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Patient and Provider Perspectives Regarding Enrollment in Head and Neck Cancer Research

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Abstract

Objective.—The advent of precision oncology complicates how clinicians and participants understand how clinical care and research interface. Here we examine how key stakeholders perceive the utility of, and evaluate the decision to participate in, genomic sequencing head and neck cancer research. The goal of this study was to highlight unique considerations for our community as this type of research proliferates across the country.

Study Design.—Prospective multimethod qualitative and quantitative embedded ethics protocol.

Setting.—Single-institution National Cancer Institute–designated academic cancer center.

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Author Contributions

Andrew G. Shuman, conception, supervision and design of the study and collection, analysis, and interpretation of data and in writing the manuscript; **Michele C. Gornick**, analysis and interpretation of data and in editing the manuscript; **Collin Brummel**, collection, analysis, and interpretation of data and in writing the manuscript; **Madison Kent**, analysis and interpretation of data and editing the manuscript; **Kayte Spector-Bagdady**, supervision and design of the study and collection, analysis, and interpretation of data and in writing the manuscript; **Elliot Biddle**, analysis and interpretation of data and editing the manuscript; **Carol R. Bradford**, conception and supervision of the study and analysis, and interpretation of data and in editing the manuscript; **J. Chad Brenner**, design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

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Ethics Approval and Consent to Participate

All participants provided informed consent. This research was approved by the University of Michigan IRBMED.

Availability of Data and Materials

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Subjects and Methods.—Multimethod study using paired surveys and semistructured interviews among patients and providers involved in a prospective precision head and neck oncology sequencing protocol (116 survey patient-participants, response rate 82%) with 18 interviewees.

Results.—Participants were generally enthusiastic about enrollment in research, both to help future patients and as a way of giving back to the community. They described reliance on information from and trust in their cancer doctor regarding the decision to participate in research, but paradoxically there was discordance in how doctors and patients reported their respective influence in the decision-making process. Clinicians also stressed the importance in separating clinical and research-informed consent processes, although patients did not describe this tension.

Conclusion.—As we enter an era of increasing personalized medicine and targeted therapies, the relationship between clinicians, scientists, and patients plays a larger role in how we individualize and contextualize cancer research. Our data are another step toward the ultimate goal of respecting and protecting patients as participants in head and neck translational oncology.

Keywords

research ethics; head and neck cancer; precision oncology; research informed consent

Background

There has been much written about patients' motivations for, and challenges regarding, enrolling as participants in clinical research protocols.^{1,2} A long history of transgressions by researchers against subjects³ has founded a complex regulatory climate that attempts to ensure appropriate protection of today's research participants.⁴ Despite such safeguards, the threshold requirement for accepting both the risks and burdens of research is the informed consent of the participant—but we know that the consent process does not always effectively achieve consent that is actually informed.⁵

Previous studies also indicate that recruiting patients with cancer into research is a unique process. This study population might be more interested in and potentially vulnerable to coercion regarding enrolling in oncology-related protocols.^{6–9} In past studies, patients struggled even to grasp the incurable nature of their metastatic cancer in addition to understanding goals of unproven chemotherapy for palliative intent.¹⁰ Patients with head and neck cancer may be more vulnerable due to receptive and expressive communication challenges inherent to their disease burden. These invariably require even more effort on the part of both clinicians and patients to understand and describe risks, benefits, and alternatives so that patients can effectively make good decisions for themselves.¹¹

The advent of molecularly based precision oncology research further complicates how clinicians and subjects understand how clinical care and research interface.² The National Cancer Institute and many tertiary care centers throughout the country are creating programs using genetic information to apply personalized, targeted therapy to cancer treatment.¹² Genetic discoveries with prognostic and therapeutic implications for head and neck cancer are constantly being discovered.¹³ The potential clinical utility of information derived from

large-scale sequencing is tantalizing, and technology is making it increasingly possible to rapidly and affordably do so for many patients. But we do not yet understand enough information about the special relationship between a patient with head and neck cancer and his or her physician—and whether or how that relationship influences the patient's decision to enroll as a participant in a precision medicine trial.

If head and neck precision oncology is to accomplish stated goals of helping determine therapies of the future, we must first appreciate the motivations, comprehension, and aspirations of the patients and providers who are investing their lives and practices in this new approach to cancer discovery. Here we examine how key stakeholders—patients and their medical, surgical, or radiation oncologists—perceive the utility of and evaluate the decision to participate in genomic sequencing head and neck cancer research. The goal of this study was to highlight unique considerations for our community as this type of research continues to proliferate across the country.

Methods

We conducted a multimethod qualitative and quantitative embedded ethics protocol using surveys and semistructured interviews of patients enrolled in the Michigan Otolaryngology Sequencing Study (MiOtoSeq) trial and their cancer doctors. Data were collected from June 2016 to February 2019. This research was approved by the University of Michigan IRBMED.

Overarching Study Design

Our study was nested within MiOtoSeq, which is an institutional review board–approved precision medicine study in the Michigan Medicine Department of Otolaryngology–Head and Neck Surgery.¹⁴ MiOtoSeq aims to recruit patients diagnosed with head and neck cancer of any subsite and perform upfront, targeted genomic sequencing. Our work embedded a multimethod prospective empirical ethics protocol within the broader MiOtoSeq study, with the goal of more fully understanding the decision-making process of both participants and their clinicians as well as any goals or challenges with enrollment. In this article, we focus on patient motivations for enrollment in research generally, the influence their physicians had on that decision, and physician concerns regarding the research informed consent process.

Surveys

All patient-participants who enrolled in MiOtoSeq received a survey regarding their comprehension of and motivation to participate in MiOtoSeq. This survey could be completed on paper at the clinic or online using Qualtrics (a generalized survey service permitting the creation of survey instruments, distribution of the surveys, data storage, and analysis).¹⁵ The survey was designed to further explain themes suggested by the existing empirical literature regarding enrollment of patients with cancer into precision medicine research.^{7–9} Surveys were distributed to the patient at the time of enrollment. Patients either took the paper survey home to return by mail or completed the survey in clinic. We

distributed the survey to 142 potential patient-participants and had a response rate of 82% (n = 116).

We also distributed surveys to the physicians of the patient-respondents, who referred them to the MiOtoSeq study in the first place. The physicians (including medical, radiation, or surgical oncologists) were emailed the link or asked to complete a paper version of our survey, with corresponding measures to the patient survey, to compare responses and identify any discrepancies in the way the decision-making process was represented as between the patient and his or her own doctor. We were able to collect a matching clinician survey (n = 116) for each patient survey response.

The analysis of the survey data reflected the exploratory nature of this study and limited sample size. Only descriptive statistics were used to characterize the sample in terms of reporting demographics and perceived influence of the referring cancer doctor on the patient's decision to enroll in MiOtoSeq.

Interviews

A subset of both patient- and clinician-participant survey respondents was also recruited for semistructured interviews to further explore our quantitative data. Interview sampling was purposive to ensure diversity in clinical, demographic, and oncologic factors. We continued to recruit patient- and clinician-participants until thematic saturation was achieved.^{16,17} Here we analyze 10 patient interviews and their corresponding physician interview. Two of our interviewed physicians took care of 2 of our interviewed patients each. In these cases, we conducted 2 separate interviews with the physicians, one to focus on each separate patient.

In both groups, semistructured interviews were conducted to assess how patients and their doctors viewed influential factors in the decision-making process to enroll in the MiOtoSeq trial. Interviews were performed by trained researchers using an interview guide to ensure consistency and proper technique, while also allowing for flexibility to more deeply explore patient-specific responses. Interviews lasted approximately 1 hour and were conducted in a private conference room. Each interview was audio recorded and professionally transcribed to ensure fidelity of the data, and all identifiers were removed. All data were entered into and maintained in Mbox, a secure cross-platform data management program.

The interviews were then analyzed using thematic and content-driven techniques. Codebooks were developed separately for patient and clinician responses by study team members. Transcribed interviews were also double coded separately by study team members. Where discordance between the codes existed, a third individual was consulted. Coding schema evolved through a systematic, line-by-line analysis of the data. The semistructured nature of the interviews allowed for both inductive and deductive coding, which, in turn, enabled a comparative dimension to the exploratory inquiry to describe, analyze, and interpret the data.¹⁸

Results

Table 1 presents demographic data of our patient survey and interview participants. Overall, patient-participants were majority male (78% of survey respondents; 60% of interview participants), white/Caucasian (97% of survey respondents; 90% of interview participants), and between the ages of 50 and 69 years (69% of survey respondents; 50% of interview participants). Clinician-participants were 75% male and were all doctors of medicine (MDs) with head and neck subspecialties, with a median of 6 years (range, 2–11 years) in posttraining practice. For this article, we focus on 3 main themes from both the interview and survey data: (1) motivation for enrollment in research generally, (2) reliance on and trust in the clinical enterprise, and (3) the need to separate clinical from research consent.

Motivation to Enroll in Research

In response to a preliminary prompt, many participants discussed their motivations and goals for enrolling in MiOtoSeq. Several were supportive of research generally. As 1 patient put it, “I’m all for research. I don’t care what it is” (P03). Another described it as “an honor” (P05). A third pointed out that while he was there as a patient to “get fixed,” the researchers might as well be learning: “Learn as much as you can while you got me, you know? Call me ‘guinea pig!’ Go for it!” (P04).

Others justified that they were likely currently benefiting from research that patients had engaged in before them: “I believe for me to get the treatment I’m getting now—it’s because somebody out there agreed to have this done and ... scientists put 2 and 2 together and they kind of figured what treatment they would recommend!” (P08). As another agreed: “How is somebody ever going to learn if you don’t give them a chance? How is the study ever going to go forward ... if nobody signs up for it?” (P07).

Several discussed trying to help future patients like them. For example, to “help the next girl that’s my age, dying of the same stupid disease ... [and] not to leave a husband so young that’s a widow” (P07) or to protect a future patient “so they don’t have to go through all the rough parts I’m going through” (P03).

Last, several patients discussed contributions of research as altruism or giving back to society. For example, one said that future patients will “benefit by [my] giving back. I’m retired and I volunteer ... this is just another way to give back” (P04). Two others framed their contributions in religious terms: “My involvement has to do with my faith. I’m a devout Christian, and I simply know that I’m here not just for my own purposes. And so, I’m willing to give of myself” (P10); the other described their involvement as “Just to be helpful to other humans, you know: ‘I will spend my heaven doing good upon the earth’” (P11).

Reliance and Trust in the Clinical Enterprise

A second important theme for participants—despite the separation between clinical care and research that the physicians hoped to achieve—was that of reliance on and trust of the referring physician and clinical center when considering whether to enroll in research. As 1 participant put it, “I needed no arm twisting at all” (P05) and another: “If my doctor is okay with it, I’m okay with it. You trust the pro, and he’s the pro” (P04).

In fact, our survey data found that the vast majority (84%, n = 98) of patient-participants said that they talked to their cancer doctor about their decision to have their genome sequenced as part of the study. However, when we compared survey results of individual patients with their own clinician, we found that patients and physicians disagreed 13% (n = 15) of the time regarding whether they actually had this discussion. Out of discordant pairs, clinicians reported that they spoke with their patient 7% (n = 8) of the time regarding enrollment in the study when the patient said that they had not.

This quantitative finding was also reflected in our qualitative work, with the doctors being more concerned about their own potential undue influence than their patients were—although many patients admitted that they were readily open to enrollment. As 1 clinician observed, when asking whether the patient wanted to hear more about potential enrollment, “He just kind of said, ‘yeah, yeah, yeah, I’ll do anything’ basically” (C03). That clinician’s patient rejoined, “I don’t always do what they say” (C03) but also added, “It’s like I told him: I trust him, because he has explained everything, and that’s the main thing.... There ain’t nothing complicated about it” (P03). Another clinician also voiced the concern, particularly with enrolling metastatic patients in research, that “they’re willing to say ‘yes’ to everything, and that it’s really not an informed consent process” (C07). This clinician’s patient affirmed, “I didn’t even have to know that much about [the research] to say ‘yeah,’ because I believe in research.... It was a no-brainer for me” (P07). Last, several patients discussed not just trust in their clinician but trust in the medical center generally: “I knew somebody down here knew what they were talking about ... they could help me. I already knew that before I even stepped in the building.... Because I have trust” (P03).

Our survey data added interesting color to these conversations; we found that clinicians believed that they were much more influential in the patient’s decision to enroll in the study than their own patient reported. Almost half of the patients indicated they made the decision to participate in the study with little input from their cancer doctor (48%, n = 46). On this question, there was also an impressive 91% discordance between patient and physician answers: the physician was much more likely to indicate the patient made the decision after they spoke extensively (48%) or that they made the decision together with their patient (35%).

Need to Separate Clinical and Research Consent

Related to the theme of trust and reliance, a last important theme for the clinicians we interviewed was the critical need to separate clinical and research consent. This issue was not raised by any of our patient-participants.

Several clinicians discussed their approach to bringing up the potential enrollment in research with the goal of not conflating the research with clinical care or appearing to pressure the patient to enroll in research: “I definitely say, ‘You don’t have to do this ... and that will not change your care based on what you do. I just want you to have opportunities to do these things.’ So definitely he knows it’s voluntary” (C10). Although several others admitted to tipping the scale in favor of enrolling their patients: “I do believe I indicated that I thought it would be a reasonable thing for him to do, and I would recommend that he strongly consider it, but I think the ultimate decision was his with my guidance” (C05).

Others mentioned the importance of having someone else, other than the treating physician, go through the research informed consent process with the patient: “To maintain some degree of being objective, as I also am involved in the trial, I did defer [informed consent] to the research coordinator ... to come in and explain the trial in more detail and more objectivity” (C07). Another agreed: “I don’t want to feel like I’m forcing anyone to do it ... I think [the patient is] less inclined to be pressured to sign up for it ... if it’s not their treating physician [going over the study information with them]” (C04/C06). Several clinicians remained worried, however, that “when you tell someone it’s voluntary, is it truly voluntary? I think [my patient] was happy to just be around to help” (C10).

Discussion

Overall, we found that, much like in other groups of patients previously studied,^{7–9} patients with head and neck cancer were excited about enrollment in research. While some patient-participants talked about being supportive of research generally, others discussed wanting to help future patients like them specifically or that they saw enrollment in research as a way of giving back to the community. These data corroborate studies that have found that sentiments regarding trial enrollment are frequently driven by the relationship with clinicians and researchers, rather than the specific research protocol itself.¹⁹ There have also been interesting data contextualizing how patients view altruistic goals of helping future patients and creating generalizable knowledge, which are further elucidated by our work.²⁰

Second, we found that patient-participants reported a high degree of reliance on information from and trust in their cancer doctor regarding whether to enroll in research. Trust has been recognized as a critical component of a successful research enterprise.²¹ In addition, our findings are strikingly similar to grounded theory analysis of perioperative head and neck decision making by Davies et al,²² in which patients’ trust in clinicians was the foremost predictive factor of their choice, rather than the clinical indication or surgery itself. We found that the trust cancer patients have for their clinicians appears consistent across both clinical and research decisions.

Of course, the other side of this equation requires us to recognize that trust can also exacerbate underlying vulnerabilities. Specifically, given that head and neck cancer disproportionately affects socioeconomically disadvantaged populations,²³ it is even more important that the research informed consent process remains robust and that researchers effectively communicate risks and benefits of protocols for which equipoise exists. Additional research and engagement with diverse populations are critical.²⁴

Complicating this further, while many of the clinician-participants we interviewed reported being concerned that they might unduly influence their patients’ decision to enroll in research, almost half of patient-participants reported that they made the decision with “little” input from their doctor. Thus, underlying trust in clinicians or their institution need not wholly equate with how much influence they have in a specific enrollment choice. Kraft and colleagues²⁴ also recently found that, despite robust informed consent processes, both investigator and institutional responsibility and accountability remain critical components of

precision medicine protocols—particularly given the longitudinal nature of the involvement between researchers and participants.

Last, a major theme from the clinicians' perspective was the need to separate clinical from research consent as a method of moderating perceived influence on the patient decision of whether to enroll. The overall goal appeared to be attempting to mitigate potential “therapeutic misconception” (ie, patient confusion regarding the differing goals of research and clinical care as well as overassuming benefits of research enrollment), although none of the physicians used that specific language.^{2,25}

There are several limitations to this research. First, a single institutional study might not reflect the general population of patients with head and neck cancer, although our demographics are nationally consistent with a largely human papillomavirus–positive cohort. We also know that the informed consent process and the regulation of different types of translational oncology research involving biospecimens are quite varied, and thus these findings do not necessarily apply to all such cancer research platforms.²³ In addition, the qualitative component of this study was limited and—despite robust thematic saturation—should be tested in other settings, ideally with mixed methodology, to confirm results. That said, the synergy and consistency between the multimethod qualitative and quantitative findings herein reinforce the veracity of the conclusions that we were able to draw.

Conclusions

Head and neck cancer clinicians and researchers cannot study tumors entirely disembodied from the patients from whom they are procured. As we enter an era of increasing personalized medicine and targeted therapies, the relationship between clinicians, scientists, and patients will play a larger role in how we individualize, contextualize, and enroll in cancer research. To operationalize an effective consent process to ensure that patients are fully cognizant of the risks and benefits of research and are enrolled without coercion, we must achieve a more cohesive understanding of how patients decide to enroll and best practices regarding how their clinicians should support them in this process. Our data are another step toward the ultimate goal of respecting, protecting, and potentially enrolling patients with head and neck cancer into research while maintaining the high level of existing trust.

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Table 1.**Patient-Participant Demographics.**

Characteristic	Survey Participants (n = 116), No. (%)	Interview Participants (n = 10), No (%)
Age at enrollment, y		
20–29	3 (2.5)	1 (10)
30–39	3 (2.5)	1 (10)
40–49	11 (9.5)	2 (20)
50–59	29 (25)	2 (20)
60–69	51 (44)	3 (30)
70–79	16 (14)	1 (10)
80+	2 (1)	0
Sex		
Female	26 (22)	4 (40)
Male	90 (78)	6 (60)
Race		
White or Caucasian	112 (97)	9 (90)
Black or African American	1 (1)	1 (10)
Asian or Pacific Islander	1 (1)	0
Native American or Alaska Native	1 (1)	0
Ethnicity		
Hispanic/Latino	1 (1)	0
Non-Hispanic/Latino	115 (99)	10 (100)
Primary disease site		
Oral cavity	40 (34)	2 (20)
Oropharynx	55 (47)	7 (70)
Larynx	10 (9)	0
Nasopharynx	1 (1)	0
Major salivary gland	7 (6)	1 (10)
Unknown primary	2 (2)	0
Disease state at enrollment		
Primary untreated	81 (70)	7 (70)
Recurrent, salvage	13 (11)	1 (10)
Recurrent, unresectable/metastatic	22 (19)	2 (20)