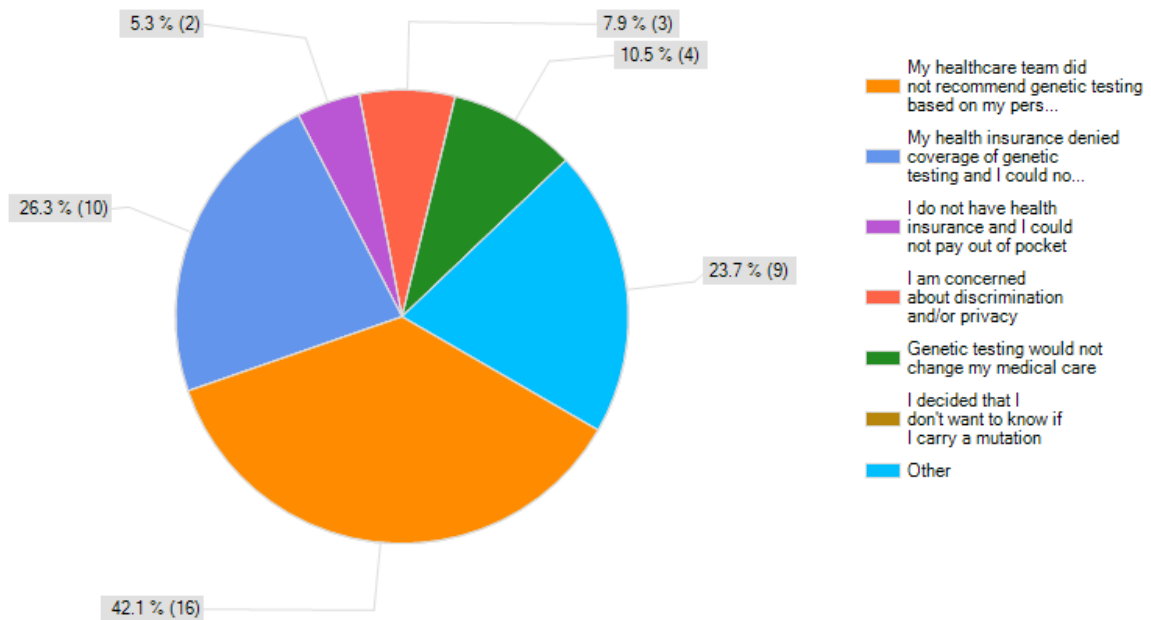


PATIENTS

Have you had genetic testing for an inherited disease or predisposition?

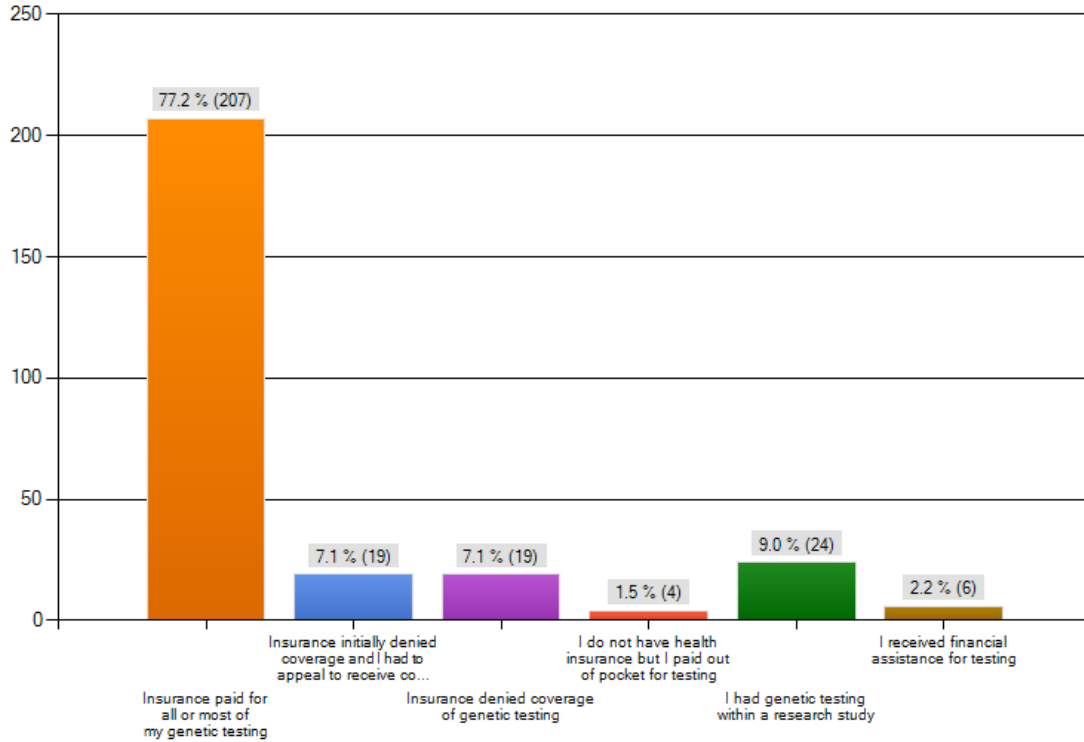


Please share why you did not have genetic testing (check all that apply):

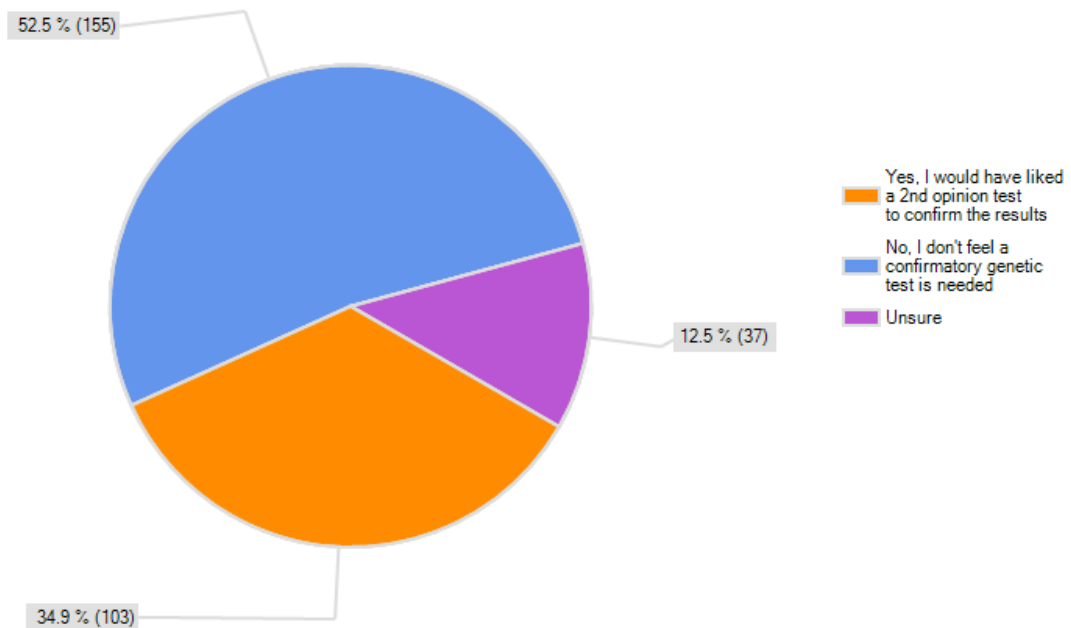


PATIENTS

Please tell us about your experience with health insurance and genetic testing (check all that apply):

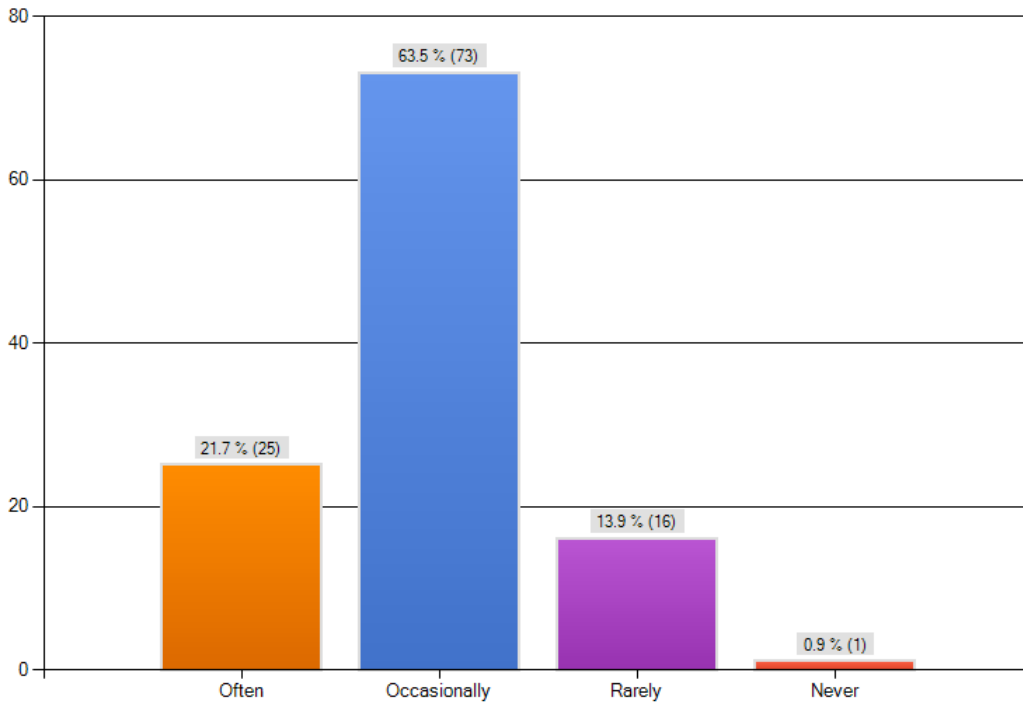


If genetic testing revealed that you carry a genetic mutation such as BRCA, would you have liked the option to have a 2nd opinion / confirmatory genetic test?

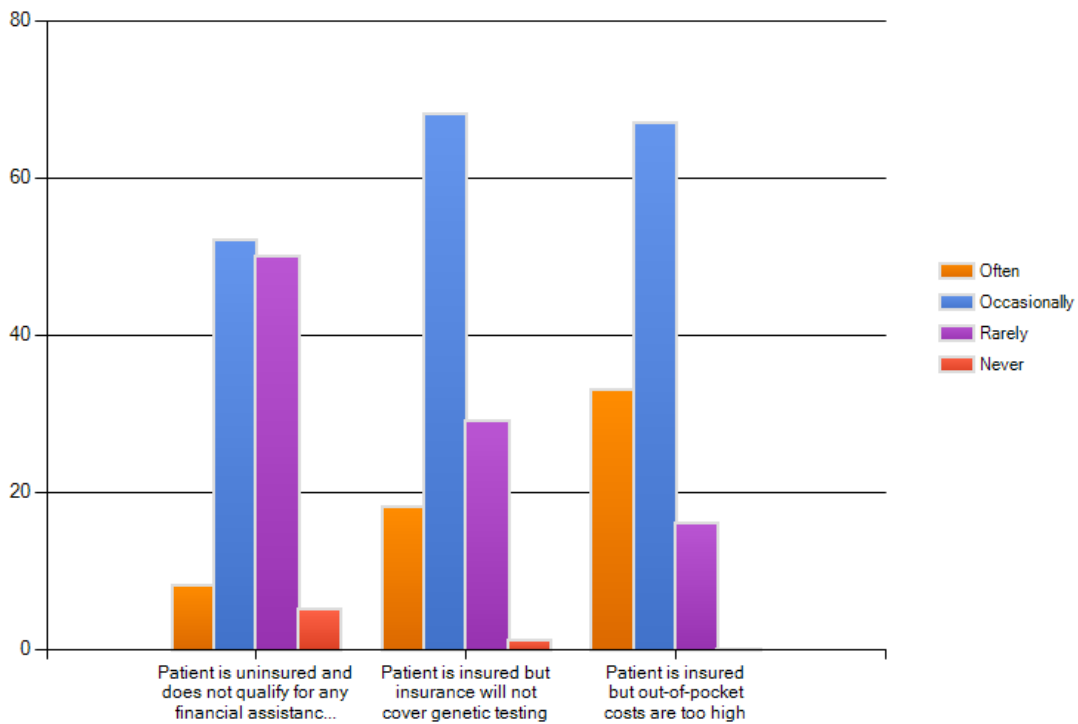


HEALTHCARE PROVIDERS

How often do your patients experience difficulty in getting health insurance coverage for genetic testing services?

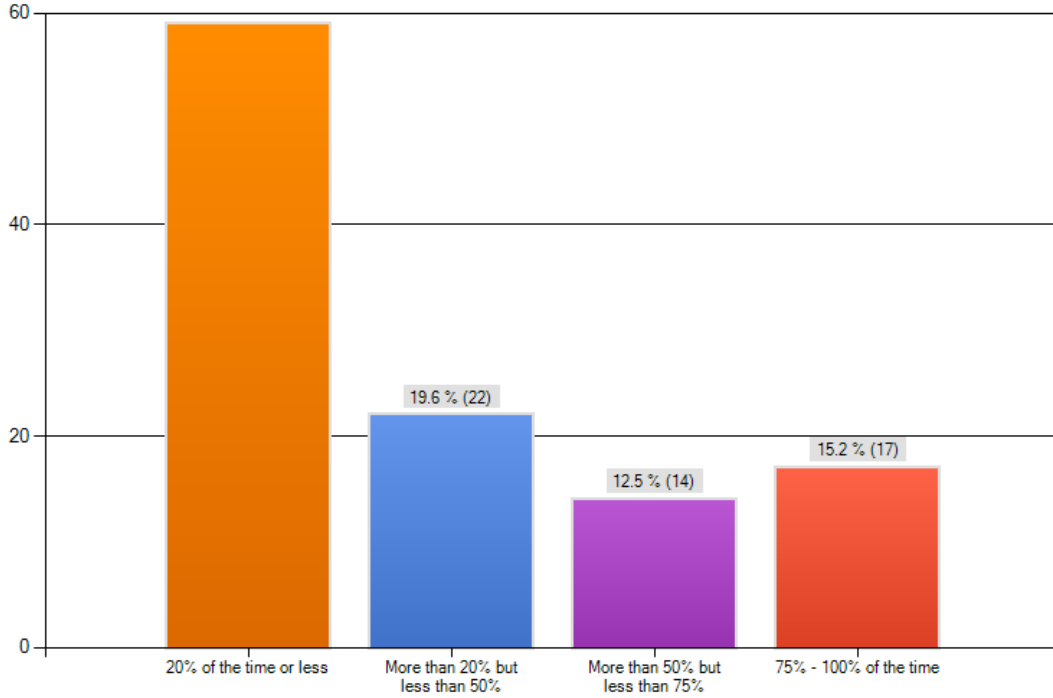


For patients who meet nationally published guidelines for genetic testing for BRCA, please indicate how frequently you encounter each of the following patient barriers to genetic testing in your practice:



HEALTHCARE PROVIDERS

For the patients who meet nationally published guidelines for BRCA testing who are uninsured or underinsured, how often are they able to access BRCA testing through other means? (ie-financial assistance, research study)



As a healthcare professional who works with the high-risk community, would you like your patients to have the option of a 2nd opinion / confirmatory genetic test?

