Title

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Journal

JCO Oncology Practice, 16(12)

ISSN

2688-1527

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Publication Date

2020-12-01

DOI

10.1200/op.20.00431

Peer reviewed

Practical Considerations and Challenges for Germline Genetic Testing in Patients With Prostate Cancer: Recommendations From the Germline Genetics Working Group of the PCCTC

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abstract

Germline genetic testing is now routinely recommended for patients with prostate cancer (PCa) because of expanded guidelines and options for targeted treatments. However, integrating genetic testing into oncology and urology clinical workflows remains a challenge because of the increased number of patients with PCa requiring testing and the limited access to genetics providers. This suggests a critical unmet need for genetic services outside of historical models. This review addresses current guidelines, considerations, and challenges for PCa genetic testing and offers a practical guide for genetic counseling and testing delivery, with solutions to help address potential barriers and challenges for both providers and patients. As genetic and genomic testing become integral to PCa care, developing standardized systems for implementation in the clinic is essential for delivering precision oncology to patients with PCa and realizing the full scope and impact of genetic testing.

JCO Oncol Pract 16:811-819. © 2020 by American Society of Clinical Oncology

INTRODUCTION

Genomics is rapidly pushing oncology closer to an actualized version of precision medicine.[1,2] In the era of poly (ADP-ribose) polymerase inhibition and immunotherapy, genetic testing may yield information that will affect therapeutic choices, in addition to informing the patient about personal and familial risk.[3-5] Multiple guidelines now include germline genetic testing for men with prostate cancer (PCa), although incorporating testing into clinical workflows remains a challenge.[5,6] This article addresses (1) current guidelines for germline testing, (2) key aspects of testing and counseling, (3) a road map for genetic testing and counseling delivery, (4) challenges of testing and possible solutions, and (5) benefits and limitations of testing.

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Accepted on July 29, 2020 and published at ascopubs.org/journal/op on September 28, 2020: DOI https://doi.org/10.1200/OP.20.00431

Germline Genetic Counseling for Men With PCa

Since the landmark article by Pritchard et al[7] that described a relatively high prevalence of germline mutations in DNA repair genes in men with metastatic PCa, other groups have reported the prevalence of germline mutations in PCa ranging between 7.5% and 19%, with *BRCA2* being the highest overall contributor.[8-11] Consequently, several groups issued recommendations for germline testing (Table 1), which place significant demands on clinical workflows and resources for genetic counseling. Genetic counselors (GCs) are trained to assess family histories for genetic risk, provide pretest and post-test counseling, order appropriate testing, and interpret test results. Unfortunately, access to genetic providers is limited, with the majority of the small workforce usually centered in urban areas and academic institutions.[12,13] In 2016, the Genetic Counselor Workforce Working Group estimated a growth of 72% in the workforce between 2017 and 2026, with demand not expected to meet population equilibrium until 2024-2030.[14] This limited access may necessitate other health care providers, including oncologists, urologists, and primary care physicians, to absorb some responsibility for genetic testing. However, these providers may be insufficiently trained in genetics, resulting in inappropriate testing and misinformation.[15-17]

The increased number of men with PCa to be tested and the scarcity of GCs suggest a critical unmet need for expanded genetic services through novel approaches outside of historic delivery models.[18] Evolving service models that incorporate phone and video telemedicine can be particularly useful when geography or public health crises, such as COVID-19, make in-person visits challenging.[19,20] Hybrid service models

that divide responsibilities between physicians and GCs are also options.[21] Collaboration between GCs and clinicians is critical to determine which approach best suits a practice, because there is no one-size-fits-all solution.

Delivery of Germline Testing and Counseling

Initiating genetic testing. One of the greatest hurdles is ensuring that appropriate patients are systematically identified for testing. Developing a plan to consistently screen and identify patients based on current guidelines is necessary (Table 1). Assigning screening to a team member or using patient-completed family history questionnaires can facilitate referral and testing processes. Automated electronic medical record (EMR) features can trigger genetic counseling referrals or alert the clinical team based on a diagnosis code for metastatic PCa or family history/pedigree functionality.

After patients are identified, several options for counseling and testing are available:

1. Referral to a geneticist or GC for in-person, telephone-based, or telemedicine counseling services in response to manual referral or automated EMR triggers.
2. Treating clinicians perform pretest consent and order germline genetic testing directly: If genetic counseling services are unavailable, testing is urgent, or workflow supports providers initiating testing, treating providers can perform pretest education, obtain informed consent, and order genetic testing.[21] Providers should consider any clinical, psychosocial, and financial issues when determining whether to pursue testing within their practice or refer to a remote/telehealth genetic service if they do not have access within the practice.
3. Patient-initiated testing (PIT) platforms: Some commercial genetic testing laboratories, such as Color and Invitae, offer clinical-grade testing that can be initiated by the patient. This process may involve a pretest clinician review and the option for post-test genetic counseling. However, there remain concerns about guidance on test selection, limitations in genetic counseling, lack of follow-up regarding future reclassification of variants, potential for misinterpretation of results, and propagation of misinformation within families. Furthermore, PIT may not include genes important to a patient's personal or family history, potentially creating a false sense of reassurance if testing is negative. Given this, provider-initiated testing is preferred.
4. Direct-to-consumer (DTC) testing platforms: DTC genetic testing has become increasingly popular, likely because of easy access and no medical provider oversight. DTC testing is not comprehensive and should not be considered a substitute for clinical-grade testing. Although 23&Me has Food and Drug Administration approval to report on the three known Ashkenazi Jewish BRCA1/2 founder variants, the National Comprehensive Cancer Network (NCCN) cautions that any results should be confirmed with a clinical-grade test.[22] Providers should be skeptical of any raw data findings from secondary companies, such as Promethease, which are prone to false positives and false negatives.[23]

Family cancer history intake. Although all patients with high-risk localized or metastatic PCa should undergo germline genetic testing regardless of family history, accurately evaluating a patient's personal and family history is essential to determine whether patients need a broader germline panel. Furthermore, gathering a family history can help inform personal and family screening recommendations in the event of negative testing. Cancer counseling sessions include a three- to four-generation pedigree with information on maternal and paternal relatives with cancer, age of diagnosis, age/cause of death, and any prior genetic testing.[22,24] For relatives with PCa, the Gleason grade, metastatic status, and/or cause of death can be useful. Information about ancestry (eg, Ashkenazi Jewish) and consanguinity should be noted. Family history questionnaires can be completed in the clinic or electronically.

Complete family histories ensure that the most informative, cost-effective testing is performed. Although the presence of other cancer types in a family history may be explained by a mutation in a PCa predisposition gene, providers should consider expanded testing for genes related to the observed cancers in a family history when necessary. For instance, hereditary pancreatic cancer and PCa typically occur in the setting of a pathogenic *BRCA2* variant. However, it may be reasonable to include other genes associated with pancreatic cancer, such as *CDKN2A* and *CDK4*.

Somatic next-generation sequencing. Somatic next-generation sequencing tumor testing is increasingly used to guide treatment decision making and can be performed in parallel with germline testing. In addition to detecting tumor-specific mutations, it can sometimes identify potential germline mutations. Most somatic testing platforms are not validated to distinguish germline from somatic-only mutations, even if paired testing with a blood or saliva sample is performed. Thus, a referral to genetics is recommended to determine whether confirmatory or more comprehensive testing is warranted. Providers should consider the variant allele frequency, actionability of the gene, classification of the variant, and tumor type when reviewing somatic variants for possible germline origin.[25]

Pretest education and informed consent. Pretest education and informed consent discussions should review the purpose of testing; general information about included genes; possible test results (Table 2); medical management implications; review of possible benefits, risks, and limitations (Table 3); and the voluntary nature of testing.[24,26] Several major medical societies have also published detailed guidelines reviewing the components of pretest counseling and informed consent to help clinicians.[24] Clinical teams

TABLE 1. Summary of the Current PCa Genetic Testing Guidelines

Organization	Source	Guidelines	Genes
National Comprehensive Cancer Network	Genetic/familial high-risk assessment: breast, ovarian, and pancreatic version 1.2020[22]	Testing is clinically indicated in the follow scenarios:	*ATM* *BARD1*[a] *BRCA1* *BRCA2* *BRIP1* *CDH1*[a] *CDKN2A*[a] *CHEK2* *MSH2* *MLH1* *MSH6* *PMS2* *EPCAM* *NBN* *NF1*[a] *PALB2* *PTEN*[a] *RAD51C* *RAD51D* *STK11*[a] *TP53*
	Hereditary cancer testing criteria	1. Individuals with any blood relative with a known pathogenic/likely pathogenic variant in a cancer susceptibility gene	
		2. Individuals meet the criteria below but with previous limited testing (eg, single gene and/or absent deletion duplication analysis) interested in pursuing multigene testing	
		3. Personal history of cancer	
		• Metastatic or intraductal PCa at any age	
		• High-grade (Gleason score ≥ 7) PCa with:	
		o Ashkenazi Jewish ancestry; or	
		o ≥ 1 close relative with breast cancer at age ≤ 50 years or ovarian, pancreatic, or metastatic or intraductal PCa at any age; or	
		o ≥ 2 close relatives with breast or PCa (any grade) at any age	
		• A mutation identified on tumor genomic testing that has clinical implications if also identified in the germline	
		• To aid in systemic therapy decision making	
		4. Family history of cancer	
		• An affected or unaffected individual with a first- or second-degree blood relative meeting any of the criteria listed above (except individuals who meet criteria only for systemic therapy decision making)	
		There is a low probability (< 2.5%) that testing will have findings of documented clinical utility in the following scenarios:	
		• Men diagnosed with localized PCa with Gleason score < 7 and no close relative with breast, ovarian, pancreatic, or PCa	
National Comprehensive Cancer Network	Prostate cancer, version 1.2020[44]	Germline testing is recommended for patients with PCa and any of the following:	*ATM* *BRCA1* *BRCA2* *CHEK2* *HOXB13* *MLH1* *MSH2* *MSH6* *PALB2* *PMS2*
		• High-risk, very-high-risk, regional, or metastatic PCa	
		• Ashkenazi Jewish ancestry	
		• Family history of high-risk germline mutations (eg, *BRCA1/2*, Lynch mutation)	
		• A positive family history of cancer:	
		o A strong family history of PCa consists of: brother or father or multiple family members who were diagnosed with PCa (but not clinically localized Grade Group 1) at < 60 years of age or who died from PCa; OR	
		o ≥ 3 cancers on same side of family, especially diagnoses ≤ 50 years of age: bile duct, breast, colorectal, endometrial, gastric, kidney, melanoma, ovarian, pancreatic, prostate (but not clinically localized Grade Group 1), small bowel, or urothelial cancer	

(continued on following page)

TABLE 1. Summary of the Current PCa Genetic Testing Guidelines (continued)

Organization	Source	Guidelines	Genes
Expert Panel	Philadelphia Consensus meeting publication, 2017[45]	Men meeting any one of the following suggested criteria should undergo genetic counseling and genetic testing:	*ATM* *BRCA1* *BRCA2* *HOXB13* *MSH2* *MLH1* *PMS2* *MSH6*
		• All men with PCa from families meeting established testing or syndromic criteria for the following:	
		o HBOC (Consensus: 93%)	
		o HPC (Consensus: 95%)	
		o LS (Consensus: 88%)	
		• Men with PCa with two or more close blood relatives on the same side of the family with a cancer in the following syndromes:	
		o Post-consensus discussion included consideration of age cutoff for this criterion. A specific age cutoff will require additional data, and age at diagnosis is important to inquire about in the genetic counseling session with patients.	
		■ HBOC (Consensus: 93%)	
		■ HPC (Consensus: 86%)	
		■ LS (Consensus: 86%)	
		• All men with metastatic castrate-resistant PCa should consider genetic testing (Consensus: 67%). Post-consensus discussion also included consideration of testing men with metastatic, hormone-sensitive PCa to identify germline mutations to inform potential future treatment options and cascade testing in families. Men with tumor sequencing showing mutations in cancer-risk genes should be recommended for germline testing, particularly after factoring in additional personal and family history (Consensus: 77%).	
AUA	Clinically localized PCa: AUA/ASTRO/SUO guideline, 2017[46]	The Panel recommends that clinicians take a detailed family history of cancers and give consideration to patient referral for genetic screening and counseling for men with localized high-risk PCa, particularly in the setting of family history of first-degree relatives with cancers of breast, ovary, pancreas, other GI cancers, and lymphoma.	No genes specified for germline testing

Abbreviations: ASTRO, American Society of Therapeutic Radiation and Oncology; AUA, American Urological Association; HBOC, hereditary breast and ovarian cancer syndrome; HPC, hereditary prostate cancer; LS, Lynch syndrome; PCa, prostate cancer; SUO, Society of Urologic Oncology.

[a]These genes are not currently associated with PCa.

should note the requirements for documentation of informed consent, which differ by state and institutional policies.

Test selection and ordering. Many commercial laboratories offer clinical genetic testing for hereditary cancer syndromes. Testing panels range from targeted, guidelines-based panels to comprehensive, pan-cancer panels that may include preliminary evidence genes. Some major laboratories, such as Ambry Genetics, Invitae, and GeneDx, offer PCa-specific panels that include the following genes: *ATM, BRCA1, BRCA2, CHEK2, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2,* and *TP53*. Genetic testing panels are subject to change, and decisions regarding specific genetic tests should be individualized based on

TABLE 2. Possible Genetic Test Results[47,48]

Interpretation	Result	Definition
Positive	Pathogenic	An alteration in the DNA that is associated with increased disease risk.
	Likely pathogenic	An alteration in the DNA that is likely to be associated with increased disease risk. Meets most but not all criteria to be classified as pathogenic.
Uncertain	Variant of uncertain significance	An alteration in the DNA that may or may not be disease causing. Insufficient evidence to classify as either pathogenic or benign.
Negative	Likely benign	An alteration in the DNA that is unlikely to be associated with increased disease risk. Meets most but not all criteria to be classified as benign.
	Benign	An alteration in the DNA that is not associated with increased disease risk.

TABLE 3. Pretest Talking Points Regarding the Benefits and Risks/Limitations of Genetic Testing[27,49]

Benefits	Risks/Limitations
May help explain personal cancer history	May increase anxiety and guilt regarding hereditary cancer risk
May help inform prognosis	Potential for uncertain results: 1) Variants of uncertain significance, or 2) Positive results in lesser established genes and those with no management guidelines currently available
May help inform risks for additional cancers	Genetic discrimination risks (life insurance or long-term care insurance)
May help guide treatment decisions	Financial barriers
May help inform cancer risks for family members	

factors such as laboratory reputation and quality, insurance networks, genes offered and customizability of panels, laboratory billing practices, follow-up testing options for family members, turnaround times, and availability of genetic counseling services.

Clinicians should recognize that larger panels increase the probability of detecting variants of uncertain significance (VUS), incidental/secondary findings (pathogenic variants in genes not related to hereditary PCa), and variants associated with syndromes that may be outside of the scope of clinicians treating PCa (Tables 2 and 3). Clinical workflows must ensure that tasks involved with ordering genetic testing include determination of insurance coverage and submission of orders, standardized collection and shipment of samples, and a clear chain of responsibility.

Insurance coverage for germline testing is in flux. Although the cost of genetic testing has decreased, the possible out-of-pocket (OOP) cost for patients can be difficult to discern because of the varying billing policies of laboratories and insurance coverages.[27] Although the NCCN hereditary breast and ovarian cancer guidelines (v3.2019) are often the primary source used by payers, including Medicare, to develop coverage policies, most have their own criteria that determine testing coverage. These criteria may not be up to date with current NCCN guidelines, potentially excluding PCa from their criteria completely, and may mandate a consultation with certified GC for approval.

Many, but not all, laboratories work with commercial insurance companies to negotiate coverage into their policies and will provide an estimate of the OOP cost of testing. Not all insurance companies require prior authorization for genetic testing. Laboratory online ordering portals will often indicate whether provider-initiated insurance prior authorization is needed. Typically, all components of the billing process, including submission of insurance prior authorization, are handled by the laboratory. Several commercial laboratories offer a patient-pay or fixed OOP cost, often $250 or lower, making testing more financially accessible. In addition, patients may qualify for a sponsored testing program at no cost in exchange for de-identified data shared with the sponsoring companies.

Results delivery and follow-up. Methods for delivering test results vary, depending on workflow, availability of genetic counseling services, and provider comfort level and training. Regardless of result type, genetic test reports should be offered to patients for their own records and uploaded into the EMR. Refer to Table 2 for information regarding the following result types. Options for returning results include:

1. Ordering provider refers all patients for post-test counseling, either through referral to a local GC or a telehealth genetic counseling service.
2. Ordering provider refers patients with complex results (eg, positive and/or VUS) for post-test counseling. This type of blended approach to genetic testing has been previously discussed and has received strong consensus across multiple disciplines.[21,26]
   a) Negative results: Clinical teams can disclose results via telephone, patient portal message, a follow-up appointment, or a letter summarizing the results and providing contact information if there are questions. A templated letter can be generated with GC input. Cancer screening recommendations should be based on the family history and should be reviewed with the patient. For example, men with a first-degree relative with PCa remain at increased risk for PCa and should initiate prostate screening at a younger age per routine guidelines. Patients should be encouraged to discuss updates to personal and family history, which may prompt consideration of additional genetic testing or altered screening recommendations.
3. Ordering provider discloses all result types. It is important to note that even in this situation, a referral can be made to genetics for post-test counseling.
   a) Positive results: Providers should discuss and document the implications of the results in terms of cancer risks associated with the identified gene mutation, additional cancer screening recommendations, appropriate referrals, and possible implications for treatment. Providers should also recommend cascade testing, which entails genetic counseling and testing in at-risk relatives of

individuals identified to carry specific genetic mutations or further testing in the family based on family history. Access to the proband's test report will be essential for family members considering testing.

b) VUS results: It is critical to review the uncertainty of whether the specific gene mutation identified is disease causing or a benign variation. The vast majority of VUS results are later reclassified to negative[28,29]; thus, they are typically treated as negatives, and screening recommendations are made based on personal and family history. Testing family members for a VUS is typically not recommended unless it is in the context of a variant resolution or research program. When a VUS is reclassified, new reports are customarily issued to the ordering provider, and it is therefore the responsibility of the ordering provider to follow up with patients over the long term concerning any reclassifications. Patients should be encouraged to check in with their providers every few years to see whether there are updates to the classification. It is also important to note the possibility of discrepant variant classifications across laboratories. These discrepancies may cause difficulty determining how to appropriately manage patients and family members. ClinVar is a free, publicly available database that aggregates variant classifications, although a limitation is that entry submissions may not be completely up to date.

Cascade testing. The concept of cascade testing should be introduced as part of pretest counseling. Family letters can facilitate genetic testing for other relatives in the event of a positive result and typically include a short description of the cancer syndrome, the specific mutation identified, information on how to contact a GC in their area, and laboratory/specimen identification for the patient's testing. A number of the genes associated with hereditary PCa, such as *BRCA1/2* and the mismatch repair genes, are associated with additional cancers and may have well-defined risk numbers and screening recommendations for males and females. Targeted testing for the known familial variant can clarify the cancer risks for other relatives, allowing for the initiation of appropriate increased cancer screening and risk-reducing therapies, and consideration of reproductive planning options.[27] Ultimately, it is the patient's decision and responsibility to inform at-risk relatives about their genetic test results, which underlies the importance of reviewing cascade testing and providing resources to help facilitate this transfer of critical information.

Additional Considerations

Pathogenic mutations identified in DNA-damage repair genes, such as *BRCA1/2* or mismatch repair genes, have implications for management and treatment.[3,4] Germline mutations are identified in approximately 12% of patients with metastatic PCa, but because some are not actionable, it is important to manage expectations concerning outcomes for germline testing.[7-11] Many of the genes included on PCa panels are newly associated with PCa and do not yet have well-defined cancer risks. This increases the possibility of a positive result in a gene associated with low-to-moderate increased cancer risk, which may not have clear screening recommendations. Providers need to be clear about the preliminary nature of findings and that there may not be an immediate impact on cancer screening or treatment options. Patients and their families should be encouraged to participate in registries or research studies to better characterize the risk associated with specific variants over time. Providers can refer patients to a GC for further discussion. Finally, as germline mutations continue to be levied for treatment purposes, providers must be aware of the risk of secondary malignancies and treatment-related adverse effects in some mutation carriers.[28-32]

Some providers may be concerned about the potential for negative consequences from genetic testing. A number of studies have found that most individuals are unlikely to experience significant psychological distress after receiving genetic test results.[33,34] Notably, the likelihood of psychological distress, family disruption, and nonadherence to surveillance guidelines was greater in settings without adequate patient education, counseling, informed consent, and follow-up.[33,35] A recent study of men with PCa undergoing genetic testing found genetic counseling to be beneficial.[35]

Some patients are hesitant about genetic testing because of concerns about discrimination. The Genetic Information Nondiscrimination Act (GINA), a federal law passed in 2008, protects individuals from genetic discrimination from health insurance companies and employers, with specific limitations on the type of employer and size of the company. Importantly, GINA protections do not extend to life, disability, or long-term care insurance. Some states have passed genetic discrimination laws that extend protection beyond GINA. Information regarding GINA is often included in the consent forms for testing laboratories, and summary handouts could be given to patients with additional questions.

Practical Strategies to Overcome Genetic Service Barriers

ASCO and other major health societies strongly encourage and often provide additional education training for non-genetics providers who are interested in responsibly incorporating genetic services into their practice. Courses on genomic cancer risk assessment for physicians, advanced practice providers, nurses, GCs, and other health care professionals are available through organizations such as City of Hope, American Urological Association, and ASCO.

Alternatives to in-person pretest counseling, such as educational handouts, videos, and presentations, are allowing genetic counseling expertise to be shifted to the post-test setting, prioritizing visits for complex counseling patients and/or abnormal results, and facilitating a hybrid service delivery model.[18,36] Data are still emerging regarding the

effectiveness of these models and patient satisfaction. Other practical strategies have focused on increasing GC efficiency and patient volumes, leading to the creation of new support roles, such as GC assistants; incorporation of technologies that reduce appointment time, such as online pedigree collection tools; and group genetic counseling sessions.[37,38] There are now chatbots, such as Genetic Information Assistance, that can converse with patients about family history and the basics of genetic testing and insurance, and determine who qualifies for genetic testing.

Special attention and strategies to minimize disparities in genetics are essential. It has been well documented that socioeconomically disadvantaged individuals, racial/ethnic minorities, and men are less likely to receive genetic services.[18,39-43] PCa genetic testing provides a unique opportunity for providers and institutions to address possible disparities and consider offering counseling services within a male-friendly environment. It is imperative that health care providers from all specialties work together to provide equal access to genetic services by minimizing biases, improving patient education and understanding, creating culturally sensitive interfacing materials, and expanding services to underprivileged areas.

In conclusion, as genetic testing becomes integral to the care of patients with PCa, coordinated efforts across multiple disciplines are required to deliver optimal care. Developing creative, scalable strategies to deliver high-quality personalized genetics care for patients with PCa will be paramount to realizing the full scope and impact of genetic testing for individual patients and family members. It is clear that expanding education around the need for testing and developing standardized systems for implementation in the clinic are important directions for genetics care delivery and essential for delivering precision oncology to men with PCa.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

Disclosures provided by the authors and data availability statement (if applicable) are available with this article at DOI https://doi.org/10.1200/OP.20.00431.

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Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

ACKNOWLEDGMENT

B.M.S. and L.A.F. are co-first authors. A.K.M., H.H.C., and A.R.M. contributed equally to this work.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Practical Considerations and Challenges for Germline Genetic Testing in Patients With Prostate Cancer: Recommendations From the Germline Genetics Working Group of the PCCTC

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).

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No other potential conflicts of interest were reported.