Integration of Genetic Testing and Counseling in Patients With Breast Cancer in a Large, Multisite Community-Based Practice

Molly A. Mendenhall, RN, BSN[1]; Andrew Guinigundo, APP[2]; Dan Davies, BS[1]; Patrick Ward, MD, PhD[1]; David R. Drosick, MD[1]; and David M. Waterhouse, MD, MPH[1]

DOI https://doi.org/10.1200/OP.22.00794

ABSTRACT

PURPOSE Despite data-driven consensus recommendations, there remains significant nonadherence to genetic screening and testing. More than 300,000 patients are diagnosed with breast cancer annually, with one third of these estimated to be eligible for homologous recombination deficiency (HRD)/BRCA testing following National Comprehensive Cancer Network (NCCN) guidelines. Only 35% of eligible patients are referred for genetic counseling.

METHODS The goal of this project was to apply NCCN guidelines for germline genetic testing to all new patients with breast cancer within a large community oncology practice to improve HRD/BRCA testing. Plan-Do-Study-Act methodology was used, and cycles were built on a proven teaching infrastructure. In cycle 1, providers were educated and directed to use electronic health record (EHR) templates in the setting of an initial diagnosis visit and treatment planning. Discreet data fields were created in the EHR during cycle 2 to streamline and automate the process. Appropriate patients were referred to the genetics team for further evaluation, counseling, and testing. Adherence to the plan was maintained and measured using data analytic reports and chart audits.

RESULTS Of the 1,203 patients with breast cancer eligible for inclusion, 1,200 (99%) were screened according to NCCN guidelines. Of the screened patients, 631 (52.5%) met the referral/testing criteria. In total, 585 (92.7%) of the 631 were referred to a genetic specialist. Seven percent had previous referrals. A total of 449 (71%) patients were acceptable to genetics referral while 136 (21.5%) patients refused.

CONCLUSION The implemented methods of education, NCCN guidelines imbedded within provider notes, and discreet data fields in the EHR have proven to be highly effective in screening appropriate patients and ordering subsequent genetic referrals.

ACCOMPANYING CONTENT

Accepted May 22, 2023
Published June 27, 2023

JCO Oncol Pract 00:1-6

View Online Article

INTRODUCTION

Despite data-driven consensus recommendations, local and national data suggest significant nonadherence in genetic screening, counseling, and testing. More than 300,000 patients are diagnosed with breast cancer annually in the United States, with one third of these estimated to be homologous recombination deficiency (HRD)/BRCA-testing eligible following the National Comprehensive Cancer Network (NCCN) guidelines.[1,2] Only 35% of these eligible patients are being referred for genetic counseling and testing.[3] Referral and testing rates are even lower among historically underserved and under-represented populations.[4-6] Lack of adherence to evidence-based clinical practice guidelines (CPGs) has been well recognized and is not unique to breast cancer genetic screening. After a large, comprehensive systematic review, Bierbaum et al identified four themes related to barriers to clinical practice guideline (CPG) directed adherence: (1) concern over CPG content and currency; (2) concern about the evidence underpinning CPGs; (3) clinician uncertainty and negative perceptions of CPGs; and (4) organizational and patient factors. In addition, four themes were identified as facilitating CPG adherence: (5) CPG accessibility and ease of use; (6) endorsement and dissemination of CPGs and adequate access to treatment facilities and resources; (7) awareness of CPGs; and (8) belief that CPGs support decision making, improve care, reduce clinical variation, and reduce costs.[7]

METHODS

Oncology Hematology Care (OHC), a large independent, community-based oncology practice, was awarded a 2-year

CONTEXT

Key Objective

The goal of this project was to assure that National Comprehensive Cancer Network (NCCN) guideline compliant germline genetic testing (homologous recombination deficiency/BRCA) was made available to all new patients with breast and/or metastatic breast cancer within a large community oncology practice.

Knowledge Generated

The implemented methods of education, awareness, NCCN guidelines within provider notes, and discreet data fields in the EHR proved to be highly effective at screening appropriate patients, ordering, and obtaining subsequent breast cancer genetic testing, with 93% of eligible patients receiving a genetics referral. The halo effect of an increase in nonbreast genetics appointments is encouraging.

Relevance

The importance of germline genetic testing continues to grow in significance. Education and improved processes heightened awareness of the providers to the value of genetic screening resulting in increased NCCN guidelines adherence. Successful implementation of the reported standardized workflows and discrete data fields in the EHR provide a feasible, scalable, and financially viable solution.

quality improvement (QI) grant to integrate appropriate breast genetic NCCN guidelines for all new patients with breast cancer. The OHC baseline referral rate to genetics was estimated. During the 6 months before the grant submission (January 1, 2018-July 31, 2018), OHC provided care to 388 new patients with breast cancer. Presuming that 35.6% of these patients would have met the NCCN guidelines for genetic testing, we would have expected 138 genetic counseling referrals. Only 28 of the 388 new patients had referrals for testing, suggesting a baseline referral/testing rate of approximately 7% (28 of 388).

The project design builds on a proven infrastructure put in place to support the Oncology Care Model program.[8] All new patients with cancer receive comprehensive teaching with their care team centered around the advanced practice providers.[9] Plan-Do-Study-Act methodology was used to integrate a genetic screening component into the current processes. At project start-up, OHC added the NCCN breast genetic guidelines to every provider's New Breast Cancer Patient Note. The template included the Genetic/Familial High-Risk Assessment for Breast and Ovarian NCCN Guidelines for BRCA testing[10] (Fig 1). The template was designed such that it could be updated, when indicated, as NCCN guidelines are modified and expanded. Care teams were provided comprehensive education on the current NCCN guidelines, testing recommendations, template implementation, workflow changes, and compliance expectations. During cycle 1 of the QI project, this template was used for all patients with newly diagnosed breast cancer. At the initial patient visit, physicians had the opportunity to manually enter the data. Advanced practitioners were also given this responsibility and expected to confirm that the template was complete, and a genetics referral was made at any subsequent teaching visit.

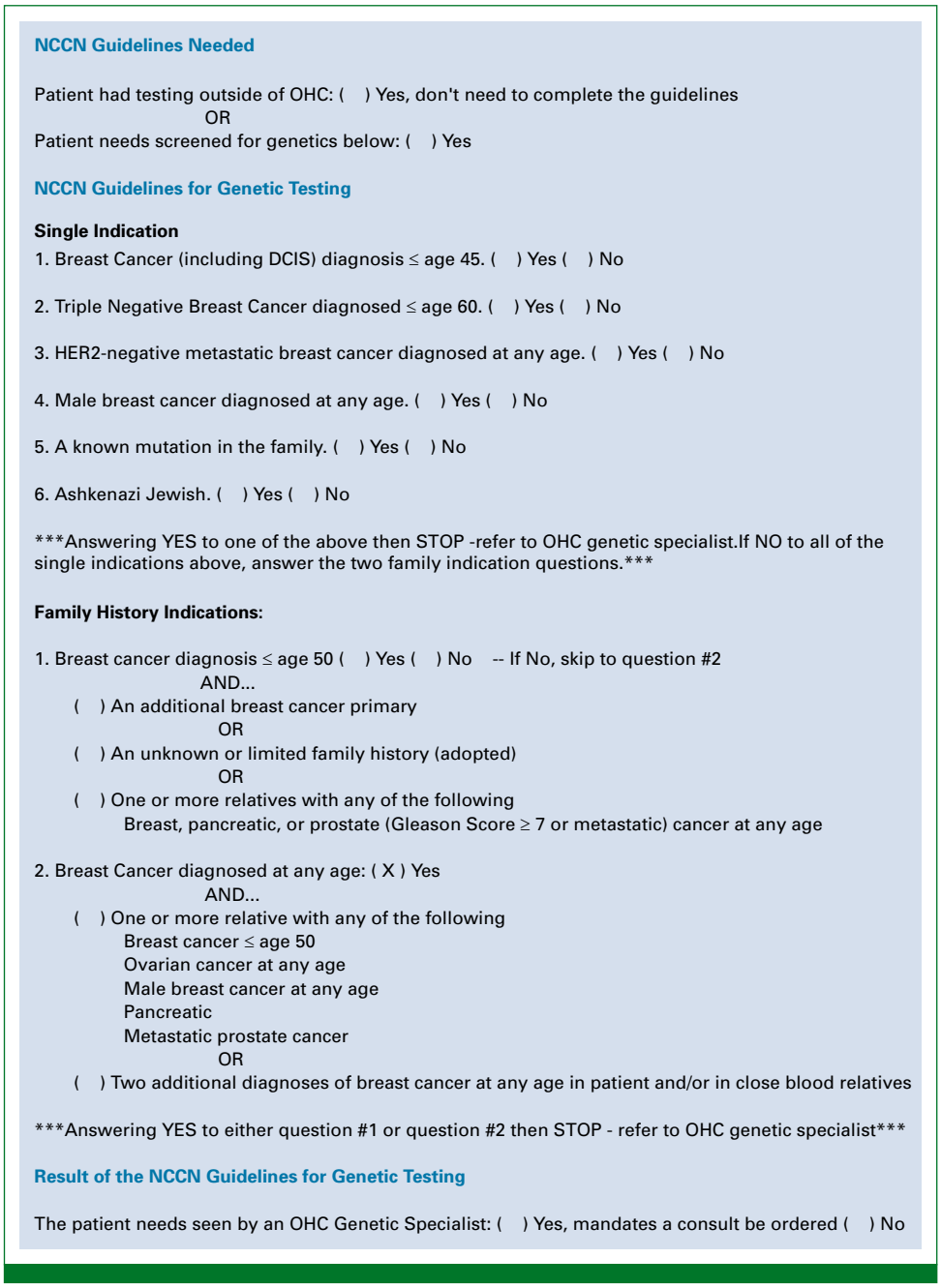
During cycle 2, OHC partnered with McKesson and The US Oncology Network to create structured data fields in the US Oncology Electronic Health Record (EHR) (IKnowMed G2).[11,12] The goal was to establish reliable, reproducible, and measurable metrics using structured EHR data fields. The structured fields were designed to automate the data collection and auditing processes. With the discreet data fields built into the EHR, providers were able to document the NCCN breast guidelines using radio dial buttons versus manual documentation.

The genetics team also conducted weekly audits to verify that providers screened all appropriate patients with breast cancer following the NCCN guidelines. During both project cycles, reminder notifications and additional provider education took place with providers who had missed completing the template or were nonadherent to the guidelines. Patients who met the NCCN guidelines were then, with prior universal consent of their providers, reflexively referred to one of OHC's genetic specialists and offered genetic testing as indicated.

RESULTS

Over the 2-year study period, 1,527 new patients with breast cancer and/or metastatic breast cancer were observed at OHC. Of this population, 324 patients were excluded because of either a diagnosis date out of the range of the study or a diagnosis out of the included criteria. This resulted in a total QI project breast cancer population of 1,203 patients who were included in the final grant project (Fig 2).

Of the 1,203 new patients with breast cancer, 1,200 (99.8%) were screened using the current NCCN breast guidelines. Of those patients screened, 631 (52.5%) required an NCCN compliant referral to a genetic specialist for HRD/BRCA



NCCN Guidelines Needed

Patient had testing outside of OHC: ( ) Yes, don't need to complete the guidelines
OR
Patient needs screened for genetics below: ( ) Yes

NCCN Guidelines for Genetic Testing

Single Indication

1. Breast Cancer (including DCIS) diagnosis ≤ age 45. ( ) Yes ( ) No

2. Triple Negative Breast Cancer diagnosed ≤ age 60. ( ) Yes ( ) No

3. HER2-negative metastatic breast cancer diagnosed at any age. ( ) Yes ( ) No

4. Male breast cancer diagnosed at any age. ( ) Yes ( ) No

5. A known mutation in the family. ( ) Yes ( ) No

6. Ashkenazi Jewish. ( ) Yes ( ) No

Answering YES to one of the above then STOP -refer to OHC genetic specialist.If NO to all of the single indications above, answer the two family indication questions.

Family History Indications:

1. Breast cancer diagnosis ≤ age 50 ( ) Yes ( ) No -- If No, skip to question #2
AND...
( ) An additional breast cancer primary
OR
( ) An unknown or limited family history (adopted)
OR
( ) One or more relatives with any of the following
Breast, pancreatic, or prostate (Gleason Score ≥ 7 or metastatic) cancer at any age

2. Breast Cancer diagnosed at any age: (X) Yes
AND...
( ) One or more relative with any of the following
Breast cancer ≤ age 50
Ovarian cancer at any age
Male breast cancer at any age
Pancreatic
Metastatic prostate cancer
OR
( ) Two additional diagnoses of breast cancer at any age in patient and/or in close blood relatives

Answering YES to either question #1 or question #2 then STOP - refer to OHC genetic specialist

Result of the NCCN Guidelines for Genetic Testing

The patient needs seen by an OHC Genetic Specialist: ( ) Yes, mandates a consult be ordered ( ) No

FIG 1. Initial breast cancer genetic testing template. DCIS, ductal carcinoma in situ; HER2, human epidermal growth factor receptor 2; NCCN, National Comprehensive Cancer Network; OHC, Oncology Hematology Care.

testing, with 585 (92.7%) patients receiving the referral. Forty-six (7.2%) patients were not referred, primarily because they had already been referred by their treating surgeon. Providers reported that the screening process and data entry usually required no more than 5-10 minutes. Among the 585 patients with breast cancer who were referred to a genetic specialist, another 136 (23.3%) refused their appointment with a genetic specialist for to a variety of reasons, including future genetic appointments outside of the grant window, patients who died before appointment or testing, patient requesting to move appointments back because of COVID, or other undocumented patient issues. Ultimately, 449 (71%) of the 631 patients requiring a NCCN compliant referral completed their genetics evaluation and were genetically tested where appropriate.

An unplanned effect of the study was the halo effect on other cancer diagnoses. Despite the coronavirus pandemic slowdown, there was a 130% increase in nonbreast genetic appointments over the course of the grant. Evaluating the

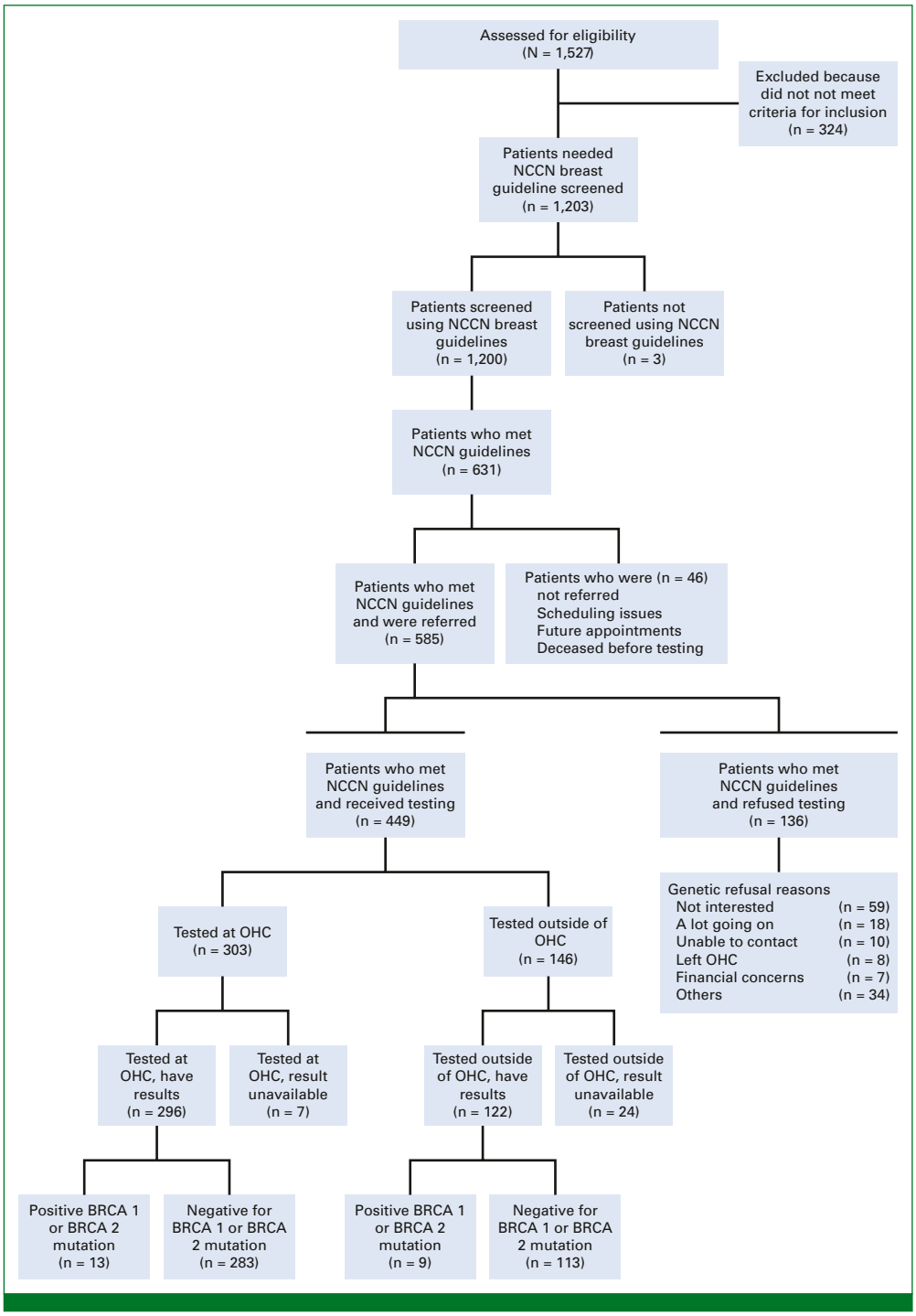


FIG 2. Flow diagram. NCCN, National Comprehensive Cancer Network; OHC, Oncology Hematology Care.

overall financial feasibility of the model, we found that the program growth in breast cancer and other actionable diagnoses resulted in a 136% increase in billed charges from baseline to the end of the 2-year study period.

DISCUSSION

Until recently, the results of germline genetic testing informed prognosis, risk stratification, and surgical decision making. With the recent publications of data sets demonstrating positive results using therapies targeting specific mutations across multiple malignancies, the importance of germline genetic testing only grows in significance.[13]

The national average for patients with breast cancer who meet NCCN breast guidelines for HRD/BRCA genetics referral is estimated at 35.6%. At the end of the 2-year grant period, OHC was able to achieve a 92.7% referral rate for those

patients who met NCCN breast guidelines and recommended to see a genetic specialist. We were then successful at completing a genetics evaluation in 449 (37.3%) of 1,203 patients with breast cancer seen, representing 71% of the 631 patients requiring a NCCN compliant referral. The guideline-driven HRD/BRCA genetics referral rate of 71% represents a remarkable increase over our estimated historic rate of 7% and significantly higher than the national average. The genetics appointment refusal rate of 23.3% merits further investigation.

Physicians were initially a bit slow to adopt and complete the template and to order the genetics referral. However, the advanced practice providers were quick to capture these failures and assure near 100% compliance with screening and genetics referral. Very few patients were not screened or referred appropriately for a genetics evaluation after their initial consult and subsequent teaching visit. The greatest value of the genetics team audits was the ability to identify the provider failures, largely physician, and direct additional teaching. Simply using a custom template advising best practices and creating a simple check on compliance will likely result in significant improvement.

OHC found that education and improved processes heightened awareness of the providers of the importance of genetic screening resulting in increased NCCN guideline adherence. We suspect that this awareness might have also triggered the increased non-breast cancer genetic referrals. The 130% increase in non-breast genetic appointments over the course of the grant was encouraging.

OHC serves the entire Cincinnati Tri-State area, allowing for cancer care provisions for the medically underserved populations. Our quality initiative was directed at all patients within our large, diverse community–based practice. With 92.7% of our patients receiving an appropriate NCCN compliant genetics referral, we can suggest the methodology that does reflect the population of patients we serve.

Successful implementation of these standardized workflows and discrete data fields in the EHR provide a potential scalable solution that could be deployed to additional US Oncology Network practices and non-US Oncology Network practices. Structured data fields support the capturing of potential genetic testing patients—not only for patients with breast cancer but, in the future, also for other disease states such as ovarian and prostate cancer.

A limitation of the study is the recognition that not all practices have immediate access to a genetics specialist team. Multiple efforts are ongoing to improve such access including telehealth, collaboration with nongenetics health care providers, and technological solutions to maximize efficiency and access.[14]

The implemented methods of education, awareness, NCCN guidelines within provider notes, and discreet data fields in the EHR proved to be highly effective at screening appropriate patients, ordering, and obtaining subsequent genetic testing. The program's growth and financial return outweighed the investment for training and certification of additional genetic specialists confirming the financial feasibility, profitability, sustainability, and potential for scaling of the model in both community oncology and academic settings.

AFFILIATIONS

[1]Oncology Hematology Care (OHC), Cincinnati, OH
[2]Cincinnati Cancer Advisors, Cincinnati, OH

CORRESPONDING AUTHOR

David M. Waterhouse, MD, MPH, Director, Early Phase Clinical Trials, OHC (Oncology Hematology Care), 4350 Malsbary Rd, Cincinnati, Ohio 45242; e-mail: David.waterhouse1@usoncology.com.

PRIOR PRESENTATION

Presented as poster and slide at ASCO Quality Symposium, September 24-25, 2021.

SUPPORT

Funded through a 2-year grant supported by ACCC/Pfizer.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI https://doi.org/10.1200/OP.22.00794.

AUTHOR CONTRIBUTIONS

Conception and design: Molly A. Mendenhall, Andrew Guinigundo, Patrick Ward, David R. Drosick, David M. Waterhouse
Administrative support: Dan Davies, David R. Drosick
Provision of study materials or patients: Patrick Ward
Collection and assembly of data: Molly A. Mendenhall, Andrew Guinigundo, Dan Davies, Patrick Ward, David M. Waterhouse
Data analysis and interpretation: Molly A. Mendenhall, Andrew Guinigundo, Dan Davies, Patrick Ward, David M. Waterhouse
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

REFERENCES

1. American Cancer Society: Breast Cancer Facts and Figures. 2017. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2017-2018.pdf
2. Childers C, Childers K, Maggard-Gibbons M, et al: National estimates of genetic testing in women with a history of breast or ovarian cancer. J Clin Oncol 35:3800-3806, 2017
3. Chun D, Berse B, Venne V, et al: BRCA testing within the department of veterans affairs: Concordance with clinical practice guidelines. Fam Cancer 16:41-49, 2017
4. Jagsi R, Griffith KA, Kurian AW, et al: Concerns about cancer risk and experiences with genetic testing in a diverse population of patients with breast cancer. J Clin Oncol 33:1584-1591, 2015
5. McCarthy AM, Bristol M, Domchek SM, et al: Health care segregation, physician recommendation, and racial disparities in BRCA1/2 testing among women with breast cancer. J Clin Oncol 34: 2610-2618, 2016
6. Cragun D, Weidner A, Lewis C, et al: Racial disparities in BRCA testing and cancer risk management across a population-based sample of young breast cancer survivors. Cancer 123:2497-2505, 2017
7. Bierbaum M, Rapport F, Arnolda G, et al: Clinicians' attitudes and perceived barriers and facilitators to cancer treatment clinical practice guideline adherence: A systematic review of qualitative and quantitative literature. Implement Sci 15:39, 2020
8. Center for Medicare & Medicaid Innovation: Oncology Care Model. 2018. https://innovation.cms.gov/initiatives/oncology-care/
9. Mendenhall M, Dyehouse K, Hayes J, et al: Practice transformation—Early impact of OCM on hospital admissions. J Oncol Pract 14:e739-e745, 2018
10. National Comprehensive Cancer Network: NCCN Guidelines Genetic/Familial High-Risk Assessment: Breast and Ovarian, Version 2-2019. 2018
11. McKesson Specialty Health: 2018. https://www.mckessonspecialtyhealth.com/
12. The US Oncology Network: https://www.usoncology.com/
13. Tutt A, Garber JE, Kaufman B, et al: Adjuvant olaparib for patients with BRCA1 or BRCA2 mutated breast cancer. N Engl J Med 384:2394-2405, 2021
14. Cohen SA, Bradbury A, Henderson V, et al: Genetic counselling and testing in a community setting: Quality, access and efficiency. Am Soc Clin Oncol Educ Book 39:e34-e44, 2019

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Integration of Genetic Testing and Counseling in Patients With Breast Cancer in a Large, Multisite Community-Based Practice

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated unless otherwise noted. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/op/authors/author-center.

Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

Molly A. Mendenhall
Research Funding: Pfizer (Inst)

Andrew Guinigundo
Employment: US Oncology Network
Honoraria: Harborside Press, BroadcastMed
Consulting or Advisory Role: G1 Therapeutics, Amgen, Pharmacosmos, Jazz Pharmaceuticals
Speakers' Bureau: Amgen, Pfizer, Astellas Pharma, GlaxoSmithKline

Dan Davies
Employment: Oncology Hematology Care

Patrick Ward
Employment: Bon Secours Mercy Health (I)
Consulting or Advisory Role: Amgen

David M. Waterhouse
Consulting or Advisory Role: Bristol Myers Squibb, AZTherapies, AbbVie, Amgen, McGivney Global Advisors, Janssen Oncology, Seagen, Jazz Pharmaceuticals, Exelixis, Eisai, EMD Serono, Merck, Pfizer, Mirati Therapeutics, Sanofi/Regeneron, Fresenius Kabi, Lilly, Sanofi, Astellas Pharma, Gilead Sciences
Speakers' Bureau: Bristol Myers Squibb, Janssen Oncology, Merck, AstraZeneca, Amgen, EMD Serono
Travel, Accommodations, Expenses: Bristol Myers Squibb

No other potential conflicts of interest were reported.