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Patient-Centered Communication for Discussing Oncotype DX Testing

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Abstract

Oncotype DX testing (ODX), a tumor gene expression test, may improve breast cancer care, however communicating results remains challenging. We identified patient-centered communication strategies/gaps for discussing ODX results. We applied a patient-centered communication framework to analyze qualitative interviews with oncologists about how they communicate about ODX with patients, using template analysis in Atlas.ti. Overall, providers discussed four patient-centered communication domains: exchanging information, assessing uncertainty, making decisions and cross-cutting themes. Providers did not report discussing emotional aspects of managing uncertainty, assessing decision-making preferences, and evaluating decisions. A patient-centered approach may be a model for communicating about tumor gene expression tests.

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Keywords

breast cancer; patient-centered communication; communication; tumor gene profiling; qualitative methods

1. Introduction

In 2015, the Precision Medicine Initiative was announced with the ultimate goal of moving genetic and genomic technologies into clinical care. Cancer care has already become more targeted, as providers use unique tumor genetics to inform treatment plans. Oncotype DX (Genomic Health, Redwood City, CA) (ODX) is an example of a precision medicine tool that is currently recommended in clinical guidelines for women with node negative, hormone receptor positive breast cancer ^[1]. ODX is a 21-tumor gene expression test that predicts average rate of 10-year distant recurrence and benefit from adjuvant chemotherapy by categorizing women into low (recommended to forgo chemotherapy), intermediate (unclear evidence for chemotherapy benefit), and high (recommended to have chemotherapy) risk groups ^[2, 3]. Evidence suggests that ODX decreases overuse of adjuvant chemotherapy among women with low risk tumors, protecting women from the unnecessary costs and harms ^[4, 5].

While ODX testing has the potential to improve the quality of cancer care, providers have reported barriers to communicating with patients about ODX testing ^[6], and patients demonstrate low recall accuracy about ODX testing ^[7]. This suggests potential gaps and challenges in patient-provider communication about genetic technologies. As use of such technologies increases, high-quality, patient-centered communication will be critical to adequately describe these tests and results to patients.

The NCI Framework for Patient Centered Communication suggests that effective patient-centered communication in cancer care requires: exchanging information, fostering healing relationships, recognizing and responding to emotions, managing uncertainty, making decisions, and enabling patient self-management; the framework also contains a cross-cutting domain including time, setting, roles of communication, and partnership-building [8]. Our goal was to use this framework to examine current practices for discussing ODX testing with patients, and to identify aspects of patient-centered communication that are and are not being employed by providers.

2. Materials and Methods

2.1 Study Design

In 2014, we conducted ~30-minute semi-structured telephone interviews with oncologists across North Carolina (NC) until saturation of themes was reached. A qualitative approach allowed for a nuanced understanding of the complex communication and decision-making that occurs about ODX in the clinical encounter and cannot be adequately captured through quantitative analyses alone. Our interview guide sought to elicit providers' perspectives about barriers and facilitators of using ODX testing in clinical practice; this included use of ODX testing for patients with early stage, hormone receptor positive breast cancer, with

lymph node negative or lymph node positive disease. Of note, at the time of the study, ODX was only guideline recommended for women with node negative breast cancer. We also collected information about how providers communicate information about ODX testing and results to their patients. Interviews were conducted by one author (MCR); a second author (AB) listened, identified areas for probing, and took notes. All interviews were digitally recorded, professionally transcribed, de-identified and transferred to Atlas.ti (Berlin, Germany) for analysis.

2.2 Participants

We used purposive sampling to identify surgical and medical oncologists who practice in community or academic settings using the NC Oncology Association website, NC Medical Board website, and referrals from oncologists at the University of North Carolina-Chapel Hill. Providers were emailed or faxed a recruitment letter asking them to contact us, should they wish to participate. Providers were eligible if they practiced in NC and saw at least five breast cancer patients/week to establish care, to undergo treatment, or for follow-up. After scheduling a phone interview, providers completed an electronic informed consent and brief demographic survey. Providers received \$100 gift cards for participating. Informed consent was obtained from all individual participants included in the study.

2.3 Data Analysis

We used a method called "template analysis", which combines inductive and deductive approaches to coding interview transcripts with emergent and *a priori* codes or themes. Template analysis allows *a priori* codes to be modified, removed and augmented ^[9]. We applied an *a priori* set of codes (a template) to the first five transcripts using Atlas.ti. A conceptual framework from implementation science was used to compile the semi-structured interview guide and *a priori* codes, focusing on the adoption and use of ODX testing for treatment decision-making ^[10]. Next, the template was revised and emergent thematic codes were added to create the final coding template, which was expanded to include provider communication codes prior to and after ordering ODX testing (Electronic Supplement: Appendix 1). This final code template was applied to all transcripts by two coders (MCR, AB). Consensus was reached on coding for the first five transcripts to ensure high inter-rater reliability; coded transcripts were merged across coders using Atlas.ti. This paper focuses on results about ODX communication.

2.4 Conceptual Model

During data analysis, we focused on four domains of the patient-centered communication framework ^[8] that were most relevant to decision-making about ordering and using ODX testing for treatment decision-making (Electronic Supplement: Appendix 2). Of note, this framework differs from the conceptual model used to develop the interview guide. First, exchanging information is the reciprocal exchange of information between the patient and provider about ODX testing and chemotherapy by (a) sharing information, (b) exploring knowledge, beliefs and information needs, (c) providing information resources, and (d) facilitating the understanding of information. Second, managing uncertainty includes four subdomains: identifying uncertainty (e.g., whether to take chemotherapy, how to interpret intermediate ODX risk scores); understanding uncertainty; emotion-focused management

strategies (e.g., reducing anxiety and stress caused by uncertainty around treatment decision-making); and problem-focused management strategies (e.g., taking steps to reduce uncertainty, such as creating a plan for interpreting intermediate risk scores). Third, the making decisions domain focuses on the decision-making process (e.g., whether to use ODX testing, how to use results in chemotherapy decision-making). Subdomains include communicating about decisional needs (e.g., whether ODX testing is necessary for chemotherapy decision-making), preparing for decision (e.g., considering the choices for ODX testing and chemotherapy decision-making), making a choice and implementing a plan (e.g., whether to use ODX testing, subsequent treatment plans), and assessing decision-quality. Finally, there are cross cutting themes include the timing, setting, and care team roles for communication during the ODX test decision-making process.

3. Results

We reached thematic saturation after 15 interviews (5 surgical and 10 medical oncologists). The majority worked in academically-affiliated settings; on average, providers had practiced for 16 years, saw 25 patients/week (56% of whom had breast cancer), and ordered about 4 ODX tests/month (Table 1).

3.1 Exchanging Information

3.1.1 Sharing information—During initial conversations (before ordering ODX), all but one provider discussed sharing general information with patients about cancer biology, gene expression, risk of recurrence, ODX, and adjuvant chemotherapy. They described discussing how the test was developed (n=3), its costs (n=4), and how ODX fits into their cancer care plan (n=8). As one provider mentioned, "the more information [patients] can have, the more comfortable they are."

3.1.2 Exploring knowledge, beliefs, and information needs and preferences—

One third of providers discussed exploring knowledge and beliefs, patient preferences, and patient needs, reciprocally with patients. They discussed the importance of assessing patient preferences for chemotherapy prior to ordering ODX testing. For example, if a patient had an informed preference against chemotherapy, providers discussed not ordering ODX testing, as the result would not inform decision-making. However, some providers questioned whether patients' preferences about chemotherapy were informed, because of patients' "preconceived notions against chemotherapy":

I think a lot of times they may be generalizing all cancer. And as we know, there are certain cancers that are much more aggressive than breast cancer and many times it will all be sort of lumped together in the patient's head. So, sometimes it includes reeducation about what breast cancer is, how it behaves and how the chemotherapy might differ for a breast cancer patient as opposed to a lymphoma patient who gets five chemotherapeutic agents in one cycle.

When eliciting patient preferences, providers mentioned that reciprocal exchange of information facilitated shared decision-making, which activated women:

I think it's also empowered a lot of women to be able to tell their doctors why or why not they think chemo would be a benefit to them. So, it's opened up the discussion between providers and patients.

About 1/3 of doctors mentioned being sensitive to potential financial concerns about ODX testing:

Before the test is run, the patient is aware and agrees to that and we make certain that the finances are not going to be burdensome.

3.1.3 Providing informational resources—Most oncologists provided patients with resources, including pamphlets and sample ODX reports to help frame and prepare for discussions about the test and results and as a reference at home:

What's difficult I think is having the initial discussion about the Oncotype ...So, what I've done is...print out sort of a mock report. And so I tend to use that in my discussion. So I can show them what the results look like and we can talk about the low, intermediate, high-risk group That way when they come back for their results, they already know "well, what group am I in?" It's a much easier discussion at that point.

The most commonly discussed strategy to facilitate patients' assimilation and recall of information was repeated educational sessions about ODX testing both before it was ordered and after results were returned. About 40% of providers reported that they used multiple techniques to facilitate assimilation of complex concepts such as risk of recurrence and the ODX recurrence score. For example, they framed recurrence scores as favorable news for women with low and intermediate risk scores:

, I'll often say to people, "Look. In the next 10 years there's a 7% chance of it coming back." But what that really means is there's a 93% chance it won't. And so I'll point that out because those numbers look-- 13%, that's terrible. But, actually it's 87% it won't, and I'll always make them understand that number.

Three providers discussed sharing risk of recurrence scores in absolute terms with patients, for example:

... We try to not really talk in [relative] numbers... More like "Out of 100 people being treated, three people will have benefitted and 97 will maybe go through it without having needed it."

Six providers used relative risks to describe risk of recurrence. One provider described:

Chemotherapy is going to give you a 3% benefit over endocrine therapy," everybody [would say]"no," right?...But if you say like "you're going to have a 50% reduction but it's from 6% to 3%, people are like "I better take the chemo!"... It's a really big deal.

Two providers used metaphors as a technique both to introduce information and also to help patients assimilate the complex nature of risk. For example, to distinguish population and individual risks, one provider said:

One of the examples that I use there is...if you're the third-grade teacher and the second-grade teacher says, "here's a B class." Well, maybe there's 30 kids and even though they average a B they don't all make a B and some of them are smart and make an A and some of them are not so smart and make D's or whatever. And so just trying to use that example to say every two centimeter that's node negative and ER positive, while we might overall estimate that that's a 20% risk of recurrence, you know, maybe there are some that the risk is less than 10% and there are some where it's maybe greater than 30 and this is what the test is designed to do.

Furthermore, some providers used analogies for describing how ODX testing works, for example:

I usually explain it by saying a couple different ways...You might [see] somebody that's really well dressed and...got a nice suit on, but they might be some bad criminal or you might see somebody who looks like they live in the street and might be a completely honest person. I'll say, "Cancer cells can be the same way. They can look bad and behave well or vice versa."

Other providers discussed ODX testing more technically, in the context of tumor biology:

...[I characterize] it as a first generation genomic test and explain that it's really looking at the biology of the cancer. We're measuring these genes that are expressed in the tumor itself and that is a way of trying to get a better handle on the aggressiveness or lack of aggressiveness of the biology of the cancer. But then I go on to explain that the test actually is measuring the estrogen and progesterone and HER2 receptors in a different way with a different technique and that it is also measuring the growth rate, proliferation rates that kind of lines up with the grade of their tumor as well.

Overall, most providers gauged patients' baseline knowledge and perceptions, provided information and resources, and used multiple strategies to describe ODX testing and related, complex concepts (e.g., risk of recurrence) to enhance information exchange during chemotherapy decision-making.

3.2 Assessing Uncertainty

3.2.1 Constructing, defining, assessing and understanding uncertainty—Over

1/3 of providers identified and discussed the uncertainty around adjuvant chemotherapy benefit with patients, and framed ODX testing as a way to help manage uncertainty about chemotherapy decision-making. This discussion often extended to risk reduction:

If they are an appropriate person to consider [for ODX] then I usually talk to them about [chemotherapy].... And I'll tell them we've typically used (chemotherapy) before this test and now we have this new test that has a little bit better risk stratification for this particular lump of women who fall in this category of node negative, ER positive tumors. And it can help us decide a little bit more clearly if they're higher or lower risk and it can also help us decide if we think chemotherapy is going to be beneficial or not or how beneficial.

Current evidence is unclear whether women with intermediate ODX risk scores receive significant benefit from adjuvant chemotherapy, as such most providers discussed uncertainty about chemotherapy benefit for patients with intermediate ODX risk scores:

I say, "If you come back intermediate, you come back in and you and I talk about what to do...." Again, that's always a second conversation if they come back in that gray area.

A few providers discussed the overall uncertainty about ODX testing and risk of recurrence:

And I'll try to tell them that this is based on how they did the study where they developed the test and they validated it...And I try to tell them that it's not a crystal ball. It's not written in stone. This is the way it works but this gives us a pretty good estimate.

3.2.2 Problem-based management strategies—Providers formed actionable problem-based plans to manage uncertainty around the adjuvant chemotherapy decision. Providers explained how test results reduce uncertainty about chemotherapy benefit for women who have tumors with low and high risk scores.

I basically just say, "Look. [Results are] split into three categories: low, medium and high. If you come back high risk, this is a more aggressive tumor, more likely to spread and you would benefit from chemotherapy." Then I say the exact opposite for low risk.

Providers emphasized to patients that the ODX results would not eliminate all uncertainty around adjuvant chemotherapy decision-making. Instead, they developed management plans to prepare patients for uncertainty if their tumors were intermediate risk. One provider described a communication strategy for dealing with intermediate scores:

And I try to prepare them upfront. You know, I'll say, before we get the results if I talk to them ahead of time, that an intermediate score can be difficult to sort out and that if it's closer to high risk we might lean towards chemotherapy. If it's closer to low risk, we might lean against it just depending upon other factors and stuff. If you come back in the intermediate group, we're going to make our decisions the same way we used to 10 years ago as if this didn't exist. I definitely warn them about it.

3.3 Making Decisions

Identifying and developing a plan for addressing uncertainty around decision-making was further developed in this domain before and after ordering ODX testing in two ways: (1) preparing for/deliberating about choices and (2) implementing choice and action decisions. During preparation and deliberation, providers presented options for decision-making and elicited patient preferences for ODX testing and chemotherapy. For both choices, providers used resources provided by Genomic Health, for example, visual displays of a patient's ODX test results and risk of recurrence:

Sometimes I'll show them that bar graph on page two [of the results report] which shows sort of the confidence intervals. I find that more helpful.... But I'll say, "Look, your cure rate might go up 5%. It might not go up at all. It could even be

harmful." I said, "It's not like this high risk one where you can see 25%, that bar go up." I'll say, "We're not really sure about this. And that's an average of all of the ones in the intermediate. So, it's the good intermediates and the bad intermediates."

After discussing the test results, providers and patients made decisions about initiating adjuvant chemotherapy and formed a treatment action plan, including discussion of adjuvant chemotherapy and endocrine therapy. For example:

And generally, obviously if it's a low risk group it's an easy discussion. "Great news. You don't need chemo. You're not going to benefit from it." For the high risk patients, again there's that visual picture where they see the lines going up and usually it's a no-brainer for most and you can explain how the addition of chemotherapy will likely impact their disease free survival, overall survival. We talk about the chemotherapy options at that point...side effects...and anti-estrogen therapy.

Deliberation for patients with intermediate risk scores was more complex because of uncertainty about the benefit of adjuvant chemotherapy ^[3]. As such, there is overlap between managing uncertainties and making decisions. Providers did not discuss other aspects of making decisions, including reflecting on the patients' choice and experience and eliciting the patient's preferred role in decision-making.

3.4 Cross Cutting Themes

Providers discussed aspects of patient-centered communication that crossed all domains, including care team members' roles during ODX testing and adjuvant chemotherapy decision-making. One surgical oncologist said:

I'm the first person to see them and they're going to go on and see radiation oncology after surgery. So, I usually tell them kind of broadly that the next steps of treatment are going to depend on the surgical pathology. And if the lymph nodes are involved, many women will get chemotherapy. But if the lymph nodes are normal, the medical oncologist will likely go on and order a test called the Oncotype DX test and this tests the tumor itself to determine how much chemotherapy would benefit these patients above and beyond endocrine therapy."

Because decision-making and interpretation can span surgical oncology, medical oncology, and pathology, it may be important for patients to understand the roles of cancer care physician in discussing ODX testing and their diagnostic and treatment trajectory. Other cross-cutting considerations were ensuring enough time for these discussions and using an attentive listening approach. To this end, most providers held discussions related to ODX over multiple routine visits. This not only broke the conversation into smaller, more digestible pieces of information, but also allowed repetition to reinforce patient's understanding of critical information.

4. Discussion

4.1 Discussion

Providers face challenges when discussing complex genetic technologies and their treatment implications with their cancer patients ^[6]. Patient-centered communication strategies are critical to ensure that patients' preferences are considered. Our findings demonstrate that providers already are employing aspects of patient-centered communication techniques to facilitate discussion about ODX testing and adjuvant chemotherapy initiation for early stage, hormone receptor positive breast cancer patients.

Overall, providers reported spending significant time sharing background information with patients about ODX testing and adjuvant chemotherapy. Prior to exchanging information, some providers elicited patient knowledge and experiences to gauge what patients needed to know. To address identified knowledge gaps, providers used various strategies ranging from metaphors to technical descriptions of tumor biology. Furthermore, most providers utilized visuals to explain ODX testing and chemotherapy and gave these resources to patients for reference. Notably, this exchange of information occurred before and after ordering ODX testing.

Providers expressed uncertainty around how well patients understood complex risk and genetic information. Current literature supports these concerns, demonstrating that, on average, patients have poor understanding and knowledge of ODX testing ^[7, 11, 12]. This suggests that there may be room for improvement in information exchange about ODX testing with patients. Though not discussed by providers, eliciting from patients what level of detail and information they want or need may be important for tailoring informational exchange for each individual patient. Tailoring informational content and exchange strategies to a patient's knowledge, needs, beliefs, and preferences may help achieve more effective patient communication.

Discussing uncertainty was also an important aspect of patient-centered communication. Providers helped patients identify, understand and resolve uncertainty about ODX testing, especially for women with intermediate risk scores. Strategies for addressing anxiety and stress related to uncertainty were not discussed. It is possible that patients may receive such support through mechanisms other than the medical provider, such as support groups and counseling. It is also possible that providers did not feel qualified to implement strategies that address emotional aspects of uncertainty. Our interview guide did not explicitly probe about providers' use of such strategies, which may have led to under-representation of these topics in our data.

Finally, providers used patient-centered approaches when discussing decision-making. They tried to present clear choices about ODX testing and adjuvant chemotherapy. Providers incorporated both clinical evidence and patient preferences into these conversations, sometimes giving patients the ODX test result reports to help inform decision-making. Two aspects of decision-making were not often discussed: (1) the role the patient wished to take in decision-making and (2) re-evaluating the decision. This, may in part, result from not having interview questions, which explicitly asked about these topics. However,

determination of what role the patient wants to take in deciding about the use of genetic tests and interpretation of the results may be an important first step in the decision-making process. On the back end, providers may wish to reflect and evaluate how the patient feels about her decisions around using ODX testing and adjuvant chemotherapy.

Our study has several limitations. First, our small sample of oncologists in North Carolina limits the generalizability of our findings. Furthermore, oncologists who agreed to participate in this study may differ from those who did not respond. The majority of participants had an academic affiliation and our results may not generalize to physicians practicing outside of academic-affiliated sites. For example, evidence suggests that providers with academic affiliations may be more likely to specialize in one type of cancer and may be more likely to adopt innovations [13], such as ODX, possibly making them more knowledgeable about ODX than physicians in other practice settings. Second, we did not assess three domains of patient-centered communication: recognizing and responding to emotions, fostering healing relationships, and enabling self-management and patient navigation. A priori, we viewed these domains as farther removed from our primary focus on the uptake and use of ODX testing and subsequent decision-making; as such, we did not ask questions for these domains during interviews. Third, the study is based on physicians' selfreport and, as such, we do not know whether it reflects their actual behavior. While themes around emotional aspects of managing uncertainty, assessing decision-making preferences, and evaluating decisions did not emerge, it is possible that providers do address these subdomains within patient interactions. Notably, patient-centered communication must be assessed not only through eliciting information from providers, but also from patients: Future research should investigate patients' preferences about ODX communication to determine how well patient preferences and provider communication strategies are aligned [14, 15].

4.2 Conclusions

We found that oncologists reported using patient-centered communication strategies to discuss ODX testing and decision-making about adjuvant chemotherapy. More attention to patient communication preferences, re-evaluating treatment decisions, and developing emotion-based strategies for handling anxiety and stress related to uncertainty may be warranted. For example, providers should engage with patients on their preferred role in treatment decision-making^[8], and assess the need for psychosocial interventions among patients presenting with anxiety^[16]. Engaging in patient-centered communication about these complex genetic technologies is critical to respecting patients' preferences in decision-making. Future research into the effectiveness of the patient-centered communication framework, as well as the nuances of describing genetic technologies is needed. This will become increasingly important as cancer care continues to become more targeted through the use of precision medicine.

4.3 Practice Implications

This study provides insights on how patient-centered communication can be integrated into the clinical practices of oncologists as they discuss both complex genetic testing and how to

use test results to help make decisions consistent with patients' preferences. This patient-centered approach to communicating ODX testing and treatment planning may serve as a model as we move into an era of precision medicine both within and outside cancer care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1Characteristics of participating oncologists, their patients, and practices.

Characteristics		Mean
Provider	Gender (%Male)	53.3
	Race (% White vs. Non-white)	86.7
	Oncology Specialty (% Medical vs. Surgical)	66.7
	Years of practice	15.8 ± 7.8
	Number of ODX ordered per month	4.4 ± 3.4
Patient Mix	Medicaid (%)	20.7
	Uninsured (%)	10.5
	Non-White (%)	38.1
	Breast Cancer Patients (%)	56.4
	Breast Cancer Patients/wk (%)	25.1 ± 13.9
	Breast Cancer patients with HR+ breast cancer (%)	68.1
Practice	Academic Affiliation (%)	73.3