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DEPARTMENT OF SURGERY

TITLE: Pilot Qualitative Study of the Therapeutic Alliance between Latino/a Patients with Advanced Cancer and their Oncologists

CITY OF HOPE PROTOCOL NUMBER: IRB # 22466

PROTOCOL DATE: 01/26/24

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PRINCIPAL INVESTIGATOR:

*Designs, responsible for study conduct
and data analysis*

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COLLABORATING INVESTIGATOR(S):

*Key individual; Assists in study design and development;
May be involved in analysis of data*

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PARTICIPATING CLINICIANS:

*Enrolls and follows eligible patients on study;
Not involved in study development or data analysis
(Physician or research support staff)*

None

STUDY PROTOCOL

Title: Pilot Qualitative Study of the Therapeutic Alliance between Latino/a Patients with Advanced Cancer and their Oncologists

Version 04

Protocol date: 01/26/24

Study Personnel

Ana I. Tergas, M.D., M.P.H., Principal Investigator
Genesis Sandoval
Lauren Cai

1.0 Purpose of the Study

The purpose of the study is to examine perceptions, barriers, and facilitators of a therapeutic alliance (TA) between advanced cancer patients and their oncologists.

2.0. Specific Aims

To qualitatively explore patient and oncologist perceptions of TA, barriers and facilitators of TA, and the perceived influence of Latino/a ethnicity on TA via in-depth interviews with oncologists (N=4) and focus groups and interviews with patients (N=25 patients).

3.0 Background

The therapeutic alliance (TA) is a concept that reflects the depth and quality of a patient-physician interaction. A TA between patients and providers can create a better working relationship and promotes trust and open communication between patient and provider. Advanced cancer patients with a strong working alliance with their physicians and nurses are more likely to share both personal and medical concerns regarding their healthcare. [1] In addition, advanced cancer patients who had a higher level of TA with their oncologists also reported an overall better quality of life. [2] Another study that examined factors associated with better quality of life found that advanced cancer patients who had a TA had the highest quality of life at the end of life. [3] Cancer patients with higher TA with their providers are more likely to collaborate with their oncologists to address their problems, have a role as an active participant in treatment decisions, and build a common knowledge of treatment and well-being objectives. [2] Using the Herth Hope Index, a study found that engaging in advanced care planning or end-of-life (EoL) discussions was not associated with diminished hope. [4] Oncologists may inadvertently serve as therapists for their patients by providing support, building relationships with patients, acknowledging their effort, and working as a team on their goals. [5] Thus, a TA between cancer patients and their oncologists can improve overall communication and patients' quality of life.

As noted, strong communication was found to be an important component in fostering TA and facilitating EoL care conversations. Among pediatric oncologists, human connection, empathy, pretense, partnering, inclusivity, humor, and honesty were found to be core characteristics of a strong TA. [6] However, studies show that ethnic minorities are less likely to engage in

conversations with their providers about their plan of care. Latinos are less likely to engage in EoL conversations, have an advanced care plan, or use palliative services. [7] Studies also found that Latina patients with cervical cancer and metastatic ovarian cancer were less likely to use palliative care compared to non-Hispanic White patients with the same cancers. [8] These studies suggest that Latinos are less likely to engage in EoL conversation or advanced care planning with their providers.

Evidence suggests that Latino/a cancer patients experience suboptimal EoL care compared to non-Latino/a patients. For instance, Latino/a patients are less likely than non-Latino/a patients to engage in advance care planning (ACP) [9-14] – a practice to assist patients and family caregivers in clarifying and achieving patients' EoL goals of care. Consistent with the lower rates of ACP, Latino/a advanced cancer patients are more likely to receive aggressive EoL care than non-Latino/a advanced cancer patients. [15-17] Aggressive EoL care (e.g., ICU stays, resuscitation) fails to cure or significantly enhance patients' survival, seriously impairs patients' quality of life, [18-21] comes at great public expense,[19] and is often counter to patient values. [21] Latino/a cancer patients are also more likely to report inaccurate expectations of survival. [22-24] One study demonstrated that prognostic communication, a fundamental component in quality EoL care, [21, 25-30] occurred less frequently for Latino/a patients. [31] Latino/a patients are more likely to die in the hospital [32] and less likely to use hospice services, [17, 32-35] and are also less likely to receive preference-concordant EoL care. [21, 36-40]

Established as the single most important predictor of treatment effectiveness in the psychotherapy field, TA is defined as a sense of mutual respect, trust, understanding and collaboration between a physician and patient, in order to achieve shared treatment goals. [41] [42] The Human Connection (THC) Scale is a reliable and valid measure of TA between oncologists and advanced cancer patients (Cronbach $\alpha=0.90$). [41] Among cancer patients, TA is an important predictor of quality of life and decreased ICU care at the EoL [20], and emotional acceptance of terminal illness. [41] Results from our preliminary studies demonstrate that Latino/a immigrants have significantly lower TA scores vs. U.S.-born Latinos, non-Latino/a immigrants and U.S.-born non-Latinos. These studies suggest that improving TA between providers and Latino/a advanced cancer patients may be a modifiable factor in reducing disparities in EoL care.

4.0 Eligibility/Population

Patients: The study population of patients will be drawn from patients who receive the majority of their oncologic care at the Duarte campus of City of Hope. Patient eligibility criteria include: (1) identifying as ethnically Latino/a; (2) locally advanced or metastatic cancer (gynecologic, lung, gastrointestinal, colorectal) and have received at least one line of adjuvant therapy and (3) ability to provide informed consent. Patient exclusion criteria include: (1) not fluent in English or Spanish; (2) severely cognitively impaired [44]; (3) too ill or weak to participate in an interview or focus group; (4) age under 21; and (5) patients deemed inappropriate for the study by their treating oncologist. There will be approximately 25 patients recruited to participate in an interview or focus groups.

Providers (oncologists): Oncologists who work at City of Hope and serve the above defined patient population at the Duarte campus of City of Hope will be identified by convenience and purposive sampling. In-depth interviews will be conducted with 4 oncologists.

5.0 Study Rationale

Cancer is the leading cause of death among US Latinos. [45] Latinos are now the largest minority group in the US, [46] and by 2060, 28.6% of the US population is projected to be Latino/a. [47] Thus, optimal cancer care delivery for Latino/a patients is a large and growing public health concern. Evidence suggests that Latino/a cancer patients experience suboptimal EoL care compared to non-Latino/a patients. For instance, Latino/a patients are less likely than non-Latino/a patients to engage in advance care planning (ACP) [9-14] – a practice to assist in clarifying and achieving patients' EoL goals of care. Latino/a advanced cancer patients are more likely to receive aggressive EoL care than non-Latino/a advanced cancer patients. [15-17] Aggressive EoL care (e.g., ICU stays, resuscitation) fails to cure or significantly enhance patients' survival, seriously impairs patients' quality of life, [18-21] comes at great public expense, [19] and is often counter to patient values. [21] Latino/a cancer patients are also more likely to report inaccurate expectations of survival. [22-24] One study demonstrated that prognostic communication, a fundamental component in quality EoL care, [21, 24-30] occurred less frequently for Latino/a patients. [31] Latino/a patients are more likely to die in the hospital, [32] less likely to use hospice, [17, 32-35] and less likely to receive preference-concordant EoL care. [21, 36-40]

The Institute of Medicine's landmark report, *Dying in America*, states that "frequent clinician–patient conversations about EoL care values, goals, and preferences are necessary to avoid unwanted treatment....Clinicians need to initiate conversations about EoL care choices and work to ensure that patient and family decision making is based on adequate information and understanding." [48] A key assumption underlying this recommendation is that frequent EoL conversations will result in the delivery of value-consistent care and avoidance of unwanted treatment. Extensive evidence demonstrates that communication skills training (CST) significantly improves the observed communication skills in simulated settings and in clinical practice. [49-51] However, there is much less evidence for an effect on more distal patient outcomes, such as quality of life or hospice use. [51-55] [56] [57, 58] [59]

The TA is defined as a sense of mutual respect, trust, understanding and collaboration between a physician and patient, developed for the purpose of achieving shared treatment goals. [41] It has been established as the single most important predictor of treatment effectiveness in the psychotherapy field, where it was first described. [42] Among advanced cancer patients, TA is an important predictor of quality of life at the EoL, [20] and has been associated with decreased ICU care at the EoL, as well as emotional acceptance of terminal illness. [41] In a study of 102 caregivers in the VOICE trial, stronger TA between caregivers and oncologists was associated with better caregiver perceptions of the quality of the patient's EoL care and quality of death, and less decisional regret. [60] These studies imply that improving TA between physicians, patients, and caregivers may have widespread effects on reducing disparities in EoL care.

6.0 Study Hypothesis

The purpose of this study is to qualitatively explore patient and oncologist perceptions of TA, barriers and facilitators of TA, and the perceived influence of Latino/a ethnicity on TA via in-depth interviews with oncologists (N=4) and interviews and focus groups with patients (N=25 patients). We hypothesize that we will be able to better understand the TA between Latino/a advanced cancer patients and their oncologists through the conduct of these focus groups and structured interviews.

7.0 Sample Size and Study Methods

Patients. We will conduct focus groups with approximately 3-5 patients in each focus group as well as one on one patient interviews for a total of up to 25 patients (N=25) that will be recruited from City of Hope. Patients will be asked to either participate in a focus group or an interview. Focus group and interview participants will be recruited from the patients of participating oncologists, based on the eligibility criteria as above. Research staff will screen clinic rosters for eligible patients. PI will then review medical records to confirm eligibility. PI or research staff will contact eligible patients, inform them of their potential eligibility for the study, and provide information about the study as detailed in the information sheet. The research staff or PI will invite the patient to participate in an interview or focus group with other patients and obtain permission to record the interview or focus group if the patient agrees to participate. The interviews and focus groups will explore patient perceptions of TA, barriers and facilitators of TA, and the perceived influence of Latino/a ethnicity on TA. Participants will be asked to provide demographic information. Only patients that complete both the demographics survey and the interview or focus group will be considered accrued.

Attachments: Patient Information Sheet, Patient Demographics Survey and Patients Focus Group Guide). The interviews and focus groups will last approximately 60 minutes.

Providers (oncologists). We will conduct in-depth interviews with oncologists (N=4) who work at City of Hope. Oncologists will be identified by convenience and purposive sampling. Oncologists will be contacted via email and invited to participate in a structured interview to explore oncologist perceptions of TA, barriers and facilitators of TA, and the perceived influence of Latino/a ethnicity on TA. Oncologists will also be provided with an information sheet and be asked permission to record the interview. Individual interviews will last around 30 to 45 minutes. Only oncologists that complete both the demographics survey and the interview will be considered accrued.

Attachments: Oncologist Information Sheet, Oncologist Demographics Survey and Oncologist Interview Guide

We will conduct in-depth interviews and focus groups with oncologists, patients to gain a more nuanced understanding of the TA and its relationship to EoL care for Latino/a advanced cancer patients.

The focus groups and structured interviews will be conducted via the Zoom platform. The audio from the focus group will be securely recorded and transcribed through the Zoom platform. Automated transcriptions will be edited for accuracy by members of the research team. Zoom automatically records both video and audio, but only the audio portion of the recording will be used in the analyses. Oncologists and patients will receive a \$50 gift card for participation. We will pilot the interview guide and focus group guide with 1 oncologist and research staff.

All hard copy, electronic copy, and audiotapes of data will be used for research purposes only. Study participants' name and preferred mailing address will be collected for the sole purpose of mailing gift card incentives, and this information will be stored separately from the de-identified transcripts. All computers used to store data will be password-protected with access granted only to staff directly involved in the project.

8.0 Source of Data

The data source will be individual interviews with oncologists and interviews and focus groups with patients. Interviews and focus groups will be transcribed. Interview transcripts and demographic surveys will be de-identified and labeled with Study ID (not by name) and stored separately from study enrollment logs. Study enrollment logs will contain study participants' name and address for the sole purpose of mailing gift card incentives to participants.

9.0 Data Analysis and Statistical Considerations

All audiotape recordings will be transcribed and translated verbatim. Digital audio recordings will also be deidentified. Members of the research team will read and re-read the transcripts to develop themes and subthemes that are important to understanding perceptions and beliefs about TA and the factors related to the theoretical framework (e.g., empathy, trust, shared-decision making, and patient-centered communication). They will meet to compare their list of themes and develop a single list that removes redundancy, conceptually clarifies each theme and develop codes for each theme and subtheme. They will then independently apply these codes to additional transcripts and afterward assess how adequately they captured all the themes in the additional transcripts. New themes and associated codes will be added as needed. The same process will be applied until a complete list of themes with associated codes is developed. Under the guidance of the mentorship team members, the PI will generate theories to explain relationships among themes and negative results that do not confirm the dominant themes.

10.0 Informed Consent or Waiver

Consenting of the focus group participants and interview participants will be done by the study staff. The consenting process will be documented by including date, time, and person consenting on the focus group recording. The informed consent process will be allotted as much time as necessary to ensure that the subject understands all the information covered in the consent form. The subject will be given the opportunity to ask questions, and those questions will be answered to their satisfaction. Consent will be obtained in the participant's primary language. Potential participants will be reminded that participation is completely voluntary, and they can opt not to participate at any time. A waiver of documentation of informed consent is being requested. Instead, an information sheet will be provided, and permission to record the focus groups and structured interviews will be obtained from willing participants.

11.0 Data Safety and Monitoring Plan

This project is a low-risk study, as defined in the [City of Hope Institutional Data and Safety Monitoring Plan \(DSMP\)](#), because it involves interviews and questionnaires, and the risk of harm is low. The study Principal Investigator is responsible for monitoring protocol conduct and reporting all reportable events to the City of Hope Data and Safety Monitoring Committee and Institutional Review Board in accordance with the City of Hope Institutional Deviation policy, and [Clinical Research Adverse Event and Unanticipated Problem policy](#).

12.0 Data Reporting/Protocol Deviations

The Principal Investigator or designated research team member will enter all deviations into OnCore and report deviations meeting the definition of major per the Deviation Assessment Guide, in OnCore and iRIS, within 5 business days of notification of the event. For anticipated deviations, the PI or designated research team member will submit a Planned Protocol Deviation form in iRIS prior to its occurrence.

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