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TITLE: Incontinence Morbidity Following Radical Prostatectomy:
Psychosocial Impact on African American and White Men

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13. Abstract (Maximum 200 Words) (abstract should contain no proprietary or confidential information) The purpose of this study is to determine how ethnicity and age influence psychosocial adaptation to urinary incontinence following radical prostatectomy. This study will: (1) characterize the impact of postprostatectomy urinary incontinence qualitatively in African American and white men; and (2) identify how individual identity, including ethnic background and age, effect one's perception of incontinence morbidity and it's influence on psychosocial adaptation to illness. Both qualitative and quantitative methodologies have been proposed to be used in two separate study phases. In Phase One 90-minute telephone interviews have been completed with 6 men, aged 50 to 75 years. A quota sample of 20% continent men (n = 8) will be recruited so that perceptions of incontinent men can be compared with responses of continent men. Data from Phase One are being analyzed using methods informed by grounded theory. Eligible men have been recruited from a Middle Atlantic Veterans Administration Medical Center and a New England-based University-affiliated Medical Center.			
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Introduction

The purpose of this study is to examine how ethnicity and age influence psychosocial adaptation to prostate cancer treatment within the context of postprostatectomy urinary incontinence. Accordingly, the following two objectives will be defined: (1) Characterize the impact of postprostatectomy urinary incontinence qualitatively in African American and white men; and (2) Identify how individual identity, including ethnic background and age, effects one's perception of incontinence morbidity and its influence on psychosocial adaptation to illness. Both qualitative and quantitative methodologies integrated into two separate study phases were proposed. The qualitative portion of the study was planned on the basis of 40 patient telephone interviews in Phase One, whereas quantitative methodology was identified to analyze data from a mail survey of 200 men in Phase Two. Study sites were selected based on the congruence of Center demographic characteristics with the study objectives. They include two sites, a Middle Atlantic Veterans Administration medical center originally projected to treat 100 predominately African American patients annually for localized prostate cancer with radical prostatectomy, and a New England University-based medical center annually treating 250 predominantly white patients with radical prostatectomy. As described in the 2003 Annual report, unforeseen administrative delays postponed the start of the study by sixteen months.

Body

This section is organized according to the original Statement of Work (Appendix A). Accomplishments relative to the identified tasks are reviewed and summarized below. Phase One tasks 1 and 2 were accomplished and reviewed in the 2003 Annual Report. The focus of this report will be on Phase One tasks 3 and 4.

Task 3: Participant Interviews

New England-based medical center

During the first year the investigator identified one advanced practice nurse at each study site to act as the study site investigator. Both study site investigators work as nurse practitioners in their respective Center's urology practices and therefore have a clinical rapport with men treated for prostate cancer at their institutions. The study site investigators were familiar with the study and the investigator developed written role descriptions of their participation in the study. The study site investigators first identified men in electronic databases at their institutions of men the study eligibility criteria. Men who met the study eligibility criteria were sent letters of invitation to participate in a telephone survey. The letter, signed by the study site investigator, acknowledged the potential participant's care at the Center and introduced the work of the investigator. An opt-out postcard was also sent in the mailing and was to be returned to the study center if the potential participant did not want to be contacted. Of those who were eligible, 60 names remained after the names of men who returned the opt-out postcard were subtracted from the original list.

This list was then sent to the investigator who called each man to reestablish his eligibility and interest in participating in the study. If the man agreed to participate, a telephone interview was scheduled at some later date convenient to the participant. After this first screening telephone call, the investigator sent a letter describing the study and a consent form to the participant. Signed consent forms were then returned to the investigator in prepaid, addressed envelopes. No interviews took place prior to receipt of the signed consent form. Thus the time lapse from the original screening telephone call until the actual study interview ranged from 2 to 4 weeks, depending on when the consent form was returned and the availability of the subject for the interview. In one instance, the interview had to be rescheduled because the signed consent form was not received pending the designated interview date.

Once the designated interview date came about, the investigator called the participant, reestablished the convenience of the interview and reaffirmed the participant's permission to tape the interview. An interview guide with open-ended questions based on the framework of the life course paradigm was used to facilitate participant interviews. Essentially, participants were asked to give an account of their biographies, recollect the months preceding their diagnosis of prostate cancer, and describe their experience with prostate cancer and the course of their recovery thus far with/without urinary incontinence.

The investigator also kept a journal during the study containing personal reflections of the interviews. It included impressions of the researcher/participant interaction, data collection strategies, how data were coded, and decisions about the inclusion of categories. Participants were not paid for their participation. However after completing the interview, each participant received a thank you letter and a MCI telephone calling card.

A Microsoft Access™ database was created to merge the list of eligible men with a tracking mechanism for the various steps of the study procedure. The database was designed to track when the letter of invitation was sent, the date consent forms were sent and received, the date of telephone interview, completion of telephone interview, and the date the thank you letter and telephone calling card was sent. It was also designed so that subsequent steps could not be implemented unless preliminary steps had been completed and documented. During the period October through December 2003, 6 men returned signed consent forms and completed the audio-taped 90-minute interviews.

Middle Atlantic Veterans Administration medical center

In the same manner as recruitment proceeded at the New England-based medical center, the nurse practitioner/study site investigator at the Middle Atlantic Veterans medical center searched the database of eligible men at that Center. Men who met the study eligibility criteria were sent letters of invitation to participate in a telephone survey and an opt-out postcard to be returned to the study center if they not want to be contacted. Of those who were eligible, 31 men remained after the names of men who returned the opt-

out postcard were subtracted from the original list. The list of names was returned to the investigator in December 2003.

The investigator then attempted to contact men by telephone to reestablish their eligibility and interest in participating in the study, however of eleven men contacted, no one was contacted directly. That is, telephone calls were placed, however messages left either with a family member or on a recorded message to return a call to the investigator were not returned. Some men no longer lived at the telephone number given; some agreed to consider the study but did not call back. The investigator made follow-up calls, however no calls were returned. One man agreed to participate, and after two reminder phone calls, returned the consent form, however when the scheduled interview came about, he was not at home and he did not return subsequent telephone calls to reschedule the interview.

Following these unsuccessful telephone calls to potential participants, several conference calls were set up with the nurse practitioner/site study investigator to brainstorm strategies that might be more successful in reaching potential participants at this Center. It was thought that even though participants had received a letter of introduction about the study and the investigator, the investigator was not personally known to them, and therefore may have been reluctant to return telephone calls to someone previously unknown to them. Therefore, the strategy that was agreed on included dividing the list of eligible men into groups. The study site nurse, who knew and had a clinical relationship with the men, would attempt to contact one group at a time by telephone. She would tell the potential participant the purpose of her call and explain that the investigator would be calling within twenty-four hours to describe the study and invite their participation. Once the study site investigator and the study investigator had completed calls to potential participants in the first group, they would begin calling potential participants in the second group. The study is currently under review at the local IRB and therefore we are awaiting approval prior to proceeding with the new calling plan.

Task 4: Analysis

New England-based medical center

Beginning in January 2004 tape recordings of the interviews were sent to a transcription service and all tapes were fully transcribed verbatim according to the protocol. Transcripts were received from the transcription service in late February and analysis began in March. Data were analyzed using methods informed by grounded theory. Three levels of coding were used in the analysis. In Level I coding, the investigator marked and extracted significant statements and phrases that directly related to the phenomena of the life course and experiences of men with urinary incontinence to examine them for similarities and differences. Level II coding involved further distillation of these significant statements so that meaning could be derived and formulated. These statements were then organized into themes that will ultimately lead to the development of the structure of the phenomena developed from the data.

It was determined that it was important to establish a protocol for analysis for the remaining interviews as well as to determine if the interviewing strategies had been successful. Therefore the first 6 interviews were analyzed as a group prior to continuing with the remaining participants. Data analysis of these 6 transcripts took place from March through May.

Continuing Support

Due to an anticipated reduction in resources at this New England-based medical center, the study investigator was recently informed that there is no longer support for this study. Correspondingly the investigator has proposed that the study remain open for the purpose of interviewing the 14 participants originally planned since men have already been recruited to learn of the study. The study is currently under review at this Center's IRB. While it has been proposed that the Center support completion of the 14 remaining interviews, Phase Two of the study will not take place at this Center.

Key Research Accomplishments

Completion of Phase One Task 3 and portions of Task 4 as designated in the Statement of Work were accomplished:

- Task 3. Participant Interviews
 - a. Conduct Interviews
 - b. Begin immediate ongoing analysis

- Task 4. Analysis
 - a. Continuation of grounded theory analysis

Reportable Outcomes

Despite persistent logistical problems, Phase One Task 3 and portions of Task 4 were accomplished. In total 91 men were recruited to consider participation in the study. Six interviews were completed and analyzed and a protocol for analysis of the remaining interviews was developed.

Conclusions

Given the multiple delays that have occurred during this study, and well as the logistical problems at the VA medical center, and the unanticipated lack of resources that have been announced at the New England-based medical center, the remaining study time (one year extension to July 2005) will be used to complete Phase One interviewing and analysis, and make recommendations for instrumentation. In this way full attention can be placed on conducting this study in a sound and rigorous manner.

Appendices

Appendix A: Statement of Work

STATEMENT OF WORK

Incontinence Morbidity Following Radical Prostatectomy: Psychosocial Impact on African American and White Men

Year One

- Task 1.* Develop interview protocol, Month 1
- a. Dissect interview process and specify protocol for individual interviews.
 - b. Set up equipment needs and software requirements
 - c. Develop coding plan

- Task 2.* Develop Preliminary Phase One Study Plan, Months 2-4
- a. Define study sample and recruitment efforts and define eligible sites.
 - b. Obtain Institutional Review Board approval from all sites.
 - c. Review patient databases and narrow sample based on eligibility criteria.
 - d. Begin recruitment

- Task 3.* Participant Interviews, Months 5-7
- a. Conduct interviews.
 - b. Begin immediate ongoing analysis.

- Task 4.* Analysis, Months 8-12
- a. Continuation of grounded theory analysis.
 - b. Follow-up interviews/phone calls with participants.
 - c. Identification of items to be used for instruments.

Year Two

- Task 1.* Phase Two study start-up, Months 13-16
- a. Prepare and submit manuscript from Phase One.
 - b. Conduct reliability and validity testing on any items generated from Phase One.
 - c. Review patient data files and generate subject recruitment plan.

- Task 2.* Recruitment and survey mailing, Month 17-18
- a. Send out letters of invitation to potential subjects.
 - b. Send study questionnaire to respondents.

- Task 3.* Analysis Preparation, Months 19
- a. Set up secure files for subject data collection.
 - b. Develop SAS program files and quality control measures in anticipation of data entry.
 - c. Develop coding book and decision log.