

Anticipated Uptake and Impact of Genetic Testing in Hereditary Breast and Ovarian Cancer Families

Jeffery P. Struewing,¹ Caryn Lerman, Ronald G. Kase, Therese R. Giambarresi, and Margaret A. Tucker

Genetic Epidemiology Branch, National Cancer Institute, Bethesda, Maryland 20892 [J.P.S., M.A.T.]; Lombardi Cancer Research Center, Georgetown University Medical Center, Washington, DC 20057 [C.L.]; and Westat Research, Inc., Rockville, MD 20850 [R.G.K., T.R.G.]

Abstract

In anticipation of the identification of the *BRCA1* gene, we studied the interest in and anticipated reaction to DNA testing for mutations in this gene in members of high-risk families. We surveyed 91 female and 49 male subjects using a structured interview by study nurses. All subjects were members of inherited breast-ovarian cancer families participating in a genetic linkage study at the National Cancer Institute. The main outcomes of the study were interest in genetic testing and anticipated impact of test results. Seventy nine % of subjects indicated that they would “definitely” want to be tested, and 16% would “probably” want to be tested for mutations in the *BRCA1* gene. Subjects with a high self-perceived risk of having an altered *BRCA1* gene were more likely to definitely want testing ($P = 0.02$), while estimated true genetic risk did not predict interest in the test. Females were significantly more likely to definitely want testing ($P = 0.005$) and had a significantly greater mean anticipated negative-impact score (2.3) compared to males (1.0) ($P < 0.001$). We found a high level of interest in genetic testing for *BRCA1* among members of inherited breast-ovarian cancer families participating in a genetic linkage study. While utilization may fall below levels of interest reported in this and other preliminary surveys, given the potential for early detection and treatment of breast and ovarian cancer, interest in *BRCA1* testing may translate into high rates of uptake. These results indicate that it will be critical to incorporate follow-up counseling and support into *BRCA1* testing programs.

Introduction

Genetic linkage studies have provided overwhelming evidence for a gene on chromosome 17 that confers susceptibility to breast and ovarian cancer (1, 2). This gene, named *BRCA1*, appears to act in an autosomal dominant fashion, with mutations conferring an approximate 80–90% risk for breast cancer and somewhat lower risk for ovarian cancer

(3). The majority of families with several cases of breast cancer and at least one case of ovarian cancer appear to be linked to *BRCA1*, while about 50% of families with breast cancer only may be linked (2).

At present, genetic testing and counseling is possible only in rare families based on linkage analysis alone (4–6). However, a candidate *BRCA1* gene has reportedly been cloned (7) and genetic testing based on knowledge of the gene sequence should soon be possible. This will allow much more accurate risk determination and hence better targeting of screening and preventive measures. Despite these potential benefits, genetic testing may also result in adverse psychological and social outcomes (8). In anticipation of the availability of *BRCA1* testing, we studied members of hereditary breast-ovarian cancer families to determine their interest in and anticipated reactions to genetic testing.

Materials and Methods

Study Subjects. Study subjects included 91 female and 49 male members of 19 self-referred and physician-referred hereditary breast-ovarian cancer families participating in genetic linkage studies at the National Cancer Institute. These 19 families were a subsample of cancer-prone families from a registry maintained by the Genetic Epidemiology Branch. All families had at least one case of ovarian cancer (mean number of cases per family, 3.5; range, 1–12) and most also had cases of breast cancer (mean number of cases, 2.7; range, 0–7), and are therefore *a priori* likely to be linked to *BRCA1* (2). While no family had a lod score for linkage to *BRCA1* high enough to have a posterior probability of linkage greater than or equal to 99%, most of 5 families extensively tested were consistent with linkage.

All family members contacted during a 9-month period were eligible for this interview study. This subsample was selected based on the timing of periodic contact with members of the registry. While this was not a randomly selected sample, there is no reason to expect a systematic bias in the sampling method. All family members either had participated in or were being recruited for studies of genetic and environmental causes of ovarian and breast cancer. Contact over the past 3 years included newsletters describing the study and related medical matters, telephone calls, and personal visits either at NIH or near their homes. All members contacted gave informed consent to undergo a structured telephone or in-person interview by study nurses. Three eligible family members did not complete the interview because they refused to participate in any aspect of the study, but none specifically refused to complete the interview.

Measures. In addition to basic sociodemographic, reproductive, risk factor, and screening information for females, the interview included items relating to interest in and

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¹ To whom requests for reprints should be addressed, at Genetic Epidemiology Branch, National Institutes of Health, Building EPN, Room 439, 6130 Executive Boulevard, MSC 7372, Bethesda, MD 20892-7372.

motivations for *BRCA1* testing, self-perceived risk, and anticipated impact of test results. These questions were adapted from a validated instrument used in a previous study of first-degree relatives of ovarian cancer cases (9). Likert-style items were used to assess reasons for wanting or not wanting to be tested (1, strongly agree to; 4, strongly disagree) and intention to be tested (1, yes, definitely; 2, yes, probably; 3, probably not; and 4, definitely not). A negative impact score, ranging from 0 to 6, was created by summing the number of responses suggesting a negative psychosocial outcome to a test result (*i.e.*, become depressed or anxious or have a negative impact on marriage or mood if tested positive, or feel guilty or regret previous decisions if tested negative) (coefficient α , 0.60).

The closest relative affected with breast or ovarian cancer was determined for each subject. Although some affected individuals may be phenocopies, in the absence of linkage markers for most individuals, the closest affected relative was used to estimate their true risk at birth of being a mutation carrier (*i.e.*, 12.5% for third-degree relatives, 25% for second-degree relatives, or 50% for first-degree relatives).

Data Analysis. χ^2 tests were used to identify demographic and risk variables associated with level of interest in *BRCA1* testing. Frequencies were generated to characterize the reasons for subjects wanting/not wanting testing. Kruskal-Wallis tests were used to identify individual demographic and risk variables associated with the negative-impact score, and least squares linear regression was used to assess the joint contributions of age, sex, and objective genetic risk to this score.

Results

Characteristics of Study Population. Demographic and risk factor information is given in Table 1. Study subjects ranged in age from 19 to 73 years and over 75% had at least some college education. Of the 91 females, 11 were affected with breast and/or ovarian cancer. Because of the possibility of phenocopies, and the fact that many of these women will desire testing for *BRCA1*, affected women were included in the analyses where appropriate. Forty % of unaffected females were first-degree relatives of affected family members, and over one-half of the males were first-degree relatives of affected members. Three women had undergone prophylactic mastectomy, while nearly one-third of women had undergone prophylactic oophorectomy.

As shown in Table 2, self-perceived risk of having an altered *BRCA1* gene among unaffected females was generally higher than their estimated risk based on their position in the pedigree. Among the 32 females with an affected first-degree relative (*i.e.*, 50% risk of being a mutation carrier at birth), 31% of them perceived their risk to be 50:50, while 53% of these females felt there was a 75% chance or greater of having an altered *BRCA1* gene. Unaffected females without an affected first-degree relative also overestimated their risk, with 30% of unaffected females reporting a self-perceived risk of 75% or greater. Overall, self-perceived risk among males was lower than it was for females. For example, 17% of males with affected first-degree relatives perceived their risk of having an altered *BRCA1* gene to be 25% or less. However, about one-half of men without an affected first-degree relative reported that their risk was 50% or greater.

Table 1 Demographic characteristics of hereditary breast/ovarian cancer family members completing interview

| Demographic Variable | Female | Male | Total |
|--|-----------|-----------|------------|
| | n (%) | n (%) | n (%) |
| Total | 91 | 49 | 140 |
| Age | | | |
| 19–34 | 24 (26.4) | 9 (18.4) | 33 (23.6) |
| 35–49 | 35 (38.4) | 24 (49.0) | 59 (42.1) |
| 50–73 | 32 (35.2) | 16 (32.7) | 48 (34.3) |
| Race | | | |
| White | 87 (95.6) | 47 (95.9) | 134 (95.7) |
| Black | 3 (3.3) | 2 (4.1) | 5 (3.6) |
| Other | 1 (1.1) | | 1 (0.7) |
| Education | | | |
| At least some college | 70 (76.9) | 37 (75.5) | 107 (76.4) |
| Marital Status | | | |
| Currently married | 66 (72.5) | 36 (73.5) | 102 (72.9) |
| Closest Affected Relative ^a | | | |
| Third degree | 7 (8.8) | 5 (10.2) | 12 (9.3) |
| Second degree | 41 (51.3) | 18 (36.7) | 59 (45.7) |
| First degree | 32 (40.0) | 26 (53.1) | 58 (45.0) |
| Parity ≥ 1 | 70 (76.9) | | |
| Post-menopausal | 43 (47.3) | | |
| Ever used oral contraceptives | 61 (67.0) | | |
| Ever used estrogen replacement therapy | 31 (34.1) | | |
| Status post-oophorectomy ^b | 33 (37.9) | | |
| Prophylactic ^b | 28 (32.2) | | |

^a Excludes 11 subjects with breast and/or ovarian cancer.

^b Excludes 4 subjects with ovarian cancer.

Interest in *BRCA1* Testing. One hundred ten (78.6%) subjects anticipated they would “definitely” want the genetic test when it is available and an additional 23 subjects (16.4%) said they probably would want the test. As shown in Table 3, females were significantly more likely to “definitely” want testing (86%) than were males (65%) ($\chi^2 = 7.8$; $P = 0.005$). Five males said they probably wouldn’t want to have genetic testing, while two males were undecided. Subjects with a higher self-perceived risk of being a mutation carrier were significantly more likely to definitely want genetic testing (χ^2 ($df = 1$, trend) = 9.8; $P = 0.02$), while no such trend was noted with objective risk of being a mutation carrier based on the closest affected relative. In fact, 92% of subjects at 12.5% risk of being a mutation carrier at birth (third-degree relatives of an affected relative) definitely wanted testing compared to 75% of those with an affected first- or second-degree relative.

Motivations for Testing. The most commonly cited reason for wanting genetic testing was to learn if one’s children were at risk. (Fig. 1). This was also cited by 54% of subjects as the most important reason for wanting testing. About two-thirds of females wanted the test to decide about having preventive oophorectomy and one-third of females wanted the test to decide about the need for a preventive mastectomy. Fifteen % of unmarried subjects wanted the test to decide about marriage, and about one-third of subjects wanted the test to decide about having children. Thirteen % of females said that worries about insurability would deter them from having genetic testing but otherwise there were few reasons given for not wanting testing.

Table 2 Risk of being a BRCA1 mutation carrier among members of hereditary breast-ovarian cancer families

| Closest affected relative | Unaffected females (n = 79) ^a | | | | |
|---------------------------|--|-------------------------|-----|-----|------|
| | Estimated true risk at birth | Self-perceived risk (%) | | | |
| | | 0% | 25% | 50% | 75+% |
| Third degree (n = 7) | 12.5% | 0 | 57 | 29 | 14 |
| Second degree (n = 40) | 25% | 0 | 28 | 40 | 33 |
| First degree (n = 32) | 50% | 0 | 16 | 31 | 53 |

| Closest affected relative | Males (n = 45) ^b | | | | |
|---------------------------|------------------------------|-------------------------|-----|-----|------|
| | Estimated true risk at birth | Self-perceived risk (%) | | | |
| | | 0% | 25% | 50% | 75+% |
| Third degree (n = 4) | 12.5% | 0 | 50 | 50 | 0 |
| Second degree (n = 18) | 25% | 6 | 44 | 39 | 11 |
| First degree (n = 23) | 50% | 4 | 13 | 70 | 13 |

^a Excludes 11 females with breast and/or ovarian cancer. One female did not answer the risk perception question.

^b Four males did not answer the risk perception question.

Table 3 Interest in genetic testing according to gender, self-perceived risk of being a gene carrier and estimated true genetic risk

| | No. (%) definitely interested in test | |
|--|---------------------------------------|---------------------------------------|
| Sex | | |
| Female | 78 (85.7) | $\chi^2 = 7.8$ $P = 0.005$ |
| Male | 32 (65.3) | |
| Self-perceived risk of being gene carrier | | |
| "No chance" | 0 | $\chi^2_{(df=1)} = 9.8$ $P = 0.02$ |
| "Small chance (25% or less)" | 25 (75.8) | |
| "Moderate chance—about 50:50" | 41 (77.4) | |
| "High chance—75% or greater" | 41 (87.2) | |
| Closest affected relative (estimated true risk) | | |
| Third degree (12.5% risk) | 11 (91.7) | $\chi^2_{(df=1)} = 5.0$ $P = 0.2$ |
| Second degree (25% risk) | 44 (74.6) | |
| First degree (50% risk) | 44 (75.9) | |
| Affected with breast or ovarian cancer (100% risk) | 11 (100) | |

Anticipated Impact of Testing. Descriptive data on the expected impact of both positive and negative test results are reported in Table 4. Women were more likely to anticipate becoming both depressed and anxious in response to a positive test result than were men (depression and anxiety versus gender, $\chi^2 = 4.1$; $P = 0.04$). About 37% of both men and women said they would be less likely to have children if they tested positive for the gene, and almost 73% of women said they would feel better about previous decisions they had made (generally regarding having children and preventive oophorectomy) if they tested positive. In response to a negative test result, 36% of women would worry the test was wrong, 21% would still want preventive oophorectomy, and 69% would still want screening tests more often. Twice as many women as men said they would be more likely to have children if they tested negative. Several women anecdotally reported that, because of their family history, they had fewer children than they desired.

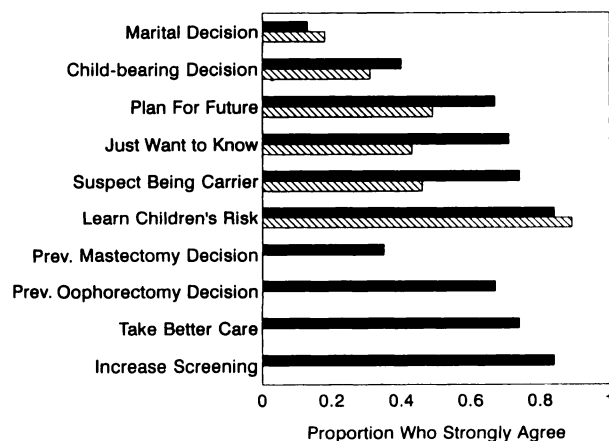


Fig. 1. Reasons for wanting the breast-ovarian genetic test. More than one response was possible for each subject. ■, females; ▨, males.

As measured by the negative impact score, females (mean, 2.3) were significantly more likely to anticipate a negative impact from genetic testing than males (mean, 1.0) ($H = 17.5$; $P < 0.001$) (Fig. 2). Younger women had higher negative impact scores than older women ($H = 4.2$; $P = 0.04$) but there was no association with age for men. Age and gender were significant independent predictors of the negative impact score when both were included in a linear regression model, but there was no significant interaction between age and gender, and both self-perceived and true genetic risk were not significant predictors when added to this model.

Discussion

Genes predisposing to chronic, adult-onset diseases are being identified at a rapid rate. Although the implications of these discoveries are far reaching for the entire population, the most immediate impact will likely come from being able to offer genetic testing for the clearly hereditary families participating in studies leading to gene identification of a gene. Careful studies of these unique populations, already

Table 4 Expected impact of genetic testing

| | Female ^a | Male | Total (%) |
|---|---------------------|-----------|-----------|
| Positive test result | | | |
| Psychological impact | | | |
| Become depressed | 42 (46.2) | 8 (16.7) | (35.7) |
| Become anxious | 66 (72.5) | 16 (32.7) | (57.1) |
| Negative effect on marriage | 6 (9.1) | 1 (2.3) | (6.9) |
| Negative effect on mood | 41 (45.6) | 10 (20.4) | (36.7) |
| Feel in better control of life | 66 (73.3) | 25 (52.1) | (65.5) |
| Feel better about previous decisions | 51 (72.9) | 7 (16.7) | (51.8) |
| Behavioral impact | | | |
| Want screening tests more often | 76 (84.4) | | |
| Less likely to have children | 24 (37.5) | 15 (35.7) | (36.8) |
| More likely to have oophorectomy ^b | 36 (73.5) | | |
| More likely to have mastectomy ^c | 20 (26.0) | | |
| Negative test result | | | |
| Psychological impact | | | |
| Become less depressed | 44 (57.1) | 15 (42.9) | (52.7) |
| Become less anxious | 69 (79.3) | 19 (47.5) | (69.3) |
| Positive effect on marriage | 25 (51.0) | 5 (18.5) | (39.5) |
| Positive effect on mood | 61 (70.1) | 15 (36.6) | (59.4) |
| Still worry test was wrong | 32 (36.0) | 6 (12.8) | (27.9) |
| Feel guilty if relative tested Pos. | 17 (18.9) | 6 (12.5) | (16.7) |
| Regret previous decisions | 12 (14.5) | 4 (9.3) | (12.7) |
| Behavioral impact | | | |
| Still want preventive oophorectomy | 15 (20.8) | | |
| Still want screening tests often | 63 (69.2) | | |
| More likely to have children | 33 (53.2) | 9 (25.7) | (43.3) |

^a The number of responses ranged from 49–90 for females and 27–49 for males.

^b Among women who have not had bilateral oophorectomy and are undecided about preventive oophorectomy.

^c Among women who have not had bilateral mastectomy and are undecided about preventive mastectomy.

participating in long-term studies, are important to determine the actual medical and psychological impact of such testing.

We studied the interest and anticipated impact of genetic testing for the *BRCA1* gene among a group of subjects participating in a genetic linkage study of breast and ovarian cancer. None of the families was informative enough to provide genetic counseling based on genetic marker results only, and genetic testing and counseling can only be offered after the cloning of the *BRCA1* gene. Not unexpectedly, we found a high level of interest in genetic testing among this group of highly educated subjects who were participating in a genetic linkage study. Interest in testing did not differ significantly for any demographic variables except gender, with all females and 86% of males anticipating they would want the test. No females and only five males said they probably wouldn't want the test. This level of interest is comparable to the 95% level found in a study of 121 first-degree relatives of ovarian cancer patients, 39% of whom had at least two relatives affected with breast or ovarian cancer (9). While it is possible that utilization will fall below levels of interest reported in preliminary surveys, as was the case for Huntington's disease (10, 11), given the potential for early detection and treatment of breast and ovarian cancer, interest in *BRCA1* testing may translate into a high level of actual demand.

Based on the closest affected family member with ovarian or breast cancer, males and females were roughly equal with respect to their estimated risk of being a mutation carrier. However, self-perceived risk of the female subjects was significantly higher than it was for males and in many

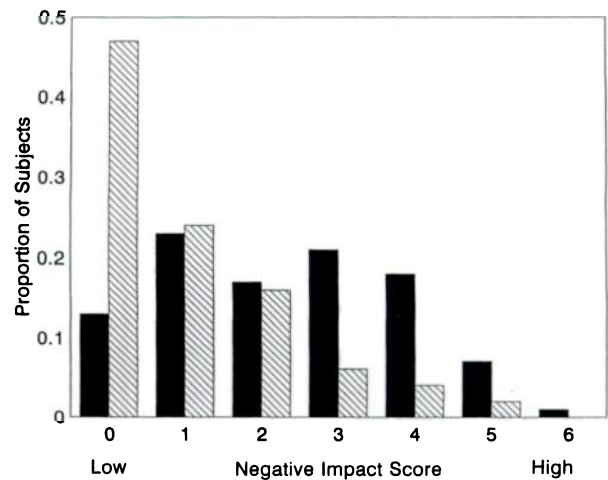


Fig. 2. Anticipated negative impact of genetic testing for *BRCA1*. Negative impact score is the sum of responses suggesting a negative outcome from testing. Maximum score, 6. ■, females; ▨, males.

cases was higher than the estimated true risk. For example, 30% of females thought they were at 75% or greater risk of being a mutation carrier when their nearest affected family member was a third-degree relative. More men than women underestimated their objective genetic risk. Self-perceived risk of being a mutation carrier was positively correlated with interest in genetic testing. For the objective risk of being a mutation carrier, on the other hand, there was a nonsignificant negative relationship with interest in testing; 91% of subjects with an affected third-degree relative were interested compared to 75% of those who had an affected first- or second-degree relative. This points to a need to educate family members about their estimated true risk status in order to facilitate informed decision making about *BRCA1* testing.

Subjects cited many reasons for wanting genetic testing, but the most common and important reason was to learn if their children were at risk. The importance of learning if one's children face risk is consistent with motivations for predictive testing for Huntington's disease (11). For males, this reason was cited twice as often as the next most common reason. Frequently cited motivations for testing among females included better information with which to make decisions about screening tests and preventive surgeries. Although relatively few subjects (13.5%) cited concerns about insurability as a barrier to testing, this issue will certainly take on greater importance when testing moves from the research setting into common clinical practice (12). The absence of insurance concerns points to the need for full disclosure of the risks of genetic testing in the informed consent process.

About one-third of subjects anticipated that a positive test result would make them depressed and would have a negative effect on their mood, while over 50% thought they would become anxious about a positive result. Although the average negative impact score was only 2.3 for females and 1.0 for males, about 10% of females had a score of 5 or 6 (of 6). In addition, negative results were also expected to have psychological costs; 36% of women expected that they would still worry about their risk and 18% would feel

guilty if they tested negative for a *BRCA1* mutation. The findings suggest that it will be important to integrate follow-up psychological counseling and support into *BRCA1* testing programs. Similar findings have been demonstrated in Huntington's disease predictive testing programs (13) and have been highlighted in initial reports of *BRCA1* linkage testing (4).

We found marked differences between men and women with regard to motivations for testing and expected impact of testing. These results may reflect differences between female identification with vulnerability to the disease sites or to gender differences in emotional expressivity, or both. It would be interesting to compare similar measures in families with inherited susceptibility to cancer sites that do not favor one gender.

In addition to educating members of high-risk families about the risk of disease to carriers and noncarriers, these results underscore the importance of disclosure of the benefits and limitations of current screening and prevention options. For example, if they tested negative, 21% would still want preventive oophorectomy and 69% would still want frequent screening tests. Seventy four % of females anticipated they would want a prophylactic oophorectomy if they tested positive and 26% would want a prophylactic mastectomy. These reports are similar to reports of members of a hereditary breast-ovarian cancer family following receipt of *BRCA1*-linked marker results (6). This underscores the need to accurately determine the likelihood of breast and/or ovarian cancer (or other outcomes) for all the mutations that may be detectable in the *BRCA1* gene, as well as the efficacy of methods for prevention and surveillance for these outcomes, prior to offering *BRCA1* testing as part of routine medical care (14).

Extrapolation of these results to the general population should be made with caution. The subjects in this study were not actually offered *BRCA1* testing and since all responses are hypothetical the results may not reflect actual uptake once a test is available. In addition, this is a highly selected sample of individuals participating in a genetic linkage study, some for as long as 25 years, many of whom have already given a blood sample. Most families had been identified because of a preponderance of ovarian cancer, and their attitudes toward prophylactic surgery and psychological responses may be different than the majority of families linked to *BRCA1* in which only breast cancer is present. Nevertheless, members of such families will be the individuals who are targeted initially for *BRCA1* testing in a research setting. Thus, it is important to learn as much as possible from these hereditary cancer families in order to prepare for testing and counseling for the large number of individuals who may request *BRCA1* testing in the future.

In summary, the results of this study suggest that there will be a strong demand for *BRCA1* testing among members of hereditary breast and ovarian cancer families participat-

ing in genetic studies. Although probably less than 95% of individuals eligible for testing programs will want to participate, the demand for this information among individuals with increased risk is likely to be great (9). Research to develop and evaluate protocols for pretest education and counseling is urgently needed (15). In addition, the medical system must be prepared to respond to requests for preventive surgeries and screening from identified carriers of *BRCA1* mutations based on empirical data on the efficacy of these procedures in this population.

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