

# Cancer genetic counseling in rural North Carolina oncology clinics: program establishment and patient characteristics

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Cancer genetic counseling (CGC) has become standard of care for individuals at increased risk of hereditary cancer. However, because access to CGC is limited in rural communities, several groups are underserved by CGC, and little knowledge exists about characteristics and decisions of individuals who have CGC in a rural setting. We describe pilot data from an outreach CGC program from the Duke Hereditary Cancer Clinic to six rural North Carolina oncology clinics. We assessed whether the program was successfully established and whether outreach patients' characteristics differed from those of patients seen in the tertiary care center. Between February 2005 and February 2006, genetic counseling was provided to 57 patients in the outreach clinics and 275 patients in the tertiary care clinic. We found the program reached individuals less likely to receive CGC otherwise and that patients were satisfied with it. Differences found between outreach and tertiary care patients in race, insurance type, risk of having a hereditary cancer syndrome, and genetic testing decision highlight the importance of continued research to characterize rural CGC patients and understand their decisions.

Cancer genetic counseling (CGC) has become standard of care for individuals at increased risk of a hereditary cancer syndrome. Numerous professional groups, including the American Society of Clinical Oncology<sup>1</sup> and US Preventive Services Task Force,<sup>2</sup> recognize genetic counseling as integral to the process of genetic testing for hereditary cancer syndromes. Indeed, the latter group states that women at increased risk of hereditary breast and ovarian cancer (HBOC) syndrome “would benefit from genetic counseling that allows informed decision making about testing and further prophylactic treatment” and that these benefits “may be substantial.”<sup>2</sup> Others have noted the benefits of CGC in terms of facilitating surgical decision making,<sup>3</sup> increasing cancer genetics knowledge,<sup>4,5</sup> decreasing cancer anxiety,<sup>5</sup> and improving adherence to cancer risk management.<sup>6-9</sup> Patient reports of satisfaction

with CGC reflect recognition of these benefits.<sup>10</sup> Further, cancer genetics services appear to be sufficiently cost-effective<sup>11,12</sup> and may be associated with increased survival and quality of life.<sup>13</sup>

However, what is now considered standard of care is not reality of care for those US citizens without easy access to urban tertiary care centers, where the majority of cancer genetic counselors practice. This hinders access to CGC for certain groups, particularly those in rural communities, and is one reason that CGC patients have historically been demographically homogeneous—white, well educated,

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and financially secure.<sup>14-16</sup> Particular groups that have been underserved by CGC include blacks and rural residents.<sup>17</sup> These groups often lack access to genetic counseling and genetic testing via the model shown to have the benefits previously listed above (master's level genetic counselors supervised by a medical oncologist or medical geneticist). If they are presented with opportunities for genetic testing without such genetic counseling, they may be seen by health care professionals who have inadequate genetics training, raising the possibility of suboptimal advice regarding genetic testing options; inappropriate offering of genetic testing; lack of discussion of the ethical, legal, and social complexities involved in genetic testing; and misinterpretation of genetic testing results.<sup>18</sup>

Concentration of CGC services in tertiary care centers has also meant that little is known about characteristics and decisions of individuals who have counseling in a rural setting. The reported benefits of CGC described above<sup>3-13</sup> are all from studies performed with tertiary care patients. And, because existing research on the uptake of genetic testing is also from tertiary care or urban populations,<sup>15,16,19-21</sup> we do not know to what extent rural patients will choose to have genetic testing—the primary tool in determining one's hereditary cancer risk. Knowing who attends genetic counseling in rural settings and what they decide regarding testing and follow-up could help genetics providers in these settings to optimize their services.

North Carolina cancer genetic counselors mirror the national trend in practice location. There are only approximately 10 full-time genetic counselors specializing in cancer in the state.<sup>22</sup> All are concentrated in four teaching hospitals in North Carolina's larger metropolitan areas (eg, Charlotte, Research Triangle). Patients who visit the urban tertiary

centers to see cancer genetic counselors in North Carolina often have round-trip travel times that can easily cause loss of a full day of work.

To address this limited access to CGC in North Carolina, we developed an outreach program from the Duke Hereditary Cancer Clinic (HCC) in Durham, NC, to provide no-cost counseling in six rural North Carolina oncology clinics. One Board-certified genetic counselor visited each of the clinics once a month. This article summarizes pilot data from the first year of the outreach program (February 2005–February 2006) to determine (1) whether the outreach program was successfully established to provide services for traditionally underserved patients (as measured by tracking referral data, comparing patient demographics with those of clinic counties, and assessing patient satisfaction) and (2) whether characteristics, decisions, and predictors of decisions of outreach patients differed significantly from those of patients seen at the HCC during the same 1-year period (as measured by comparing patient characteristics abstracted from a clinical database).

## Methods

### *Establishment of outreach CGC*

The six clinics in which outreach CGC was offered are located in towns ranging in size from about 8,800 to 22,600 residents.<sup>23</sup> Through their affiliation with the Duke Oncology Network, these clinics have provided access to medical oncology (and, in some, radiation oncology) services and clinical trials to residents of these towns and the surrounding counties for several years. The clinics' communities are populated by groups historically underserved by CGC.<sup>14-17</sup> They have substantial black, American Indian, and Hispanic populations (27%, 12%, and 7%, respectively).<sup>24</sup> Residents of the clinic counties generally have a lower education level than the

state average (29% have less than high school education and 13% are college graduates, compared with 22% and 23%, respectively, for the state). The proportion of county residents living below the poverty level exceeds the state average (17% vs 14%).<sup>24</sup>

We met with staff from the outreach clinics to determine how the genetic counseling service would best fit in and put as little burden as possible on clinic staff. We also relied on advice from outreach clinic staff to determine which methods would be most effective for publicizing the genetic counseling service to referring physicians and potential patients. On the basis of this advice, we publicized availability of the new CGC service via clinic newsletters, staff training sessions, presentations to cancer support groups, articles in local newspapers, and brochures placed in clinic waiting rooms.

### *Assessing success of outreach program establishment*

We used three methods to assess establishment of outreach CGC during the first year that counseling was available in the clinics (February 2005–February 2006): (1) review of referral data to determine the appropriateness of referrals and the effectiveness of referral procedures, (2) comparison of outreach patients' demographics with those of counties in which clinics are located (to determine the extent to which the program reached historically underserved patients), and (3) assessment of patient satisfaction with genetic counseling.

The first method entailed reviewing our clinical database for the following referral information: number of patients referred, indication for referral (eg, evaluation for HBOC syndrome), source of referral (eg, medical oncologist, primary care physician), and new patient appointments scheduled and completed. The clinical database contains information in personal and family histories collected

during the genetic counseling process for all patients seen by a Duke cancer genetic counselor, including those seen in the outreach program.

The second method to determine program effectiveness used data from two sources: an anonymous, self-administered written questionnaire completed by outreach patients and the clinical database. Items on the questionnaire assessed patient characteristics not typically collected or stored in the clinical database. The counselor handed this questionnaire

to outreach patients immediately before each new-patient counseling session. The questionnaire used demographic items shown to be well understood by participants in our previous research.<sup>25</sup> We compared data on household income and education level from this questionnaire, as well as race and ethnicity data from the clinical database, with census data on race, ethnicity, education, and income<sup>24</sup> for counties in which outreach clinics are located. The pre-session questionnaire also contained other items intended to characterize outreach patients, including marital status and reason for the visit (asked an open-ended question).

A patient satisfaction questionnaire constituted the third method for determining program effectiveness. Immediately after each new-patient genetic counseling session, the counselor handed patients an anonymous, self-administered, written questionnaire, this one assessing satisfaction with the session. To minimize the risk of social desirability bias, the counselor reminded patients that the questionnaire was anonymous and left the room while they completed it and put it in an envelope. This questionnaire, which we developed for this study, was designed to determine whether goals identified by professional organizations as being integral to CGC sessions<sup>1,26</sup> were accomplished. Such goals included helping patients understand cancer risk, benefits and limitations of genetic testing, and cancer prevention and early detection. Patients rated their agreement as to whether these goals had been met on 5-point Likert-scale items (1 = strongly disagree to 5 = strongly agree). The questionnaire also used 5-point Likert-scale items to assess satisfaction with the genetic counselor (whether he was knowledgeable, caring, and effective at explaining topics). All items were worded positively (ie, a higher number indicates greater satisfaction).

#### *Comparison of outreach versus HCC patients*

To determine whether characteristics and genetic testing decisions of outreach patients differed from those of HCC patients, we queried the clinical database for deidentified information about patients seen at the outreach clinics and patients seen during the same 1-year period at the Duke HCC. Data on age, race (as self-reported), health insurance type, cancer status (affected vs unaffected), risk for having HBOC or Lynch syndrome, and percentage who chose genetic testing after having genetic counseling were abstracted from the database. Patients who were evaluated for a syndrome other than HBOC or Lynch syndrome (a relatively small proportion of both the outreach and HCC groups) did not have a risk score, because no models are available to calculate risks for less common hereditary cancer syndromes. We calculated risks for having HBOC or Lynch syndrome (hereafter referred to as risk score) using BRCAPRO<sup>27</sup> and MMRpro<sup>28</sup> models—Bayesian software programs that estimate risk of the respective syndrome based on the number of relatives with and without cancer, ages of relatives now or at death, and, for those with cancer, type of cancer and age at diagnosis.

All data collection and study procedures were approved by the Duke University Health System Institutional Review Board.

#### *Analyses*

Our first research question assessed whether the program was successfully established. We considered the program to be successfully established if (1) referral data showed that appropriate patients were consistently being referred and seen, (2) outreach clinic patients were representative of the counties in which the clinics are located, and (3) patients reported satisfaction with genetic counseling. Referral data were summarized

**TABLE 1**

#### Referral sources, reasons, and outcomes (February 2005–February 2006)

Measure	Number (%) of patients
Referral sources (n = 102):	
Medical oncologist	90 (88%)
Primary care physician	5 (5%)
Obstetrician-gynecologist	3 (3%)
Radiation oncologist	2 (2%)
General surgeon	1 (1%)
Self	1 (1%)
Referral reasons <sup>a</sup> (n = 86):	
HBOC syndrome	60 (70%)
Syndrome unclear	9 (10%)
Lynch syndrome	8 (9%)
HBOC + Cowden syndrome	3 (3%)
HBOC + Lynch syndrome	2 (2%)
HBOC + Li-Fraumeni syndrome	1 (1%)
Li-Fraumeni syndrome	1 (1%)
Familial melanoma	1 (1%)
Dyskeratosis congenita	1 (1%)
Referral outcomes (n = 102):	
Seen by genetic counselor February 2005–February 2006	58 (57%)
Seen by genetic counselor after February 2006	7 (7%)
Never reached	19 (19%)
Appointment scheduled but not kept ("no show")	12 (12%)
Declined genetic counseling	5 (5%)
Genetic counseling deemed inappropriate	1 (1%)

HBOC = hereditary breast and ovarian cancer

<sup>a</sup> As determined by genetic counselor after reviewing pedigree or indication

via frequencies. We compared outreach patients' race (as recorded in the clinical database) and education level (from the patient characteristics questionnaire) with the most recent census data of clinic counties via chi-square test. Outreach patients' ethnicity (as recorded in the clinical database) and household income (from the patient characteristics questionnaire) were compared with census data of clinic counties via frequencies. For patient satisfaction, we report mean and standard deviation for the Likert-scale items in the satisfaction questionnaire.

Our second research question assessed whether characteristics, decisions, and predictors of decisions of outreach patients differed significantly from those of patients seen at the HCC during the same 1-year period. The Student's test was used to identify differences between counseling groups for the continuous variables of age and risk score. The Fisher's test or the Pearson chi-square test was used to identify differences between counseling groups in categorical variables. We used multivariate unconditional logistic regression to calculate odds ratios and 95% confidence intervals to assess the association between the decision to have genetic testing and the following variables: age (continuous), sex, race (nonwhite vs white), cancer status (unaffected vs affected), insurance type (Medicare/military vs private; Medicaid/none vs private), risk score (continuous), and counseling group. We also stratified our data by counseling group and performed a separate logistic regression analysis within each subset to see whether predictors of test decision differed by counseling group. Data management and analyses were performed using Microsoft Excel (Microsoft Corp, Redmond, WA) and SAS version 9.1 (SAS Institute Inc, Cary, NC). All statistical tests were two-sided; findings with  $P \leq 0.05$  were considered statistically significant.

## Results

### *Establishment of outreach CGC*

As shown in Table 1, 64% of the 102 patients who were referred to the outreach clinic were eventually seen. Thirty percent were never reached or missed an appointment and could not be recontacted; only 5% of referred patients declined genetic counseling. Most patients (88%) were referred by a medical oncologist. Review of pedigrees or indications on the referral form showed that the large majority (77%) were referred for evaluation of HBOC syndrome, either alone or in combination with other syndromes. Only one referred individual was deemed to be inappropriate for genetic counseling because personal and family histories did not indicate a hereditary cancer syndrome for which the patient could be evaluated.

Outreach patients appeared to be more representative of their counties in income than in education level, race, or ethnicity. The distribution in income level among outreach patients, with 54% having an annual household income less than \$40,000 (Table 2), suggested that they were similar

**TABLE 2**

Characteristics of outreach patients from the pre-session questionnaire

Characteristic	Number (%) of patients
Education level completed (n = 57):	
Grade school/junior high school	1 (2%)
Some high school	7 (12%)
High school graduate	17 (30%)
Trade/technical/vocational school	4 (7%)
Some college	12 (21%)
College graduate	10 (18%)
Postgraduate work or graduate degree	6 (11%)
Marital status (n = 58):	
Married	32 (55%)
Living with partner	2 (3%)
Single, never married	5 (9%)
Divorced	8 (14%)
Separated	3 (5%)
Widowed	8 (14%)
Household income (n = 57):	
< \$20,000	17 (30%)
\$20,000–\$40,000	14 (25%)
\$40,001–\$60,000	10 (18%)
\$60,001–\$80,000	8 (14%)
\$80,001–\$100,000	3 (5%)
> \$100,000	5 (9%)

**TABLE 3**

Outreach patients' satisfaction with genetic counseling (n = 57)

Item	Score, mean (SD) <sup>a</sup>
It was easy to set up a genetic counseling appointment.	4.67 (0.48)
Genetic counseling helped you understand...	
a. your chances of getting cancer.	4.51 (0.63)
b. the pros and cons of genetic testing for a cancer gene mutation.	4.53 (0.60)
c. ways to prevent cancer and find it early.	4.33 (0.76)
Genetic counseling will help you make decisions about...	
a. ways to prevent cancer or find it early.	4.45 (0.67)
b. genetic testing for a cancer gene mutation.	4.56 (0.63)
Overall, you were satisfied with genetic counseling.	4.75 (0.47)
You would recommend genetic counseling for others in your situation.	4.82 (0.43)
The genetic counselor seemed to know what he was talking about.	4.89 (0.31)
The genetic counselor explained things clearly.	4.84 (0.38)
The genetic counselor answered all your questions.	4.88 (0.33)
The genetic counselor cared about your feelings.	4.84 (0.41)
Overall, you were satisfied with your genetic counselor.	4.86 (0.35)

<sup>a</sup> On a 5-point scale, where 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree; SD = standard deviation

TABLE 4

Comparison of patients seen for genetic counseling in outreach clinics versus the Hereditary Cancer Clinic (HCC)

Characteristic	Outreach patients (n = 58)	HCC patients (n = 275)	P value
Mean age, years (SD)	50.6 (15.2)	46.5 (12.2)	0.054
Mean risk score (%)	8.1 (17.0)	20.8 (27.4)	< 0.0001
Sex, number (%)			0.22
Female	57 (98)	257 (93)	
Male	1 (2)	18 (7)	
Race, number (%)			0.02
White	43 (74)	226 (84)	
Black	9 (16)	32 (12)	
American Indian	4 (7)	1 (<1)	
Asian	1 (2)	7 (3)	
Other	1 (2)	4 (1)	
Cancer status, number (%)			0.07
Affected	49 (84)	201 (73)	
Unaffected	9 (16)	74 (27)	
Insurance, number (%)			< 0.0001
Private	31 (53)	198 (84)	
Medicare	14 (24)	23 (10)	
Medicaid	9 (16)	7 (3)	
Military	1 (2)	2 (1)	
None	3 (5)	6 (3)	
Genetic testing decision, number (%)			< 0.0001
Accepted	24 (41)	196 (71)	
Declined	34 (59)	79 (29)	

to clinic county residents in income (median household income in 2004: \$35,898<sup>24</sup>). Education level differed significantly ( $P < 0.01$ ), with a greater proportion of outreach patients having a college education (28% vs 13%) and a smaller proportion having less than a high school education (14% vs 29%) than clinic county residents. A greater proportion of outreach patients than clinic county residents were white (74% vs 60%) and a lesser proportion of outreach patients were black (16% vs 27%); however, this difference was not statistically significant ( $P = 0.08$ ). None of the outreach patients was of Hispanic ethnicity, compared with 7% of county residents. As shown in Table 2, patients were predominantly married or living as married (59%).

All but 1 of the 58 outreach patients completed a satisfaction questionnaire at the end of the initial genetic counseling session. Patients reported high levels of satisfaction, with little deviation, on items assessing several aspects of genetic counseling and of the genetic counselor (Table 3). Overall, patients were satisfied with genetic counseling (mean = 4.75; standard deviation [SD] = 0.47) and with the genetic counselor (mean = 4.86; SD = 0.35) and would recommend genetic counseling for others in their situation (mean = 4.82; SD = 0.43).

#### *Comparison of outreach patients versus HCC patients*

Outreach patients differed significantly from HCC patients seen during the same period (Table 4). They were more racially diverse

than HCC patients, were less likely to have private insurance and more likely to have Medicare or Medicaid, had a lower estimated risk of having HBOC or Lynch syndrome (based on mean risk scores), and were much less likely to choose genetic testing. There were no statistically significant differences between the two patient populations in sex, age, or cancer status, although a difference in the latter two approached statistical significance, with outreach patients tending to be older and more likely to have cancer.

After finding that testing decision differed by counseling group in bivariate analysis, we sought to determine whether this association persisted in multivariate analysis. We ran an unconditional multivariate logistic regression model that included counseling group as a predictor of testing decision while adjusting for age, risk score, sex, race, cancer status, and insurance type. The model showed that HCC patients were 3.5 times as likely to choose genetic testing as their outreach counterparts (Table 5). Risk score, cancer status, and insurance type (Medicaid/none vs private) were independently associated with genetic testing decision as well.

To assess whether predictors of genetic testing decision differed by counseling group, we used unconditional multivariate logistic regression. As shown in Table 6, risk score, cancer status, and insurance type (Medicaid/none vs private) were independently associated with genetic testing decision among HCC patients. Odds ratios for these same variables in the outreach group appeared similar to those in the HCC group, although, only risk score reached statistical significance because of the smaller sample size. In both groups, as risk score increased, so did the likelihood of choosing genetic testing. Patients unaffected with cancer and those with Medicaid or no insurance were less likely to choose genetic testing.

## Discussion

Results of the first year of outreach CGC from the HCC to six rural North Carolina oncology clinics show that such a program can be established, well used, and result in high patient satisfaction. Referral procedures led to consistent and appropriate referrals, primarily from medical oncologists in participating clinics. Few individuals declined genetic counseling, but 30% of referred individuals either could not be reached or missed appointments. Although we do not know why these individuals missed appointments or refused passively by never returning phone or mail contact, review of HCC referral outcomes over the same period revealed similar outcomes (no-show rate = 8%; never reached rate = 33%), indicating rural individuals were no more likely than their tertiary care counterparts to miss an appointment or be inaccessible.

Comparison of outreach patients' race, ethnicity, education, and household income with those of county populations of outreach clinics indicated that, although the program did reach groups historically underserved by CGC (eg, rural populations, low-income individuals), certain groups (blacks, Hispanics, and those with less than high school education) were underrepresented. Additional research to determine effective methods for reaching these underserved groups is warranted.

Outreach patients who completed a genetic counseling session and subsequent satisfaction questionnaire were satisfied with genetic counseling and with the genetic counselor, indicating that the program met goals set by the American Society of Clinical Oncology and National Society of Genetic Counselors as integral to CGC.<sup>1,26</sup> These satisfaction data are consistent with data from a previous examination of satisfaction with CGC in a tertiary care setting.<sup>10</sup>

Hence, methods for meeting goals of CGC may not need to differ for rural patients.

Although patients seen in the outreach clinics did not exactly mirror the demographic composition of their counties, they did differ significantly from the patient population that received genetic counseling at the HCC during the same time period. The greater representation among outreach patients of racial minorities and individuals covered by Medicaid or Medicare indicates that provision of the service in the outreach clinic setting may have made it available to types of patients less likely to come to the tertiary care center. The difference in race was not surprising, given that outreach patients were somewhat representative of their counties and that race of HCC patients was consistent with that of previous studies of CGC patients in tertiary care centers.<sup>14-17</sup> The difference in insurance type between counseling groups also likely reflects differences in patients typically seen in rural communities versus those seen in tertiary care centers.

Patients seen in the outreach clinics also differed from HCC patients in their risk of having a hereditary cancer syndrome (indicated by risk score). The reason for this difference (lower mean risk among outreach vs

**TABLE 5**

Relationship between patient characteristics and the odds of deciding to have genetic testing among patients overall (n = 235)<sup>a</sup>

Characteristic	Odds ratio (95% CI)
Group (HCC vs outreach clinic)	3.49 (1.64–7.43)
Age (per 1-year increase)	1.00 (0.96–1.03)
Risk score (per 1% increase)	1.04 (1.02–1.06)
Sex (female vs male)	2.00 (0.50–7.97)
Race (nonwhite vs white)	0.63 (0.25–1.57)
Cancer status (unaffected vs affected)	0.22 (0.10–0.50)
Insurance type:	
Medicare/military vs private	0.72 (0.23–2.28)
Medicaid/none vs private	0.05 (0.01–0.25)

HCC = Hereditary Cancer Clinic; CI = confidence interval

<sup>a</sup> Based upon patients with complete data

HCC patients) may be that several of the HCC patients had a 50% risk score because a close relative had a hereditary cancer mutation, whereas none of the outreach patients came from families with an identified mutation (and the accompanying elevated risk score).

We also found a significant difference in genetic testing uptake between outreach and HCC patients in the bivariate analysis, prompting examination of predictors of testing

**TABLE 6**

Relationship between patient characteristics and the odds of deciding to have genetic testing, by group

Characteristic	Outreach patients, OR (95% CI) (n = 58)	HCC patients, OR (95% CI) (n = 177)
Age (per 1-year increase)	1.00 (0.94–1.06)	0.99 (0.95–1.04)
Risk score (per 1% increase)	1.08 (1.01–1.16)	1.04 (1.01–1.06)
Sex (female vs male)	– <sup>a</sup>	1.14 (0.22–5.77)
Race (nonwhite vs white)	0.30 (0.04–2.06)	0.67 (0.21–2.19)
Cancer status (unaffected vs affected)	0.18 (0.02–1.84)	0.22 (0.09–0.54)
Insurance type:		
Medicare/military vs private	1.05 (0.19–5.93)	0.53 (0.11–2.63)
Medicaid/none vs private	0.13 (0.01–1.19)	0.02 (0.00–0.20)

HCC = Hereditary Cancer Clinic; OR = odds ratio; CI = confidence interval

<sup>a</sup> Model did not include sex because only one outreach patient was male.

decision via multivariate analysis. After adjusting for potential predictors of testing decision (age, risk score, sex, race, cancer status, and insurance type), within each counseling group, risk score, cancer status, and insurance type were independently associated with testing decision. Given that each of these variables has been associated with the uptake of *BRCA1/2* genetic testing in previous research,<sup>16,29</sup> these associations are not unexpected.

What is unexpected is that the bivariate difference between counseling groups (HCC vs outreach) in genetic testing uptake persisted in a multivariate analysis. A multivariate logistic regression model that added counseling group to the potential predictors listed above found that counseling group joined risk score, cancer status, and insurance type as an independent predictor of testing decision, with HCC patients being 3.5 times as likely as outreach patients to have genetic testing. This is a novel finding that cannot be accounted for by risk score, cancer status, or insurance type.

Might this difference between groups in genetic testing uptake be the result of differences in education, income, or marital status—variables collected in our pre-session questionnaire that have been shown to be associated with uptake of genetic testing for hereditary cancer syndromes?<sup>15,19,29</sup> Unfortunately, we were unable to link these variables to genetic testing decision in the outreach group because the pre-session questionnaires were anonymous. Nor did we collect education, income, or marital status data on HCC patients, a clear study limitation. To thoroughly examine the difference in cancer genetic testing uptake in rural versus tertiary care populations, one should compare uptake in the two populations while adjusting for the above demographic variables and for other variables suggested by previous research (eg, age, race, religious heritage,<sup>20,29</sup> family cancer history,<sup>15,16,20,29</sup> financial con-

siderations,<sup>16</sup> and knowledge and attitudinal factors<sup>21</sup>).

Given the differences between outreach and HCC patients, one must wonder what other factors differ between rural and urban CGC patients. Previous research on CGC's benefits<sup>3-9</sup> and predictors of genetic testing decision<sup>15,16,19-21,29</sup> has been conducted in urban or tertiary care populations. Might rural patients react differently to or derive less of a benefit from CGC? Are individuals in all rural settings less inclined to have genetic testing? As CGC continues to be integrated into oncology and genetic testing maintains a central role in determining hereditary cancer risk, these are crucial questions to explore.

Study limitations not already noted include missing data in the clinical database, use of a nonvalidated satisfaction questionnaire, and reliance on self-report to ascertain race/ethnicity. First, nearly 100 HCC patients did not have insurance or risk score information in the clinical database (either because such information was not available, as in the case of hereditary cancer syndromes for which no risk calculation program exists, or because genetic counselors failed to enter it). This raises the question of whether the differences found between HCC and outreach patients would have persisted if data were available for all HCC patients. Nevertheless, the pilot data presented here show that a more thorough comparison of rural and urban CGC patients is warranted. Second, using a validated satisfaction questionnaire (such as the Genetic Counseling Satisfaction Survey,<sup>10</sup> of which we were unaware of when we began the outreach program) would have increased confidence that we were accurately measuring the necessary elements of a CGC encounter. Third, self-reporting of race/ethnicity has inherent limitations, especially when comparing two populations, as was done in this study.

Finally, it is important to point out that our study's genetic counselor was funded by grant support. Clinics that practice the traditional model of CGC (master's level genetic counselors supervised by a medical oncologist or medical geneticist) can recoup some of the cost of a genetic counselor by billing the genetic counseling Current Procedural Terminology (CPT) code (96040) or by having the supervising physician see genetic counseling patients with the counselor and bill the corresponding Evaluation and Management codes. Yet most clinics have to rely on downstream revenue from CGC (estimated at up to \$5,000 per patient<sup>30</sup> for cancer risk management such as prophylactic mastectomy, breast magnetic resonance imaging, and colonoscopies) to provide the bulk of support for a counselor. Oncology clinics that do not receive revenue from surgeons or imaging services, as is the case for many community oncology clinics, will be unable to reap these downstream benefits. This may mean that community clinics interested in offering CGC will have to explore other service models (eg, telemedicine).

## Conclusion

We found that an outreach CGC service could be successfully established, that it seemed to reach individuals who would have been less likely to receive it otherwise, and that patients were satisfied with the service. The differences we found between outreach and tertiary care patients in race, insurance type, risk of having a hereditary cancer syndrome, and genetic testing decision highlight the importance of continued research to characterize rural CGC patients and to understand their decisions. Additionally, the experience emphasizes the need to explore other service models for providing this critical service. As the era of genomic medicine opens, this need will become more acute.

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## References

- American Society of Clinical Oncology. American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. *J Clin Oncol* 2003;21:2397-2406.
- U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med* 2005;143:355-361.
- Schwartz MD, Lerman C, Brogan B, et al. Impact of BRCA1/BRCA2 counseling and testing on newly diagnosed breast cancer patients. *J Clin Oncol* 2004;22:1823-1829.
- Meiser B, Butow PN, Barratt AL, et al. Long-term outcomes of genetic counseling in women at increased risk of developing hereditary breast cancer. *Patient Educ Couns* 2001;44:215-225.
- Pieterse AH, Ausems MGEM, Van Dulmen AM, Beemer FA, Bensing JM. Initial cancer genetic counseling consultation: change in counselees' cognitions and anxiety, and association with addressing their needs and preferences. *Am J Med Genet A* 2005;137:27-35.
- Scheuer L, Kauff N, Robson M, et al. Outcome of preventive surgery and screening for breast and ovarian cancer in BRCA mutation carriers. *J Clin Oncol* 2002;20:1260-1268.
- Watson M, Kash KM, Homewood J, Ebbs S, Murday V, Eccles R. Does genetic counseling have any impact on management of breast cancer risk? *Genet Test* 2005;9:167-174.
- Hadley DW, Jenkins JF, Dimond E, de Carvalho M, Kirsch I, Palmer CGS. Colon cancer screening practices after genetic counseling and testing for hereditary nonpolyposis colorectal cancer. *J Clin Oncol* 2004;22:39-44.
- Collins VR, Meiser B, Ukoumunne OC, Gaff C, St John DJ, Halliday JL. The impact of predictive genetic testing for hereditary nonpolyposis colorectal cancer: three years after testing. *Genet Med* 2007;9:290-297.
- Demarco T, Peshkin B, Mars B, Tercyak K. Patient satisfaction with cancer genetic counseling: a psychometric analysis of the genetic counseling satisfaction scale. *J Genet Couns* 2004;13:293-304.
- Balmana J, Sanz J, Bonfill X, et al. Genetic counseling program in familial breast cancer: analysis of its effectiveness, cost and cost-effectiveness ratio. *Int J Cancer* 2004;112:647-652.
- Griffith GL, Edwards RT, Gray J. Cancer genetics services: a systematic review of the economic evidence and issues. *Br J Cancer* 2004;90:1697-1703.
- Griffith GL, Edwards RT, Gray J, et al. Estimating the survival benefits gained from providing national cancer genetic services to women with a family history of breast cancer. *Br J Cancer* 2004;90:1912-1919.
- Hughes C, Gomez-Caminero A, Benkendorf J, et al. Ethnic differences in knowledge and attitudes about BRCA1 testing in women at increased risk. *Patient Educ Couns* 1997;32:51-62.
- Armstrong K, Calzone K, Stopfer J, Fitzgerald G, Coyne J, Weber B. Factors associated with decisions about clinical BRCA1/2 testing. *Cancer Epidemiol Biomarkers Prev* 2000;9:1251-1254.
- Kieran S, Loescher LJ, Lim KH. The role of financial factors in acceptance of clinical BRCA genetic testing. *Genet Test* 2007;11:101-110.
- Olopade OI, Fackenthal JD, Dunston G, Tainsky MA, Collins F, Whitfield-Broome C. Breast cancer genetics in African Americans. *Cancer* 2003;97(1 suppl):236-245.
- Department of Health and Human Services. Coverage and Reimbursement of Genetic Tests and Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society. Available at: [http://oba.od.nih.gov/sacghs/sacghs\\_documents.html](http://oba.od.nih.gov/sacghs/sacghs_documents.html). Accessed February 10, 2009.
- Biesecker B, Ishibe N, Hadley DW, et al. Psychosocial factors predicting BRCA1/BRCA2 testing decisions in members of hereditary breast and ovarian cancer families. *Am J Med Genet* 2000;93:257-263.
- Ropka ME, Wenzel J, Phillips EK, Siadaty M, Philbrick JT. Uptake rates for breast cancer genetic testing: a systematic review. *Cancer Epidemiol Biomarkers Prev* 2006;15:840-855.
- Codori A, Petesen GM, Miglioretti DL, et al. Attitudes toward colon cancer gene testing: factors predicting test uptake. *Cancer Epidemiol Biomarkers Prev* 1999;8:345-351.
- National Society of Genetic Counselors. National Society of Genetic Counselors, Inc. ResourceLink: National Society of Genetic Counselors, Inc. Search. Available at: <http://www.nsgc.org/resourcelink.cfm>. Accessed February 10, 2009.
- North Carolina Office of State Budget and Management. Population estimates and projections. Available at: <http://demog.state.nc.us/>. Accessed February 10, 2009.
- U.S. Census Bureau. State & County QuickFacts. Available at: <http://quickfacts.census.gov/qfd/states/37000.html>. Accessed February 10, 2009.
- Skinner C, Rawl S, Moser B, et al. Impact of the Cancer Risk Intake System on patient-clinician discussions of tamoxifen, genetic counseling, and colonoscopy. *J Gen Intern Med* 2005;20:360-365.
- Trepanier A, Ahrens M, McKinnon W, et al. Genetic cancer risk assessment and counseling: recommendations of the National Society of Genetic Counselors. *J Genet Couns* 2004;13:83-114.
- Berry DA, Iversen ES Jr, Gudbjartsson DF, et al. BRCAPRO validation, sensitivity of genetic testing of BRCA1/BRCA2, and prevalence of other breast cancer susceptibility genes. *J Clin Oncol* 2002;20:2701-2712.
- Chen S, Wang W, Lee S, et al. Prediction of germline mutations and cancer risk in the Lynch syndrome. *JAMA* 2006;296:1479-1487.
- Armstrong K, Micco E, Carney A, Stopfer J, Putt M. Racial differences in the use of BRCA1/2 testing among women with a family history of breast or ovarian cancer. *JAMA* 2005;293:1729-1736.
- Ho C. How to develop and implement a cancer genetics risk assessment program: clinical and economic considerations. *Oncol Issues* 2004;Nov/Dec:22.

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