Physician-Related Barriers and Facilitators to Accrual to Lung Cancer Clinical Trials

Scholar: Jason Tran
Mentor: Dr. Carmen Guerra, MD, MSCE, FACP
Overview of My Study

I am interested in understanding the provider-related barriers and facilitators to enrolling underrepresented minorities onto lung cancer clinical trials.

I conducted a pilot study to understand the provider-related barriers and facilitators to enrolling patients onto cancer clinical trials.

- Study design, study questionnaire, study interview guide, IRB application, pilot testing, preliminary coding
Background

Lung Cancer Mortality Rates

Lung cancer is the leading cause of all cancer deaths.

Different incidence and morality rates exist between ethnic/racial minorities and Caucasians.
Cancer Clinical Trials

Cancer clinical trials are new, innovative treatments that are still in the experimental phase. Clinical trials are the only way to access cutting edge cancer treatment.

Successful findings result in standard care treatment.

Less than 5% of adult cancer patients participate.
Nationally, ethnic/racial minorities are underrepresented on cancer clinical trials, with only 2% of studies focusing on non-Caucasian groups.

In 2013, the Abramson Cancer Center had approximately 43 available lung cancer clinical trials, and yet, only 11% of participants were underrepresented minorities (Elshaddai Ephrem).
The Leaky Pipe of Clinical Trial Participation


276 patients seen by 18 physicians
38% CONSIDERED ineligible by physician (now 171)
47% no available, appropriate local trial (Now 90)
84% ACTUALLY eligible (Now 76)
49% not willing to sign consent form
14% accrual rate (39 patients enrolled out of 276)

Courtesy of Jeff Belkora, PhD, UCSF Breast Center of Excellence

© 2013 ENACCT Inc. All Rights Reserved
Parent Study

Reasons for Institution-related barriers
1. Trial Inventory
2. Prescreening Process

Reasons for Provider-related barriers and facilitators
3. Chart Review
4. Provider Questionnaire
5-6. Patient Questionnaire

6. Patient remained on trial
5. Patient enrolled
4. Physician offered trial
3. Patient eligible by physician triage
2. Patient eligible by prescreening
1. Trial available

Patient not available
Patient not eligible
Patient did not offer trial
Patient did not enroll
Patient dropped out of trial
Pilot Study

Reasons for Institution-related barriers
1. Trial Inventory
2. Prescreening Process

Reasons for Provider-related barriers and facilitators
3. Chart Review
4. Provider Questionnaire

Reasons for Patient-related barriers and facilitators
5-6. Patient Questionnaire
Pilot Study

Pilot studies help researchers effectively design their research methods.

In my pilot study, I focused on all cancer types, giving me more opportunities to ask about a greater range of clinical trials. This allowed me to better design the interview guide and frame other future directions.
Methods

Qualitative Study

Qualitative studies aim to gain deep understanding of a specific organization. They provide descriptions and patterns about people’s perspective and motivation towards a specific topic.

1. We recorded and interviewed providers using a semi-structured interview.
2. We transcribed results and preliminarily coded to group transcriptions into major themes.
My Roles

1. Focused on the provider-related barriers and facilitators to enrolling patients onto a lung cancer clinical trial
2. Developed an Institutional Review Board application and consent form
3. Developed and piloted a two-part study instrument (self-administered questionnaire and interview guide)
4. Conducted, recorded, and transcribed interviews
5. Coded transcripts into major themes
Three medical fellows from the Hematology and Oncology Division at Penn Medicine participated. They filled out a brief questionnaire ascertaining their demographics and knowledge about clinical trials. Their interviews were transcribed. Transcripts were coded to identify major themes. They were interviewed using a semi-structured interview.
Hypotheses

1. The provider-related barriers to enrolling patients onto cancer clinical trials are:
   a. lack of awareness about cancer clinical trials
   b. time-consuming steps towards enrollment

2. The provider-related facilitator to enrolling patients onto cancer clinical trial are:
   a. strong support from hospital staff members
Study Design

Triangulation of Qualitative Methods

- Chart-Stimulated Recall
- Brief Questionnaire
- Semi-Structured Interview
Data Collection

Self-Administered Questionnaire

1. What is your age, sex, ethnicity, race, year graduated from medical school, and number of years practicing as a provider?
2. Where do you get your information about clinical trials?
3. What percentage of your patients enters clinical trials?
4. What are some of the reasons that prevent you from offering a clinical trial to your patients?
5. What do you think would help you offer clinical trials to more of your patients?
Interview Guide Questions

1. What are your facilitators to recommending a clinical trial?
2. What are your barriers to recommending a clinical trial?
3. Please rank them from most significant to least significant within their group.
4. Would you rank the barriers and facilitators differently when you think about your interactions about cancer clinical trials with underrepresented minorities versus white patients.
5. Give us an example of your interaction with a patient who was an underrepresented minority.
1. Physician pulls five charts of patients seen within last two weeks
2. Review chart inclusion/exclusion criteria
3. Physician provides one line summary of encounter: race/ethnicity, age, disease and stage, why he or she was there, and what visit number this was.
4. Was a clinical trial offered? Why or why not?
5. Did the patient choose to enroll? Why or why not?
6. Did patient ask about clinical trials? If yes, what were the questions?
## Results

### Demographics (N=3)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Range</td>
<td>29, 30, 31</td>
</tr>
<tr>
<td>Sex</td>
<td><img src="image" alt="Female &amp; Male Counts" /></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>All Non-Hispanics</td>
</tr>
<tr>
<td>Race</td>
<td>Two Caucasians, One “Other”</td>
</tr>
<tr>
<td>Year Graduated From Medical School</td>
<td>One Reported 2009, Two Reported 2010</td>
</tr>
<tr>
<td>Number of Years As A Provider</td>
<td>None Are Attending Physicians</td>
</tr>
<tr>
<td>Type of Physicians</td>
<td>All Are Oncologists</td>
</tr>
<tr>
<td>What Percentage of Your Patients Enter Clinical Trials?</td>
<td>Two Reported 11%-20%, One reported 21%-30%</td>
</tr>
</tbody>
</table>
Overview of Barriers to Enrollment

Lack of Easy Access to Information About Clinical Trials

Lack of Tissue To Send To Molecular Testing

Provider Perceptions of Patient Burden

Language Barriers

Lack of Access to Clinical Trial Related Paperwork
“[The Abramson Cancer Center website is] set up by disease area and then phase of the trial... studies that are mis-assigned by disease area ... it’s difficult to track down which trial is appropriate for which patient... then just the contact information for the research coordinator seems to be inaccurate”
“[S]ome of the clinical trial require tissue sample...in order to began the process of enrolling in the trial you need often times a repeat biopsy or a retest of old tissue specimen...”
Lack of Access to Clinical Trial Related Paperwork

“I don’t have access to the actual consent form in the protocol… they are available electronically on the iDrive not every computer in Penn has the iDrive you have to find the right computer in the clinic room …I have to leave the clinic room and go to the work space pull up the iDrive find the protocol print it go back to the patient and then give to the patient”
1. “I remember there was... a head and neck cancer patient... they had communication barriers based on their actual illness from East Asia and the phone interpreter cannot understand anything they said... our conversation was so limited that maybe we would have considered a clinical trial if we had a better rapport”

2. “[S]hould have had an interpreter”
“Maybe my perception of patient characteristics is ... if they seem unreliable... if they’re coming from a distant or I feel like the burden of coming for a clinical trial with all of its rigorous would be difficult for a patient and their family... I may not mention it. I probably wouldn’t consider that necessarily in the best interest of the patient”
Overview of Facilitators to Enrollment

Facilitators

- Reminders
- Supportive Attending Influence
- Patient Inquires About A Clinical Trial
“Doctors said they have flow charts and it says non small cell lung cancer small cell lung cancer... it will say stage... potential options... trials... visual reminder that are in the work space I thought more... would be helpful”
“I also make the effort and try to print out patient instruction... highlight what those options... so they don’t forget what we talk about... I’ll do recommendations... I’ll write the trial”
“I think that having some updated...email once every couple of weeks to just remind us to what trials are open for what kind of general disease state...would be helpful”
“When [patients] come in and ask about it that definitely jogs the memory and it forces me to look... even when I didn’t initially thought there was a trial out there”
Supportive Attending Influence

“I work with one particular clinician most of the time who is very deeply involved in most of the trials... every patient that is a new patient referral is being considered for trials very aggressively... that’s sort of like a transitive property of mentorship”
Ranking Barriers and Facilitators

For the purpose of this study, we did not include the ranking in this presentation, because there were only three providers. Results did not show overlap and consistency.
Lack of Underrepresented Minority Patients

Using chart-stimulated recall, we asked providers to identify the race and ethnicity of the patients:

1. Less than 15% of the patients identified were underrepresented minorities.

2. Description of interactions with underrepresented minority patients appear to lack detail and richness.
Example of One Provider’s Recall

Out of five patients described, one patient was an underrepresented minority.

We looked at the word count of the provider’s initial description of each patient.

The provider used the least amount of words to describe the visit of the underrepresented minority.
Conclusion

1. Similar to studies done at other health centers, we find that ethnic and racial minorities are heavily underrepresented within the Abramson Cancer Center.

2. Barriers include lack of easy access to information about clinical trials, lack of tissue to send to molecular testing, provider perceptions of patient burden, language barriers and lack of access to clinical trial related paperwork.

3. Facilitators include reminders, patient inquires about a clinical trial, and supportive attending influence.
Limitations

1. The pilot study did not elucidate the barriers and facilitators for only lung cancer clinical trials but cancer clinical trials overall.

2. Only three providers were interviewed. Results cannot be generalized to whole populations of providers.

3. Not all participants had same semi-structured interview. For the first interview, we asked the participant to focus on the first visit. However, we asked future participants to focus on the second to fourth visits.
Future Directions

Increase sample size

Conduct interviews on more providers to get a more holistic view of provider-related barriers and facilitators to offering lung cancer clinical trials
Potential Interventions

Based on this preliminary analysis of this pilot date, potential interventions could include:

1. Educating providers about clinical trials, especially lung cancer clinical trials
2. Educating patients about the pros/cons of clinical trials
3. Reorganizing and increasing access to the database of clinical trials, as it is unorganized and outdated
4. Increasing health system reminders about clinical trials
Lessons Learned

1. I learned how to create an IRB and consent form.

2. I learned how to develop an interview guide and construct questionnaires.

3. I learned how to conduct semi-structured interviews, record these conversations, and transcribe them.

4. I learned how to code transcripts and group them into major themes.

5. I learned how to collaborate with others and work as a team.
Acknowledgments

1. Dr. Carmen Guerra, MD, MSCE, FACP
2. Joanne Levy, MBA, MCP and Safa Browne
3. Elshaddai Ephrem, Anitra Persaud, Brenda Bryant, and other group members
4. Hoag Levins and Megan Pellegrino
5. Other LDI Staff and Faculty Members
6. Participating Providers in My Study
7. Abramson Cancer Center and Leonard Davis Institute of Health Economics