Prevalence and Healthcare Actions of Women in a Large Health System with a Family History Meeting the 2005 USPSTF Recommendation for BRCA Genetic Counseling Referral

Cecelia A. Bellcross1, Steven Leadbetter2, Sharon Hensley Alford3, and Lucy A. Peipins2

Abstract

Background: In 2005, the United States Preventive Services Task Force (USPSTF) released guidelines which outlined specific family history patterns associated with an increased risk for BRCA1/2 mutations, and recommended at-risk individuals be referred for genetic counseling and evaluation for BRCA testing. The purpose of this study was to assess the prevalence of individuals with a USPSTF increased-risk family history pattern, the frequency with which specific patterns were met, and resulting healthcare actions among women from the Henry Ford Health System.

Methods: As part of a study evaluating ovarian cancer risk perception and screening, 2,524 randomly selected participants completed a detailed interview (response rate 76%) from an initial eligible cohort of 16,720 women.

Results: Approximately 6% of participants had a family history fulfilling one or more of the USPSTF patterns. Although 90% of these women had shared their family history with their provider, less than 20% had been referred for genetic counseling and only 8% had undergone genetic testing. Caucasian women with higher income and education levels were more likely to receive referrals. Among the 95 participants in the total study cohort who reported BRCA testing, 78% did not have a family history that met one of the USPSTF patterns.

Conclusions: These results suggest a higher prevalence of women with an increased-risk family history than originally predicted by the USPSTF, and lack of provider recognition and referral for genetic services.

Impact: Improvements in healthcare infrastructure and clinician education will be required to realize population level benefits from BRCA genetic counseling and testing. Cancer Epidemiol Biomarkers Prev; 22(4); 728–35. ©2013 AACR.
Table 1. USPSTF increased-risk family history patterns (1)

**Non-Ashkenazi Jewish Women:**
1. Two first-degree relatives with breast cancer, 1 of whom received the diagnosis at age 50 years or younger
2. A combination of 3 or more first- or second-degree relatives with breast cancer regardless of age at diagnosis
3. A combination of both breast and ovarian cancer among first- and second-degree relatives
4. A first-degree relative with bilateral breast cancer
5. A combination of 2 or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis
6. A first- or second-degree relative with both breast and ovarian cancer at any age
7. A history of breast cancer in a male relative

**Women of Ashkenazi Jewish Heritage:**
8. Any first-degree relative (or 2 second-degree relatives on the same side of the family) with breast or ovarian cancer

The USPSTF estimated that 2% of adult women in the general population would have an increased-risk family history according to their definition (16).

Though not the stated intent, this estimate and these specific family history patterns appear in some measure to have been interpreted as a guide for public health activities and clinical implementation. However, there are limited data regarding the prevalence of women in the general population whose family history meets one or more of the USPSTF increased-risk patterns. This is in part because large population health surveys have not collected information on cancer history in second-degree relatives, or other features such as bilaterality, breast and ovarian cancer in the same individual, or Jewish ancestry.

Two previous studies examined family history of breast/ovarian cancer in first-degree relatives only from the 2000 and 2005 National Health Interview Surveys (17, 18). In both cases, less than 1% of the population met “high-risk” criteria consistent with the USPSTF recommendations (17, 18). In contrast, 2 publications that evaluated cohorts using detailed family history found that 7.5% to 12.4% of women met USPSTF “increased-risk” family history patterns (19, 20). These findings suggest that the original USPSTF approximation of 2% may have been an underestimate, and underscores the importance of collecting detailed family history.

Recently, a Healthy People 2020 objective based on the USPSTF guidelines was established to increase the proportion of women with a family history of breast and/ or ovarian cancer who receive genetic counseling (21). If use of these patterns truly identifies up to 12% of women as increased-risk, it might significantly impact efforts to achieve this goal as it is unlikely that the existing healthcare infrastructure could provide appropriate cancer genetic counseling and risk assessment services on this scale (22). A better understanding of the prevalence of women meeting the USPSTF increased-risk family history patterns could help guide program and educational efforts surrounding the Healthy People 2020 objective.

In the current study, we evaluated the prevalence of individuals meeting one or more of the USPSTF increased-risk family history patterns among a cohort of women from a large health system. In addition, we examined whether participants had talked with their healthcare provider about their family history, been referred for genetic counseling, or had undergone BRCA testing. While other guidelines for BRCA counseling and testing exist, we elected to focus on the 2005 USPSTF guidelines for this analysis, as they are the only recommendations produced as a result of a systematic evidence review by an independent panel of healthcare experts, and as such carry significant weight with respect to population-based health policy decisions.

These data provide new knowledge regarding the use of these services among individuals who are at increased risk for deleterious BRCA1/2 mutations according to the USPSTF-defined family history patterns.

**Materials and Methods**

**Study population, eligibility criteria, and design**

We used data from a study conducted by the Centers for Disease Control and Prevention (CDC) that evaluated ovarian cancer risk perception and screening among women at high, elevated, and average risk of ovarian cancer in the Henry Ford Health System (HFHS; Detroit, MI). CATI-assisted telephone interviews were conducted between January 16 and December 13, 2008 among eligible women (≥ age 30 years, no previous history of ovarian cancer, or bilateral oophorectomy). The survey eligibility screener asked about personal history of breast or ovarian cancer, prior oophorectomy, and knowledge of breast and ovarian cancer among first- and second-degree relatives. For random sampling purposes, we classified women into 3 risk groups based on the number of first- and second-degree relatives with breast or ovarian cancer and personal history of breast cancer. HFHS administrative data identified 55,887 potential study participants, 20,483 underwent eligibility screening (36.7%), and 16,720 (81.6%) were deemed eligible. The CATI system randomly selected 3,307 women for participation in the study and 2,524 women were consented and interviewed (response rate 76.3%). Data collected included demographics;
Classification using USPSTF patterns

We determined whether the participants without breast cancer met one or more of the USPSTF increased-risk family history patterns (hereafter referred to as patterns) as given in Table 1. The following adjustments were made to account for details not specified by USPSTF: (i) in situations satisfying patterns 2, 3, and 5 with 2 second-degree relatives, they were required to be from the same family side (i.e., both maternal or both paternal); (ii) for pattern 7, a history of male breast cancer in either a first- or second-degree relative was counted, and (iii) satisfying pattern 7 was also considered indicative of an increased-risk pattern for individuals of Jewish ancestry (16).

We defined a second set of participants who met USPSTF patterns by including women with a personal history of breast cancer from the perspective of a hypothetical unaffected sister. For example, a subject with breast cancer at age 45 was considered as an unaffected woman having a sister. For all 3 groups, the percentage of women who had talked with a healthcare provider about their family history was significantly higher among those who met a USPSTF pattern than those who did not (Wald $\chi^2$, $P \leq 0.01$). Although approximately 90% of participants in all 3 groups who met a USPSTF pattern talked with their provider about their family history, only 13.6%, 19.5%, and 41.8%, respectively, were referred for cancer genetic counseling. Referral was

Table 2. Prevalence of participants meeting USPSTF increased-risk family history patterns

<table>
<thead>
<tr>
<th>USPSTF Increased-risk family history pattern</th>
<th>All participants* ($n = 2,524$) %</th>
<th>Participants without breast cancer ($n = 2,087$) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any pattern</td>
<td>5.9</td>
<td>5.0</td>
</tr>
<tr>
<td>Two first-degree relatives with breast cancer, at least 1 relative under age 50</td>
<td>1.4</td>
<td>0.9</td>
</tr>
<tr>
<td>Three or more first- or second-degree relatives with breast cancer at any age</td>
<td>1.8</td>
<td>1.4</td>
</tr>
<tr>
<td>Both breast and ovarian cancer among first- and second-degree relatives</td>
<td>2.6</td>
<td>2.3</td>
</tr>
<tr>
<td>A first-degree relative with bilateral breast cancer</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>Two or more first- or second-degree relatives with ovarian cancer any age</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>A first- or second-degree relative with both breast and ovarian cancer</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Male relative with breast cancer</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Any 2 patterns</td>
<td>1.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Any 3 or more patterns</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Jewish pattern</td>
<td>0.4</td>
<td>0.3</td>
</tr>
</tbody>
</table>

NOTE: All prevalence estimates are weighted to account for the oversampling of high and elevated objective risk group.

*Includes participants with a personal history of breast cancer considered from the perspective of a hypothetical unaffected sister.

Results

Table 2 provides the prevalence of participants who met the increased-risk family history patterns as defined by the USPSTF. Approximately 5% of participants without breast cancer fit one or more of the USPSTF patterns, increasing to 6%, when participants with breast cancer were included from the perspective of a hypothetical unaffected sister. The most common pattern was a combination of breast and ovarian cancer among first- and second-degree relatives, followed by 3 or more first- or second-degree relatives with breast cancer regardless of age at diagnosis. Less than 1.5% of the study population fit 2 or more of the patterns and less than 0.5% fit 3 or more. Table 3 provides a breakdown of participants who talked with their healthcare provider about their family history, were referred for cancer genetic counseling, underwent BRCA testing, and reported a positive test result—according to whether they met a USPSTF increased-risk pattern. This evaluation involves 3 groups: all participants including women with a personal history of breast cancer from the perspective of a hypothetical unaffected sister, only participants without breast cancer, and only participants with breast cancer. For all 3 groups, the percentage of women who had talked with a healthcare provider about their family history was significantly higher among those who met a USPSTF pattern than those who did not (Wald $\chi^2$, $P \leq 0.01$). Although approximately 90% of participants in all 3 groups who met a USPSTF pattern talked with their provider about their family history, only 13.6%, 19.5%, and 41.8%, respectively, were referred for cancer genetic counseling. Referral was
Prevalence of Women Meeting 2005 USPSTF BRCA Recommendation

Table 3. Prevalence of healthcare actions taken by USPSTF pattern status: met or not met

<table>
<thead>
<tr>
<th>Healthcare action</th>
<th>Total study population</th>
<th>All participants* (n = 2,524)</th>
<th>Participants without breast cancer (n = 2,087)</th>
<th>Participants with breast cancer* (n = 437)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Met (n = 552)</td>
<td>Not met (n = 1,972)</td>
<td>Met (n = 440)</td>
<td>Not met (n = 1,647)</td>
</tr>
<tr>
<td>Talked to HCP about family history (%)</td>
<td>70.0</td>
<td>89.8</td>
<td>90.5</td>
<td>68.3</td>
</tr>
<tr>
<td>Referred for genetic counseling (%)</td>
<td>4.2</td>
<td>19.5</td>
<td>13.6</td>
<td>2.6</td>
</tr>
<tr>
<td>Had BRCA1/2 Testing (%)</td>
<td>1.6</td>
<td>8.2</td>
<td>3.6</td>
<td>0.8</td>
</tr>
<tr>
<td>BRCA1/2 mutation positive (%)</td>
<td>8.6</td>
<td>8.8</td>
<td>12.5</td>
<td>6.9</td>
</tr>
</tbody>
</table>

NOTE: All prevalence estimates are weighted to account for the oversampling of high and elevated objective risk groups. USPSTF pattern met versus not met comparisons tested with Wald $\chi^2$. All tests were significant with $P \leq 0.01$.

*Participants with a personal history of breast cancer considered from the perspective of a hypothetical unaffected sister.

**HCP, healthcare provider

†Among those undergoing testing. The BRCA1/2 test result outcomes were not statistically compared given the small numbers.

significantly more likely among those who met a USPSTF pattern than among those who did not (Wald $\chi^2$, $P \leq 0.0001$). Women with a personal history of breast cancer were more likely to report a genetic counseling referral, irrespective of whether they met a USPSTF pattern. For all 3 groups, participants who met a USPSTF pattern were also significantly more likely to have reported BRCA1/2 testing (Wald $\chi^2$, $P \leq 0.01$), with the highest percentage (25.3%) among women with a personal history of breast cancer. The number of women reporting a positive BRCA1/2 test result was too small to accommodate meaningful comparisons.

Table 4 provides demographic characteristics of all study participants and of those without breast cancer meeting a USPSTF increased-risk pattern by genetic counseling referral status. The population is primarily white, married or partnered, well educated, and in the middle- to upper-income brackets. Significant demographic differences by referral status were noted. Participants receiving genetic counseling referrals were more likely to be under age 61, hold a graduate degree, and have household incomes of $75,000 or more, whereas those with at most a high school education or household incomes less than $35,000 were less likely to be referred. Among all study participants, racial differences were also noted, with non-Hispanic whites significantly more likely to be referred than non-Hispanic blacks.

Discussion

In this large cohort of women representing a primary care population, 5% of women without breast cancer met USPSTF-defined increased-risk family history patterns for BRCA1/2 genetic counseling referral. When women with a personal history of breast cancer were included from the perspective of a hypothetical unaffected sister, 6% met one or more of the USPSTF patterns. These findings are consistent with previous studies suggesting a substantially higher percentage of women meeting these patterns than the original 2% estimated by the USPSTF (19, 20). Given that women with a previous oophorectomy or ovarian cancer were not included in the study cohort, it is possible that our results underestimate the true number of families in this health system who could potentially benefit from genetic counseling referral and consideration of BRCA1/2 testing.

Though the majority of women who met a USPSTF pattern had talked with their healthcare provider about their family history, less than 20% of these participants reported having been referred for genetic counseling. This is concerning as genetic counseling is readily available and a covered service within HFHS. In addition, of women who reported a family member with a positive BRCA1/2 test ($n = 23$), only 26.8% had been referred and 24.6% had undergone testing. While the numbers are small, this is perhaps more concerning as it is these women who are at the highest risk to carry a mutation and for whom testing is most informative. Furthermore, preferential referral of women with higher incomes and level of education suggest that perhaps it is the patient, rather than the clinician, who may be the driving force behind obtaining cancer genetic services. These combined results confirm previous studies suggesting a need to improve provider knowledge of BRCA1/2 and referral indications (25, 26).

Of participants without breast cancer meeting a USPSTF pattern who had been referred for genetic counseling, only 18.3% reported undergoing BRCA1/2 testing. This result is not unexpected as these individuals may learn that they are not appropriate candidates for testing, or may decline testing for personal reasons. However, less expected was the finding that among the 16 women without breast cancer meeting a USPSTF pattern who underwent BRCA1/2 testing, 31.3% had not received a genetic counseling referral.

Talking with a healthcare provider about family history, being referred for genetic counseling and undergoing BRCA1/2 testing were all significantly more likely in
participants who met a USPSTF pattern compared with those who did not. However, among participants who were referred for genetic counseling \((n = 226)\), or underwent \(BRCA1/2\) testing \((n = 95)\), 77.8\% did not meet a USPSTF pattern. It is important to note that this does not imply that referral and testing was inappropriate for these women. Rather, it suggests that use of the USPSTF increased-risk family history patterns may not be the most appropriate method to identify women who should receive genetic services. Potentially related is our finding that referral and testing were substantially higher among women with a personal history of breast cancer, regardless of whether they met a USPSTF pattern. These women are under the care of surgeons and oncologists, who tend to be more familiar with issues related to \(BRCA1/2\) than family physicians or internists (26). Furthermore, it is well documented, and was noted by USPSTF, that testing is most informative if a mutation is first identified in an affected family member, and it is standard of care to offer testing to affected women with a reasonable likelihood of carrying a \(BRCA1/2\) mutation (27, 28). Although small numbers, it is worth noting that of the 6 women with a personal history of breast cancer who reported having a “positive” \(BRCA1/2\) test; only 2 met the USPSTF patterns even when considered from the perspective of a hypothetical unaffected sister. These findings likely reflect in part the use by providers of alternate and updated guidelines such as those of the National Comprehensive Cancer Network (NCCN), which include more definitive family history and pathologic features (28).

Table 4. Demographics of all study participants and participants without breast cancer who met a USPSTF pattern by genetic counseling referral status

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>All Participants who met a USPSTF pattern ((n = 552))</th>
<th>Participants without breast cancer who met a USPSTF pattern ((n = 440))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group</td>
<td>% Referred ((n = 107))</td>
<td>% Not referred ((n = 442))</td>
</tr>
<tr>
<td>50 years or younger</td>
<td>31.4</td>
<td>31.1</td>
</tr>
<tr>
<td>51–60 years</td>
<td>45.8</td>
<td>38.1</td>
</tr>
<tr>
<td>61 years or older</td>
<td>22.8</td>
<td>30.8</td>
</tr>
<tr>
<td>Race(^c)</td>
<td>White non-Hispanic</td>
<td>73.7</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>17.9</td>
<td>30.6</td>
</tr>
<tr>
<td>All other</td>
<td>8.5</td>
<td>5.7</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married/partner/significant other</td>
<td>65.4</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>20.6</td>
<td>18.5</td>
</tr>
<tr>
<td>Single/never married</td>
<td>7.5</td>
<td>7.4</td>
</tr>
<tr>
<td>Widowed</td>
<td>6.5</td>
<td>7.4</td>
</tr>
<tr>
<td>Education level</td>
<td>&lt; High School/high school graduate</td>
<td>21.2</td>
</tr>
<tr>
<td>College &lt; 4 years</td>
<td>30.9</td>
<td>32.5</td>
</tr>
<tr>
<td>College 4 years or more</td>
<td>19.5</td>
<td>19.3</td>
</tr>
<tr>
<td>Graduated degree</td>
<td>28.4</td>
<td>14.6</td>
</tr>
<tr>
<td>Household income</td>
<td>&lt; $35,000</td>
<td>15.7</td>
</tr>
<tr>
<td>$35,000 – &lt; $50,000</td>
<td>16.1</td>
<td>17.8</td>
</tr>
<tr>
<td>$50,000 – &lt; $75,000</td>
<td>22.4</td>
<td>24.7</td>
</tr>
<tr>
<td>$75,000 or more</td>
<td>45.8</td>
<td>35.5</td>
</tr>
</tbody>
</table>

NOTE: All prevalence estimates are weighted to account for the oversampling of high and elevated objective risk groups. Percentages do not necessarily sum to 100% because of rounding.

\(^a\)Women with a personal history of breast cancer were considered from the perspective of a hypothetical unaffected sister.

\(^b\)Wald \(\chi^2\) comparisons (overall) and \(t\) tests (individual levels) were used to contrast demographic characteristics between women referred and not referred for genetic counseling. All significant \(P\) values \((\leq 0.05)\) are bolded.

\(^c\)Unknown race excluded. The “all other” race group includes all non-Hispanics from the American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, and Multiracial race groups, as well as Latinas.

\(^d\)The genetic counseling referral prevalence estimates are unstable because of small sample sizes.
Since release of the 2005 recommendation, the USPSTF increased-risk family history patterns appear to have been viewed by some health professionals as the "criteria" or "gold standard" for determining appropriateness of genetic counseling referral (17, 19, 21, 29), and in some cases to determine who should be tested for BRCA1/2 mutations (30). If the USPSTF increased-risk family history patterns are taken as the basis for referral and insurance coverage for genetic counseling and genetic testing, it could result in lack of access to these services for those at substantial risk (e.g., women with breast cancer and positive family histories) and over-referral of women unlikely to carry a BRCA1/2 mutation (e.g., a woman with 3 second-degree relatives diagnosed with breast cancer after the age of 70 years). It needs to be emphasized that USPSTF did not attempt to address the merits or disadvantages of referral and testing of affected women, which should not be construed to imply that such services are inappropriate. There is a substantial body of literature regarding the importance of identifying women with breast cancer who carry BRCA1/2 mutations with respect to surgical management (lumpectomy vs. bilateral mastectomy), MRI screening for second primary breast cancers, prevention of ovarian cancer, as well as emerging data on differential treatment with PARP2 inhibitors (31). Other recognized guidelines, including those of the NCCN (28, 32), specifically focus on issues of referral and testing of affected women. Finally, insofar, as our data and others suggest that substantially more than 2% of women will meet one of these patterns, and given the recognized limitations of access to qualified genetics professionals, especially in rural areas, serious consideration will need to be given to increasing the number of genetic service providers and developing alternative service delivery models.

Several strengths of this study are worth noting. First, the survey was conducted in a large, racially diverse managed care population. Much of the research on genetic risk and counseling has been conducted among women from high-risk families attending specialized clinics, who may differ from those receiving care in community settings (33). Our population provided a reasonable compromise between a general population-based survey and a clinic-based survey. While this sample cannot be assumed to be fully representative of women in the general population, it does reflect the population of women with access to medical care including genetic counseling and BRCA1/2 testing. A second strength was our use of an eligibility-screening interview, which allowed preliminary classification into risk groups for sampling purposes. Finally, a response rate of 76.3% was achieved for the full interview.

Study limitations include self-report of genetic counseling referral, BRCA1/2 testing, positive test results, and family cancer history. Depending on self-report might have led to biased results with respect to prevalence of genetic counseling referral and BRCA testing, although detailed description of these processes were provided by the interviewers. In addition, only 0.3% and 4% of survey respondents answered “don’t know” to the questions regarding counseling referral and BRCA testing, respectively, and no subject refused to answer. In contrast, 10.5% of women who reported BRCA testing indicated they did not know their results, though only one refused to answer. These response patterns suggest that our findings might reflect a small bias toward underestimation of the prevalence of BRCA testing in this population. With respect to family history, sharing cancer information within families and the accuracy of reporting depends on multiple factors such as geographical distance, familial culture of communication, degree of relatedness, gender, and knowledge about cancer (34–36). Reporting of first-degree relatives and breast cancer is generally more accurate than reporting of second-degree relatives and other cancers (37–39), with ovarian cancer often underreported (38, 39). Because the USPSTF risk classification depends on the number and relatedness of affected relatives, an underreporting of ovarian cancer may have led to an underestimation of the number of women at high-risk. Another potential source of underestimation of women at high-risk was the exclusion of women with a prior oophorectomy or personal history of ovarian cancer from the survey, although ovarian cancer survivors comprise less than 0.2% of women aged 30 or more in the United States (40).

To address these limitations, future studies should include women with a personal history of ovarian cancer or prior oophorectomy, and in at least a subset of the population, medical record verification of reported cancers, completion of genetic counseling, and BRCA1/2 testing results in participants and family members. Factors influencing physician referral for genetic counseling, and the roles of the healthcare system, healthcare provider, and patient characteristics in both referral and uptake of genetic counseling and BRCA1/2 testing should also be evaluated. Finally, these study findings suggest that further research is needed to examine the effectiveness of using the USPSTF patterns in identifying those appropriate for genetic counseling referral.

In summary, this study involving 2,524 female participants from a large integrated healthcare system showed both a significantly higher percentage of women at potential risk for hereditary breast/ovarian cancer based on family history than that originally predicted in the USPSTF 2005 recommendations, and evidence of significant underreferral of high-risk women for cancer genetic counseling despite in-system availability of these services. These findings indicate that efforts directed toward improving provider education and increasing the cancer genomics workforce are needed. Such efforts, further strengthened by a focus on enhancing public awareness of the importance of family history and the availability of genetic counseling and testing will be needed if the potential benefits of identification and management of individuals and families who are impacted by the presence of a BRCA1/2 mutation are to be realized.

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www.aacjrournals.org Cancer Epidemiol Biomarkers Prev; 22(4) April 2013 733

Published OnlineFirst January 31, 2013; DOI: 10.1158/1055-9965.EPI-12-1280

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Disclosure of Potential Conflicts of Interest
No potential conflicts of interest were disclosed.

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Conception and design: C.A. Bellcross, S. Leadbetter
Development of methodology: C.A. Bellcross
Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): S. Leadbetter, S. Hensley Allford, L.A. Pepins
Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): C.A. Bellcross, S. Leadbetter

References
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