

Pretest genetic counseling as a prerequisite for hereditary cancer testing: what do patients do?

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Introduction

To ensure informed consent and appropriate test utilization, certain health insurers require individuals seeking certain hereditary cancer (HC) genetic testing to undergo pre-test genetic counseling (GC).¹ The effect of this requirement on patient access to HC testing has not been fully studied, though one analysis found that 37% of women were completing genetic counseling sessions in advance of BRCA testing.²

As a laboratory that performs genetic analysis of BRCA genes, we sought to assess the impact of this prerequisite on completion of genetic testing among patients who are at increased risk for germline mutations.

“The intent of our genetic counseling program is to ensure that our members receive detailed and complete information about the value of the BRCA test they are seeking.”¹

—Medical Executive, UnitedHealthcare

Methods

Upon receiving a physician-ordered germline cancer test, the patient’s insurance benefits are reviewed for coverage estimates and the need for pretest genetic counseling. In this sample set, orders received for patients covered by either of two large national payers were referred to a third-party telephone-based service (“GC service”) to fulfill the counseling requirement.

Patients were contacted by the GC service to schedule an appointment. Counseling is fee-based, at a rate consistent with in-person consultations, and patients are informed of the possibility of insurance coverage for the counseling and out-of-pocket expenses.

After contact, patients may follow 1 of 3 routes:

1. Accept counseling, after which the patient may proceed with an insurance claim, elect the self-pay option (\$349), or cancel altogether.
2. Decline counseling, after which the patient may elect the self-pay option or cancel altogether.
3. Not respond after multiple contact attempts, after which the patient is automatically given the self-pay option, with few exceptions (see footnotes and results diagram).

In this analysis, we reviewed the test requisitions of 327 patients needing pretest counseling and assessed the germline mutation risk as “high” or “low” based on NCCN criteria³ (which are in general alignment with coverage criteria for the two relevant insurers). Then, patient decisions with regard to counseling, testing, and final results were tracked.

Results

All decisions are detailed in the Figure above. Noteworthy findings were:

Counseling uptake, among patients at increased mutation risk:

- 50% did not undergo pretest counseling
- In this non-counseled group, 79% (40% of total dataset) elected to undergo testing through the self-pay option
- 8% (n=20) canceled the test, with all but 1 occurring at the point of being informed of the counseling requirement
- 40% of those with positive results did not complete the pretest counseling requirement
- 40% of those with positive results utilized the self-pay option and declined insurance coverage altogether

Counseling uptake of all patients, by test result:

- Of 27 with positive results, 14 (52%) elected pretest counseling
- Of 23 with VUS, 8 (35%) elected pretest counseling
- Of 251 with negative results, 128 (51%) elected pretest counseling

Conclusions

Among all tests in this dataset, more than half of individuals did not fulfill the pretest genetic counseling requirement. Of those, the majority circumvented the requirement by waiving their potential insurance benefits and paying out-of-pocket. Perhaps more concerning, 1 in 12 physician-ordered tests were canceled outright, without genetic counseling, even though the majority of these cancellations came from patients meeting high-risk criteria of having a germline mutation.

The data here suggest that for a substantial portion of patients, the pretest counseling requirement did not meet its stated goal of delivering detailed and complete information about testing. Furthermore, some high-risk individuals may have been dissuaded from obtaining any benefit of genetic testing.

REFERENCES 1. Maas A. “UHC fine-tunes policy on genetic counseling prior to BRCA test.” URL: <https://aishealth.com/archive/nspn0116-04>. Accessed August 30, 2016. 2. Armstrong J, et al. Utilization and outcomes of BRCA genetic testing and counseling in a national commercially insured population. *JAMA Oncol* 2015; 1(9):1251-1260. 3. National Comprehensive Cancer Network. NCCN Guidelines Version 2.2016: Genetic/Familial High-Risk Assessment: Breast and Ovarian. URL: nccn.org.

FOOTNOTES

- * Risk stratifications derived from personal and family medical history provided on test requisition form and based on NCCN Guidelines for genetic and familial high-risk assessment for breast and ovarian cancer³.
- † 8 individuals at increased mutation risk did not undergo the requisite counseling but nonetheless proceeded with an insurance claim. This was done upon their request and when it was determined that coverage might still be valid.
- ** 2 individuals at increased mutation risk elected the self-pay option but ultimately did not submit a valid specimen. After a period of non-response, the test order was canceled by Counsyl. Payment was not collected.

Figure
Patient decision flow

Risk stratification*

Counseling decision

Payment decision

