



# Pruritus in patients with solid tumors: an overlooked supportive care need

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## Abstract

**Purpose** Pruritus is a common symptom in cutaneous malignancies, but its impact on patients with solid tumors is unclear. We explored the impact and management of pruritus in patients with solid tumors, using patient-reported outcomes (PRO) data from a real-world registry.

**Methods** From 2006 to 2011, patients seen in the Duke Cancer Institute reported their symptoms via the Patient Care Monitor v2.0, a validated PRO tool that includes a 0–10-point question about pruritus severity. From > 25,000 encounters, 203 patients reported severe pruritus (> 6/10) on at least one visit and 506 total visits were abstracted where patients reported either moderate or severe pruritus (> 3/10). From this cohort, we abstracted demographics, diagnosis, stage, cancer therapy, anti-pruritic therapy, and clinicians' responses.

**Results** Mean age was 59.8 (SD 13.3), 134 (66%) were female, 125 (62%) were Caucasian, and 65 (32%) were African American. Breast cancer was the most common tumor (36.5%), followed by lung cancer (23.2%). Mean pruritus severity score was 6.8 (SD 1.8) for patients on chemotherapy, 6.9 (SD 1.8) for patients on targeted therapy alone or in combination, and 7.1 (SD 1.8) for patients off treatment. Overall, 67% of patients reported at least two episodes of moderate-severe pruritus (mean # of visits 4.2 (SD 2.7)). Despite frequent report of severe and persistent pruritus, this was mentioned in just 28% of clinician notes and an intervention was recommended/prescribed in only 7% of visits.

**Conclusions** Pruritus is an under-addressed symptom in patients with solid tumors. Additional research is needed to understand the burden of pruritus in affected populations.

**Keywords** Pruritus · Patient-reported outcomes · Patient experience research · Supportive care · Symptoms

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## Introduction

In 2016, there were nearly 1.7 million new cases of cancer in the USA [34]. People with cancer face numerous physical, psychological, and financial challenges, all of which significantly decrease quality of life. As cancer-related mortality decreases and the number of cancer survivors increases each year [9, 34], there has been an increased focus on quality of life issues among people living with, or beyond, a cancer diagnosis [22]. Effective symptom reporting and management appears to increase both survival and the quality of life of people with cancer [6, 7, 20, 37].

Some symptoms, such as fatigue, occur in over 60% of patients with cancer [18, 31], and patients often suffer from multiple physical symptoms during cancer treatment. Recent evidence suggests that symptom monitoring via patient-reported outcome (PRO) assessments can heighten clinicians'

understanding of the issues that bother patients most [6, 7, 14, 20, 37, 38]. However, there is no standard PRO system used in routine care, nor any unifying guidelines for assessing symptoms in people with cancer. Just one out of five commonly used PRO tools, the Memorial Symptom Assessment Scale, includes pruritus in its standard questionnaire [8, 12, 25, 26, 29, 30]. The impact of pruritus on patients with cancer is thus often missed and is an under-explored area in studies assessing cancer patients' experiences of illness.

Pruritus is likely a common symptom in patients with cancer, but its impact is not well described in the literature outside of cutaneous malignancies [13, 27, 40]. While a few studies have examined pruritus in palliative care patients, these studies did not focus on patients with cancer [4, 5, 28, 33]. Overall, there are very few published reports on pruritus in patients with solid tumors, yet there is reason to think that pruritus may be an increasingly common issue in this population, given the increase in use of novel targeted therapeutics and immunotherapies in cancer care. Some of these therapies are associated with higher rates of pruritus than traditional treatments and may be more likely to have off-target effects [10, 11, 15, 32].

Using a large PRO registry spanning multiple solid tumor types and several years of cancer care at Duke University, we aimed to improve understanding about pruritus and its management in patients with solid tumors in the targeted therapy era. We hypothesized that pruritus is infrequently or inadequately addressed by clinicians in routine practice.

## Methods

### Study population and assessments

From 2006 to 2011, patients seen in the Duke Cancer Institute solid tumor clinics directly reported their symptoms on electronic tablets as part of routine care, using a system called the "Patient Care Monitor, version 2.0" (PCM) [2, 35]. The PCM consists of 80 symptom items for men and 88 for women. It has been tested and utilized across multiple cancer types and validated in electronic form (both in comparison to paper report, and also compared to similar symptom and quality of life PROs commonly used in oncology trials) [1, 3, 24, 36]. Each item is reported on an 11-point ordinal scale ranging from 0 (not a problem) to 10 (severe problem), also anchored by categories of "mild," "moderate," and "severe" for scores of 1–3, 4–6, and 7–10, respectively. The PCM asks about symptoms during the past week. Unlike other symptom screeners and quality of life assessment tools, the PCM includes a question about pruritus, thereby making this dataset ideal for studying this issue.

Eligible patients were at least 18 years of age, had at least one cancer diagnosis, received care from an oncologist at the

Duke Cancer Institute, and had at least one episode of severe pruritus (defined by a severity of > 6 out of 10). We chose to include only those patients with severe pruritus so that this analysis could identify the most significant unmet needs for these patients, and to describe the management thereof in routine practice. Patients were excluded if there was no follow-up visit after one symptom report, or if the patient had in situ cancer.

Patients with severe pruritus had multiple visits, and we abstracted forward from the "index visit," which was the point at which clinically important pruritus became apparent. Clinically important pruritus was considered to be a single report of > 6 or at least two consecutive reports of > 3. Once the index visit was identified, we only abstracted data from those visits with reports > 3. Visit data were abstracted for the analysis cohort through December 2014. Visits were excluded if the patient did not complete the PCM instrument correctly, or if there was no oncologist visit or associated progress note.

### Data elements and analysis

In addition to PRO data, patient and disease-related data were abstracted from the electronic medical record by a trained oncology nurse abstractor, using structured case-report forms (CRFs). The CRFs were created by the research team. They were initially piloted and then iteratively revised until they adequately addressed all applicable clinical situations that arose in early abstractions. Abstracted data included demographics, diagnosis, stage, cancer therapy (none, cytotoxic chemotherapy, or targeted therapy/both targeted and cytotoxic chemotherapy), history of liver failure/cirrhosis, history of chronic skin disease, anti-pruritic therapy, and an assessment of the documented clinician response to the pruritus (when applicable). Charts were reviewed longitudinally until the point at which pruritus was resolved and did not recur again during the study period, or until there were no further recorded visits with PRO data. Statistical analysis was carried out using SAS version 9.1 (SAS Institute USA) and included descriptive statistics and chi-square analyses as appropriate.

### Ethical approval

This study was reviewed and approved by the Duke University School of Medicine's institutional review board.

## Results

### Demographics and study cohort

Between 2006 and 2011, there were > 25,000 patient encounters recorded among > 8000 patients who contributed PRO data as part of their cancer care at Duke. There were 1112

patients who reported moderate to severe itching (> 3 out of 10), with 324 patients reporting severe itching (> 6 out of 10) on at least one visit. Two hundred ten of these patients met the other eligibility criteria described above and were thus designated as the analysis cohort (Fig. 1). We excluded seven patients who were receiving investigational drugs, resulting in a final sample size of 203 patients. These 203 patients had 1484 encounters in our database, of which 80 had missing PRO data, and thus 1404 visits could be abstracted. Of these 1404 visits, 427 were before the index visit and were not abstracted. We only abstracted data from visits with pruritus scores > 3, and therefore, of the remaining 977 visits, 506 were finally abstracted (and 471 with no to mild pruritus were not).

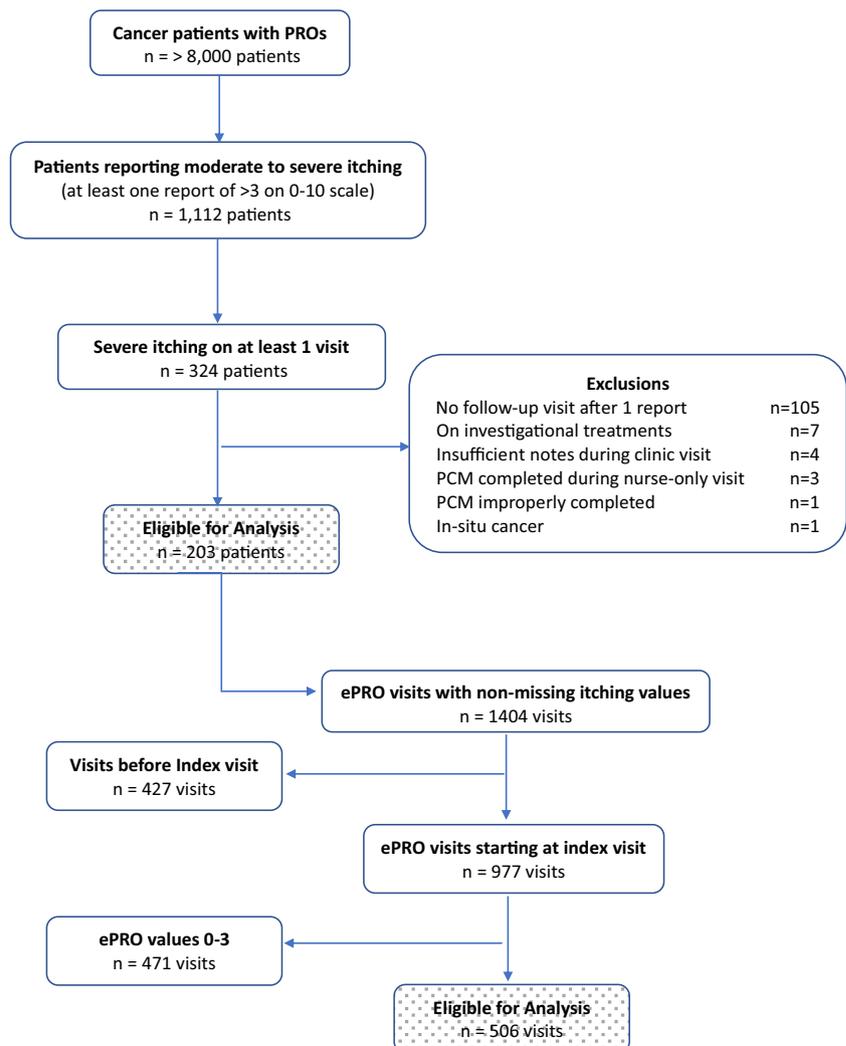
The mean age of patients in this cohort was 59.8 (SD 13.3) years (Table 1). One hundred thirty-four (66%) were female; 125 (62%) were Caucasian; and 65 (32%) were African American. Breast cancer was the most common tumor type with 74 patients (36.5%), followed by lung cancer with 47 patients (23.2%). Thirty-seven (18%) of patients received some form of radiation during the study period.

## Pruritus severity scores

From our cohort of 203 patients, 67 patients had a single episode of severe pruritus, which resolved by the next visit and did not recur during the study period. The other 136 patients had persistent pruritus (defined as consecutive visits with moderate or severe reports), or recurrent pruritus (defined as severe pruritus which resolved but recurred at a moderate or severe level at a later visit). In these persistent/recurrent patients, the mean number of visits was 4.2 with a minimum of 2, maximum of 14, and median of 3 visits within our study period (Table 2).

The median severity score across all pruritus complaints was 7 (IQR 6–8) (Table 3). There were 209 reports of moderate pruritus (median 5, IQR 4–6), and 297 reports of severe pruritus (median 8, IQR 7–9). Within the 209 visits where moderate pruritus was reported, 25.4% (53) of patients were receiving no active cancer treatment, 41.6% (87) were receiving targeted therapy alone or in combination, and 33.0% (71) were receiving traditional chemotherapy alone (within 45 days of the visit). The breakdown was similar for the 297 visits where severe

**Fig. 1** Patient and visit selection



**Table 1** Demographics

	Total ( <i>N</i> = 203 patients)
<b>Age</b>	
Mean (SD)	59.8 (13.3)
Median	59.0
Q1, Q3	51.2, 68.6
Range	(31.7–90.8)
Female	134 (66.0%)
<b>Race</b>	
White	125 (61.6%)
Black/African American	65 (32.0%)
Asian	2 (1.0%)
American Indian/Alaska Native	3 (1.5%)
Other	4 (2.0%)
Unknown	4 (2.0%)
<b>Ethnicity</b>	
Hispanic or Latino	3 (1.5%)
Unknown	200 (98.5%)
<b>Cancer diagnosis</b>	
Missing	5 (2.5%)
Breast cancer	74 (36.5%)
Lung cancer	47 (23.2%)
Prostate cancer	9 (4.4%)
Colon or rectum cancer	10 (4.9%)
Kidney cancer	18 (8.9%)
Sarcoma	5 (2.5%)
Melanoma	5 (2.5%)
Pancreas cancer	6 (3.0%)
Oral cavity (i.e., tongue, mouth) or pharynx cancer	6 (3.0%)
Bladder cancer	2 (1.0%)
Stomach/gastric cancer	4 (2.0%)
Other	12 (5.9%)
<b>Did radiation occur during the study period?</b>	
Radiation	37 (18.2%)

pruritus was reported, with 29.6% (88), 40.7% (121), and 29.6% (88) being on no therapy, targeted therapy alone or in combination, and chemotherapy alone, respectively. The mean pruritus severity score was 6.8 (SD 1.8) for patients on chemotherapy, 6.9 (SD 1.8) for patients on targeted therapy alone or in combination, and 7.1 (SD 1.8) for patients off treatment across all types of visits. Skin rash or eruption was noted as a potential etiology of pruritus in just under 4% of cases. There was no difference in pruritus scores by race or ethnicity.

### Clinician responses to pruritus

Although there were 506 visits in which patients reported either severe pruritus or persistent/recurrent moderate pruritus, clinicians only documented a discussion about pruritus in 139 (27.5%) of visits (Table 4). Patients were already receiving anti-pruritus treatment in 96 (19.0%) visits. We performed thorough chart reviews looking for prescriptions, referrals/consults, and any other mention of an intervention for pruritus, but the pruritus was addressed via additional interventions in only 26 (8.8%) visits where severe pruritus was reported, and only 8 (3.8%) visits where moderate pruritus was reported. Anti-histamine therapy was only started at 8 (1.6%) visits, though some patients already had these drugs in their medication list as above. Instead, there were a wide variety of actions taken, including use of other non-topical drugs (10 visits), other topical drugs (9 visits), and discontinuing medications (9 visits), and the use of topical or oral steroids (5 visits).

### Discussion

Symptom management is an important pillar of high-quality, person-centered cancer care. Recent evidence suggests that routine, proactive monitoring of symptoms leads to improved patient experiences and may even lead to increased survival [7, 14, 20, 37, 38]. Our analysis of longitudinal PRO data from patients with solid tumors yields two important findings that

**Table 2** Pruritus severity and persistence

	Single severe encounter ( <i>N</i> = 67 visits for 67 patients)	Multiple severe/moderate encounters ( <i>N</i> = 439 visits for 136 patients)	Total ( <i>N</i> = 506 visits for 203 patients)
<b>ePRO value for pruritus complaint</b>			
Mean (SD)	8.1 (1.1)	6.8 (1.8)	6.9 (1.8)
Median	8.0	7.0	7.0
Q1, Q3	7.0, 9.0	5.0, 8.0	6.0, 8.0
Range	(7.0–10.0)	(4.0–10.0)	(4.0–10.0)
<b>Frequency count</b>			
Mean (SD)	1.0 (0.0)	4.2 (2.7)	3.8 (2.7)
Median	1.0	3.0	3.0
Q1, Q3	1.0, 1.0	2.0, 5.0	2.0, 5.0
Range	(1.0–1.0)	(2.0–14.0)	(1.0–14.0)

**Table 3** Pruritus severity by therapy type

	Moderate pruritus ( <i>N</i> = 209)	Severe pruritus ( <i>N</i> = 297)	Total ( <i>N</i> = 506)
ePRO value for pruritus complaint			
<i>N</i>	209	297	506
Mean (SD)	5.1 (0.8)	8.2 (1.1)	6.9 (1.8)
Median	5.0	8.0	7.0
Q1, Q3	4.0, 6.0	7.0, 9.0	6.0, 8.0
Range	(4.0–6.0)	(7.0–10.0)	(4.0–10.0)
Cancer therapy			
None	53 (25.4%)	88 (29.6%)	141 (27.9%)
ePRO value for pruritus complaint, mean (SD)			7.1 (1.8)
Targeted therapy or combination	87 (41.6%)	121 (40.7%)	208 (41.1%)
ePRO value for pruritus complaint, mean (SD)			6.9 (1.8)
Chemotherapy alone	69 (33.0%)	88 (29.6%)	157 (31.0%)
ePRO value for pruritus complaint, mean (SD)			6.8 (1.8)

**Table 4** Clinician response to pruritus

	Moderate pruritus ( <i>N</i> = 209)	Severe pruritus ( <i>N</i> = 297)	Total ( <i>N</i> = 506)
The patient is already receiving an anti-pruritus treatment	34 (16.3%)	62 (20.9%)	96 (19.0%)
Hydroxyzine (Atarax)	16 (7.7%)	22 (7.4%)	38 (7.5%)
Diphenhydramine (Benadryl)	3 (1.4%)	14 (4.7%)	17 (3.4%)
Oral steroids	0 (0.0%)	3 (1.0%)	3 (0.6%)
Topical steroids	7 (3.3%)	30 (10.1%)	37 (7.3%)
Other topical drug	12 (5.7%)	10 (3.4%)	22 (4.3%)
Other non-topical drug	6 (2.9%)	15 (5.1%)	21 (4.2%)
Clinician discussed* pruritus with the patient	34 (16.3%)	105 (35.4%)	139 (27.5%)
Clinician addressed* pruritus at the visit	8 (3.8%)	26 (8.8%)	34 (6.7%)
Clinician started new anti-pruritus treatment	2 (1.0%)	19 (6.4%)	21 (4.2%)
Hydroxyzine (Atarax)	1 (0.5%)	6 (2.0%)	7 (1.4%)
Diphenhydramine (Benadryl)	0 (0.0%)	1 (0.3%)	1 (0.2%)
Oral steroids	0 (0.0%)	1 (0.3%)	1 (0.2%)
Topical steroids	0 (0.0%)	4 (1.3%)	4 (0.8%)
Other topical drug	0 (0.0%)	9 (3.0%)	9 (1.8%)
Other non-topical drug	1 (0.5%)	9 (3.0%)	10 (2.0%)
Clinician took other action			
Started new chemotherapy	1 (0.5%)	1 (0.3%)	2 (0.4%)
Stopped chemotherapy drug	2 (1.0%)	3 (1.0%)	5 (1.0%)
Other	4 (1.9%)	6 (2.0%)	10 (2.0%)
Biopsied area	1 (0.5%)	0 (0.0%)	1 (0.2%)
IV steroids	0 (0.0%)	1 (0.3%)	1 (0.2%)
Referred to dermatology	0 (0.0%)	1 (0.3%)	1 (0.2%)
Stopped concomitant medication	2 (1.0%)	2 (0.7%)	4 (0.8%)
Treated infection	0 (0.0%)	1 (0.3%)	1 (0.2%)
Treated herpes zoster	1 (0.5%)	1 (0.3%)	2 (0.4%)

\*Discussed: had a conversation with the patient about the pruritus at the visit and documented this in the clinical note; addressed: took action for the pruritus, such as via prescribing, recommending an over-the-counter product, or referral to a specialist

add to the supportive care literature. First, in this cohort of selected patients with a clinically significant burden of pruritus, there was variability in presentation, including both patients receiving chemotherapy and targeted therapies, and even patients receiving no active cancer treatment. Second, we found that pruritus, even when present to a severe and persistent degree, is infrequently acted upon by clinicians. Pruritus thus appears to be an often-overlooked supportive care need in cancer care.

We were surprised to find that this cohort of patients with moderate to severe pruritus was not predominately comprised of those receiving targeted therapies. This is particularly surprising given the literature describing pruritus as a common side effect of targeted therapies [10, 11, 15, 32]. Further research into this question is needed. Perhaps, this finding is a reflection of the vast range of potential causes of pruritus in clinical practice. It is also possible that this finding is an artifact of our study design in that, for example, we did not abstract records for all patients receiving targeted therapies and calculate the prevalence of pruritus, but instead began with the population of patients reporting moderate to severe pruritus and then abstracted type of therapy. Nevertheless, clinicians should be aware of the possibility of significant pruritus in all patients, regardless of treatment type. While we have likely selected the most severe cases via our cohort inclusion criteria, this was necessary to first see if there was unmet need in the most obviously symptomatic group. Now that we have demonstrated the unmet needs therein, further studies are needed to assess the epidemiology of pruritus in patients with cancer of various types and stages, followed by intervention development.

Clinicians' overall failure to recognize and adequately address pruritus was surprising, particularly since the electronic PRO system being used in the clinics included annotated symptom report printouts for clinicians to review during each appointment. These reports clearly indicate which symptoms are severe (using orange highlighting), and also utilize colored arrows beside each symptom to denote direction of change (if any) from the prior report. Yet, when persistent moderate pruritus or even severe pruritus was reported, we found that clinicians had discussed it in only 27.5% of cases, and that it was acted upon (addressed) just 6.7% of the time. Admittedly, physicians face significant time constraints, with the average oncologist spending 22.9 min with each patient per visit [17]. In that 22.9 min, they must address current disease state, treatment plans and tolerability, prognosis, symptom management, laboratory monitoring, and psychosocial well-being, and conduct any necessary physical examinations, document the content of the encounter, write prescriptions, and plan follow-up visits or treatments. Time pressures may be worse in the era of the electronic medical record, which complicates documentation and communication [23]. In this environment, less morbid symptoms, like pruritus, may be relegated to the

background, amid all the other competing demands. Pruritus may also be a symptom that patients are less likely to mention amid other pressing concerns, although it does impact their overall quality of life. A previous cross-sectional study found that patients with pruritus were more likely to have a concomitant malignancy than patients without pruritus, further adding to the importance of addressing pruritus in any clinical setting. [21] Ultimately, several factors may explain the failure to document and/or address pruritus in the clinic, including (1) a lack of awareness that the symptom occurred (perhaps they ignored this section of the PRO printout), (2) failure to document an intervention or discussion that indeed took place, and (3) the expectation that interventions to address pruritus are often either not very well tolerated or are not particularly effective. In the latter case, clinicians may well have recommended over-the-counter remedies like diphenhydramine, which do not always end up on a patient's medication list, and which may cause marked side effects like somnolence.

The use of an electronic symptom monitoring tool in our study enabled us to capture these data when otherwise they might not be known to the clinician, thus providing a more accurate picture of patients' experiences. This finding adds to the literature suggesting that routine collection of PROs can enhance clinicians' ability to detect problems that patients might not otherwise discuss, such as sexual well-being [36–38]. Recent evidence suggests that the electronic collection of symptom data can improve health-related quality of life and even overall survival among patients with advanced cancer receiving chemotherapy [4, 7]. Our results suggest one potential mechanism whereby these outcome improvements are achieved, by highlighting the increased awareness that can result from formally assessing patients' symptom burden.

There are a few limitations to this study. First, since retrospective chart review was used to add context to the PRO data, some data elements (such as clinician response to pruritus) were limited to what was charted. It is likely that clinicians did not chart everything that was discussed during each visit. However, the rate at which pruritus was discussed or addressed was so low that even a significant underestimation of the rate at which clinicians addressed this symptom would still leave a sizeable proportion of patients' pruritus unnoticed or unaddressed. Second, this was a single-site study that focused only on those patients with severe pruritus, and thus may not be representative of the entire cancer population; in the absence of denominator data, it cannot tell us the true incidence of pruritus among patients receiving cancer treatment. Further epidemiologic study is needed to delineate these important factors. Lastly, since we did not include patients with no or low pruritus, or single episodes of moderate severity pruritus, we cannot determine which treatments actually led to higher rates of pruritus. In addition, we cannot comment on any association with novel checkpoint inhibitor therapies, which were not widely in use during the time of our data

collection. Lastly, we were not able to explore the relationship, if any, between pain and pruritus intensity. Further research is needed.

In conclusion, our findings suggest that pruritus is an under-recognized issue in people living with cancer. While we expected that pruritus might be more of an issue in patients on lower-dose, long-term therapies like oral targeted drugs, we found a clinically significant burden of pruritus among patients receiving traditional chemotherapy, as well as those receiving no cancer therapy at all. Unfortunately, we found that clinicians often fail to discuss or intervene upon moderate to severe pruritus, which has been shown to have a significant effect on quality of life [16, 19, 39]. Further study is needed to assess the prevalence and impact of more moderate or mild degrees of pruritus in patients with cancer. In addition, interventions are needed to improve clinicians' attention to assessing and addressing pruritus in their patients. Pruritus appears to be an overlooked supportive care need in modern cancer care.

### Compliance with ethical standards

This study was reviewed and approved by the Duke University School of Medicine's institutional review board.

**Conflict of interest** Tom LeBlanc has full control of all primary data and agrees to allow the journal to review these data if requested, provided this is done in accordance with Duke University policies regarding data. He reports consulting fees/honoraria in the last 12 months from Amgen, Abbvie, Agios, AstraZeneca, Celgene, Helsinn, Heron, Medtronic, Otsuka, Pfizer, Seattle Genetics, and Flatiron Health, as well as research grants to Duke University from the American Cancer Society, AstraZeneca, the Cambia Health Foundation, and Seattle Genetics. Amy Abernethy is a full-time employee of Flatiron Health, a member of the Roche Group; she advises SignalPath Research, The One Health Company and Robin Care; she is on the Board of Directors for Aetnahealth; and she has consulting fees from Bristol Meyers Squibb and Genentech. The remaining authors have no disclosures to report.

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