Published in final edited form as:

Psychooncology. 2013 September ; 22(9): 2110–2116. doi:10.1002/pon.3264.

Conveying genomic recurrence risk estimates to patients with early stage breast cancer: Oncologist perspectives

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Abstract

Objective—The development and increased use of genomic profiling has led to refinement of breast cancer treatment. This study sought to examine medical and surgical oncologists' perceptions of factors related to the translation and integration of *Oncotype DX*[®] into routine clinical care.

Methods—Twenty oncologists (10 medical and 10 surgical oncologists) participated in qualitative interviews. Questions centered on the following themes: oncologists' perceptions about the clinical utility of testing, the impact of patient preferences on the decision to test and use results to inform treatment decisions, methods of communicating risk associated with test results to patients, and benefits of and barriers to incorporating testing into multidisciplinary care settings.

Results—Oncologists found *Oncotype DX*[®] test results useful in their practice, but had concerns as well. These included that some oncologists either used testing inappropriately or placed undue emphasis on the results at the expense of other clinical information. The use of intermediate test results, which have less clear clinical implications, incorporating results with patient treatment preferences, and the use of testing in multidisciplinary teams were noted as specific challenges.

Conclusion—Oncologists noted several benefits of testing, but also many challenges, despite wide dissemination and common use. Education for health providers should include specific training in how to interpret and communicate the uncertainty inherent in genomic tests while integrating patient preferences to inform treatment decision making.

Keywords

qualitative; physician; communication; 21-gene; breast cancer; oncology

Introduction

The development and increased use of genomic profiling has led to refinement of breast cancer treatment. Several practice guidelines incorporate genomic profiling of early-stage, estrogen-receptor (ER+) breast tumors with existing pathologic features (i.e., tumor size) to refine recurrence estimates and guide shared decisions about chemotherapy for women with node-negative disease [1]. As research continues on the clinical utility of genomic tests, significant challenges arise in effectively communicating this risk information to patients and integrating this information in shared treatment decision making [2].

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The *Oncotype DX*[®] Recurrence Score assay, a widely-used genomic test, is a 21-gene assay which measures breast cancer recurrence risk and chemotherapy benefit in early-stage, estrogen receptor positive patients. Using a categorization system of low, intermediate, and high recurrence scores, *Oncotype DX*[®], when combined with standard pathological features, provides information that oncologists and patients can use in making treatment decisions about chemotherapy based on the patient's score. For example, patients with a high Recurrence Score will likely benefit from chemohormonal therapy in order to increase their odds of survival, whereas patients with a low Recurrence Score can be treated with hormonal therapy alone, safely avoiding chemotherapy and its side effects [3-5]. Treatment benefits for patients with intermediate Recurrence Scores are less clear [6], as is the utility of testing in node-positive patients [7-9]. This introduces uncertainty into treatment decisions, making shared decision making processes more important, as they will rely more heavily on patient preferences. Testing occurs in the broader context of breast cancer treatment decisions that are already complex and anxiety-producing [10]. Given that promoting patient knowledge about their disease and available management options can change treatment preferences and subsequent decisions, communicating test results in ways that promote understanding and integrate patient preferences is critical to supporting effective treatment decisions [11-14].

The translation of new genomic technologies into oncology care presents several challenges for oncologists. They must decide which innovations to use and then interpret available genomic information in the context of other clinical data. One of the first steps in translation includes the oncologists' evaluation of the clinical utility of testing [15]. Oncologists' perceptions of low utility would limit dissemination, while the presence of national guidelines and widespread insurance reimbursement would foster dissemination. Overall utility may be conveyed to patients as part of the risk communication that will inform treatment decisions [16,17]. The most effective ways for oncologists to communicate this complex health information to patients remains unclear [18-24]. For instance, patients frequently misinterpret results provided via *Oncotype DX*[®] reports, such as misidentification of their Recurrence Score category [25]. The ambiguity introduced by intermediate *Oncotype DX*[®] results presents additional communication challenges [26]. Finally, testing often occurs within multidisciplinary care teams. While guidelines do not suggest that test results should impact surgical decisions, testing can be ordered at the time of surgery for women who meet clinical testing guidelines [1]. This allows for streamlining of care and additional discussion and support [27-29]. However, testing prior to the medical oncology consult does not allow for testing to be informed by conversations about the benefits and drawbacks of chemotherapy and the patient's preferences towards chemotherapy after having that discussion [30].

In the present study, we assessed medical and surgical oncologists' perceptions of factors related to the clinical integration of *Oncotype DX*[®]—one of the first genomic tests to be widely translated. Specifically, questions centered on four themes: oncologists' perceptions about the clinical utility of testing (i.e., whether test results are clinically useful when applied to the physicians' decision to recommend chemotherapy and the patient's decision to choose this treatment), the impact of patient preferences on the decision to test and use results to inform treatment decisions, methods of communicating risk associated with test results to patients, and benefits of and barriers to incorporating testing into multidisciplinary care settings.

Material and Methods

Participants

Eligibility included being a board-certified medical or surgical oncologist whose practice included or was solely dedicated to the treatment of breast cancer. We purposively sampled medical and surgical oncologists, as both can order testing and they may offer different perspectives. We also purposively sampled oncologists from several geographical regions of the US (Northeast, Southeast, Midwest) practicing in diverse settings (comprehensive cancer centers, hospital-based and private practices).

We approached oncologists via email, phone, mail or in-person contact from August 2010 through March 2011. We identified participants through professional networks of the authors and “cold calls” to oncologists. Among the 24 oncologists approached, none actively declined, but four did not respond or were not interviewed due to scheduling conflicts. Interviews continued until saturation was achieved [31]. Ultimately, twenty oncologists (10 medical and 10 surgical oncologists) participated. Each oncologist was compensated \$50 for his/her time.

Data Collection

We scheduled interviews at a time convenient to the oncologist. The interviews took place by phone and lasted approximately 20 minutes. Interviews began with eliciting sociodemographic information, years in practice, and current practice setting. Next, a semi-structured interview elicited perspectives on the four main themes: oncologists’ perceptions about the clinical utility of testing, the impact of patient preferences on the decision to test and use results to inform treatment decisions, risk communication, and benefits of and barriers to incorporating testing into multidisciplinary care settings. (See Table 1). Questions were developed through a literature review on the development and validation of *Oncotype DX*[®], cancer treatment decision making, physician-patient communication, and the clinical translation of novel technologies. Interviews were conducted by the project primary investigator (S.C.O.). The study was approved by the Institutional Review Board of Georgetown University.

Data Analysis—We used a phenomenological approach to guide our analysis, as we were most interested in the professional experiences of these oncologists and their perceptions of clinical translation. Interviews were audiotaped and transcribed verbatim by a research team member (E.S.). Data were organized, coded and analyzed using NVivo9 software by a primary (S.C.O.) and secondary (E.S.) coder. We used thematic analysis techniques, inductively interpreting data through a systematic, iterative process of identifying and summarizing subthemes related to the four main themes and then applying codes to the phrases and sentences associated with subthemes to allow for summation and comparison across interviews [32]. This process occurred iteratively, with the coders discussing subthemes that emerged on an ongoing basis.

Results

Most oncologists in our sample were female ($n = 14$; 70%), white ($n = 16$; 80%), and practiced in one of seven unique comprehensive cancer centers ($n = 14$; 70%; see Table 2). They averaged almost ten years in independent practice ($M = 9.9$, $SD = 9.89$). On average, medical oncologists had significantly longer histories of ordering the test than surgical oncologists ($t = 2.92$, $p = .009$). Themes appeared to vary by subspecialty. Therefore, we continue to differentiate medical and surgical oncologists. Table 3 shows the four main themes and subthemes within each.

Perceptions about the clinical utility of Oncotype DX[®]

All oncologists interviewed used the test in their practice. When asked which patients were appropriate for testing, 14 (70%) noted using the test either according to guidelines (i.e., NCCN) or noted specific guideline criteria (i.e., ER+, node-negative disease). They perceived Oncotype DX[®] to be a useful clinical tool for tailoring chemotherapy choices and personalizing patient care. In particular, many noted that results inform treatment choices by identifying patients who would gain little benefit from chemotherapy and could safely avoid its harmful effects, rather than the potential of identifying patients who are at high risk of recurrence who should receive chemotherapy.

“I think it's great. I think we treat a lot of women with hormone receptor positive disease for a very small benefit in terms of survival.” Surgeon

“It has really represented a paradigm shift...in the approach to chemotherapy decisions. It's trained us to pay attention to (cancer biology)...if we could have only one piece of information about the woman's cancer, most people would pick the Oncotype DX[®] over any of those other parameters. So I think it has a massive impact.” Surgeon

While oncologists did not express concerns about how they used the test in their own practice, several (N = 4; 20%) expressed concern that Oncotype DX[®] sometimes was ordered or applied inappropriately by other oncologists.

“And I have seen it used inaccurately. ... So you always worry that people are using it where it's not been validated or probably has little benefit.” Medical Oncologist

“So sometimes I find it...disconcerting how people use the information. I've seen somebody who, because they're young, wanted to give them chemo(therapy) even though they were in the low-risk category....that's not how the test should be used.” Medical Oncologist

Some also expressed concern about whether the data supporting the test is congruent with the weight that some of their colleagues placed on the results (N = 7; 35%). They believed that, in some cases, too much weight is placed on the result in comparison to other clinical information.

“People put a lot of value in that one number: the recurrence number... some people really scrutinize that single number...and it's a little scary because it's just one piece of the picture.... I think it's worrisome that there's so much enthusiasm...people seem to forget that it's one piece of information. And it's not perfect.” Surgeon

Perceptions about the impact of patient preferences

All but one oncologist reported that patients' preferences for chemotherapy impacted both their decision to order testing and how the results would be used. Responses of oncologists who indicated that patient preferences impacted testing and treatment decisions can be separated into two categories. Most (N = 16, 80%) would not order testing if a patient was certain of her decision about chemotherapy.

“If a patient says flat out that they are not going to take chemotherapy under any circumstances, then there's no point in doing the test.” Medical Oncologist

In contrast, three oncologists (15%), all of them medical oncologists, reported ordering testing to specify recurrence risk despite the patient's preference for or against having chemotherapy. These oncologists reported using the result as a risk communication tool to further demonstrate that a patient could either benefit from or safely avoid chemotherapy.

“So issues that come up if a patient is particularly resistant to the idea of chemotherapy but all of her indications say that she really may benefit from it. Sometimes the Oncotype DX[®] is run knowing that it's going to be high to help further illustrate to the patient the severity of her condition.” Surgeon

“Patients who are really resistant to taking any chemotherapy ... and the patients are like, ‘You know, I need something else to really justify that I need to do chemotherapy.’ And uniformly, those patients agree to get treatment.” Medical Oncologist

Risk communication

While surgeons reported broadly discussing the implications of test results with patients, medical oncologists said they integrated results into discussions of adjuvant treatment plans. Oncologists were clear regarding the implications of high or low risk results for adjuvant care. However, even with these results, many (N = 12; 60%) discussed other clinical and patient variables that influence adjuvant treatment decisions.

“Most of the time with low, I recommend just endocrine therapy. There is the occasional 40-year-old who comes back with a score of 16 which is like technically low ... where I hmm and haw a little bit and discuss chemotherapy anyway.” Medical Oncologist

“I don't think I could pigeon hole anything.... we try to tailor because we have the privilege of having a lot of effective agents in treating breast cancer.” Medical Oncologist

When asked how they convey the risk information associated with the test and what level of detail they share, all reported using both the Recurrence Score and its category (low, intermediate, high). Many (N = 11; 55%) specifically indicated that they used the Oncotype DX[®] report as their primary communication tool, noting that they found the report particularly useful in shaping their discussion with patients.

“I show them the graph and the recurrences and where they fall. I think the visual picture is easier to portray that way.” Surgeon

“I do primarily use their report for the graphic presentation of..how to interpret the score.” Medical Oncologist

Many oncologists (N = 12; 60%) noted that intermediate risk results pose a significant challenge to communicate with patients due to the moderate magnitude of risk and lack of data to support treatment decisions. In light of higher clinical uncertainty, other clinical parameters and patient values take on even greater importance.

“My other concern is that the intermediate score is very difficult to explain to a patient. It's very difficult for the oncologists to help them make decisions and I've had lots of patients tell me they're so torn because now they have this extra piece of information that tells them maybe or maybe not they need it. Now I don't know what to do with that.” Surgeon

“Oh I think it's tough... Are you someone who has to have every percentage point done or you won't sleep at night? Or are you the kind of person whose sister went through chemotherapy and you swore that you would never do it? So they have to draw on their own values system to help them get through that. There is no right answer at this time.” Medical Oncologist

“But within that (intermediate) range, all those other personal factors begin to weigh even more heavily.” Medical Oncologist

Finally, several medical oncologists (N = 4; 40% of this subgroup) noted the specific challenge of how to communicate with previously-tested patients who they determine have not been fully informed about the test and its implications by other providers.

“So the most troubled patients when they get a recurrence score back are those who were never appropriately informed about what the assay can tell them or not tell them. And they get the report with that box with the number and they just fixate on the numbers. But if you spend the time, just like with any other test, you just have to inform them about it.” Medical Oncologist

“What I'm always shocked at is when patients come to me with their records and they have a recurrence score, it's in the paper work and they don't even know what it really was. They saw that number and they're like in orbit and that pains me.” Medical Oncologist

Benefits and barriers to incorporating in multidisciplinary care

Oncologists found advantages and disadvantages in multidisciplinary coordination regarding the ordering and use of *Oncotype DX*[®] testing among surgical and medical oncologists. Many described difficulties with multidisciplinary care coordination and expressed different views on whether medical oncologists or surgeons should order testing. The majority of the medical oncologists (N = 8; 80% of this subgroup) preferred that surgeons *not* order testing.

“We're finding that ... the surgeon has already ordered testing before they ever come to us...most of the time it's ordered appropriately. But there are actually times when they've ordered *Oncotype DX*[®] testing and I wouldn't have. And so that's awkward because they've already ordered the test, the patients are kind of looking to us to... interpret it for them and to put it in the context of how we treat them.” Medical Oncologist

“The surgeons have a pretty good understanding of this sort of thing.... But I also think that they might assume that it's going to be helpful to us... And I appreciate that thought. But it's probably better in the overall scheme of things that we order it.” Medical Oncologist

Although surgeons were aware of these concerns, the remaining medical oncologists (N = 2) and all surgeons believed that surgeons' ordering of tests facilitated care and minimized delays.

“When the patient's clearly going to benefit from testing or the testing is clearly going to impact the clinical management recommendations, arranging for the testing to happen as soon as possible, ideally ordered around the time of surgery in order to expedite receipt of the results has been our practice pattern.” Surgeon

“We have a good enough understanding in our group that the surgeon often times will order it on someone that they know is going to want the information. But there are situations that are much more ambiguous, and I'll have the conversation with the patient first.” Medical Oncologist

Discussion

Our data provide valuable insight into medical and surgical oncologists' perspectives on the translation of one of the first genomic innovations to enter routine care. The oncologists in our study found clinical utility in *Oncotype DX*[®] testing and incorporated testing into their practice. Many expressed concerns that are common to new technologies [33], including that some of their colleagues either used the test inappropriately or placed undue weight on the test result in the context of the numerous other clinical factors at hand.

Incorporation of patient preferences into shared treatment decisions has been widely practiced in oncology care for almost 20 years [34] and is part of state and national health initiatives [35,36]. This is especially true for preference-sensitive decisions, for which more than one treatment could be appropriate, as is often the case in early-stage breast cancer. However, providers often find engaging in shared treatment encounters to be challenging and time-consuming [37]. Clinical guidelines suggest the incorporation of genomic profiling tests, but also highlight that not using these tests would be acceptable as well [1]. All but one respondent in our study indicated that patient preferences towards chemotherapy influence whether or not they order testing, despite clinical guidelines.

Most of these oncologists indicated that they would not order testing if the patient was certain of her decision for or against chemotherapy. However, this practice, which is in keeping with the process of shared decision making [38], assumes that treatment preferences are static and would not be influenced by additional information. In our prior research, we demonstrated that among women receiving *BRCA1/2* test results, receipt of a positive result can change the perceived pros and cons of risk-reducing surgery. These pros and cons are then predictive of uptake of surgery in the year after testing [39]. This pattern of results is reflected in the comments of three of our oncologists, each of whom specifically noted the utility of the *Oncotype DX*[®] test result in convincing a patient of the value of treatment which could be life-saving. One could also question whether a decision about the treatment with chemotherapy without results is fully informed. This specific scenario demonstrates the ongoing tension between two significant trends in medicine, shared decision making and evidence based practice [40,41]. Given that women's risk for recurrence exists on a continuum, there may be women for whom testing and the use of results are truly preference-sensitive, whereas women who have a very high risk of recurrence should be counseled about these risks using all of the information available, perhaps in a more directive fashion. However, this does not fully incorporate women's autonomy and preference not to receive this information. Given that some of the respondents in our study indicated that the presence of guidelines has allowed for testing to be routinely used early in the treatment process, such as at the time of surgery and before the initial medical oncology consult, how patients' treatment preferences influence the application of test results will likely evolve over time.

Oncologists in this study indicated their belief that the incorporation of *Oncotype DX*[®] testing into their practice both enhanced and challenged risk communication with patients. On one hand, many noted that high or low risk results can be a useful tool to explain treatment recommendations. While some test results provide clarity, others underscore the uncertainty that comes with weighing clinical information to inform treatment recommendations [42]. Most also noted that the report provided by Genomic Health, the company who provides *Oncotype DX*[®], as valuable to their practice and communication with their patients. These results should be viewed in light of previous research which shows that patients frequently misinterpret results provided via these reports, such as misidentification of their Recurrence Score category [25]. This suggests that risk communication in clinical encounters should continue to be examined and, if need be, supplemented with additional risk communication and decision support tools.

Respondents also noted that the communication of uncertainty, especially around intermediate test results and their treatment implications, was the greatest clinical challenge associated with *Oncotype DX*[®] testing. In part, this is likely due to the fact that there are several sources of uncertainty associated with intermediate results. Han and colleagues point to several sources of uncertainty in health care relevant in this context, [26] such as the probability associated with the risk of recurrence and potential benefits and harms of treatments, the ambiguity associated with the scientific evidence supporting the *Oncotype*

DX[®] test and the recommendations for women with intermediate results, and the patient's values and preferences. These are in addition to the overarching and well-recognized uncertainties associated with breast cancer diagnosis, treatment, and survivorship [43]. Our respondents indicated that they engage patients in this uncertainty, incorporating other available clinical information and patients' values. Previous work suggests that oncologists can help their patients cope with uncertainty by answering their questions, referring them to reputable resources for additional information, remaining open and sympathetic, and explaining the complexities of whatever uncertainty causes their distress [44-46]. Additional data is needed to determine what specific strategies for discussing this uncertainty are most beneficial for patients who receive *Oncotype DX*[®] testing.

The above challenges are reflected in the discussions of multidisciplinary care. Many medical oncologists preferred that they order the test after discussing adjuvant treatment options with patients. This approach would take patient preferences towards treatment into account and, most likely, these preferences would be more informed than prior to this visit. However, clinical guidelines provide direction to determine which patients who would be appropriate for testing. This guidance allows surgeons to order testing early in the diagnostic process. In many cases, surgeons are the primary oncology provider for women as they begin to process their diagnosis [47,48]. Further, decision processes often benefit from several perspectives and the additional time to reflect on these perspectives [49]. Therefore, providing test result information to patients in the context of this clinical relationship may carry its own benefits. We are applying the knowledge gained from this study to a prospective study of patient treatment decision making.

Our work is among the first to assess oncologists' perspectives on this new genomic technology. Despite these strengths, our results should be interpreted in the context of certain limitations. Oncologists with specific opinions of testing may have been more willing to discuss their perspectives than others. Our sample was female, white, worked in multidisciplinary care settings, and consisted of board certified oncologists, many of whom have decades of experience and are leaders in their field. Responses may not be transferable to other oncologists. Of note, however, while most of our sample was drawn from comprehensive cancer center settings, which could be a limitation, the sample was drawn from seven unique cancer centers in different geographical regions of the US.

Determining how oncologists choose to use genomic technology and translate the information to their patients informs the use of current genomic tests and the many to follow. The deluge of genomic tests that will come in the near future has led to calls for not only traditional genetics education, but also integration of more cross-cutting themes and tools. These include health informatics software designed to ease test interpretation, as well as decision support interventions for providers and patients [50]. Clinical communication skills that will be necessary to discuss this information with patients also should be emphasized. Despite the fact that the oncologists in the current study were actively-practicing oncologists, many with decades of experience in communicating probabilistic information and uncertainty, participants noted the challenge of applying this genomic information, especially in the case of intermediate results. Indeed, perhaps it is because of this experience that they appreciate the challenges in conveying this information; less experienced providers might have given less nuanced responses. Education could include specific training for interpreting and communicating the uncertainty inherent in genomic tests [51,52] while integrating patient preferences.

Acknowledgments

Study support: MRSG-10-110-01-CPPB (SCO). . The project was supported, in part, by Award Number P30CA051008 from the National Cancer Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Cancer Institute or the National Institutes of Health.

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Table 1

Interview guide

Interview Questions	Probe
Are you aware of the test?	When did you first become aware of the test?
Do you order the test in your current practice?	If yes, when did you start using <i>Oncotype DX</i> [®] testing?
Which patients do you think are most appropriate for <i>Oncotype DX</i> [®] testing?	Does a patient's attitudes toward adjuvant treatment enter into your decision to test?
What do you think about the utility of <i>Oncotype DX</i> [®] to aid in treatment decisions?	What concerns, if any, do you have about testing?
What is the value of the <i>Oncotype DX</i> [®] test to you in your clinical practice?	What added value does <i>Oncotype DX</i> [®] testing bring to the way you treat your patients?
At what point in the clinical process do you think it is best to order <i>Oncotype DX</i> [®] testing?	Why do you think this is the best time for testing?
Do you discuss <i>Oncotype DX</i> [®] testing with your patients before the test is ordered?	What do you tell them?
Do you discuss <i>Oncotype DX</i> [®] test results with patients?	How do you convey the risk information? Do you discuss that they fall into one of three categories, low, intermediate, and high? What level of detail do you share?
How frequently do you find that the patient's surgeon has discussed testing with them prior to your initial consultation?	
What treatment do you offer patients with low, intermediate, and high risk results?	When adjuvant treatment suggested by <i>Oncotype DX</i> [®] test results conflict with the treatment suggested with risk conferred through standard clinical parameters, how do you decide which treatment to suggest?
What role does testing play in your practice?	What are the advantages and disadvantages of ordering testing prior to the patient seeing her medical oncologist?

Table 2

Sociodemographic and Professional Characteristics of Physician Participants

	N = 20 (%)	Mean (SD)
Female	14 (70)	
<u>Race/ethnicity</u>		
Caucasian	16 (80)	
African American	3 (15)	
Asian or Pacific Islander	1 (5)	
<u>Practice Type</u>		
Comprehensive Cancer Center	14 (70)	
Private Practice	2 (10)	
Hospital Practice	4 (20)	
<u>Geographic Regions</u>		
Northeast	12 (60)	
Southeast	6 (30)	
Midwest	2 (10)	
<u>Years in Practice</u>		9.90 (9.89)
Years Using Test in Clinical Practice		
Medical Oncologist		4.20 (1.03)
Surgical Oncologist		2.70 (1.25)

Table 3

Themes and Subthemes

Themes	Medical Oncologists (N = 10)	Surgical Oncologists (N = 10)	Total (N = 20)
Perceptions of clinical utility			
1. Mention clinical guidelines	9	5	14
2. Results help tailor chemotherapy	9	5	14
3. Inappropriate use of testing	3	1	4
4. Inordinate weight on results	4	3	7
Impact of patient preferences			
1. Would not order testing if patient was certain about chemotherapy decisions	7	9	16
2. Would order testing to use result as a risk communication tool to change treatment preferences	3	0	3
Risk communication			
1. Integrate clinical and patient variables beyond <i>Oncotype DX</i> [®] result	9	3	12
2. Use <i>Oncotype DX</i> [®] report as primary communication tool	5	6	11
3. Communication of intermediate score	7	5	12
4. Communication with patients not fully informed by previous providers	4	0	4
Multidisciplinary care			
1. Prefer testing by medical oncologists	8	0	8
2. Prefer testing by surgical oncologists	2	10	12