|  |
| --- |
| TITLE:Understanding the perspectives of palliative care and advance care planning in patients with pulmonary arterial hypertension and the physicians caring for them |
| PRINCIPLE INVESTIGATOR(S): | Crystal E. Brown |  | SITE(S) (if applicable): |
| Click here to enter text. |
| COORDINATING SITE: | University of Washington |  |
| STUDY PERIOD |  |
| START: | April 5, 2017 |  |
| LAST SUBJECT CONTACT: | October 4, 2017 |  |
| OBJECTIVES: |
| Use qualitative research methods to understand patient- and physician-perceived barriers and facilitators to implementation of palliative care and advance care planning for patients with PAH. |
| PARTICIPANTS |
|  | ENROLLMENT | ELIGIBILITY CRITERIA |
| Patients: | 18 | Aged 18 and older; with right heart catheterization within ten years demonstrating a mean pulmonary arterial pressure of 25 mmHg or greater who have not undergone lung transplantation; and are on appropriate therapy for PAH as deemed by their treating physician in the PAH clinic.  |
| Informal Caregivers: | Click here to enter text. | Click here to enter text. |
| Health Care Providers: | 12 | Pulmonologists or cardiologists identified as specialists caring for patients with PAH in a PAH-specific clinic. Physicians will be identified via the Pulmonary Hypertension Association Doctor Directory |
| METHODOLOGY: |
| Prior to each patient interview, I will ask each participant to complete a short questionnaire about barriers and facilitators to advance care planning and end-of-life discussions. This questionnaire was developed by my mentors to examine barriers and facilitators to discussing advance care planning in patients with serious illnesses such as AIDS, cancer, and COPD. They found that, although barriers and facilitators to communication about end-of-life care were highly individual, many patients reported wanting to discuss end-of-life care with their physicians and, even those who did not, acknowledged the value of such discussions. In an additional qualitative study of patients with advanced cancer or COPD, patients provided insights into how these barriers and facilitators could be addressed to enhance communication about end-of-life care.Semi-structured interviews are an appropriate method for identifying, describing and understanding experiences that have not been previously reported. This method allows interview participants to express their opinions on sensitive issues such as end-of-life preferences and advance care planning. For Aim 1, I will focus on patient perspectives on the following: a) symptom burden; b) understanding of palliative care, including what constitutes palliative care and when is it helpful or appropriate; c) attitudes towards and experiences with advance care planning; and d) barriers or concerns to receiving palliative care, including any patient-perceived disparities associated with socio-economic status, health literacy, and medical decision making about medical therapies, including lung transplantation. For Specific Aim 2, I will focus on physician perspectives on the implementation of palliative care and advance care planning for patients with PAH including: a) understanding palliative care and perceived timing of appropriateness of referral and implementation; b) attitudes toward and experiences with advance care planning; c) barriers or concerns to initiating palliative care; and d) perspectives on differences in palliative care for patients of different socioeconomic status and race/ethnicity. Qualitative analysis: My mentors have extensive experience with qualitative research methods and development of thematic frameworks. Both patient and physician Interviews will be audiotaped and transcribed by a medical transcriptionist with extensive experience in qualitative research. Transcripts will be analyzed using thematic content analysis, a well-validated and robust analytic tool used to organize interview text into themes and thematic networks that include the following categories: a) basic themes, the lowest-order premises present in interviews; b) organizing themes, made up of categories of basic themes that help put basic themes into context; and c) global themes, encapsulating and summarizing the overall clusters of the lower order themes. Interviews will be audio-recorded and transcribed. Memoing will be performed immediately after the interviews to gather initial thoughts and impressions. I will then perform in-depth analysis first listening to the recorded interview while reviewing the associated transcript, then re-reading the transcript, and finally completing line-by-line coding of each transcript. The same process will be repeated for each transcript, and patterns of superordinate themes will be compared across interviews. Interviews and data analysis will be performed concurrently in an iterative process, generating new data while performing on-going analyses. Identification of new ideas and themes that appear during interviews and analysis of transcripts will be explored during subsequent interviews with other study participants to verify and clarify initial impressions of these ideas. To ensure that I am producing rich and substantive accounts of the transcripts, I will constantly examine my data to ensure: a) significant engagement of the interview around the phenomenon of advance care planning and implementation of palliative care; b) production of thick and rich descriptions of my data; and c) production of useful results relevant to patients with PAH and the physicians caring for them. This will be accomplished by: a) participation in reflexive exercises examining my roles as both researcher and physician, especially how my position as a physician affords me preunderstanding or knowledge about caring for patients with PAH and other chronic diseases; b) careful examination of multiple possible interpretations of study results that are outside my preconceptions and frame of references as a clinician; and c) thoughtful consideration of how developing data generates knowledge and increases understanding in the implementation of palliative care and advance care planning in patients with PAH. To ensure rigorous and accurate coding of transcripts, Drs. Curtis, Engelberg, and I will jointly code the first three transcripts from each respondent group (patients, physicians) to generate a codebook. We will discuss and refine the codes and their application to the transcript. After development of the initial codes, each group member will independently analyze a second group of three transcripts and emerging themes will be compared. After this initial development phase, I will use the codebook to code the remaining interviews. Of these, 50% will be co-reviewed by either Dr. Curtis or Engelberg to ensure the trustworthiness and inter-rater reliability of the coding. I will generate code reports and include all coded text for each transcript, review these with my mentors, and provide summary memos to synthesize the data into global themes. I will use DeDoose ([www.dedoose.com](http://www.dedoose.com)), a qualitative software package, to organize the coding and analyses. Patient surveys will be used to provide descriptive data and to look for patterns in patient perspectives about palliative care and advance care planning as captured in the endorsements of barrier and facilitator items concurrently with the thematic content analysis. |
| INTERVENTION (if applicable): |
| NA |
| MEASURES: |
| Barriers and facilitators to advance care planning and end-of-life discussions |

|  |
| --- |
| SUBJECT FLOW (CONSORT): |
|  |

|  |
| --- |
| STUDY CALENDAR: |

|  |
| --- |
| BASELINE CHARACTERISTICS (TABLE 1) |

BASELINE CHARACTERISTICS (TABLE 1)





**PCRC STANDARDIZED DATA ELEMENTS**

***Please see the separate information sheet*** [***“DISC Standardized Data Elements”***](Info%20Sheet%20-%20DISC%20Standardized%20Data%20Elements_v2018.08.docx) ***for the exact wording and format of the data elements.***

|  |  |  |  |
| --- | --- | --- | --- |
| **DATA ELEMENT** | **Collected?** | **Var Name(s)** | **Data source (e.g. self-report, EHR) or reason not applicable** |
| 1. **Site ID (if multi-site)**
 |[ ]    |   |
| 1. **Who is the research participant? (e.g., patient, caregiver, etc.)**
 |[x]    | 1. patient 2. provider |
| 1. **Sex**
 |[x]    | self-report (both) |
| 1. **Ethnicity**
 |[ ]    |   |
| 1. **Race**
 |[x]    | self-report (both) |
| 1. **Age in years**
 |[x]    | self-report (both)  |
| 1. **Current Marital Status**
 |[x]    | self-report (patient only) |
| 1. **Primary life-limiting diagnosis/illness**
 |[ ]    |   |
| 1. **Performance status (AKPS)**
 |[ ]    |   |
| 1. **Enrolled in Hospice**
 |[ ]    |   |
| * 1. **If yes to hospice, where is hospice care provided?**
 |[ ]    |   |
| 1. **Receiving Palliative Care (PC)?**
 |[ ]    |   |
| * 1. **If yes to receiving PC, where is PC provided?**
 |[ ]    |   |
| 1. **Source of Death information**
 |[ ]    |   |
| 1. **Location of Death**
 |[ ]    |   |
| 1. **Enrolled in Hospice at time of death?**
 |[ ]    |   |
| 1. **Receiving PC at time of death?**
 |[ ]    |   |

***Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.***

**PATIENT REPORTED OUTCOME INSTRUMENTS**

|  |  |  |
| --- | --- | --- |
| **CONTENT***(e.g., PS)* | **ABBREV***(e.g., AKPS)* | **INSTRUMENT NAME***(e.g., Australian Modified Karnofsky Performance Status)* |
| **P**S |   | **Barrier and Facilitators to discussing preferences around end-of-life care** |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |