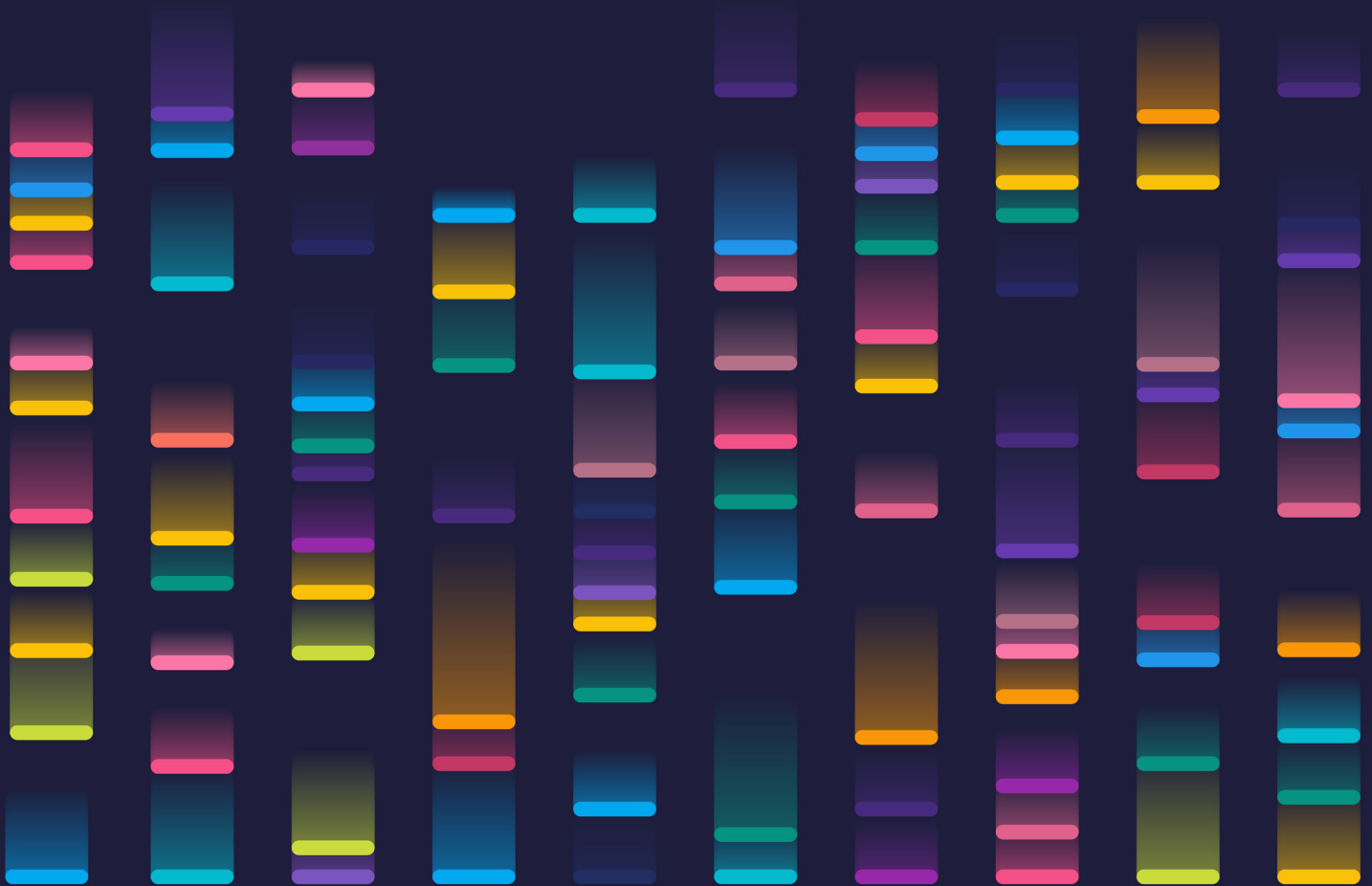


Integration and Outcomes of Universal, Multigene Panel Testing for Newly Diagnosed Breast Cancer Patients at a Community Healthcare System



Genetic testing for germline hereditary cancer syndromes has been commercially available for nearly 30 years.¹ For much of that time, testing was limited to analysis of the *BRCA1* and *BRCA2* genes alone, performed primarily in women diagnosed with early-onset breast cancers or those with a strong family history of breast and/or ovarian cancers.^{1,2} However, with the 2013 Supreme Court ruling overturning Myriad Genetics's patent on *BRCA1/BRCA2* gene testing, coupled with advances in next-generation sequencing technologies, genetic testing for hereditary cancer syndromes with multigene panels emerged.^{1,3} Yet, despite the broadening of testing panels and increased accessibility, health care practitioners still turn to published guidelines for determining which patients to refer for germline testing, thereby limiting the identification of hereditary cancer syndromes among the population.

The National Comprehensive Cancer Network (NCCN) was established in 1995 and began publishing tumor-specific guidelines that quickly became a gold standard for health care providers to help identify which patients with breast cancer should be offered germline genetic testing. With time, these guidelines have expanded, broadening not only the scope of eligibility to include testing for patients formerly discounted based on age at diagnosis, pathology, or lack of family history, but also to call for the inclusion of additional high-to-moderate risk genes beyond *BRCA1/BRCA2* on germline testing panels for patients with breast cancer.³ However, NCCN guidelines have refrained from recommending universal germline genetic testing for all these patients. In 2019, the American Society of Breast Surgeons became the first organization to release an official statement recommending that genetic testing be made available to all patients with a personal history of breast cancer regardless of age or pathologic features.⁴ Most recently, in 2024, the American Society of Clinical Oncology (ASCO) and the Society of Surgical Oncology (SSO) jointly published guidelines recommending that all women newly diagnosed with breast cancer at age 65 or younger be offered *BRCA1/BRCA2* germline genetic testing.⁵ In addition, ASCO/SSO recommend that select patients over age 65 with suggestive personal or family history, ancestry, or eligibility for poly(ADP-ribose) polymerase (PARP) inhibition therapy also be offered testing. These tests should include additional high or moderate penetrance genes when patients have supportive family histories or desire to inform personal or family cancer risk.⁵

Although multigene panel testing is now more affordable and accessible than ever, many women with a hereditary cancer predisposition syndrome remain unidentified...it is estimated that nearly 90% of those with *BRCA1/BRCA2* pathogenic germline variants have not yet been identified.

As highly regarded organizations continue to emphasize the importance of inclusive genetic testing, we have observed significant improvement with insurance coverage and reduced costs of testing, which has helped to ease financial barriers to germline testing for patients.⁶⁻⁷ Today, many labs offer complimentary targeted testing to relatives of individuals identified with pathogenic/likely pathogenic germline variants (PGVs) in a gene associated with hereditary predisposition syndrome, enabling prevention and early detection strategies for at-risk family members.

Although multigene panel testing is now more affordable and accessible than ever, many women with a hereditary cancer predisposition syndrome remain unidentified. In fact, it is estimated that nearly 90% of those with *BRCA1/BRCA2* PGVs have not yet been identified.⁸ In 2018, ASCO published data demonstrating that nearly 10% of women with a personal history of breast cancer have a PGV in a hereditary cancer gene; strikingly, half of these women failed to meet current NCCN testing criteria.⁸ Moreover, it has been demonstrated that multigene cancer panel testing is twice as likely to identify pathogenic alterations compared to *BRCA1/BRCA2* analysis alone.⁹

The timing of genetic testing is also of utmost importance. Although offering testing in a proactive setting is best to support cancer prevention and early detection, for those patients with cancer, clinical

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utility is optimized when testing is performed immediately upon diagnosis, prior to surgical intervention. When results are provided in a presurgical setting, physicians and patients can use knowledge of the presence or absence of high-risk PGVs to aid in surgical decision-making. A lack of this knowledge prior to surgical intervention may leave patients wishing they had pursued alternative surgical options, and may ultimately lead to multiple procedures.⁹ Identification of these genetic variants can also influence treatment options, with consideration of targeted treatments, such as PARP inhibitors and participation in clinical trials, providing precision oncologic care for patients.⁹ One can then also consider preventive strategies to reduce the risk of new primary cancers.

Here, we present data outcomes following the implementation of universal germline genetic testing, regardless of family history, pathology, or other historical criterion, for the newly diagnosed breast cancer population in our health care system. Our presented workflow could be considered as a model for other health care systems looking to implement universal germline genetic testing at diagnosis for patients with breast cancer.

Our Methods

We conducted a retrospective chart review analysis for all patients newly diagnosed with breast cancer between August 5, 2019, and August 5, 2022, at a community hospital in Edgewood, Kentucky. All patients were offered genetic counseling and subsequent genetic testing for hereditary cancer syndromes upon diagnosis. Patient charts were reviewed for demographic information, personal and family history of cancer, breast cancer diagnosis and treatment, and outcomes related to the offering of genetic counseling with or without genetic testing.

Genetic Counseling and Genetic Testing

In our study, patients electing to proceed with their scheduled appointment were provided a comprehensive consultation with a licensed genetic counselor. During this consultation, patients were offered genetic testing for hereditary cancer predisposition syndromes via multigene panels ranging from 37 to 93 genes analyzed by next-generation DNA sequencing, complete with gene deletion and duplication analyses. All clinical genetic testing and variant interpretation according to the American College of Medical Genetics and Genomics guidelines were performed by a

Table 1. Genes Included in Multigene Panel Testing

High Risk		Moderate Risk		Carrier Genes		
BRCA1	PTEN	ATM	NF1	BLM	NTHL1	
BRCA2	TP53	BARD1	RAD51C	MUTYH	RAD50	
CDH1	STK11	CHEK2	RAD51D	MSH3	RECQL4	
PALB2				NBN		
Other						
ABRAXA	CDK4	FANCC	KIT	PDGFRA	RET	SMARCE1
S1AIP	CDKN1B	FANCM	LZTR	PHOX2B	RINT1	SUFU
AKT1	CDKN1C	FH	MAX	PIK3CA	RUNX1	TERC
ALK	CDKN2A	FLCN	MEN	PMS2	SDHA	TERT
APC	CEBPA	GALN1	MET	POLD	SDHAF2	TMEM127
AXIN2	CTNNA1	GATA2	MITF	POLE	SDHB	TSC1
BAP1	DICER1	GPC3	MLH1	POT1	SDHC	TSC2
BMPRI1A	DIS3L2	GREM1	MRE1	PRKAR1A	SDHD	VHL
BRIP1	EGFR	HOXB13	1MSH2	PTCH1	SMAD4	WRN
CASR	EGLN1	HRAS	MSH6	RB1	SMARCA4	WT1
CDC73	EPCAM	KIF1B	NF2	RECQL	SMARCB1	XRCC2

third party, which was a CLIA-certified laboratory validated for germline genetic testing for hereditary cancer syndromes.¹⁴ All variants identified in an autosomal dominant gene associated with increased risks for developing cancer with potential impact on patient medical management were considered clinically significant PGVs.

Table 1 lists the genes included on the multigene panels used in this patient population; of note, not all genes were assessed in all cases, as testing was tailored to the unique needs of each patient. Genes tested were categorized into 4 groups based on the associated lifetime risk for breast cancer: high risk genes (50% risk or greater), moderate risk genes (10%-49% risk), other genes (autosomal dominant genes corresponding to elevated cancer risk but not evidenced for breast cancer), and carrier genes (autosomal recessive genes that have no corresponding cancer risk for the patient but could have familial or reproductive implications).

Data Review and Analysis

All patient electronic health records were manually reviewed by 2 independent study team members to extract data metrics and ensure validity. Data were recorded and stored in Research Electronic Data Capture (REDCap), a secure web application for online databases.

The primary objective was to report the workflow and outcomes associated with universal germline genetic counseling and testing in the newly diagnosed breast cancer population, with keen interest

in observing any difference between those patients who met 2020 NCCN Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic criteria compared to those who did not.

All data variables studied were binary or categorical, summarized using frequency with proportion analysis. One and 2 sample proportion methods were used for analysis of the objective. Descriptive statistics were used to describe sample demographics. Statistical analysis and interpretations were completed with assistance from the Northern Kentucky University Burkardt Consulting Center (Highland Heights, Kentucky).

Clinic Workflow

The implemented clinical workflow offering universal genetic counseling and testing to the newly diagnosed breast cancer population in this study is presented in Figure 1. In our workflow, patients are informed of the recommendation for genetic counseling at the time of disclosure of the patient’s diagnosis following breast biopsy. Pretest genetic counseling appointments occur immediately following the initial breast surgery consultation. Following completion of testing, the genetic counselor discloses the genetic testing result to the patient and communicates test results to the surgical oncologist and other medical providers. Patients are instructed to follow up directly with their surgical oncologist to finalize surgical treatment plans.

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Figure 1. Clinical Workflow for Universal Genetic Counseling Offered to All Newly Diagnosed Patients with Breast Cancer

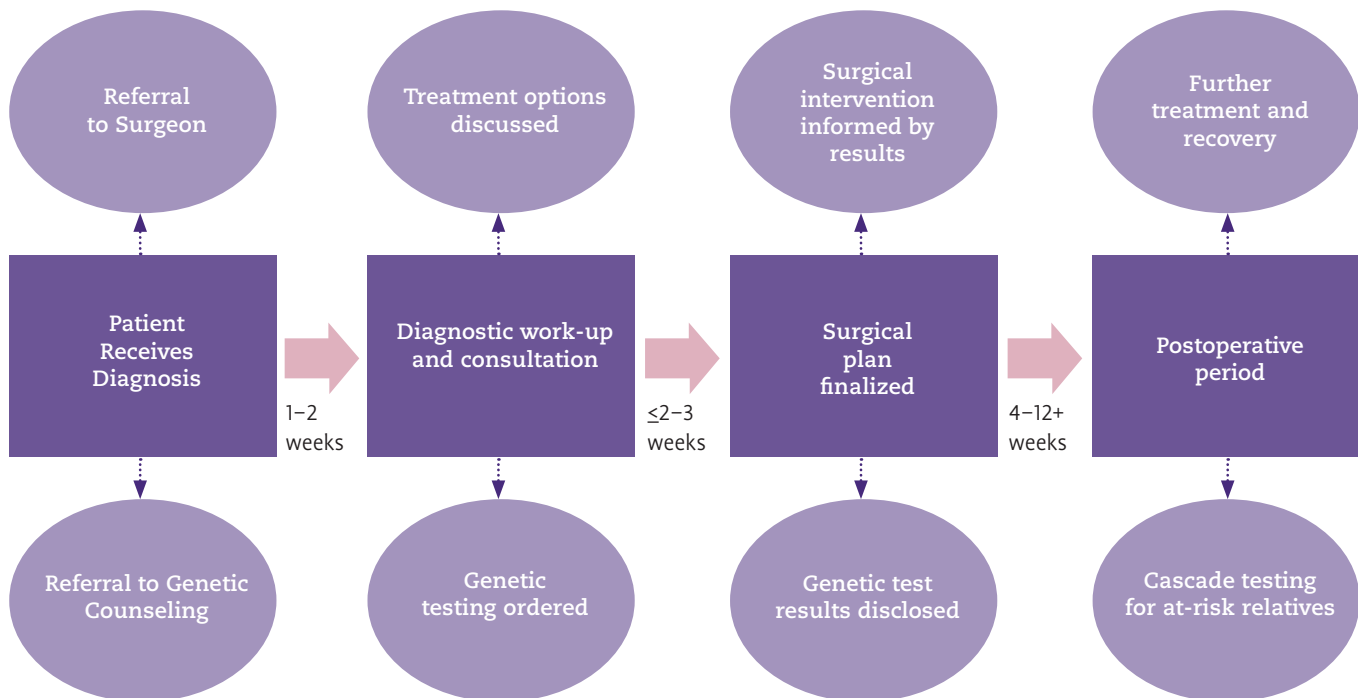


Table 2. Demographic Information for Patients Completing Genetic Testing (n=869)

SEX, % (n)	
Female	99.0% (860)
Male	1.0% (9)
RACE/ETHNICITY, % (n)	
White	93.5% (812)
Black/African American	3.3% (29)
Asian	1.3% (11)
Hispanic	1.0% (9)
American Indian and Alaskan Native	0.1% (1)
Other	0.8% (7)
AGE AT DIAGNOSIS, % (n)	
20-29	0.6% (5)
30-39	3.2% (28)
40-49	14.7% (128)
50-59	19.8% (172)
60-69	32.3% (281)
70-79	21.8% (189)
80-88	6.9% (60)
89+	0.7% (6)

Table 3. Pathologic Characteristics of Breast Cancer Diagnoses in Patients Completing Genetic Testing

TYPE OF BREAST CANCER, % (n)		BREAST CANCER PATHOLOGY, % (n)	
Invasive ductal carcinoma (IDC)	76.3% (663)	ER/PR+ HER2-	73.9% (490)
		ER/PR- HER2+	4.1% (27)
		ER/PR/HER2-	14.2% (94)
		ER/PR/HER2+	7.8% (52)
Ductal carcinoma in situ (DCIS)	11.7% (102)	ER/PR+	85.3% (87)
		ER/PR -	14.7% (15)
Invasive lobular carcinoma (ILC)	10.7% (93)	ER/PR+ HER2-	89.7 (87)
		ER/PR- HER2+	2.2% (2)
		ER/PR/HER2-	1.1% (1)
		ER/PR/HER2+	3.2% (3)
Other*	1.3% (11)	ER/PR+ HER2-	54.6% (6)
		ER/PR- HER2+	9.1% (1)
		ER/PR/HER2-	36.4% (4)

*Includes all breast cancer types not listed above (adenoid cystic carcinoma, invasive mucinous carcinoma, invasive secretory carcinoma, malignant phyllodes tumor, metaplastic carcinoma and 2 patients with both IDC and ILC tumors)

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Our Results

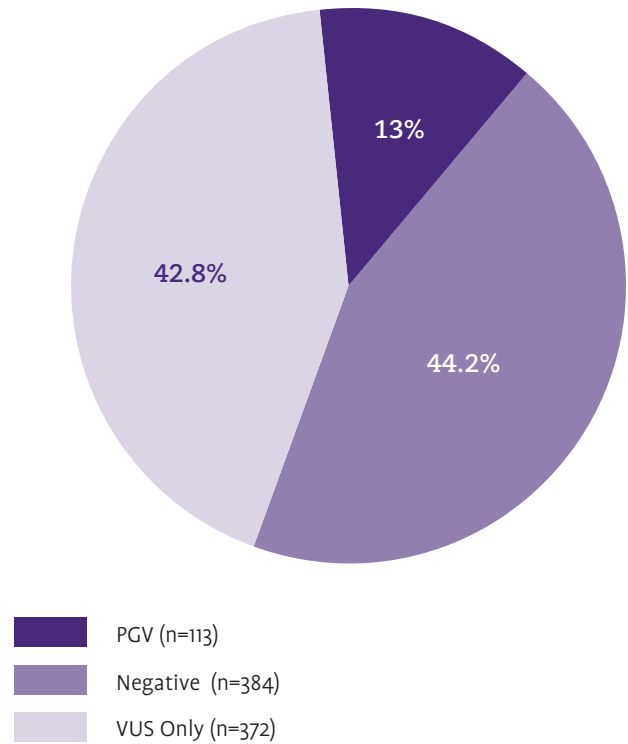
Patient Population

In total, 1002 patients were newly diagnosed with breast cancer between August 5, 2019, and August 5, 2022. All patients were offered genetic counseling and subsequent genetic testing. In total, 912 (91.0%) patients elected to have genetic counseling and 869 (86.7%) patients completed genetic testing. Of those who declined genetic testing (n=133), 39 (29.3%) reported having completed genetic testing previously. Although the reason for declining genetic counseling or testing was not always documented in the patient chart, additional reasons for declining testing included financial concerns (n=6), feeling overwhelmed (n=9), and lack of understanding of the importance of genetics (n=8). Demographic information for patients who completed genetic counseling with testing is presented in Table 2, while Table 3 summarizes breast cancer pathology.

Genetic Test Results

All patients pursuing genetic testing for hereditary cancer syndromes were offered multigene panel testing based on individual risk assessment; thus, gene panel size varied. In total, 83.9% (n=729) of patients completed testing with an 84 gene panel, 3.7% (n=32) had a 93 gene panel, 11.6% (n=101) had a 77 gene panel, and 0.8% (n=7) had other genetic panels with a minimum of 37 genes analyzed. Figure 2 displays patient testing outcomes. In total, 123 PGVs were identified among 113 patients. Ten of these patients (8.8%) had more than 1 PGV identified, with 6 patients having PGVs in multiple clinically significant genes, and 4 patients with 1 clinically significant PGV and 1 PGV in an autosomal recessive gene (carrier only). Twenty-seven patients (23.9%) with PGVs also had a variant of uncertain significance; these patients were classified as PGV, while patients with only variant of uncertain significance findings were classified as variant of uncertain significance only. Table 4 summarizes the specific genes with PGVs identified in this cohort.

Figure 2. Patient Testing Outcomes Categorized by Result Type



NCCN Criteria, Family History, and Age

Of the 869 patients tested, 488 (56.2%) met NCCN criteria. Among patients with clinically significant genetic results, 58 of the 86 (67.4%) met NCCN criteria. Furthermore, 64 patients (74.4%) with clinically significant PGVs reported a family history of cancer relevant to their specific genetic result; reported family history of nonmelanoma skin cancers were excluded and not considered relevant to patient PGVs.

Table 4. Identified PGVs (n=123) With Multigene Panel Testing

GENE CATEGORY	GENE (# of likely pathogenic/pathogenic variants identified)	PERCENTAGE OF TOTAL VARIANTS IDENTIFIED (n=123)
High risk	BRCA1 (7), BRCA2 (9), PALB2 (9), TP53 (3)	22.8% (n=28)
Moderate risk	ATM (10), BARD1 (2), CHEK2 (21), NF1 (3), RAD51D (1)	30.0% (n=37)
Carrier	MUTYH (19), NTHL1 (4), BLM (2), MSH3 (2), RECQL4 (1), NBN (1), RAD50 (2)	25.2% (n=31)
Others	PMS2 (2), MSH6 (3), BRIP1 (2), CDKN2A (2), EGFR (1), FH (3), HOXB13 (5), MITF (2), RET (1), RUNX1 (1), SDHA (3), TSC2 (1), FANCC (1)	22.0% (n=27)

Table 5. Rate of Positive Family History and Meeting NCCN Criteria Among Patients With Clinically Significant Results* (n = 86), % (n)

Gene category	Patients with a family history of cancer	Patients meeting NCCN criteria
High risk (28)	82.1% (23)	78.6% (22)
Moderate risk (34)	82.4% (29)	67.6% (23)
Others (24)	50% (12)	54.2% (13)

*Data are presented at the patient level; patients with multiple PGVs are categorized based on the variant that corresponds to the highest cancer risks.

Table 6. Patients by Age of Diagnosis as a Percentage of Total Patients With Gene Category Results, % (n)

Age at diagnosis (n = 869)	Total number of patients with clinically significant results (n = 86)	High risk (n = 28)	Moderate risk (n = 34)	Other (n = 24)
20-29 (5)	0% (0)	0% (0)	0% (0)	0% (0)
30-39 (28)	5.8% (5)	14.3% (4)	2.9% (1)	0% (0)
40-49 (128)	8.1% (7)	10.7% (3)	5.9% (2)	8.3% (2)
50-59 (172)	25.6% (22)	32.1% (9)	23.5% (8)	20.8% (5)
60-69 (281)	30.2% (26)	39.3% (11)	29.4% (10)	20.8% (5)
70-79 (189)	23.3% (20)	3.6% (1)	32.4% (11)	33.3% (8)
80-88 (60)	7.0% (6)	0% (0)	5.9% (2)	16.7% (4)
89+ (6)	0% (0)	0% (0)	0% (0)	0% (0)

Table 5 displays the rate of positive family history and rate of meeting NCCN criteria among those with high-risk, moderate-risk, and other clinically significant PGVs. Note: **Table 5** is presented at the patient level; patients with multiple PGVs are categorized based on the variant that corresponds to the highest cancer risks.

Table 6 displays clinically significant PGVs grouped by age. The average age of the total population, and of those with a positive result, was 62 years. Nearly 19% (161/869) of all patients tested were under age 50, but of those with a clinically significant result, only 13.9% (12/86) of patients were under age 50.

Impact on Treatment

The impact of identifying a PGV on medical management of a patient's breast cancer was evidenced by either prescription of PARP inhibitor therapy and/or elected bilateral mastectomies in the setting of unilateral disease. As such, 4 patients with bilateral disease and clinically significant PGV were excluded from this analysis. Chart review of the 58 patients with PGVs in high-risk or moderate-risk breast cancer genes demonstrated impact on treatment in 25 (43.1%) cases. Specifically, the PGVs identified among these patients were

present in *BRCA1* (7), *BRCA2* (6), *PALB2* (6), *CHEK2* (4), *TP53* (1), and *BARD1* (1).

Discussion

As new data continue to emerge demonstrating outcomes of universal germline testing practices in various tumor types, this study finds that 9.9% (86/869) of patients newly diagnosed with breast cancer harbor a PGV in an autosomal dominant cancer predisposition gene. This yield aligns with traditional estimations that 5% to 10% of cancer is hereditary.⁴ If autosomal recessive genes are also considered, 13.0% (113/869) of patients newly diagnosed with breast cancer harbor a PGV in a cancer predisposition gene, which is in line with findings from other studies assessing outcomes of multigene panel testing.^{9,15-18} Of those tested and found to have a PGV, 76.1% (86/113) had a clinically significant variant in a high- to moderate-risk breast cancer gene or other dominantly inherited cancer risk gene potentially impacting medical management, either pertaining to the current diagnosis or for risk reduction measures of other cancer types.

Although *BRCA1/BRCA2* are thought to be responsible for the majority of inherited breast cancer, only 18.6% (16/86) of patients

with a clinically significant PGV in our study had a variant in *BRCA1/BRCA2*, while 24.7% (21/86) of patients had a PGV identified in *CHEK2*. This is contrary to reports of *BRCA1/BRCA2* PGVs accounting for 60% of all hereditary breast cancer.¹⁹⁻²¹ In fact, among those with a clinically significant PGV, 81.4% (70/86) of patients had a PGV in a non-*BRCA1/BRCA2* cancer gene, which represents 8.1% of the total population tested (70/869). Similar pickup rates have been observed in other studies using multigene panel testing, where a substantial number of patients with hereditary PGVs would have been missed with *BRCA1/BRCA2* genetic testing alone.¹⁷⁻¹⁸ This finding is concerning given that recently published ASCO-SSO guidelines specifically recommend only *BRCA1/BRCA2* germline testing for patients aged 65 years and younger, where “high-penetrance cancer susceptibility genes beyond *BRCA1/BRCA2* should be offered to those with supportive family histories” and “testing for moderate-penetrance genes may be offered if necessary to inform personal and family cancer risk.”⁵ What seems like a significant, progressive step forward at first glance (expanding accessibility to germline testing to all women with breast cancer up to age 65) is quickly reduced by limiting this recommendation to *BRCA1/BRCA2* testing alone. Our data suggest that not only should multigene panels be offered to all patients with breast cancer who seek germline testing, but patients who were offered only *BRCA1/BRCA2* germline testing in the past, especially those with negative germline results, should be offered updated multigene panel testing.

The implementation of a universal testing protocol leads to the identification of a greater number of individuals with hereditary predisposition, allowing for optimal, well-informed treatment and prevention strategies that extend beyond patients to their at-risk relatives.

Providers turn to medical guidelines to ensure appropriate practices when recommending genetic testing to their patients. NCCN has led the charge in this area and has provided updated guidelines on a consistent basis. Although these guidelines have evolved over time to be more inclusive, criteria related to age and family history parameters continue to be foundational to the recommendation for germline testing. Examining our cohort, we found approximately half of all patients, 488/869 (56.2%) met NCCN criteria, and among patients with clinically significant PGVs, 58/86 (67.4%) met NCCN criteria. Strikingly, nearly a third of patients, 28/86 (32.6%), with a clinically significant PGV would not have been offered genetic testing outside of the practice of universal testing. Moreover, if we look specifically at age, while nearly 19% of all patients tested in our cohort were under age 50 (161/869), only 13.9% (n=12) of patients

with clinically significant PGVs were under age 50; even patients in the eighth decade of life were found to have clinically significant PGVs (7.0%, 6/86).

Furthermore, taking reported family history into consideration, we found that 64/86 (74.4%) patients with a clinically significant PGV reported a family history of cancer consistent with their specific genetic result. Therefore, approximately one-fourth of patients with a clinically significant PGV, 22/86 (25.6%), did not have a related family history of cancer. In the absence of universal testing with multigene panels, providers who exclusively follow guidelines, such as those from the NCCN, will continue to miss a quarter of patients with hereditary cancer syndromes. Traditional NCCN guidelines provided practitioners with much needed clinical guidance in the early days of *BRCA1/BRCA2* discovery and single-gene testing. However, given the advances of next-generation sequencing technology and multigene panels, it is reasonable to question whether current NCCN breast cancer germline genetic testing guidelines are antiquated and should be updated to recommend universal germline testing for all patients with breast cancer, as the NCCN has done with other tumor-specific guidelines (ie, colon²², pancreatic, metastatic prostate, and epithelial ovarian cancers²³).

Regarding clinical workflow, offering genetic counseling and testing at or near the time of diagnosis is paramount. When testing is initiated shortly after diagnosis, the patient and surgical oncologist have more time and information when considering optimal care in avoiding treatment delays, surgical consideration, and avoidance of multiple procedures in the setting of a PGV in a high-risk breast cancer gene.⁹ In our study, for patients with a moderate or high-risk PGV, we found 43.1% impact on treatment, with 25/58 individuals receiving modified, personalized treatment based on the positive gene findings, including the addition of PARP inhibitors and/or elected mastectomy when lumpectomy was otherwise recommended. Other studies have demonstrated similar rates; however, Whitworth et al. demonstrated change management in up to 75% of women with breast cancer and positive genetic test results.²⁴ These data emphasize the importance of offering genetic testing at diagnosis so that results of genetic testing can be incorporated into surgical decision-making and optimal therapy selection, potentially avoiding the need for further risk-reducing breast surgery in the future, while optimizing outcomes.

Although our study outlines a traditional model for in-person, pretest genetic counseling, we recognize that not all community health systems, particularly those in nonmetropolitan areas, will have adequate genetic counseling resources available. However, this should not deter health care systems from considering universal testing for all newly diagnosed breast cancers, especially given the overwhelming evidence that 95.3% (869/912) of newly diagnosed patients opt to proceed with genetic testing. This uptake rate is far greater than the 52% to 59% uptake rate reported in other studies.²⁵⁻²⁷ Knowing patient interest is abundant, health care providers treating patients for breast cancer should be in favor of reducing barriers and improving access to genetic testing. With genetic counseling alternative service delivery models and the advent of AI tools,²⁸⁻³⁵ we encourage all community hospitals to identify their unique barriers to implementation of universal germline breast cancer testing and consider exploring

outside-the-box options if resources are limited and/or genetic counseling recruitment is challenging.

Limitations

Limitations of this study include our rather uniform patient cohort, which was 99.0% (n=860) female and 93.4% (n=812) White. The noted genetic testing uptake rates and outcomes may not reflect that of an ethnically diverse population. We were also challenged by the number of study participants, which limited our capabilities of statistical subanalysis. In addition, there was a lack of uniformity regarding the panel ordered for patients; although multigene panel testing was offered to all patients, the panel ordered was dependent on the personalized assessment. Some patients may not have received as robust a genetic analysis as others and, therefore, may harbor a genetic variant in a gene not analyzed.


While we were interested in assessing changes in management related to genetic findings, due to our study methodology, we were limited to reporting bilateral mastectomy in the presence of unilateral disease and the prescription of PARP inhibitors only. In our study, only 16 patients carried a *BRCA1/BRCA2* PGV for consideration of PARP therapy. As such, the reported impacts on management have likely been underestimated, as many patients with a clinically significant PGV are likely to receive care related to management of other cancer risks, such as ovarian, colon, or others, that correspond to their genetic finding.

Future Studies

The uptake rate for genetic counseling and testing was incredibly high among our population. It would be of interest to study the practices of our clinic's surgical oncologist to see if their delivery for recommending genetic counseling and/or their discussion with how such results would impact surgical decision-making has a bearing on the uptake rate of genetic testing. We also call for other community hospitals to institute and publish their efforts for universal germline testing of all newly diagnosed breast cancer patients, especially those with genetic counseling alternative service delivery, so best practices can be established. In addition, the study of cascade testing outcomes among this population would be of interest, especially when thinking about differences in uptake rates between those with high-risk PGVs versus those with moderate or other clinically significant PGVs.

Concluding Thoughts

This study adds to the growing body of literature supporting universal germline genetic testing through multigene panel analysis for all patients newly diagnosed with breast cancer, regardless of age or family history. The feasibility and success of offering universal germline testing to the newly diagnosed breast cancer population in a community hospital setting is demonstrated. The implementation of a universal testing protocol leads to the identification of a greater number of individuals with hereditary predisposition, allowing for optimal, well-informed treatment and prevention strategies that extend beyond patients to their at-risk relatives. Our reported clinical workflow can be used as a model

for other health care providers who practice in a community-based setting and are looking to establish universal testing in their breast cancer clinics and/or encourage adoption of alternative service delivery models for genetic counseling in the absence of having genetic counselors on staff. All community hospitals should consider implementing standardized universal genetic testing workflows to support the identification of PGVs among patients at risk for hereditary cancer syndromes. 

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