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Evaluating the impact of the Patient Preference Assessment Tool on clinicians' recommendations for phase I oncology clinical trials

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Abstract

Objective: Many groups recommend assessment of patient preferences particularly for patients with advanced, incurable cancer. We, therefore, developed the Patient Preference Assessment Tool (PPAT) to ascertain patient preferences in order to inform clinician recommendations and improve shared decision-making. The aim of this study is to assess the PPAT's impact on clinicians' strength of recommendations for phase I oncology clinical trials.

Methods: Clinicians recorded the strength of their recommendation on a Likert scale before viewing the patient's PPAT. After viewing the PPAT, the clinician discussed the clinical trial with the patient and then recorded the strength of recommendation again. If there was a change, the clinician noted the reason for the change: clinical findings or patient preference. Clinicians were interviewed about the acceptability of the tool. Our threshold for determining if a change in recommendation due to the PPAT was significant was 20%, given the multiple factors influencing a clinician's recommendation. We also noted the type of phase I conversation observed based on classifications defined in prior work—priming, treatment-options, trial logistics, consent.

Results: $N = 29$. The strength of the clinicians' recommendations changed due to patient preferences in 7 of 29 (24%) of the conversations. The seven changes due to preferences were all

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AUTHOR CONTRIBUTIONS

Rachel S. Hianik, Taofeek Owonikoko, Margie D. Dixon, and Rebecca D. Pentz conceived and designed the study. Rachel S. Hianik, Taofeek Owonikoko, and Walid L. Shaib acquired the data. Rachel S. Hianik, Jeffrey Switchenko, Margie D. Dixon, and Rebecca D. Pentz analyzed the data. Rachel S. Hianik, Taofeek Owonikoko, Margie D. Dixon, and Walid L. Shaib interpreted the data. Rachel S. Hianik and Rebecca D. Pentz drafted the manuscript. All authors revised the manuscript and also read and approved the final manuscript.

CONFLICT OF INTERESTS

The authors have nothing to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

in the 23 treatment-options conversations, for an impact rate of 30% in this type of conversation. 82% of clinicians found the PPAT useful.

Conclusion: The PPAT was impactful in an academic setting, exceeding our 20% impact threshold. This tool helps achieve the important goal of incorporating patient preferences into shared decision-making about clinical trials.

Keywords

cancer; oncology; patient preferences; phase I clinical trials; physician recommendation; psycho-oncology

1 | BACKGROUND

Professional organizations such as the American Society of Clinical Oncology as well as the National Academy of Sciences have called for the care of patients with advanced, incurable cancer to include personalized assessment of the patient's needs, goals, and preferences throughout the course of treatment, especially during clinical trial considerations.¹⁻³ However, multiple barriers have been identified that impede clinicians from fully evaluating patients' preferences. Lack of time and reimbursement practices disfavor discussion.² In addition, suboptimal communication practices can result in clinicians thinking that preferences are discussed when patients do not.⁴ Oftentimes clinicians expect patients to spontaneously mention their preferences⁵ and overlook patients' indirect expressions of concern.⁶

Various interventions have been developed in oncology to improve patient/clinician communication about clinical trial discussions.⁷ However, interventions purposefully targeted at facilitating patient communication, such as question prompt lists, have had limited success.⁸ Studies have shown that patients consider trust in their clinician's recommendation key to decision-making about cancer clinical trials.⁹ Therefore, in a previous study we developed the Patient Preference Assessment Tool (PPAT) to switch the paradigm, focusing on informing the clinician's recommendation, rather than on improving patient/clinician communication.¹⁰ We now aim to assess the efficacy of the PPAT by analyzing how it influences clinicians' recommendations for phase I oncology clinical trials. Our secondary aims include summarizing patient preferences at an academic cancer center and describing clinicians' opinions of the PPAT.

2 | METHODS

This study was approved by the Emory Institutional Review Board #IRB00105914.

2.1 | Recruitment

Oncologists were asked to work collaboratively with a research assistant (RA) to identify eligible patients each day. Eligible patients included any patient with advanced solid malignancy with whom the clinician planned to discuss phase I cancer clinical trials. Consent for clinical trials is a process and phase I trials are mentioned at different times throughout that process. Since any phase I trial discussion was eligible, we observed any

of the four types of conversations which happen during the consent continuum outlined by Wall et al.¹¹ These four types are (1) priming conversations, that is, conversations early in the patient's care when standard of care options had not been exhausted, but in which phase I trials were discussed as future options; (2) treatment options discussions (called patient-centered in the Wall article to distinguish this type of conversation from conversations focusing on the trial details and not on patient choices) during which the patient had reached a critical junction in care and a phase I trial was one of the treatment-options; (3) trial logistics discussions during which the logistics of the trial were discussed (called trial-centered in the Wall article); and (4) the consent-signing discussions during which the patient has the opportunity to ask any questions before the consent is signed. Informed consent was obtained from each patient and clinician prior to entering the study. Consent was documented by filling out the PPAT (patients) or by completing the recommendation scale (clinicians). After consent, each patient and clinician filled out a demographic questionnaire. Twenty-five participants were recruited in the oncology consult clinic and four participants were recruited in the phase I consultation clinic, both at an academic center.

2.2 | Evaluation of the PPAT

The patient participant filled out the PPAT before the consultation. They were instructed to check, but not rank, the top three options on the PPAT that matched their current preferences. The clinician first filled out a Likert scale indicating his/her strength of recommendation for a phase I cancer clinical trial for that patient (1 being "not strong at all" and 10 being "extremely strong") and then viewed the completed PPAT before the consultation. After the consultation, the clinicians filled out the Likert scale a second time. If their strength of recommendation changed, they indicated whether it changed mainly because of clinical findings or patient preferences. Due to the importance of clinical findings as a key determinant of recommendations for clinical trials, we specified that if the clinicians' recommendations changed due to patient preferences in at least 20% of the uses, the tool would be deemed useful. Each clinician used the PPAT two to five times. The RA observed, audio-recorded and transcribed each patient/clinician conversation. Patient/clinician conversations were qualitatively coded using multilevel semantic analysis¹² in MAXqda (VERBI) to determine if the preferences checked on the PPAT were discussed in the phase I consultation. Two independent coders coded all of the conversations. Four disagreements were resolved by consensus between the two coders. Descriptive statistics were used to describe the completed PPATs and patient demographics.

2.3 | Clinician interviews

The RA interviewed each clinician who used the PPAT. The RA asked open-ended questions about the usefulness of the PPAT, how the PPAT could be improved, how the PPAT influences the clinician's recommendation, and in what setting the PPAT would be most helpful. The clinicians were also asked to comment on their patients' willingness to participate in clinical trials. Each interview was transcribed and qualitatively coded using multilevel semantic analysis in MAXqda (VERBI). Two independent coders reviewed the interviews to determine the frequency of clinician answers. Five disagreements were

resolved by consensus between the two coders. Descriptive statistics were used to summarize the interview responses and clinician demographics.

3 | RESULTS

3.1 | Participants

Twenty-nine patients participated in the study. Two patients declined to participate for a 93% response rate. Reasons for declining included being in pain and not wanting to be audio-recorded. Participant demographics are summarized in Table 1. The average participant age was 59. A majority of patients were female, white, and had a high school or an Associate's degree. Ten oncologists and one nurse practitioner participated in the study. The average clinician age was 40 and the clinicians had been practicing medicine for 3–20 years. The 10 oncologists' areas of specialization included gastrointestinal (5), breast (3), and aerodigestive (2). The nurse practitioner worked with all clinical sites in the phase I oncology clinic.

3.2 | Evaluation of the PPAT

The clinician's strength of recommendation for a phase I clinical trial changed 16 times (55%). The clinician's strength of recommendation changed nine times (31% of all conversations) due to clinical findings and seven times (24% of all conversations) due to patient preferences, thus exceeding our benchmark of 20%. The median change in strength of recommendation due to clinical findings and patient preferences was –1 and 1, respectively. As would be expected, different types of phase I conversations had different results. Our sample included four priming conversations that occurred early in care, 23 treatment-options conversations in which a phase one trial was one option for the patient's next treatment, two trial logistics conversations in which the logistics of the trial were discussed, and no consent-signing discussions. The strength of the recommendation only changed in one of the priming conversations and that was due to clinical findings. Furthermore, the strengths of the recommendations that did not change were low: 5, 2, and 1. The one that did change moved from an 8 to a 4. Neither of the trial logistics conversations' strength of recommendation changed and both were a 10, as would be expected at this point in the patient's care when the logistics of a trial were being detailed because the patient had indicated that the trial was his/her primary choice at this point. There was a change in strength of recommendation in 15 of 23 (65%) treatment-options conversations. All seven of the changes due to patient preferences occurred in treatment-options conversations (7/23; 30%). In three of these changes due to patient preferences, the recommendation was less strong after the conversation, and in four of the conversations the recommendation was stronger (Table 2).

Physicians discussed a preference chosen on the PPAT in 5 (5/29; 17%) of the subsequent conversations. Patient-chosen preferences that were discussed included “helping other cancer patients by participating in research,” “getting the best possible care from expert doctors,” “having access to best cancer treatment,” “avoiding as many research side effects as possible,” “fighting my cancer as much as possible,” and “avoiding extra travel time and time away from home.”

3.3 | Patient preferences

The number of participants who chose each preference is reported in Table 3. The three most frequently checked preferences on the PPAT were “having access to the best cancer treatment (69%),” “getting the best possible care from expert doctors (59%),” and “fighting my cancer as much as possible (48%).” Two preferences were not chosen by any participant: “Making it easier on my family so they do not have to drive me or come with me to clinic appointments (not being a burden on my family)” and “avoiding as many procedures as possible (like biopsies and blood draws).” To provide context, we also report in Table 3 the preferences chosen by the patients in our prior cohort who participated in our study to test the feasibility of the PPAT.¹⁰ Their choices were very similar to the present cohort’s. “Fighting my cancer as much as possible” was chosen more frequently in the prior cohort but the three most frequent choices were the same, demonstrating the consistency of patient choices in an academic center.

3.4 | Clinician interviews

A majority of clinicians (9/11; 82%) found the PPAT useful because it allowed them to review patients’ preferences in real time. Clinicians who said the tool was not useful explained that they already understood their patients’ preferences and that all their patients checked the same preferences. The main preferences on the PPAT that the clinicians stated would influence their recommendation if checked were “avoiding extra travel time and time away from home” and “making it easier on my family so they don’t have to drive me or come with me to clinic appointments (not being a burden on my family).” Four clinicians (36%) said the PPAT could be improved if it were streamlined or simplified to include fewer options. Other suggested improvements included using more neutral language and implementing a scoring system among preferences. While a majority of clinicians (55%) consider the PPAT to be best suited for the specialized academic oncology clinic, other clinicians suggested expanding its use to community oncologists. When asked to describe their patients’ views of clinical trials, all but one clinician (91%) stated that patients at an academic center are motivated to be aggressive in their care and willing to participate in clinical trials.

4 | DISCUSSION

Including patient preferences in the care of cancer patients has been identified as a key element for high quality healthcare. We had previously developed the PPAT to ascertain patient preferences in order to inform clinician recommendations and improve shared decision-making. We found that overall clinicians changed their strength of recommendation due to patient preferences in 24% of the conversations, while in treatment-options conversations, in which a phase I trial was a current option, the clinician’s recommendation changed strength due to patient preferences 30% of the time. The PPAT thus exceeded our conservative estimate that it would be considered influential if it influenced 20% of conversations.

The three most frequently checked preferences on the PPAT for both this cohort and our prior cohort—“access to the best treatments,” “access to expert doctors,” and “fighting my

cancer as much as possible”—suggest that patients at an academic cancer center may be self-selected to be those motivated to be aggressive in their treatments. The clinicians in this study substantiated these findings in their interviews; 91% of clinicians commented that the patients they see at an academic cancer center are often those driven to be aggressive and to pursue cancer clinical trials. Interestingly, most of these participants did not choose “taking part in a research study, if that is the only option” as one of their top three choices and only 5 (17%) chose “having access to new treatments, even if they are not proven and are part of research.” However, the preferences that suggest lack of interest in participating in a clinical trial such as, “avoiding as many trial or research side effects as possible,” “avoiding extra travel time and time away from home,” “avoiding as many procedures as possible” were infrequently chosen. Given the type of preferences checked by patients in this population seen in a tertiary academic cancer center, the PPAT tool may have greater value in a community oncology clinic setting. This potential usefulness in a community setting is further supported by the fact that the two preferences that the physicians thought would change their recommendation—“avoiding extra travel time and time away from home” and “making it easier on my family so they don’t have to drive me or come with me to clinic appointments (not being a burden on my family)” —were infrequently chosen (chosen by 1 and no participants, respectively). Our next steps could include testing the PPAT in a primary oncology clinic where the tool could help inform primary oncologists as they discuss referring a patient to an academic cancer center for a clinical trial versus continuing to give treatment locally.

That said, a majority of these academic clinicians (82%) found the PPAT useful and appreciated an explicit depiction of their patients’ preferences. Clinicians mentioned that they particularly found the PPAT helpful when discussing clinical trial options with new patients with whom they had no prior relationship. In sum, the PPAT proved influential in almost a third of treatment-options discussions and physicians appreciated its explicit presentation of the patients’ current preferences.

4.1 | Study limitations

Our study has several limitations, which should be acknowledged. It has a small sample size and is limited to a single academic cancer center. Also, there is no control sample and patient selection was through clinician identification, which could introduce a systematic bias. Our sample size was too small to analyze the impact of patient or physician demographics, which could strongly influence preferences for active care and participation in clinical trials, though it was large enough for the qualitative analyses we conducted, which usually requires between 15 and 20 participants.¹³

4.2 | Clinical implications

Given that patients often rely on their clinicians’ recommendations when deciding about their next treatment, it is important that clinicians be aware of the patients’ current preferences. This is particularly important when a clinician is recommending participation in a clinical trial. The simple one page tool tested in this study proved helpful in informing the clinician about the patient’s preferences in real time, so that the clinician could consider and incorporate the patient’s preferences into his/her recommendation. Having patients fill out

this tool can therefore be helpful to clinicians so they have easy access to what the patient prefers at this point in time (see Table 3 for the preferences listed in the PPAT). Our previous study also documented that patients found the tool useful (mean score of 4.2 on a 5-point Likert scale, with 5 being “very useful”).¹⁰

5 | CONCLUSION

This study successfully advanced our intent to provide a tool that will inform clinicians’ recommendations for phase I cancer clinical trials by incorporating patient preferences. The clinicians’ recommendations changed due to patient preferences in 24% of all conversations and in 30% of conversations in which a decision had to be made about joining a clinical trial. The tool thus exceeded our threshold of an impact in 20% of all conversations. Furthermore, 82% of the physicians found the tool helpful because it allowed them to explicitly see the patient preferences. There is wide consensus that patient preferences need to be incorporated into shared decision-making, particularly for decisions about clinical trial participation, but doing so in real time practice has been difficult. This simple tool can facilitate this important goal.

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TABLE 1

Patient demographic characteristics

Characteristic	N = 29	%
Site		
Gastrointestinal	17	59
Breast	7	24
Aerodigestive	5	17
Gender		
Male	12	41
Female	17	59
Age		
Mean (range)	59 (39–76)	–
Race		
White/Caucasian	21	72
Other ^a	8	28
Education level		
Less than high school degree	1	3
High school or associate's degree	16	55
Undergraduate degree	5	17
Graduate degree	7	24
Annual income		
<\$20,000	3	10
\$20,000–\$80,000	9	31
>\$80,000	10	35
Declined	5	17
I don't know	2	7

^aNon-White participants included seven Black/African American participants and one Asian or Pacific Islander participant.

TABLE 2

Changes in strength of recommendation

Reasons for change in strength of recommendation	Precon version strength	Postcon version strength	Change in strength	Type of conversation ^a
Change due to clinical finding	8.5	2	−6.5	2
	5	1	−4	2
	5	3	−2	2
	9	8	−1	2
	3	9	6	2
	5	10	5	2
	3	5	2	2
	7	8	1	2
	8	4	−4	1
Change due to patient preferences	10	1	−9	2
	10	1	−9	2
	10	8	−2	2
	4	8	4	2
	4	8	4	2
	9	10	1	2
	8	9	1	2
No change	10	10	0	2
	10	10	0	2
	10	10	0	2
	10	10	0	2
	10	10	0	2
	10	10	0	2
	10	10	0	3
	10	10	0	3
	9	9	0	2
	5	5	0	1
	3	3	0	2
	3	3	0	2
	2	2	0	1
	1	1	0	1

^a1—Priming conversation; 2—treatment-options conversation; 3—trial logistics conversation

TABLE 3

The frequency of the preferences chosen by patients on the PPAT in this study ($N=29$) and in the PPAT development study ($N=20$)

Patient preferences	Patients in this study (29) <i>N</i> (%)	Patients in prior PPAT feasibility study (20) <i>N</i> (%)
Having access to the best cancer treatment	20 (69)	14 (70)
Getting the best possible care from expert doctors	17 (59)	12 (60)
Fighting my cancer as much as possible	14 (48)	15 (75)
Feeling as good as possible every day given my condition (feeling good now, normal, back to old self)	10 (35)	9 (45)
Having access to new treatments, even if they are not proven and are part of research	5 (17)	3 (15)
Helping other cancer patients by participating in research	5 (17)	1 (5)
Attending an important event (like a wedding or graduation) in the future	4 (14)	0
Making my family happy by continuing to fight my cancer	3 (10)	2 (10)
Taking part in a research study, if it is my only option	3 (10)	2 (10)
Avoiding spending lots of hours in the clinic	2 (7)	2 (10)
Avoiding as many trial or research side effects as possible	1 (3)	2 (10)
Following the recommendations of my doctor	1 (3)	2 (10)
Avoiding missing fun events at home because I am in the clinic	1 (3)	0
Avoiding extra travel time and time away from home	1 (3)	2 (10)
Making it easier on my family so they don't have to drive me or come with me to clinic appointments (not being a burden on my family)	0 (0)	1 (5)
Avoiding as many procedures as possible (like biopsies and blood draws)	0 (0)	1 (5)

Abbreviation: PPAT, Patient Preference Assessment Tool.