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14. ABSTRACT This study involves patients and their spouses/partners who are attending two medical institutions: the Deane Prostate Health and Research Center in the Department of Urology at Mount Sinai Hospital, New York City and the Department of Medical Oncology at Fox Chase Cancer Center, Philadelphia. Patients will have been diagnosed with rising PSA but have no clinical evidence of cancer. Eligible patients and their spouse/partners who have agreed to participate (n = 191) will take part in a 6-months long assessment study. During this time, they will be interviewed via questionnaires three times: at the beginning (baseline), at 6-months and when they have made a treatment decision. Our research focus and the measures used for data collection are guided by our cognitive-social health information processing (C-SHIP) theoretical framework. This framework incorporates individuals' experiences, expectations, beliefs, values, and emotional responses to a health threat, and sees these components as influential factors in treatment decision making. Both the patient and the spouse/partner will be assessed. Due to the limited patient enrollment, no significant findings can be reported at this time. We plan to keep the study open as an unfunded project at both institutions to accrue more participants.					
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INTRODUCTION:

Advances in the treatment of prostate cancer have produced excellent 5-year survival chances. Despite this success, a growing number of patients experience a rise in prostate specific antigen (PSA) levels after treatment. Even if widespread disease is not found, a rising PSA is a sign that prostate cancer might have recurred. Recent estimates indicate that approximately 40% of patients who were initially treated with surgery or radiation therapy will experience a rise in PSA, yielding approximately 60,000 cases per year.

From a psychological point of view, patients and their spouses/partners are forced to deal with a disease they believed they have overcome. For a second time they face a health decision with few treatment guidelines, uncertain outcomes, and the potential for substantial side-effects. In addition, patients and their spouse/partners have to deal with the uncertainty of a cancer recurrence and cancer spread, and the possibility of death. Very little information exists in the literature how patients and their spouse partners make treatment decisions about a rising PSA and how both of their physical and emotional quality of life is changed by this condition. This application is designed to address this gap in the psycho-social management of prostate cancer.

BODY:

We obtained and renewed regulatory clearance from both Mount Sinai School of Medicine (MSSM) and Fox Chase Cancer Center (FCCC), our second study site. IRB approval for both sites was obtained on Jan 19 2006 for MSSM and Jan 17 2006 for FCCC. Regulatory approval was again required for the second phase of the study, which took the better part of the no-cost extension to obtain. Despite repeated requests to expedite the review of the protocol IRB approval at FCCC was not obtained until August 2009.

PHASE 1 Report

Mount Sinai Site: The current database tracks both male and female study participants from both study sites, Mount Sinai and Fox Chase Cancer Center. We have begun preliminary analysis with both quantitative and qualitative data. A manuscript describing the first phase of our investigation is currently in progress. Results of these analyses are also described below.

We have held several meetings with the collaborating physicians at MSSM to discuss recruitment procedures. To raise awareness of this research project we continue to meet and work with MSSM's public relation office and have the study listed on MSSM's clinical trials web-page. Furthermore, Dr. Diefenbach, in his ongoing outreach to the community continued to talk about this research project with local support groups, such as the "Man to Man" group.

Fox Chase site: The PI visited FCCC several times to discuss recruitment procedures. Recruitment was improved at FCCC. Hiring and educating a new health educator who remained dedicated to the project for the past year has helped in this respect. This new health educator improved the communication among collaborating physicians, nurses, and research staff. Monthly phone meetings were initiated with collaborating physicians and nurses to appropriately review eligibility criteria of potential study participants by reviewing patient charts and schedules. Further, study staff met on a weekly basis to identify potential patients. Physicians informed patients of the study and relayed contact information to study staff.

Analyses of Transcripts: All questionnaire data have been entered in the SPSS database; however, inferential statistical analyses have not been performed due to the small number of patients enrolled. Inferential statistics will be used to analyze data obtained from Phase II of this project. The focus group and individual interview data was transcribed and analyzed by the PI and research staff. Preliminary qualitative analysis from the transcripts reveals several themes. Patients, generally reported treatment regret. For example several men stated that they "don't know if they would have done it again" knowing what they know now and "wonder if radiation would have worked".

All male participants reported that they believe a rising PSA is a serious problem. They reported that while they were more "shocked" by the initial prostate cancer diagnosis, they are convinced that a rising PSA diagnosis

threatens their survival. Participants reported that they believe having a rising PSA means that the surgery was not successful, and that the cancer might come back “I felt like the surgeon did not get everything, like one cancer cell got away... although I do not have a prostate there may be a cancerous cell.” Others expressed confusion, “I’d be sitting around thinking...how come this is happening? I was saddened by the rising PSA.” When asked about treatment goals, participants reported a desire to manage their rising PSAs and delay the progression of the disease. One man reported, “you just want to outlive the disease, because the end of the disease is not pleasant. You’d much rather get run over by a truck, I guess.”

Several participants reported anxiety concerning their appointments with physicians saying that they have routine appointments but never know what has changed. One patient reported, “I come every three months and start to worry for about a month ahead.” Others reported that they may “freak out” or “get mopey” but they try to “do the best [they] can. Another said, “I think about having cancer... and what I am going to do, it is always in the back of my head.”, and, “I worry about dying from prostate cancer... it’s always on my mind.” Others try to limit the time they think about their rising PSA, such as thinking about it only “one minute a month”.

Many participants reported that the diagnosis of a rising PSA prompted them to gather more information about prostate cancer and “do it right” with regard to treatment. Several men reported attending seminars and joining online organizations that distribute information about prostate cancer. One participant reported, “when he said the PSA was elevated then I realized I’m not totally cured. So that’s when I dug in and started to learn about [herbal therapies] and went to symposiums.” Most men reported receiving information about rising PSA from their doctors, in addition approximately 50% of men reported using the computer and the Internet as their primary information source. “I have gotten a lot of information from doctors. I would like more. I should know more.” Participants expressed confidence in their doctors and their professional opinions. They also recognized that “each fingerprint is different” and “there is no magic bullet” in concluding that treatments do not work the same for everybody. They believe that patients have a responsibility to learn as much as they can, “If a patient is cognizant, he has to manage his own care. He can’t just sit back and say ‘oh well the doctor didn’t tell me...’ Now, he’s got to be very, very careful.”

In addition to these preliminary qualitative analyses, an additional analysis was performed using the textual analysis tool Linguistic Inquiry and Word Count (LIWC). LIWC is a text analysis software program that was designed by James W. Pennebaker, Roger J. Booth, and Martha E. Francis (2001). LIWC calculates the number of times words belonging to specific categories are used in a text. Seventy categories of words were compiled and validated as reflective of topic areas, such as cognition, affect, and references to work and leisure. This has revealed additional themes:

- I. There were trends overall in how the men talked about their experiences,
- II. There were differences in how they talked, based on the method of treatment, and
- III. There were differences in how they talked, based on levels of affect and regret they expressed.

These themes are discussed in more detail below:

- I. In term of overall word usage in these patients, we found that there were more positive emotion words used than negative emotion words ($F(1,7) = 7.80, p < .05$). Some examples of these words (underlined) in context are:

- “And I’ve lived a pretty good life”
- “And, uh, some stuff that you go through, that couples go through, it’s important that we are here for each other and encouraging each other, that’s really important.”
- “I am probably more cognizant of how valuable each day is than I was before and I am in a position where I can enjoy each day”

We also found that they tended to express themselves more often with words that did not demonstrate levels of certainty, but rather tentativeness ($F(1,7)=30.98, p=.001$). An example: “And I guess there’s a lot of other factors I don’t know of that has to do with the PSA”

Finally, overall, the language they used did tend to reflect an ongoing process of understanding, rather than reflecting insight about their situations or decision making ($F(1,7)=401.58, p< .001$). For example: “And I think in a day of medicine when numbers are important to doctors, you know the old family doctor who would advise you and counsel you, those days are over.”

- II. LIWC also allows us to compare, for example, types of treatment with outcomes of language use. While the

sample size is just too small for the differences to be statistically significant, some differences are apparent: those who did not choose surgery used more anxiety words (but did not feel more anxious), more negative emotion words, more words referring the body, more words referring to death, and more words referring to sexuality.

Anxiety words:

"I'm not anxious to be seeded about the ramifications of being seeded"

"I don't want to just you know ignore it [the cancer] but I am not anxious to start that [treatment]"

Negative emotion words:

"No not really, I still suffer. I shouldn't say suffer, but deal with, um, incontinence."

"I just think third strike [referring to his third treatment for the cancer] it's tough after this. Third strike. Third time around. It hurts a lot. It hurts a lot. Something you never expected."

[Q: Now for the most recent rise in your PSA what were your initial feelings, emotions and reactions?] Shock and anger. Deep depression.

Physical words:

"I get tired all the time."

"Besides is that the only option now? Coexisting with it? Whereas before I thought that I'd get in at it. If it's there, where does it go? In the bone? In the blood? Where does it go? I don't know where it goes now."

Death words:

"But I am still waiting to have another heart attack and die"

"...but, you know, whatever it is, it is. I can't change it. If it's meant for me to die that way, I'm going to die that way. I could get killed on my way home in a car accident. So it's really I'm going to be 67 years old, I've lived a lot longer than people at 66, but I might not make it to 68."

Sexuality words:

"There is hormone treatment okay I like to shop I do laundry I like to cook okay but I am also a hunter fisherman I am still sexually active probably too much probably more then I should be always have been the hormone thing is ah you know not looking good for me I have sensitive ...you know but I don't want it taking over my whole body"

III. We were also able to compare different states of mind on issues related to the prostate cancer and its treatment. For example, those who did not express confidence in their treating physician at the time of their initial diagnosis used more words referring to death ($F(1,7)=16.87, p<.01$). And while it was not significant, they also tended to use words in the following categories more often: negative emotion words, anxiety words, words having to do with the body, and words referring to sex, and spoke more in the future tense.

Also, those who had expressed that they were happy to be alive and/or enjoying their lives were less likely to refer to words having to do with the body, ($F(1,7)=5.98, p<.05$), or with eating ($F(1,7)=7.02, p<.05$), than those who didn't express this sentiment.

Example: "I've gained a lot of weight since this last diagnosis. I guess it's an eating thing. Fifteen pounds, twenty pounds. I don't know."

Lastly, those who believed that their rising PSA diagnosis was a serious problem were more likely to use words referring to the body/physical references, than those who did not consider it to be a serious problem. ($F(1,7)=6.46, p<.05$).

Analyses of Spouse Interviews: We performed interviews with the spouses of our participants, using a script adapted for the spouses and partners of rising PSA patients. Interviewing the partners of patients with a rising PSA was extremely informative as we gained insight of the disease from a family perspective. The spouses expressed confusion about the rising PSA, "Now that his PSA is rising again it makes no sense to me." One participant also stated that her husband is having a more difficult time dealing with his rising PSA than he may report. She said, "It's all about men trying to keep everything in... it is demeaning for them to be sick." She added, "He told me when I am not home he cries alone... he quit his job... says he is going to die anyways."

Another spouse stated that "... he's kind of a private person, more than I am. Like, I have to talk about things, where he deals with things in his own way and even with me, he has a hard time talking about certain things."

Another spouse reported that her husband has problems with her asking too many questions at the doctors.

"Um, I see it, he's not that real open with me, that's why this time I was going to sit in the waiting room because he had a problem with me always asking the questions... He always calls me Dr. Brown, that was my maiden name. But I feel what I learn, I can transfer to somebody else and help someone else..."

Spouses also showed that they talk to friends and family for advice more than the men.

"We just decided to just get it out. Take it out. So that 's why we went with it, you know. We had another friend in fact at the same exact time that was also in Vietnam, the same time that XXX was, and went for the operation 2 months before XXX. We just thought it was for the best..."

"I (Wife) would've chosen the surgery, but I did find out, the gentlemen that I used to work with before I got laid off was diagnosed with the same thing... Um, I don't know if it's regrets, because it's hard to say. I mean, I came from a family that, you know, my mother was always sick..."

Another spouse reported her confusion about prostate cancer.

"It totally blows my mind because they say the prostate cancer goes into the bones. So, why can't they do a PET scan or something to find out where it is or how fast it is going or whatever? That's what I don't understand-why they want to wait another 3 months."

LIWC also reveals differences in how spouses talk about their experiences with their husbands' rising PSA and original treatment for prostate cancer. There were differences in language among women, specifically in the following categories. While the number of transcripts analyzed was low (9 of the men's interviews and 4 of the spouses), these differences are at least marginally significant in the following categories: women used more words that reflected cognition ($F(1,11) = 3.44, p = .091$) and insight ($F(1,11) = 3.62, p = .08$), men used more words that referred to the self, or "I" words ($F(1,11) = 10.1, p < .01$), and women used more words that referred to other people ($F(1,11) = 49.82, p < .001$), and socializing ($F(1,11) = 43.77, p < .001$). In addition, women averaged more words per interview ($F(1,11) = 4.29, p = .06$).

Women used more words that reflected their struggle to understand their husbands' rising PSA. Some examples can be seen in the following excerpts:

"Um, I see it, he's not that real open with me, that's why this time I was going to sit in the waiting room because he had a problem with me always asking the questions... He always calls me Dr. Brown, that was my maiden name. But I feel what I learn, I can transfer to somebody else and help someone else..."

"We just decided to just get it out. Take it out. So that 's why we went with it, you know. We had another friend in fact at the same exact time that was also in Vietnam, the same time that XXX was, and went for the operation 2 months before XXX. We just thought it was for the best..."

"It totally blows my mind because they say the prostate cancer goes into the bones. So, why can't they do a PET scan or something to find out where it is or how fast it is going or whatever? That's what I don't understand-why they want to wait another 3 months."

Men referred less often to people other than themselves, which of course makes sense in the context of this study, as they are the patients suffering from prostate cancer. But women were more likely to mention other stories they know of friends and family that had dealt with cancer:

"I (Wife) would've chosen the surgery, but I did find out, the gentlemen that I used to work with before I got laid off was diagnosed with the same thing... Um, I don't know if it's regrets, because it's hard to say. I mean, I came from a family that, you know, my mother was always sick..."

Women also averaged more words per interview. Some spoke specifically about this:

“... he’s kind of a private person, more than I am. Like, I have to talk about things, where he deals with things in his own way and even with me, he has a hard time talking about certain things.”

“My cousin has it and he’s right now ah had the radiation...He’s in his seventies um but what nobody asks and what we would like to know is how is how is their sex life? How does it affect their sex life? You know does the cancer I mean does the surgery you know men don’t talk about that.”

Here is a comparison of a husband and wife talking about their experiences:

(Interviewer) How do your needs differ now? Compared to when your husband was first diagnosed?

(Wife) “well, there’s no sexual- he has no interest in sex at all. Not even pleasing me at all. So I, for two and a half years, haven’t had sex. So, I mean, that’s a need there. I’m only 46 years old...Ever since, I would say after, um, he had his radiation, he waited the period, and then maybe we had sex for a month, and then it hurt so much that ever since then, we haven’t even- he has no interest, he said, at all... this man used to be all over me. You know, and I told him that openly also. You know. I’m an affectionate person and I need someone to need me...”

When her husband was asked a similar question, he required prompting:

(Interviewer) “Ok, how do you think at this moment your rising PSA is currently affecting your life? (pause – additional probe by interviewer)... This is a very broad question. Let’s start with emotionally?”

His answers were also more vague:

“Well this time, I was more worried because, you know, it was just down to normal 4 months ago and now it’s way up... so it bothers me now, yeah sure”

(Interviewer) How do you think it’s affecting ((Spouse))’s life?

(Husband) I think its affecting her worse than me

(Interviewer) Really? How so?

(Husband) Well she was 140 lbs, but now she’s down to about 90 lbs. She’s worrying to death about me.

(Interviewer) I’m assuming that concerns you

(Husband) Yeah, I’m worried about her and she’s worried about me.

The husband required more questioning to provide any detail about their emotional states.

Based on these analyses, two additional scales including the Active Engagement, Protective Buffering, and Overprotection questionnaire and Stephen Lepore’s 15-item Social Constraints Scale have been added to the quantitative assessment instrument.

KEY RESEARCH ACCOMPLISHMENTS OF PHASE I:

- 1) We obtained IRB Continuation Approval from MSSM and have been recruiting patients and their spouse/partners.
- 2) FCCC obtained Continuation Approval however the approval for the addition of two questionnaires (the Active Engagement, Protective Buffering, and Overprotection questionnaire and Stephen Lepore’s 15-item Social Constraints Scale) is still pending. We expect to obtain approval for this by the end of 2008.
- 3) All quantitative data were entered into SPSS database.
- 4) All qualitative data were transcribed, coded, and analyzed.
- 5) All qualitative data were analyzed using the textual analysis tool Linguistic Inquiry and Word Count

(LIWC). LIWC is a text analysis software program that was designed by James W. Pennebaker, Roger J. Booth, and Martha E. Francis (2001). LIWC calculates the number of times words belonging to specific categories are used in a text. This program helps the researchers to identify linguistic trends from qualitative data. A manuscript has been prepared for publication.

- 6) We refined the spouse/partner focused questionnaire to better assess the spouses/partner's experience with a rising PSA.
- 7) Several in person meetings with physicians and research team at both at MSSM and FCCC were held to clarify recruitment procedures.
- 8) Monthly phone conferences were conducted between the research teams at MSSM and FCCC team to update on study progress.
- 9) Total combined recruitment for phase I at both study sites (i.e., MSSM and FCCC) consisted of 26 completed interviews (17 patients and 9 spouses).
- 10) In addition to the preliminary qualitative analyses, additional analyses have been performed.
- 11) MSSM and FCCC have completed Phase I of this project.

PHASE II Report

The goal of Phase II was to validate the themes found in Phase I. To this end we included the Active Engagement, Protective Buffering and Overprotection questionnaire and Stephen Lepore's 15-item Social Constraints Scale. We received IRB approval from the MSSM IRB and the Department of Defense in December, 2008. In contrast, the IRB at FCCC did not finalize its approval for this study until August 2009. Despite various requests to expedite the review, we encountered significant delays in the approval process. Consequently, the available time to recruit patients was severely curtailed.

Recruitment efforts at Mount Sinai School of Medicine

We implemented extensive recruitment efforts at Mount Sinai to reach our accrual goal:

1. We presented the study at Grand Rounds of the Department of Urology and introduced the study to all attending physicians, affiliated physicians, residents and fellows. Study information summaries were handed out that included background information and inclusion/exclusion criteria for the study.
2. Increased advertisements:
 - a. The study was listed on the clinical trials webpage at MSSM that lists all open clinical trials at the hospital
 - b. Study advertisements were placed in the waiting rooms of the Department of Urology to introduce the study and solicit interest from potential participants. Advertisements included tear-off strips with the contact information of the study coordinator.
 - c. IRB approved advertisements were placed on www.craigslist.org. Craigslist has a section devoted to clinical trials. We received about a dozen responses to our repeated postings, however, none of the posters were either eligible or, upon contact, proved to be legitimate patients.
3. Increased communication with referring physicians. On clinic days the clinical trials coordinator arrives before the first patients are scheduled to discuss scheduled patients with the physician. This recruitment method proved to be the most effective and we were able to recruit 19 participants into the study.

To obtain n = 19 participants we approached N = 49 patients. Of those approached, n = 20 patients did not arrive with a spouse/partner or the partners were not interested in participating. Nine patients declined because of time constraints and n = 3 patients had exposure to hormone therapy in the past.

To achieve our recruitment goals we are keeping the study open as an unfunded study for another year.

Recruitment efforts at Fox Chase Cancer Center:

Similar efforts recruitment efforts were undertaken at FCCC. The PI (Dr. Diefenbach) traveled to FCCC to meet with the site PI (Dr. Miller) and the referring physician (Dr. Hudes, a medical oncologist) and Dr. Hudes' nurse. Dr. Hudes and the nurse continued to be enthusiastic about the study, but cautioned that eligible patient volume has declined. Over the one month of active recruitment only 1-2 new patients have been seen. None of these patients were eligible or agreed to participate. Reasons for non-participation were: no time to complete questionnaire and no interest in participation in a research study.

The investigators at Fox Chase have agreed to keep the study open as an unfunded study to assist in recruitment.

REPORTABLE OUTCOMES: As of to date, enrollment numbers of Phase II are too small to conduct meaningful analyses. A draft of the qualitative analyses has been started by our former post-doctoral associate, Dr. Gina Turner. Her untimely departure from our group has put the completion and publication of the draft on hold.

CONCLUSION: There is considerable amount of uncertainty about the meaning of a rising PSA both among patients and spouses. Physicians are an important source of information, however, patients also use the rise in PSA as a motivator to obtain information from other sources, such as the Internet and support groups. In addition, a small number of patients attempt to improve their life-style by changing their diet and increasing their exercise, while another part of the sample tried to "enjoy the life," without regard to health consequences.

With regard to emotional factors, both patients and spouses expressed increased levels of worry about their condition, but also more reflection about their condition and even resignation. Spousal expression of worry tended to be higher than that of patients. The time of PSA testing is often associated with increased levels of distress. Coping varies from acceptance to resignation (i.e., I had a good life).

Overall, there is a need for more detailed information from both patients and spouses. A detailed treatment plan would be desirable, although patients realize that uncertainty is part of this condition and that physicians do not have all the answers. The rising PSA and the specter of cancer recurrence affects the entire family. Spouses worry about their husbands and husbands don't want their partners to worry. Non-communication about their respective emotional states is pervasive.

In the future, a health-educator or nurse led patient-spouse centered brief intervention is planned that would provide detailed information about the rising PSA, but mostly would focus on improving communication between partners and spouses. The goal of this intervention would be to reduce communication constraints and to improve the exchange of information about one's emotional state.

REFERENCES: none

APPENDICES: none