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Title: A Structured Genetic Risk Evaluation and Testing Program in the Community Oncology Practice Increases Identification of Individuals at Risk for BRCA Mutations

Body: Background: Genetic risk assessment is an important component of the care of the community oncology breast cancer patient. However, identification of at-risk patients is largely an ad-hoc process and practices lack a systematic approach to genetic risk evaluation. The US Oncology Genetic Risk Evaluation and Testing (USON GREAT) Program provides a structured approach to implementation of genetic risk evaluation, testing, and triage for appropriate intervention.

Methods: In 2009, our multi-disciplinary community oncology practice implemented the USON GREAT Program. The practice's program has a single dedicated nurse practitioner and physician lead, trained in part through a core educational curriculum and utilizing US Oncology Network-wide genetics resources (web-based MD, midlevel, and genetic counselor conferencing; discussion Portal; published guidelines and office procedures). NCCN guidelines were used to guide testing recommendations. Sequential risk evaluations were documented prospectively. We retrospectively analyzed how evaluation patterns changed over a 4 year time period. We also sought to capture descriptive characteristics of the evaluated population.

Results: Overall, between 2008 and 2011, our practice evaluated 1018 patients at potential risk for a BRCA mutation (mut), based on personal history of breast cancer under age 50; ovarian, fallopian or peritoneal cancer; known family history of malignancy; or known BRCA mutation in the family.

Total Risk Evaluations by Year		
Year	New Patients*	Total Evaluated
2008	1116	71 (6%)
2009	1168	270 (23%)
2010	1095	353 (32%)
2011	924	324 (35%)

* Patients with DCIS, invasive breast cancer, ovarian/fallopian/peritoneal cancers

In 2008, 6% of potential at-risk individuals were identified vs 35% in 2011. NCCN guideline exclusions for BRCA testing in invasive breast cancer were 8% in 2008 and 3% in 2010.

Test Results by Diagnosis					
Diagnosis	Number Evaluated	BRCA1	BRCA2	VUS	Negative
Invasive Breast Cancer	655	24	32	20	477
DCIS	55	2	0	1	48
Ovarian/Fallopian/Peritoneal	143	16	9	5	96
Unaffected	165	12	23	6	96
Totals	1018	54	64	32	717

150 deleterious mut and variants of uncertain significance (VUS) were identified. There was an 14.7% overall identification rate for *BRCA*1/2 (B1, B2) mut and VUS. Among mut and VUS identified by cancer type, B1 mut was more commonly identified in patients with a gynecologic malignancy (53% B1 vs 30% B2, 17% VUS); mut in invasive breast cancer were more likely to be in B2 (42% B2 vs 32% B1, 26% VUS). 7% of all tests for individuals with malignancy were declined or cancelled due to insurance or finances, vs 37% for unaffecteds, despite their high risk of mutation carrier status.

Conclusions: We report a single practice's four-year experience with implementation of the US Oncology GREAT Program. The results from this experience demonstrate that the US Oncology GREAT Program results in higher rates of identification of at-risk individuals, and promotes more appropriate guidelines-based testing in the community oncology setting. The relative frequency of BRCA2 vs BRCA1 in invasive breast cancer is of unclear significance at this time and warrants further analysis. Cost of testing remains a barrier to appropriate utilization.

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