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Implementation of a quality improvement project for universal genetic testing in women with ovarian cancer☆

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HIGHLIGHTS

- Improvement needed in efforts for universal testing in gynecology oncology.
- Implementation of simple measures can have large impact on achieving this goal.
- Education of providers is an effective way of impacting universal testing rates.
- Patients who see genetic counselors have a high rate of testing completion.

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ABSTRACT

Objective. The National Comprehensive Cancer Network recommends all women with ovarian cancer be offered genetic testing. Despite a decade of endorsement, many oncology practitioners have yet to make this a part of routine practice. Referral to genetic counseling and completion of genetic testing among patients at substantial risk of germline mutations are significantly lacking, adversely affecting patient care and squandering an opportunity to maximize cancer prevention efforts. This project determined the impact and feasibility of implementing a basic model for universal referral to genetic counseling and completion of genetic testing in women with a diagnosis of ovarian cancer in an academic gynecology oncology practice with access to electronic health records (EHRs).

Methods. Patients diagnosed with ovarian cancer from January 2008 to November 2013 were retrospectively reviewed to determine the baseline referral rate for genetic counseling and testing completion in our practice. Implementation of a process change model combining *provider training*, *patient education*, enhanced electronic *health record documentation* and improved patient *appointment scheduling* strategies were implemented. We then prospectively collected data on all newly diagnosed ovarian cancer patients that had not already undergone genetic testing presenting from December 1, 2013 to November 30, 2016.

Results. Genetic referral rates, genetic counseling and testing completion rates were markedly improved. Pre-implementation our genetic testing rate was 27% and post implementation our testing rate was 82% (p-value ≤ 0.001).

Conclusions. Low cost interventions that target education of both providers and patients regarding the importance of genetic testing along with utilization of the EHR and streamlined patient appointment services can significantly increase rates of genetic testing completion.

1. Background

Epithelial ovarian cancer (EOC), inclusive of fallopian tube and primary peritoneal cancers, are the leading cause of mortality from gynecologic cancers. Approximately 10–20% of high grade ovarian, fallopian tube and peritoneal cancers are hereditary [1]. Recognition of hereditary cancer syndromes serves an increasingly important role in the care of women with gynecologic cancers. Previously, testing for hereditary cancer syndromes was reserved for select patients with an extensive personal or family history of cancer. However, over 50% of individuals with a *BRCA1* or *BRCA2* gene mutations do not have a personal or family history that would fulfill clinical criteria for testing [2]. Strict adherence to family history as the main criteria for testing omits

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a significant proportion of at risk women from obtaining testing. In 2005 the United States Preventative Task Force opened the scope of eligibility and began to more formally recommend that genetic counseling and testing be offered to all at risk individuals [3]. Shortly after that, the National Comprehensive Cancer Network (NCCN) updated their guidelines in 2007 and recommended that all women with ovarian cancer and their immediate family members be offered genetic counseling and testing regardless of age at diagnosis or family history of cancer [4]. Similarly, other societies have endorsed this recommendation such as the American College of Obstetrics and Gynecology [5], American Society of Clinical Oncology and the American College of Medical Genetics [6,7]. Recently, the Society of Gynecologic Oncology issued a position statement emphasizing the importance of genetic testing for women affected by gynecologic cancers [8].

Germline mutations in *BRCA1* and *BRCA2* are reported to occur in 15–20% of ovarian cancer patients and are known to increase the lifetime risk of ovarian cancer by 20–50% and breast cancer by 50–80% [9,10]. Additional genes have been associated with homologous recombination and hereditary ovarian carcinoma including *RAD51C*, *RAD51D*, *BRIP1*, *PALB2*, as well as mismatch repair genes (*MLH1*, *MSH2*, *MSH6*, *PMS2*) which are believed to contribute an additional 2–4% of ovarian cancers [10–12]. *BARD1* may be a rare ovarian cancer susceptibility gene but more study is needed to define its absolute risk [10].

The potential benefits of identifying patients with genetic mutations continues to expand and includes offering risk reducing prophylactic measures, enhanced surveillance, individualization of prognosis for patients, potential utilization of targeted therapy, and increasingly inclusion in clinical trials. Despite these benefits, national and international studies have consistently shown low utilization of genetic counseling and genetic testing completion among ovarian cancer patients [13–21]. A recent study by Childers et al. found that only 1 in 5 women in the United States with history of breast or ovarian cancer meeting NCCN guidelines have undergone genetic testing [17].

Oncologists are a critical part of identifying, educating and referring eligible patients for genetic counseling. Identifying efficient strategies to incorporate this philosophy into practice, promote the referral to genetic counselors and strategies to enable oncologists to take a more active role in assisting the completion of genetic testing are needed. We compared historical rates of referrals to genetic counseling and completion rates of genetic testing for patients with ovarian cancer in our practice to rates of genetic counseling referrals and genetic testing completion post-implementation of the process change model. The goal of the project was to establish an efficient process for universal genetic testing for ovarian cancer patients in our practice.

2. Methods

All patients ≥18 years presenting to a single gynecologic oncology practice at an academic cancer center with a new diagnosis of non-mucinous epithelial ovarian, fallopian tube or primary peritoneal cancers from January 1, 2008 to November 30, 2016 were included in the data determining our baseline genetic referral and genetic testing completion rates. Patients with previous germline gene testing were excluded. Patients were divided into two cohorts based on when they presented: patients who presented prior to quality improvement measures to establish the baseline (Jan 2008–November 2013) and patients who presented after the implementation of quality improvement measures (December 2013–November 2016). Our model aimed at establishing a uniform practice norm for universal genetic counseling and testing in our clinic and included implementation of the following measures:

- All gynecologic oncology providers in our practice received a review of the rationale behind universal genetic testing and the current NCCN and Society of Gynecologic Oncology guidelines recommending genetic testing for all women with non-mucinous epithelial ovarian, tubal and peritoneal cancers. Review of the guidelines ensured that all providers would be able to initiate the discussion and the counseling for patients with applicable diagnoses.
- Creation of an electronic "smart phrase" (a quickly accessible standardized text) for use in the electronic health record (EHR). This "smart phrase" when added to a clinical encounter efficiently documented that the rationale behind genetic testing was reviewed and that the genetic counseling recommendation was made. Providers were educated on the use of this standard text to efficiently document in the EHR. The "smart phrase" essentially standardized and simplified documentation.
- Patient education regarding the role of genetic testing at the time of their diagnosis began as early as their initial consultation visit. An electronic "smart phrase" was also created for patient instructions. This text included the explanation of the rationale and benefits of seeking genetic counseling and testing in lay language. This text was added to all patient instructions in the EHR. These instructions were printed and given to patient at conclusion of their appointment with the after-visit summary, creating an efficient means of providing patient education.
- Scheduling of the genetic counseling appointment at the time of patient check out (point of care) from the gynecology oncology clinic was initiated to avoid delay in scheduling appointments and facilitate a more patient centered experience.
- Tumor Board conference documentation was updated as well to include whether genetic counseling was recommended, pending or completed as a part of all treatment recommendations for ovarian cancer patients. Tumor Board notes were made more comprehensive by including the recommendation for genetic testing in the final recommendations for applicable patients and were part of the patient's EHR. Genetic counselors also regularly attend and participate in our Tumor Board conferences.

3. Statistical analysis

The rates of completion of genetic counseling and genetic testing before and after the implementation measures were compiled and compared. For independent group comparisons, a non-parametric two-sided Fisher's exact test was used for the categorical variables and the Mann-Whitney test was used to compare continuous variables. Continuous variables are summarized as median (range). Unadjusted p-values < 0.05 were considered significant. SPSS version 24 (IBM Software, Chicago, IL, USA) was used to analyze the data.

4. Results

Data was collected entirely from the EHR which captures the patient's diagnosis, documentation of genetic counseling in the chart, whether a referral to genetics was placed, scheduling of appointment with genetics, completion of genetic counseling, completion of genetic testing and results of genetic testing. There are 2 cohorts; a retrospective portion (January 2008–November 2013) and a prospective portion (December 2013–November 2016). There was no statistical difference in patient age (years); 60 (26–88) vs 64 (22–85) ($p = 0.26$). In the retrospective portion of the study, 207 patients met inclusion criteria. Forty-two (20%) patients received documented education by their provider at the time of diagnosis regarding referral to a genetic counselor for genetic testing. Ninety-six (46%) patients had a referral order to genetic counseling placed by their provider at the time of initial diagnosis. Of the 207 patients, 67 (32%) were seen by a genetic counselor. Of those 67 patients counseled and seen by a genetic counselor, 55 (82%) patients underwent genetic testing. In summary, of the 207 patients eligible for genetic testing from January 2008–November 2013, only 27% (55 of 207 patients) completed genetic testing. As anticipated, our baseline referral rate and testing completion rate were poor, similar to national

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