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The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer offered in two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private). **Specific aims:** controlling for stage at diagnosis and co-morbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with and without prostate cancer between non-VA and VA hospitals. During the first year of this prospective cohort study, we have established successful recruitment and retention program. After finalizing the research protocol, we have recruited 310 younger (< 65 Years) patients from the Urology and Radiation Oncology clinics, University of Pennsylvania Health System and VA medical center with a retention rate of 84% for our follow-up surveys. Based on the preliminary results, we have developed two manuscripts that are accepted for publication. Three more manuscripts are under preparation.

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INTRODUCTION

Proposed Abstract:
Background: Cost and health-related quality of care are particularly relevant to prostate cancer because of multiple treatment options with varying outcomes. Due to uncertainty in the screening and treatment, debate on outcomes such as quality of life, satisfaction with care and cost of care continues. Our recent research indicated that type of treatment received for a given stage of prostate cancer varied by ethnicity and age. Men with early stage prostate cancer often live long after diagnosis and treatment and desire to maximize their quality of life. The outcome of this study will facilitate clinical and policy decision making for effective and equitable care.
Objectives/Hypothesis: The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer offered in two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private).
Specific aims: controlling for stage at diagnosis and co-morbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with and without prostate cancer between non-VA and VA hospitals.
Study Design: This study uses a prospective cohort design to assess and compare across Caucasians and African Americans, health related quality of life (HRQoL) and cost of care for prostate cancer patients, younger than 65 years. A total of 300 participants will be recruited from the urology services at the Hospital of the University of Pennsylvania (HUP) and Philadelphia VA Medical Center. Data will be collected on patient age, ethnicity, education, date of prostate cancer diagnosis and treatment, health insurance, diagnostic and therapeutic procedures, inpatient hospitalizations, PSA, PSADT, Gleason score, cancer stage (TNM), physician and ambulatory clinic visits, laboratory and x-ray, and pharmaceuticals. To assess HRQoL, all participants will receive the Prostate Cancer Index, SF-36, family out of pocket-indirect cost survey and CSQ-8 via mail and a follow up phone call. Baseline data will be collected within 1-2 weeks after diagnosis of prostate, and after recruitment for the control group. Subsequent follow up will be done at three months' interval up to two years. We will compare mean direct medical and incremental cost of care for all conditions and HRQoL across two ethnic groups, controlling for stage and Charlson co-morbidity score. HUP costs for the same services will be applied to VA patients. Cost-effectiveness of prostate cancer treatment will be compared across ethnic groups. We will obtain data on primary sources of treatment and costs from hospital medical records, chart review, and hospital based administrative database (Pennsylvania Integrated Clinical and Research Database system). Descriptive and inferential statistical (t-test, chi-square, and odds ratio) analysis will be performed. PSA doubling time will be computed and compared across ethnic groups. Logistic and pooled regression models will be used. The dependent variables of two separate regression models are total cost and quality of life. The independent variables are age, treatment type, health insurance, Charlson co-morbidity score, PSA level and Gleason score. The regressions will be repeated for both ethnic groups and parameters of estimates will be compared. Stratified analysis will be performed based on ethnicity, stage at diagnosis and treatment type. Factors associated with progression of cancer will be analyzed and compared across groups. Finally, Markov models will be used to analyze and compare cost-effectiveness and progression of prostate cancer treatments across two ethnic groups and comparison will be made between VA (public) and non-VA (private) hospitals.

BODY

After completing the final research protocol, the process of recruiting newly diagnosed prostate cancer patients for this grant was initiated in February of 2004. We have recruited 310 younger men with prostate cancer as of January 2005. The specific steps of this process are: (1) contacting the patients; (2) explaining the study; and (3) obtaining the consent.

Task 1. Recruitment of Patients (continued)

a. Design of final protocol – Completed task

b. Potential patients were contacted at the urology and radiation oncology clinics after introduction by their urologist and radiation oncologist. Newly diagnosed patients were also contacted at their pre-prostatectomy classes, organized by the urology clinic. The newly diagnosed prostate cancer patients were contacted at the Veteran Affairs Medical Center during their urology clinic visit.
Research assistant held a detailed discussion with the patients regarding the study.

c. Consent was obtained from interested patients

d. Recruitment of patients

e. Appropriate medical record abstract form has been developed to extract information from individual medical record

f. A unique patient identifier was assigned to each patient. This information is maintained as highly confidential at all times.

Table 1 shows the total number of patients recruited during the period between 2/1/2004 to 1/31/2005. Some of the newly diagnosed prostate cancer patients were at the urology clinics for a second opinion only, and were not eligible for our study. So far, we have obtained baseline data on a total of 310 newly diagnosed younger (< 65 years) prostate cancer patients from the University of Pennsylvania Hospital (n= 238) and from the Philadelphia VA Medical Center (n=72).

Table 1: Recruitment of Newly Diagnosed Prostate Cancer Patients (< 65 Years)

	Hospital of the University of Pennsylvania		Philadelphia VA Medical Center		Total	
	Number of eligible patients	Number recruited	Number of eligible patients	Number recruited	Number of eligible patients	Number recruited
TOTAL	585	238	240	72	825	310

Task 2: Baseline Data Collection (continued)

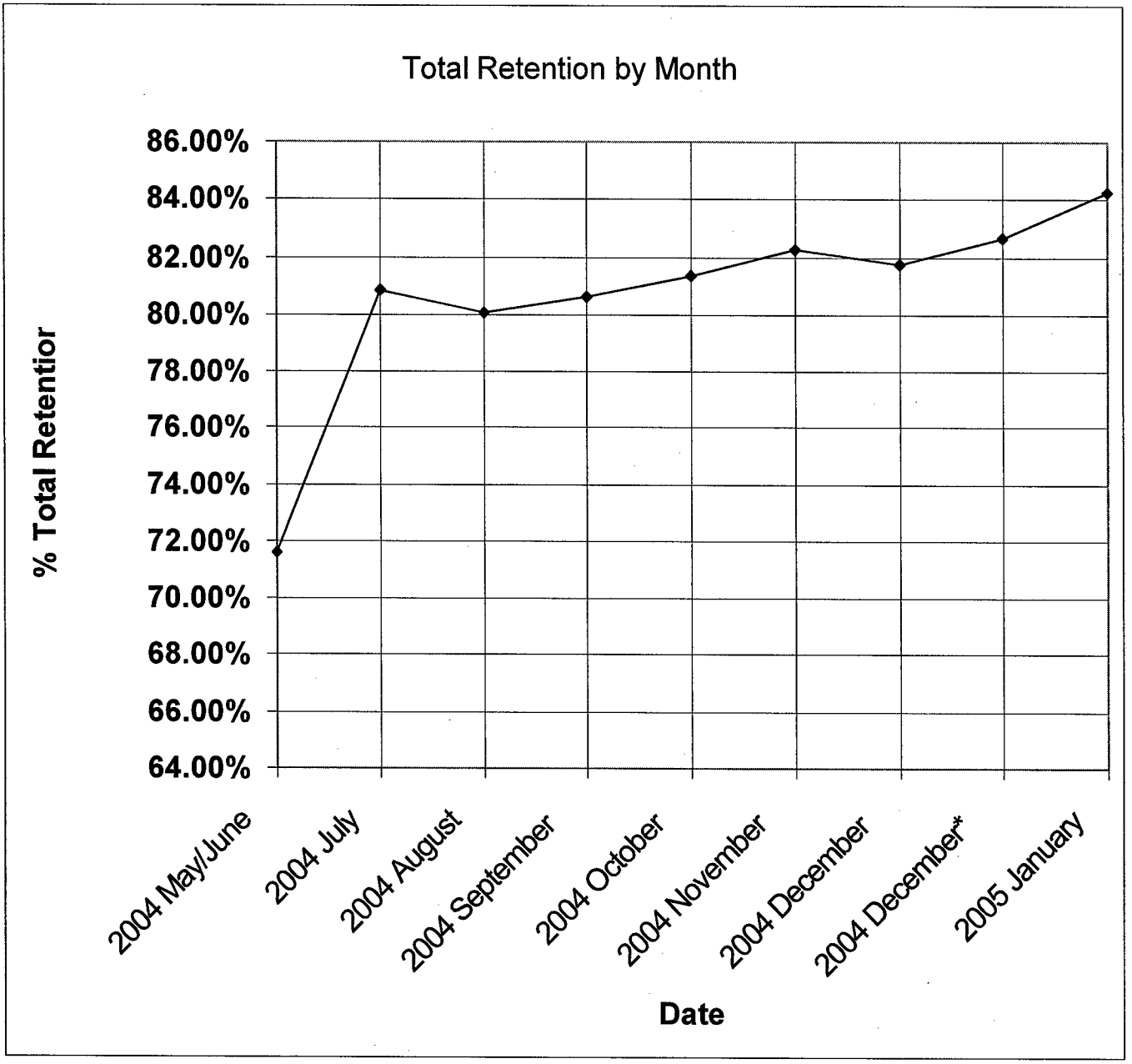
We have completed baseline data collection for all the 310 patients recruited from the UPHS and PVAMC. We need to recruit 23 more African American patients to reach our targeted sample size and hope to complete this task within next few months. We are recruiting newly diagnosed prostate cancer patients from the urology and radiation oncology clinics at the University of Pennsylvania Health System (UPHS). We are also recruiting patients from the Philadelphia VA Medical Center. After obtaining a written consent from the patient, we collect the patient's baseline demographics and quality of life data using the UCLA prostate cancer index, FACT-P, QWB-SA and SF-36. The subsequent follow-ups are done at 3, 6 12 and 24 months beyond a patient's entry into the study. Data on following variables is obtained: Age, ethnicity, types of insurance, living arrangement, marital status and mortality. All the baseline data has been entered and data cleaning is ongoing. A medical record abstraction form was developed to extract clinical data such as PSA scores, Gleason scores, stage of cancer at the time of diagnosis, type of treat received and diagnostic procedures performed from individual medical records (Appendix).

Patient Follow-up and Retention

Table 2 shows the monthly recruitment pattern over the past eleven months of the study period. Some newly diagnosed prostate cancer patients were at the urology clinics for a second opinion only, and were not eligible for our study. So far, we have recruited 238 newly diagnosed prostate cancer patients from the University of Pennsylvania Hospital and 72 from the Philadelphia VA Medical Center. To complete our required sample size, we need to recruit 23 more African American younger prostate cancer patients. We hope to complete this by end of April 2005. Figure below shows the monthly retention activity for our follow-up surveys.

Table 2: Recruitment of Newly Diagnosed Prostate Cancer Patients (< 65 Years)

Month	Hospital of the University of Pennsylvania		Philadelphia VA Medical Center	
	Number of eligible patients	Number recruited	Number of eligible patients	Number recruited
February 2004	48	12	19	4
March 2004	53	19	23	5
April 2004	49	18	18	8
May 2004	62	26	17	7
June 2004	54	22	27	4
July 2004	45	20	19	8
August 2004	44	24	18	6
September 2004	56	21	22	6
October 2004	52	23	21	6
November 2004	40	17	17	5
December 2004	30	13	18	8
January 2005	52	23	21	5
TOTAL	585	238	240	72



Task 3: Administration of Patient Satisfaction Questionnaire

The patient satisfaction care (CSQ8) survey was administered at baseline and at each subsequent follow-up. All patient data satisfaction data has been ongoing. Preliminary data are presented in Tables 17 and 18.

Task 4: Develop Plan for Follow-up Patient interview (continued)

a. A tracking system was developed to track the patient recruitment and contact process. During the follow-up period, seven patients died, (non-prostate cancer related cause), four were from the UPHS and three were from the VA. Table 2 shows patient retention and follow-up. We provide each patient with $10 in compensation at the time of recruitment into the study and $5 at each successful follow-up. This has helped in generating good response rates.

Task 5: Follow up interview and Health Related Quality of Life, and Cost (resource Utilization) Data Collection

a. Surveys are sent out at each follow-up time period to collect data from enrolled patients.

b. Non-respondents are contacted over the telephone and are offered the option to complete the survey over the telephone.

c. Data collection and data entry is being done simultaneously.

d. Date of diagnosis, date of treatment & length of stay, other relevant medical diagnoses and medications data are being obtained from medical charts.

e. Health Related Quality of Life data is collected using SF-36, QWB-SA, FACT-p and UCLA Prostate Cancer Index.

For those patients who have completed 6 months into the study, we have completed medical chart review to obtain following clinical data via medical chart review: date of diagnosis, date of treatment & length of stay; type of treatment/procedures; hospital charges & reimbursements, number and type of medications; number of other procedures, principal DRG diagnostic studies and relevant medications. The results are presented in Tables 13 to 16. Overall satisfaction with care at 3 months follow-up is presented in Table17. A comparison of satisfaction with care at 3 months follow-up by ethnicity is presented in Table 18.

Table 3: Demographics of the study group (age < 65, n=310)

Variable		Percent
Race	Caucasian	59.18
	African American	40.82
Education	8 grades or less	0.75
	Some high school	4.35
	High school graduate	24.15
	Some college	24.53
	College graduate	18.11
	Advanced or graduate training	27.92
Marital status	Married	75.09
	Single	10.57
	Widowed	2.26
	Divorced	12.08
Current employment status	Working full-time	56.92
	Working part-time	3.46
	Retired	27.31
	Other	12.31
Household income	Under $10,000	6.69
	$10,001 up to $20,000	7.87
	$20,001 up to $30,000	11.42
	$30,001 up to $40,000	5.91
	$40,001 up to $50,000	5.12
	$50,001 up to $70,000	13.78
	$75,001 or more	49.21

The demographic characteristics of the study group are presented in Table 3. The mean age was 57.2 (sd.= 4.5). Comparison of demographic characteristics by hospital is shown in Table 4).

Table 4: Comparison of demographics across VA and UPHS groups at the baseline (age<65)

Variable	VA (n= 72)	UPHS (n=238)	
Race (%) White	39.46	80.30	? = 43.2
African American	60.53	19.70	p <.0001
Education (%)			? = 29.8
8 grades or less	1.30	0.53	p =<.0001
Some high school	6.49	3.72	
High school graduate	25.97	23.40	
Some college	42.86	17.02	
College graduate	12.99	20.21	
Advanced or graduate training	10.39	35.11	
Marital status (%)			? = 41.5
Married	49.35	85.64	p <.0001
Single	24.68	4.79	
Widowed	2.60	2.13	
Divorced	23.38	7.45	
Current employment status (%)			? = 60.5
Working full-time	20.00	71.89	p =<.0001
Working part-time	8.00	1.62	
Retired	46.67	19.46	
Other	25.33	7.03	
Household income (%)			? = 92.08
Under $10,000	18.31	2.19	p =<.0001
$10,001 up to $20,000	22.54	2.19	
$20,001 up to $30,000	23.94	6.56	
$30,001 up to $40,000	8.45	4.92	
$40,001 up to $50,000	7.04	4.37	
$50,001 up to $70,000	7.04	16.39	
$75,001 or more	12.68	63.39	

Table 5 shows the baseline general health status and HRQoL (UCLA-PCI) of all newly diagnosed, elderly prostate cancer patients (UPHS and VA combined). All raw scores were converted to a scale of 0 to 100. A score of zero indicates extremely limited function/activity, whereas, a score of 100 indicates excellent function/activity. Physical functioning is a measure of activities during a typical day. Lower score on physical functioning is indicative of more limited the movements. Social functioning is a measure of how physical health interferes with social activities with family, friends, neighbors or groups. As mentioned earlier, the score varies from 0 (high problem) to 100 (no problem). Bodily pain indicates presence of bodily pain and its impact on normal work and the score ranges from 0 to 100. A score of 100 indicates no pain and a score of 0 indicates extreme or very sever pain. Vitality measures level of energy, higher score meaning better vitality. Mental health is a measure of emotional well-being. The score on mental health ranges from 0 to 100. Higher score suggests better mental health. Urinary function is a measure of urinary habits. The score varies from 0 to 100. Higher the score, better the urinary function. Bowel function indicates bowel habits and abdominal pain. Higher score on bowel function indicates better bowel function. Sexual function is a measure of sexual function and sexual satisfaction. The score ranges from 0 to 100, higher score indicating better sexual functions. Similar baseline data for comparison between UPHS and VA groups is presented in Table 6. The demographic comparison by ethnicity is presented in Table 7. Mean age and mean Charlson comorbidity scores were

comparable between African American participants and Caucasian participants (57.9 (4.5) vs. 56.9 (4.6), p=.0625; 1 .86(2.6) vs. 1.78 (2.7), p=.9080).

Table 5:Overall General Health and Prostate Cancer Index at the baseline (age< 65, n=310)

Variable	Mean (standard deviation)
General Health	
Physical functioning	65.9 (20.8)
Role-physical	77.3 (37.9)
Emotional function	73.9 (39.1)
Vitality	65.3 (22.6)
Mental health	74.2 (19.2)
Social function	80.4 (25.1)
Bodily pain	82.7 (25.2)
General health	69.9 (22.9)
UCLA Prostate Cancer Index	
Urinary function	88.8 (20.3)
Bowel function	86.8 (15.8)
Sexual function	59.9 (27.9)
Urinary bother	84.9 (25.4)
Bowel bother	89.7 (19.9)
Sexual bother	64.2 (38.1)

Table 6: Comparison of general health and HRQoL of VA and UPHS groups at baseline (age<65 yrs)

Variable	VA (n=72)	UPHS (n= 238)	p value
General Health			
Physical functioning	49.9 (25.7)	72.5 (13.8)	<.0001
Role-physical	55.2 (45.8)	86.4 (29.8)	<.0001
Emotional function	65.8 (43.5)	77.2 (36.7)	.0311
Vitality	55.4 (22.8)	69.4 (21.2)	<.0001
Mental health	69.4 (20.3)	76.1 (18.5)	.0106
Social function	69.1 (30.7)	85.1 (20.8)	<.0001
Bodily pain	67.9 (30.9)	88.9 (19.5)	<.0001
General health	56.6 (23.1)	74.1 (20.9)	<.0001
UCLA Prostate Cancer Index			
Urinary function	86.6 (19.3)	89.8 (20.7)	.2456
Bowel function	81.2 (17.1)	89.3 (14.7)	.0002
Sexual function	48.9 (29.3)	64.5 (26.0)	<.0001
Urinary bother	81.7 (25.7)	86.3 (25.3)	.1885
Bowel bother	83.4 (25.5)	92.3 (15.3)	.0057
Sexual bother	54.2 (39.6)	68.5 (36.7)	. .0057

Table 7: Comparison of demographics across ethnicity at the baseline (age<65 yrs)

Variable	Caucasian (n= 183)	AA (n=127)	
Education (%)			? = 28.22
8 grades or less	0.55	1.28	p <.0001
Some high school	2.75	8.97	
High school graduate	21.43	30.77	
Some college	19.78	35.90	
College graduate	18.68	14.10	
Advanced or graduate training	36.81	8.97	
Marital status (%)			? = 5.13
Married	79.01	66.67	p = .1621
Single	9.94	12.82	
Widowed	1.66	3.85	
Divorced	9.39	16.67	
Current employment status (%)			? = 38.96
Working full-time	69.89	29.49	p <.0001
Working part-time	2.84	5.13	
Retired	20.45	39.74	
Other	6.82	25.64	
Household income (%)			? = 49.18
Under $10,000	4.55	12.33	p <.0001
$10,001 up to $20,000	4.55	16.44	
$20,001 up to $30,000	6.25	23.29	
$30,001 up to $40,000	5.11	6.85	
$40,001 up to $50,000	3.41	8.22	
$50,001 up to $70,000	13.64	13.70	
$75,001 or more	62.50	19.18	

Table 8: Comparison of general health and HRQOL across ethnicity at base line (age<65)

Variable	Caucasian (n= 183)	AA (n=127)	P value
General Health			
Physical functioning	70.6 (17.1)	56.0 (20.1)	<.0001
Role-physical	83.8 (32.3)	62.5 (45.4)	<.0001
Emotional function	75.9 (37.1)	68.4 (43.9)	.1875
Vitality	67.9 (22.6)	59.5 (21.6)	.0054
Mental health	75.4 (19.0)	71.5 (19.7)	.1442
Social function	84.0 (22.6)	73.6 (28.2)	.0018
Bodily pain	88.2 (21.4)	70.9 (29.0)	<.0001
General health	71.9 (21.9)	62.6 (24.1)	.0039
UCLA Prostate Cancer Index			
Urinary function	89.7 (20.9)	86.6 (19.3)	.2385
Bowel function	88.8 (15.1)	82.7 (16.7)	.0070
Sexual function	62.3 (26.9)	55.8 (29.1)	.0906
Urinary bother	86.1 (25.5)	81.4 (25.9)	.1853
Bowel bother	91.6 (17.6)	85.9 (22.3)	.0292
Sexual bother	68.8 (36.2)	54.9 (39.3)	.0089

Table 9: Comparison of general health and HRQoL at 3 month (age< 65 yrs)

Variable	UPHS (n= 135)	VA (n= 42)	p value
General Health			
Physical functioning	63.9 (18.7)	44.2 (18.7)	<.0001
Role-physical	53.2 (18.7)	36.3 (18.7)	.0376
Emotional function	73.2 (18.7)	58.7 (18.7)	.0544
Vitality	64.6 (18.7)	50.1 (18.7)	.0003
Mental health	77.9 (18.7)	72.5 (18.7)	.0849
Social function	74.9 (18.7)	65.2 (18.7)	.0367
Bodily pain	79.1 (18.7)	62.1 (18.7)	.0006
General health	75.2 (18.7)	51.4 (18.7)	<.0001
UCLA Prostate Cancer Index			
Urinary function	55.9 (18.7)	68.0 (18.7)	.0094
Bowel function	87.6 (18.7)	81.4 (18.7)	.0388
Sexual function	22.9 (18.7)	26.6 (18.7)	.3913
Urinary bother	59.3 (18.7)	66.7 (18.7)	.2173
Bowel bother	88.5 (18.7)	80.4 (18.7)	.0450
Sexual bother	31.5 (18.7)	37.8 (18.7)	.3163

Table 10: Comparison of general health and HRQoL at 3 month (age <65 yrs)

Variable	Caucasian (n=128)	AA (n=49)	p value
General Health			
Physical functioning	63.2 (19.6)	49.6 (25.9)	.0003
Role-physical	55.7 (45.4)	33.5 (43.8)	.0054
Emotional function	75.9 (39.1)	56.8 (46.9)	.0091
Vitality	63.6 (22.6)	55.6 (24.0)	.0430
Mental health	78.0 (17.2)	74.0 (17.7)	.1794
Social function	76.2 (24.9)	65.8 (27.1)	.0186
Bodily pain	80.7 (23.8)	61.4 (32.9)	<.0001
General health	73.9 (21.9)	58.5 (24.2)	<.0001
UCLA Prostate Cancer Index			
Urinary function	56.8 (30.4)	59.0 (31.9)	.6769
Bowel function	87.8 (16.3)	81.9 (19.3)	.0470
Sexual function	21.8 (22.1)	29.9 (25.9)	.0447
Urinary bother	61.5 (32.6)	61.1(35.6)	.9433
Bowel bother	88.7 (20.8)	80.9 (27.9)	.0521
Sexual bother	35.4 (35.7)	26.7 (32.9)	.1582

Table 11: Comparison of general health and HRQoL at 6 month (age <65 yrs)

Variable	UPHS (n=125)	VA (n=43)	p value
General Health			
Physical functioning	69.9 (17.5)	50.0 (28.5)	<.0001
Role-physical	82.2 (33.8)	48.1 (46.5)	<.0001
Emotional function	87.4 (29.5)	64.9 (45.2)	.0004
Vitality	69.6 (21.4)	53.2 (28.4)	.0001
Mental health	80.3 (16.6)	75.4 (16.8)	.0998
Social function	84.5 (24.2)	66.2 (31.5)	.0022
Bodily pain	88.4 (18.9)	64.8 (31.2)	<.0001
General health	74.4 (21.7)	52.1 (26.4)	<.0001
UCLA Prostate Cancer Index			
Urinary function	72.3 (26.6)	66.9 (30.1)	.2753
Bowel function	88.8 (13.5)	76.3 (20.1)	<.0001
Sexual function	27.3 (23.1)	22.9 (22.0)	.2784
Urinary bother	76.2 (29.2)	66.5 (33.4)	.0757
Bowel bother	89.8 (21.6)	79.4 (28.2)	.0150
Sexual bother	33.7 (33.8)	26.8 (32.3)	.2587

Table 12: Comparison of general health and HRQoL at 6 month (age <65 yrs)

Variable	Caucasian (n=121)	AA (n=47)	p value
General Health			
Physical functioning	69.3 (18.2)	53.3 (28.2)	<.0001
Role-physical	82.2 (33.6)	52.9 (47.9)	<.0001
Emotional function	86.3 (30.8)	70.8 (42.8)	.0145
Vitality	68.8 (21.8)	56.8 (28.8)	.0054
Mental health	80.9 (15.8)	75.2 (17.8)	.0519
Social function	84.5 (24.6)	68.6 (30.9)	.0009
Bodily pain	87.5 (20.8)	69.2 (29.4)	<.0001
General health	73.3 (22.4)	55.9 (27.5)	<.0001
UCLA Prostate Cancer Index			
Urinary function	70.9 (26.5)	71.8 (30.4)	.8572
Bowel function	87.8 (15.4)	80.0 (17.2)	.00611
Sexual function	27.3 (23.6)	24.9 (20.9)	.5750
Urinary bother	76.9 (28.4)	66.3 (34.5)	.0493
Bowel bother	89.4 (22.6)	82.1 (26.1)	.0886
Sexual bother	35.5 (34.2)	23.1 (30.2)	.0433

Table 13: Baseline Clinical Characteristics (age<65 yrs. n=144)

Variable		Percent
Marital Status		
	Married	77.46
	Single	9.86
	Widowed	0.70
	Divorced	11.97
Pre-hospital Living Arrangement		
	In community	76.39
	Lives alone	20.14
	Don't know	3.47
Health Insurance		
	Medicare	7.19
	Medicare/Managed Care	0.72
	Private	79.14
	None	12.95
TNM Stage of Cancer		
	T1a to T1c	67.61
	T2a to T2c	19.71
	T3a to T3b	12.68
Mean Charlson comorbidity score		1.83 (2.7)
Mean PSA at the time of diagnosis		7.3 (8.2)
Mean Gleason score at the time of diagnosis		6.3 (0.74)

Table 14: Treatment pattern (age<65 n= 144)

Treatment		Percent
Radiation	Yes	13.99
	No	86.01
Surgery	Yes	85.42
	No	14.58
Hormone Therapy	Yes	9.72
	No	90.28
Watchful Waiting	Yes	3.47
	No	96.53
Other Procedures	Yes	4.17
	No	95.83

Table 15: Baseline Clinical Characteristics Comparison by Ethnic group (age <65 yrs)

Variable	Caucasian (n= 103)	African American (n= 41)	p value
Marital Status			? = 25.76
Married	85.44	54.05	p <.0001
Single	9.71	10.81	
Widowed	0.97	0.0	
Divorced	3.88	35.14	
Pre-hospital Living Arrangement			? = 18.9
In community	81.62	52.63	p <.0001
Lives alone	11.54	44.74	
Don't know	3.85	2.63	
Health Insurance			? = 34.1
Medicare	4.95	13.89	p <.0001
Medicare/Managed Care	0.99	0.00	
Private	99.10	47.22	
None	3.96	38.89	
TNM Stage of Cancer			? = 9.3
T1a to T1c	68.93	62.16	p = 0.0023
T2a to T2c	16.5	29.74	
T3a to T3b	14.57	8.1	
Mean Charlson Comorbidity score	1.78 (2.7)	1.86 (2.6)	.9080
Mean PSA at time of diagnosis	6.48 (4.39)	9.76 (14.1)	.0354
Mean Gleason score at time of diagnosis	6.29 (0.57)	6.36 (1.1)	.6212

Table 16: Comparison of Treatment Pattern by Ethnic group (age <65 yrs)

Treatment		Caucasian (n= 103)	African American (n=41)	p value
Radiation	Yes	8.74	28.95	? = 9.3140
	No	91.26	71.05	p = .0023
Surgery	Yes	92.31	65.79	? = 15.53
	No	7.69	34.21	p <.0001
Hormone Therapy	Yes	4.81	23.68	? = 11.16
	No	95.19	76.32	p = .0008
Watchful Waiting	Yes	3.85	2.63	? = .1209
	No	96.15	97.37	p = .7281
Other Procedures	Yes	4.81	2.63	? = .3257
	No	95.19	97.37	p = .5682

Table 17: Satisfaction with Care at 3 month (age <65 n= 177)

Variable	Percent
How would you rate the service you have received?	
Poor	1.75
Fair	4.68
Good	31.58
Excellent	61.99
Did you get the kind of service you wanted?	
No, definitely	0.58
No, not really	6.43
Yes, generally	35.09
Yes, definitely	57.89
To what extent has your program met your needs?	
None of my needs have been met	0.60
Only a few of my needs have been met	3.55
Most of my needs have been met	31.14
Almost all of my needs have been met	61.68
If a friend were in need of similar help, would you recommend our program to him or her?	
No, definitely not	1.18
No, I don't think so	3.55
Yes, I think so	23.67
Yes, definitely	71.60
How satisfied are you with the amount of help you have received?	
Quite dissatisfied	0.58
Indifferent or mildly dissatisfied	5.26
Mostly satisfied	33.33
Very satisfied	60.82
Have the services you received helped you to deal more effectively with your problems?	
No, they seemed to make things worse	0.00
No, they really didn't help	4.76
Yes, they helped somewhat	32.14
Yes, they helped a great deal	63.10
In an overall sense, how satisfied are you with the services you have received?	
Quite dissatisfied	2.92
Indifferent or mildly dissatisfied	5.85
Mostly satisfied	31.58
Very satisfied	59.65
If you were to seek help again, would you come back to our program?	
No, definitely not	0.60
No, I don't think so	3.57
Yes, I think so	27.38
Yes, definitely	68.45
To what extent has you insurance influenced your decisions about treatment of prostate cancer?	
Not at all	68.64
A little	4.73
Somewhat	9.47
A lot	17.16

Table 18: Satisfaction with Care at 3 months, Comparison by Ethnicity (age<65 n=177)

Variable		Caucasian	AA	P value
How would you rate the service you have received?				? = 2.47
	Poor	0.82	4.35	p = .4790
	Fair	4.92	4.35	
	Good	31.15	32.61	
	Excellent	63.11	58.70	
Did you get the kind of service you wanted?				? = .7446
	No, definitely	0.82	0.00	p =.8627
	No, not really	5.74	6.52	
	Yes, generally	34.43	39.13	
	Yes, definitely	9.02	43.35	
To what extent has your program met your needs?				? = 3.21
	None of my needs have been met	0.00	2.22	p =.3608
	Only a few of my needs have been met	5.88	8.89	
	Most of my needs have been met	31.93	28.89	
	Almost all of my needs have been met	62.18	60.00	
If a friend were in need of similar help, would you recommend our program to him or her?				? = 5.75
	No, definitely not	0.00	4.44	p =.1242
	No, I don't think so	4.13	2.22	
	Yes, I think so	23.97	22.22	
	Yes, definitely	71.90	71.11	
How satisfied are you with the amount of help you have received?				? = 3.35
	Quite dissatisfied	0.00	2.17	p =.3402
	Indifferent or mildly dissatisfied	5.74	4.35	
	Mostly satisfied	31.15	36.96	
	Very satisfied	63.11	56.52	
Have the services you received helped you to deal more effectively with your problems?				? = .0304
	No, they seemed to make things worse	0.00	0.00	p =.9849
	No, they really didn't help	5.00	4.44	
	Yes, they helped somewhat	31.67	31.11	
	Yes, they helped a great deal	63.33	64.44	
In an overall sense, how satisfied are you with the services you have received?				? = 1.84
	Quite dissatisfied	2.46	4.35	p =.6067
	Indifferent or mildly dissatisfied	5.74	6.52	
	Mostly satisfied	28.69	36.96	
	Very satisfied	63.11	52.17	
If you were to seek help again, would you come back to our program?				? = 4.92
	No, definitely not	0.83	0.00	p =.1778
	No, I don't think so	4.96	0.00	
	Yes, I think so	23.14	36.36	
	Yes, definitely	71.07	63.64	
To what extent has your insurance influenced your decisions about treatment of prostate cancer?				? = 3.77 p =.2873
	Not at all	68.03	72.73	
	A little	6.56	0.00	
	Somewhat	9.84	6.82	
	A lot	15.57	20.45	

Task 6: Indirect Cost Data Abstraction Design

A survey to obtain indirect cost data was developed and this survey is sent out with each follow-up to obtain indirect cost data. The data entry and analysis is currently ongoing.

Task 7: Abstraction of Medical Records

a. Medical record abstraction is complete for those who have completed 6 months into the study (n=144). The results are presented in Tables 13-16. For rest of the participants, medical record abstraction is currently being performed and will continue during the follow-up periods.

b. Data entry and quality control measures are ongoing.

Task 9: Data entry and coding (continued)

a. Data dictionary was created

b. Databases were set up in Microsoft Access and Excel

c. All the data obtained is being coded and entered (ongoing).

Task 10: Interim Analysis, Months22-24

a. Interim statistical analyses of data will be performed periodically

b. Second annual report will be written.

Task 11:Cost-Effectiveness Model, Moth 30-33

a. Cost-Effectiveness analysis and Markov decision model will be developed.

b. Simulation results will be obtained.

Task 12: Interim Analyses and final analysis- Months 18-36

a. Interim statistical analyses will be performed at the second year of the study. The final analyses will be performed during 3rd year of the study.

Task 13: Publishable reports will be developed – Months 30-36

This task is currently ongoing. With the help of preliminary data, we have developed two manuscripts, one of which has been accepted for publication by the Urologic Oncology Journal and the second manuscript is under review by the Journal of Urology. We have also presented four peer reviewed abstracts at the various conferences.

KEY RESEARCH ACCOMPLISHMENTS

During the study period between 2/1/2004 to 1/31/2005, we have established the recruitment/follow up mechanism and have continued to recruit patients. We have successfully recruited total of 310 newly diagnosed, younger (< 65 yrs.) prostate cancer patients from the Urology clinic, Radiation Oncology clinic of the University of Pennsylvania and VA Medical Center. Patient recruitment as well as data collection on Health Related Quality of Life, Satisfaction with Care, Direct and Indirect medical cost at baseline and follow-up is ongoing. During this report period, we have achieved a retention rate of 84%. In order to reach our goal of sample size, we need to recruit additional 23 African American prostate cancer patients. We hope to complete the recruitment process in the next few months. Using our preliminary data, we have developed two manuscripts, one of which is accepted for publication by the Urologic Oncology Journal and the other by the Journal of Urology. We have presented the results in four conferences.

REPORTABLE OUTCOMES

Manuscripts:

1. Jayadevappa R, Chhatre S, Weiner M, Bloom BS Malkowicz B,. Direct Medical Care Cost of Patients with Prostate Cancer Across Age and Ethnicity. Urologic Oncology (forthcoming)

2. Jayadevappa R, Bloom BS, Chhatre S, Wein A, Malkowicz B. Health Related Quality of Life and Cost of Care of Newly Diagnosed Prostate Cancer Patients. The Journal of Urology (forthcoming).

Working Manuscripts:

1.Jayadevappa R, Malkowicz SB, Chhatre S, Bloom BS. Health Related Quality of Life and Cost of Care of older Prostate Cancer Patients. Journal of the American Geriatrics Society.
2.Jayadevappa R, Bloom BS, Malkowicz SB Chhatre S,. Variations in Health Related Quality of newly Diagnosed Prostate Cancer Patients Across Ethnicity. Health Services Research.
3. Jayadevappa R, Bloom BS, Malkowicz SB Chhatre S, Treatment pattern and Health Related Quality of Life of VA and non-VA prostate cancer patients. Medical Care.

I. Peer Reviewed Abstract:

1. Jayadevappa R, Chhatre S, Johnson K, Bloom BS, Malkowicz SB. (2004). Quality of Life of Newly Diagnosed Prostate Cancer Patients. AcademyHealth-Annual Research Conference.
2. Jayadevappa R, Chhatre S, Rosner A, Fimberstein K, Bloom BS, Malkowicz SB (2004). Quality of Life of newly diagnosed Elderly Prostate Cancer Patients. Journal the American Geriatrics Society.
3. Jayadevappa R, Chhatre S, Rosner A, Fimberstein K, Johnson K, Bloom BS, Malkowicz SB. (2004). Quality of life of newly diagnosed prostate cancer patients in a public vs. private setting. Value in Health, 7 (3):253.

Grants:

1.Principal Investigator - Effectiveness of stress reduction program on health related quality of life and progression of cancer among elderly prostate cancer patients- Department of Defense. 7/1/05 – 6/30/08 (under review)

2.Principal Investigator – Quality of Life in long-term survivors of prostate cancer. NIA-NIH RO3. 4/15/05 – 3/15/07 (under review)

CONCLUSIONS

Most of the proposed targeted activities have been achieved during the study period. We have a well-established recruitment and retention mechanism in place. The support of Urologist has been very helpful toward this. As of now, we have recruited 310 newly diagnosed younger prostate cancer patients. The recruitment is ongoing and our retention rate is currently higher than 84%. Most of the data has been entered, with established quality control measures. We have completed the preliminary analysis. Once all the chart abstraction and follow-up is complete we will perform the final analysis. Also, after we obtain all the cost and HRQoL data, we will develop cost-effectiveness model. In addition, we have been able to publish and present the preliminary results (please see appendix).

APPENDIX

1. Jayadevappa R, Chhatre S, Weiner M, Bloom BS Malkowicz B,. Direct Medical Care Cost of Patients with Prostate Cancer Across Age and Ethnicity. Urologic Oncology (forthcoming)

2. Jayadevappa R, Bloom BS, Chhatre S, Wein A, Malkowicz B. Health Related Quality of Life and Cost of Care of Newly Diagnosed Younger Prostate Cancer Patients. The Journal of Urology (forthcoming).

3. Medical Records Abstraction Sheet

Title Page

THIS MANUSCRIPT HAS BEEN ACCEPTED FOR PUBLICATION BY THE JOURNAL OF UROLOGIC ONCOLOGY

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ABSTRACT

Objective: To analyze variations in direct medical care cost of patients with prostate across two racial groups after controlling for age, disease stage, and comorbidity.

Methods: In this retrospective cohort control study, we randomly selected 120 newly diagnosed prostate cancer patients (60 African Americans and 60 Caucasians) from the administrative database of a large urban academic hospital. Medical care costs data and clinical data were obtained. The control group consisted of 240 men without cancer, and matched by age and race. Demographics, clinical variables and treatment patterns were compared across race using t-test and chi-square. Mean medical care cost for prostate cancer patients were compared by race, using bootstrap and log t-test. Regression models were used to estimate the incremental cost of prostate cancer, and to analyze the association between race and direct medical care cost.

Results: Caucasians were more likely to receive radical prostatectomy, while African Americans were more likely to receive radiation therapy. The incremental cost of prostate cancer was 1.30 times higher than controls. Charlson comorbidity was a significant predictor of type of treatment received and cost. Race was not associated with total direct medical care cost after controlling for age, Charlson comorbidity and stage of cancer at diagnosis.

Conclusions: Charlson Comorbidity score was a predictor of type of treatment and direct medical care cost. While analyzing the association between race and cost of care, potential bias-inducing factors such as clinical characteristics at diagnosis and provider characteristics (physician and hospital) must be addressed.

I. Introduction

Cost and health status utility are relevant to many health conditions. The multiple treatment strategies for prostate cancer provide a unique arena for examining associated costs and utilization of care. Prostate cancer is the leading cancer diagnosed among men in the United States and accounts for a significant proportion of health care cost (1-9). The American Cancer Society reported that in 2003 approximately 230,110 men were diagnosed with prostate cancer and 29,900 might have died of it (1,3,4). The economic burden of this slow, progressive disease is substantial and growing (5-9). The annual cost of treating prostate cancer in the U.S. amounts to several billion dollars. As majority of the men diagnosed with prostate cancer are elderly, Medicare shoulders most of the cost burden (3,7,9). Despite the cost, uncertainty exists regarding the effectiveness of various treatments for prostate cancer (7-13).

Age, ethnicity and a family history of prostate cancer are the only well established risk factors for prostate cancer (1-8,11). The incidence of prostate cancer in African American men is 1.6 times greater than that in Caucasian men (1,3,4). Among African American men, prostate cancer is the leading type of newly diagnosed cancer (39%), and second leading cause of death (16.3%) (4). Incidence rates of prostate cancer increase more sharply with age than for any other cancer (1). Sixty percent of all newly diagnosed prostate cancer cases and almost 80% of all deaths occur in men aged 70 years or older (3,4). Prostate cancer mortality has been steadily declining over the past two decades (1). However, the decline in mortality rate among African American men lags that among Caucasian men (1). African American men have higher mortality, present late stage of cancer at diagnosis, and have lower mean age at death than Caucasian men (1, 14-19). Race and comorbidity are shown to be independent predictors of mortality for localized prostate cancer patients in addition to age, Gleason score and clinical stage of cancer (17,18,20,21). There exists an ongoing debate regarding racial/ethnic variation in treatment modalities and cost of care for prostate cancer. The relationship between patient characteristic, health insurance status, provider characteristics (physician and hospital) and geographic characteristics is complex and must be taken into consideration while assessing the association between race/ethnicity and medical care cost for prostate cancer patients. This study aims to analyze (1) the incremental cost of prostate cancer, and (2) association of race with of direct medical care cost of prostate cancer. We hypothesized that racial variation exists in the direct medical care cost for prostate cancer care in a large urban academic hospital setting.

II. Materials and Methods

A retrospective cohort control study design was used to collect clinical and cost data on a randomly selected group of 60 African American and 60 Non-Hispanic Caucasian prostate cancer patients treated at a large urban academic medical center. The two groups were matched by age and residential zip code. To be eligible for inclusion in the study, a patient had to be treated for prostate cancer between 1998- 2001, with a minimum of two years of enrollment in the health system; had to be at least 40 years of age, and had to be of either African American or Non-Hispanic Caucasian race. Patients were excluded if they had un-staged prostate cancer, or visited the urology clinics to obtain a second opinion only and not to receive treatment. The control group consisted of 240 people without any cancer, matched by age, race, health insurance and residential zip code, selected from the same health care system database. Thus, this control group offered the appropriate baseline levels of healthcare/health status costs unrelated to cancer and enabled us to deal with the joint product issue that often afflicts cost of illness studies.

Data Description

Detailed data on health resource utilization, types of procedures performed, and direct medical care charges were obtained from the Pennsylvania Integrated Clinical and Research Database (PICARD). This database integrates administrative, inpatient and outpatient information from the university practices, and data from other clinical networks. Sixty seven percent of the population in this database was Caucasian and 20% was African-American. Thus the database reflected the area demographics served by this health system. The data used for measuring direct medical care costs of prostate cancer illness were: hospital care costs, physician and other professional caregivers payments, medication, costs related to detection, costs associated with initial and follow-up treatments, and treatment of complications. Medical care costs are defined as charges for specific services by any part of the health care organization. Costs per service were attributed to each service for every diagnosis for each study patient from actual charges for that patient. We used cost-to-charge ratio of .80 to compute actual medical center costs. Data on type and number of services received by a patient, including those attributable to prostate cancer, were obtained using CPT codes. Mean direct medical care cost per patient during the 12 months period was compared between racial groups. Two cost estimates of prostate cancer were

developed and compared by race. First, mean costs of medical care attributable to prostate cancer were identified for specific services related to prostate cancer and compared between two racial groups (22). Next, mean incremental direct medical care cost for patients with prostate cancer was compared between two racial groups. The difference in mean direct medical cost of care between the prostate and non-prostate groups was the incremental cost (marginal cost) that could be attributed to prostate cancer treatment specifically.

Demographic characteristics (age, race, type of insurance, living arrangement, marital status and mortality) and clinical data (prostate specific antigen [PSA] level, Gleason score, Charlson comorbidity score, TNM stage of cancer, and type of treatment) were obtained from the clinical records and surgical pathologic reports using a structured chart abstraction sheet. Prostate cancer treatments included (1) Radiation (external beam, interstitial, extended field); (2) Surgery (pelvic LN dissection, TURP, orchiectomy, and radical prostatectomy); (3) Hormonal therapy and (4) Watchful waiting. Comorbidity is an important confounder for health resource utilization patterns. We computed Charlson comorbidity score (CHS) annually for each study participant. The Charlson comorbidity index is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of the burden of illness (23). The Charlson comorbidity score has been used effectively in many longitudinal studies using administrative data (23-25).

Statistical Analysis

Most cost data suffer from non-normal distribution and our data was not an exception to this (skewness statistic=1.96). Log transformation of direct medical care cost data reduced the skeweness, but did not make the distribution normal (skewness statistic=-0.60). Thus, in addition to parametric tests, we also used non-parametric tests. For both groups (prostate cancer and control), we used bootstrap and t-test on log transformed data for comparing the mean direct medical care cost by race. Wilcoxon rank sum test was used to compare median direct medical care cost by race. Chi-square, Fisher's Exact and Student-T tests were used to compare age, Gleason score, PSA and treatment pattern across race. We determined factors associated with prostate cancer group and analyzed the incremental cost of prostate cancer using General Linear Model (GLM) for the log transformed data and Weibull model (26,27). For the prostate cancer group, in the models for predicting total cost, we used the following independent variables: age, race, Charlson comorbidity score, and stage of

cancer at the time of diagnosis. For estimating incremental cost, we used the entire sample (prostate cancer cases and controls) with the following independent variables: age, race, Charlson comorbidity score and presence of prostate cancer (yes/no). Ordinary least Square (OLS) regression may not prove to be appropriate for cost data as they tend to be highly skewed and a few extreme observations can influence the results. We corrected this problem by log transformation of the cost data.

We also analyzed cost data by using the Weibull model. This model is based on assumptions that are also appropriate for non-normally distributed cost data. In situations where these assumptions hold, the Weibull model proves to be an efficient model for cost data analysis. We used GLM model (for log-transformed cost data) and Weibull model to analyze the association between race and direct medical care cost. The response on log scale was retransformed and smearing estimator was used to correct for the retransformation bias (28).

III. Results

Demographic Characteristics

Demographic characteristics of the study population are presented in Table 1. Mean age of African American prostate cancer patients was 72.6 years, and that of Caucasian prostate cancer patients was 69 years. African American prostate cancer patients had higher Charlson comorbidity scores compared to Caucasians, indicating higher prevalence of co-existing morbidity. The mean Charlson comorbidity score was different between African Americans and Caucasians (4.5 vs. 2.0, p=<.0001). Charlson comorbidity score increased with age for both racial groups. Health insurance status was comparable across race. For the control group (Table 2), the mean age of African Americans and Caucasians was not different (72.6 vs. 69.1, p=.0855). The Charlson comorbidity score was different between African Americans) and Caucasians (3.87 vs. 1.46, p=<.0001). As with the prostate cancer group, the health insurance status of controls was comparable across race. These results indicated that cases and controls were well matched.

Table 3 shows clinical characteristics and type of treatment received by the prostate cancer group at the time of diagnosis. The PSA level was higher among African Americans than Caucasians, though the difference was not statistically significant. Gleason scores were comparable between racial and age groups and indicated that the tumor grades were moderately differentiated with a score 6.7 for African Americans and 6.5 for Caucasians. There was no difference in TNM stage of cancer at the time of diagnosis between the two racial groups. Proportion of patients with lymph node involvement and bone metastesis was similar across racial groups.

As seen from Table 4, a higher proportion of African Americans received radiation treatment, whereas a higher proportion of Caucasians received surgery. For both racial groups, a higher percent of elderly prostate cancer patients (• 65 yrs) received radiation and hormone therapy. On the other hand, a higher percentage of younger patients (< 65 yrs) received surgery (results not reported). There was no racial difference among proportion of patients having hormone therapy, though older patients mostly received hormone therapy. Compared to African Americans, a higher proportion of Caucasians received surgery alone.

Table 5 presents comparisons by race using parametric and non-parametric tests of mean and median direct medical care cost for prostate cancer and control groups. Costs were not different across race for prostate cancer group using all three methods. However, controls showed significantly higher cost for African Americans than Caucasians.

Figure 1 shows the relationship between total direct medical care cost and Charlson comorbidity score for both groups. For controls, we found an increasing trend between direct medical care cost and Charlson comrobdity score, leading to an inverse relationship between incremental cost of prostate cancer and Charlson comorbidity score. The highest incremental cost of $10,000 was observed between prostate cancer and control group when the Charlson comorbidity score was 0. This cost difference was reduced to $1000 as Charlson comorbidity score increased to between 1-3, and remained constant thereafter. This suggests that prostate cancer patients with no comorbidity received the most intensive treatment leading to higher incremental cost. As comorbidity increased, prostate cancer patients might not have received aggressive treatment, as treating other chronic diseases then receives priority over a slow progressive disease such as prostate cancer.

Results of GLM with log-transformation (PROC GLM) and Weibull model (PROC LIFERG) to predict the incremental cost of prostate cancer were comparable and are presented in Table 6. Results from log-linear GLM model indicate that prostate cancer patients had 1.49 times higher total direct medical care cost compared to cancer-free controls. The Weibull model estimated incremental cost of prostate cancer to be 1.30 times the direct medical care cost of controls. The standard error for the Weibull model was comparable and smaller than the GLM model, indicating a better fit to the data. Both models were consistent in indicating that Charlson comorbidity score and presence of prostate cancer were statistically significant predictors of cost. Additionally, age was a significant predictor of direct medical care cost in the Weibull model.

We analyzed the effects of race as a predictor of total direct medical care cost for the prostate cancer group. The results of all both models yielded comparable results (Table 7). The statistic of interest is the coefficient of race after controlling for age, Charlson comorbidity score and TNM stage of cancer at the time of diagnosis. Race showed no effect on total direct medical care cost for prostate cancer patients, after controlling for these covariates. Also, in a secondary analysis (results not reported), we found that treatment modality was mostly influenced by comorbidity and age, rather than race.

IV. Discussion

We observed some differences in treatment pattern by race. Caucasian prostate cancer group had lower comorbidity at diagnosis and a higher percent of them received surgery. Comrobidity, but not race, was a predictor of aggressive treatment. Earlier research has indicated that treatment patterns differ across racial/ethnic groups (19, 29-34). African Americans were less likely to receive aggressive therapy than Caucasians (29,31). For localized and regional disease stages, Caucasian men were more likely than African Americans to receive radical prostatectomy, while African Americans were more likely to receive radiation therapy (29-31). However, recent studies have shown a decreasing trend in racial/ethnic disparities in treatment modalities for the prostate cancer and, in an academic hospital, race was shown to be a conditional predictor of outcome (33,34). Age, too, strongly influenced treatment pattern, with younger men tending to have radical prostatectomy, middle aged men tending to have radiation therapy and older men tending to have either no treatment or hormone therapy (20,30). Our results regarding age and treatment pattern appeared to be supportive of these earlier findings.

Initial cost of prostate cancer decreases with age and more than 50% of treatment costs of prostate cancer were accrued during the patient's last year of life (12). Other studies have reported significant differences in cost across type of treatment (10, 35,37, 39-48). Wide ranges of cost estimates associated with prostate cancer across different stages of cancer were derived using prospective and retrospective study design (6,9,11,35-49). In addition, earlier research indicated that cost of care for prostate cancer varied significantly by race (22). However, in this study, clinical data on TNM stage, Gleason and PSA scores at the time of diagnosis was not used. No adjustment was made for provider characteristics (type of hospital and physician); the issue of joint product in the analysis of cost data was not addressed. Finally, non-normal distribution of cost data was not rectified. In this study, after controlling for age, stage of cancer at the time of diagnosis, hospital characteristics and stage of cancer, we found no association between race and direct medical care cost of prostate cancer. The incremental cost of prostate cancer was 1.3 times higher than comparable controls.

V. Conclusions

Incremental cost analysis is an integral part of health outcomes research. The economic burden of prostate cancer, more clearly defined by incremental cost analysis in control studies, is significant. Patients with prostate cancer had at least 1.3 times higher total annual direct medical cost compared to non-cancer patients, after controlling for age and Charlson comorbidity score. African American patients with prostate cancer presented with higher comorbidity and higher PSA level, with these two variables influencing direct medical care cost. Also, age influenced treatment patterns, which in turn influenced direct medical care cost. Thus, we conclude that total direct medical care cost of prostate cancer treatment offered in a large urban academic hospital setting was not associated with race after controlling for age, Charlson comorbidity score and PSA level at the time of diagnosis. As comorbidity increases, the chances of receiving aggressive treatment for prostate cancer decrease, thus leading to a reduction in incremental cost. Also, as age at diagnosis increases, so does the probability of dying from causes other than prostate cancer, especially for patients with lower-grade or earlier-stage disease.

Further work is needed to validate our results, with a comprehensive study using a large national database. Such a study would be able to address the issues of bias due to geographical variations in treatment patterns, a small sample providers, bias due to socioeconomic status, insurance status, and bias due to provider characteristics (physician, hospital).

Study limitations:

Study limitations are: (1) potential bias for inconsistency in the reported (PICARD) and actual services provided; (2) unknown external validity given that the study population is from a single university medical center, albeit one with large group of prostate cancer patients. However, the percent of African Americans patients in the Urology department at this medical center mirrors that of the 8-county region from which the large majority of all medical center patients are drawn; (3) indirect cost of prostate cancer (associated with caregivers, loss of productivity, early morality, etc) are not considered in our analysis which could considerably effect total cost.

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Table 1: Characteristics of prostate cancer patients and controls across ethnicity

Prostate cancer patients	African American (n=60)	Caucasians (n=60)	P value
Mean age (years)	72.63 (sd=11.9)	69 (9.5)	.07
Charlson comorbidity score	4.5 (sd=3.35)	2 (sd=2.4)	<.0001
Marital status			.0572
Married	37 (62.7%)	47 (81.03%)	
Single	10 (16.9%)	8(13.80%)	
Widowed	8 (13.6%)	1 (1.70%)	
Divorced	4 (6.8%)	2 (3.50%)	
Health Insurance			.224
Medicare	7 (11.7%)	6 (10.2%)	
Managed care	13(21.7%)	23(38.9%)	
Medicare-HMO	38(63.3%)	29(49.2%)	
Other	2(3.3%)	1 (1.7%)	

Table 2: Characteristics of controls across ethnicity

	African American (n=120)	Caucasian (n=120)	P value
Age	72.64 (12.27)	69.11 (9.83)	.0855
Charlson comorbidity score	3.87	1.46	<.0001
Health Insurance			.234
Medicare	14 (11.72%)	13 (11%	
Managed care	26 (21.7%)	46 (38.3%	
Medicare-HMO	76 (63.3%)	59 (50%	
Other	4 (3%)	2 (2%)	

Table 3: Disease characteristics and variations in treatment across ethnicity

Characteristics	African American (n=60)	Caucasians (n=60)	p value
PSA score (at the time of diagnosis)	19.4 (sd=28.5)	13.4 (sd=20.1)	0.197
PSA score (after treatment)	3.10 (sd=10.3)	.94 (sd=1.6)	0.167
Mean Gleason score	6.71 (sd=1.66)	6.49 (sd=1.21)	0.44
Lymph node involved-yes	5 (12.2%)	2 (4.3%)	0.169
TNM Stage T1c T2a T2b T3a T3b T3c T4a	 0 (0.0%) 32 (62.75%) 19 (37.25%)	 5 (10.2%) 27 (55.10%) 17 (34.69%)	.0640
Positive for bone metastasis	5 (10.2%)	2 (4.4%)	.1164

Table 4: Variations in treatments received by prostate cancer patients across ethnicity

Treatment Type	African American (n=60)	Caucasians (n=60)	P
Radiation	33 (57%)	24 (42.1%)	.113
Surgery	30 (52%)	40 (70%)	.054
Hormone Therapy	27 (47.4%)	21 (36.8%)	.255
Watchful waiting	3 (5.08%)	2 (3.39%)	.318
Radiation	7 (11.67%)	3 (5.08%)	.118
Surgery + Radiation	7 (11.67%)	5 (8.47%)	.204
Radiation + Hormone therapy	13 (21.67%)	11 (18.67%)	.166
Surgery	14 (23.33%)	27 (45.76%)	.010
Surgery + Hormone therapy	3 (5.0%)	3 (5.0%)	.320
Surgery + Radiation +Hormone	6 (10.0%)	5 (8.5%)	.238
Hormone	5 (8.33%)	2 (3.4%)	.167

Table 5: Cost of prostate cancer patients across ethnic groups

Cost	African American (n=60)	Caucasians (n=60)	p value
Total cost for PC			
Mean	15,749	16,674	log ttest = .54
Median	10,579	11,926	Wilcoxon Rank Sum test =.52
Standard Deviation	18,126	16,601	Bootstrap p = .37
Total cost of controls			
Mean	14,605	11,397	log ttest = .005
Median	10,133	4,860	Wilcoxon Rank Sum test =.014
Standard Deviation	13,802	14,183	Bootstrap =.897
Incremental cost			
Mean	1,144	5,277	log ttest =.326
Median	675	4,891	Wilcoxon rank sum test=.12
Standard Deviation	21,916	20,473	Bootstrap =.85
Prostate cancer cost (using CPT codes)			
Mean	4,021	5,739	log ttest =.089
Median	1,101	3,924	Wilcoxon rank sum test=.05
Standard Deviation	5,526	6,894	Bootstrap =.65

Table 6: Incremental cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	P value	PE	SE	P value
Intercept	2208	.55	<.0001	3288	.47	<.0001
Age	1.008	0.008	.279	1.016	.006	.013
Ethnicity (1=AA)	1.04	0.194	.82	.96	.159	.83
Charlson comorbidity	1.66	0.232	.029	1.29	.192	.049
Prostate cancer (1=yes)	1.49	0.232	.016	1.30	.138	.05

Table 7: Direct medical care cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	P value	PE	SE	
Intercept	6836	.21	<.0001	14617	.17	<.0001
Age (• 65 yrs=1)	1.30	.22	.24	.98	.19	.94
Ethnicity (1=AA)	.69	.22	.1044	.70	.19	.07
Charlson comorbidity	1.11	.036	.0036	1.09	.031	.005
Stage (early stage=1)	1.17	.22	.459	.95	.19	.81

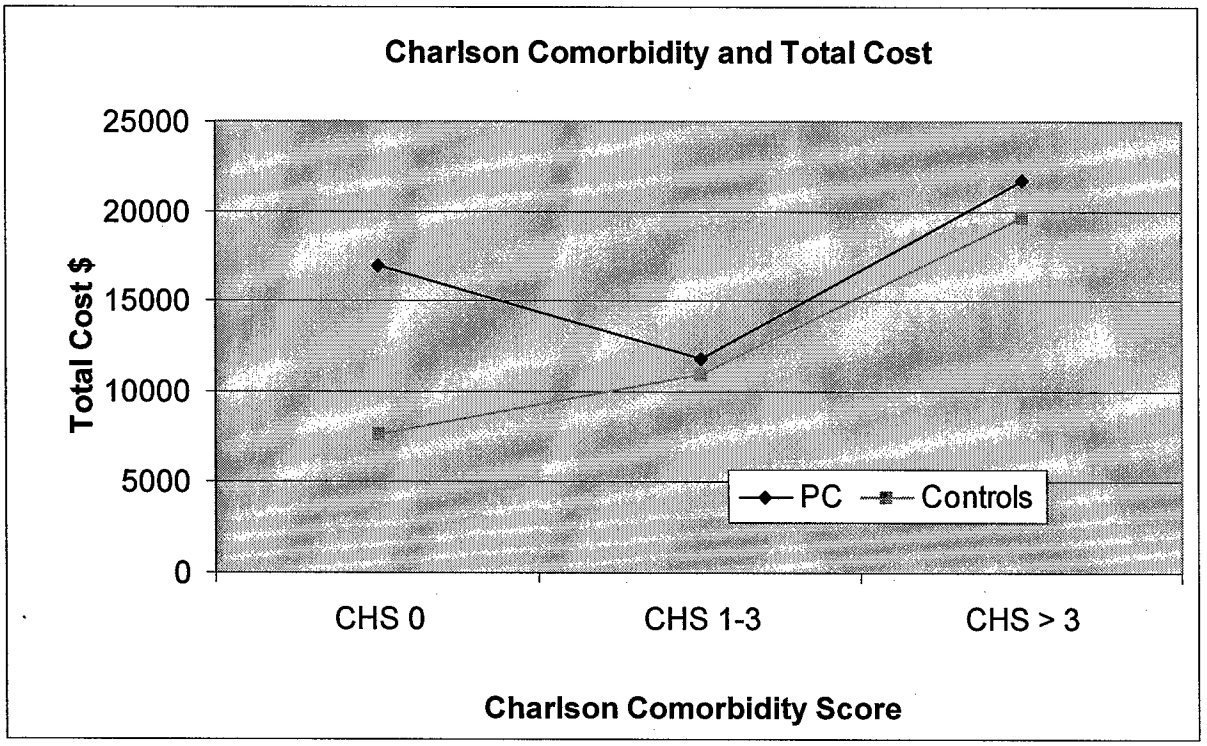

Figure 1: Direct medical care cost and Charlson comorbidity

Title Page

THIS MANUSCRIPT HAS BEEN ACCEPTED FOR PUBLICATION BY THE JOURNAL OF UROLOGY

Title: Health Related Quality of Life and Direct Medical Care Cost of Newly Diagnosed Younger Men with Prostate Cancer

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ABSTRACT

Purpose: We evaluated health related quality of life (HRQoL) and direct medical care cost (DMC) for young men receiving radical prostatectomy.

Materials and Methods: In this prospective cohort study, 40 newly diagnosed PCa patients (< 65 years) were matched with 40 cancer free men. Participants completed SF-36 and UCLA-PCI surveys prior to treatment, and at 3, 6, 12 and 24 months follow-up. Cost data were obtained from a hospital based administrative database and clinical data were obtained via structured medical chart review. Demographics and HRQoL were compared using T-test, Fisher Exact and Chi-sq. Wilcoxon and log-T tests were used to compare DMC. Multivariate regression models were used to assess incremental cost of PCa and predictors of 24 months prostate specific HRQoL.

Results: PCa patients had a mean annual DMC of $4,160 for the treatment year with 3.5 days of mean length of stay. They had 3 times higher DMC than controls. At 12 months, generic HRQoL were similar to baseline values. Sexual function showed trends toward improvement at 6 months after surgery. Urinary function improved significantly by 6 months, however, it declined thereafter. Bowel function and bother returned to baseline values by 3 months. In a multivariate regression, marital status was a significant predictor of sexual, urinary and bowel functions at 24 months.

Conclusions: PCa patients reported weaker sexual function, urinary function and sexual bother at two years post treatment compared to their baseline values. There exists an opportunity for improving prostate specific HRQoL of men with early stage of PCa.

I. INTRODUCTION

Health Related Quality of Life (HRQoL) and cost of care are important issues in the arena of Prostate Cancer (PCa) care. Men diagnosed with PCa have several treatment options such as radical prostatectomy, radiation (external beam radiation and interstitial brachytherapy), hormonal therapy and watchful waiting. These treatments affect a patient's quality and quantity of life. With an increasing prevalence of PCa in younger men, the economic burden of this disease is substantial and growing (1,2). Potentially curative procedures are normally offered to younger men with early stage cancer. Due to uncertainty in effectiveness of screening and treatments of PCa and variable natural history, debate on resulting HRQoL continues (1-3). Many young men live for years post-diagnosis and wish to maximize their HRQoL. An assessment of the effects of treatment choices on short and long-term HRQoL and cost of care will facilitate effective clinical and policy decisions. The objective of this study was to analyze the HRQoL and direct medical care cost of young men with newly diagnosed PCa and receiving radical prostatectomy.

II METHODS

Subjects: For this prospective cohort observational study, we recruited 40 young men (< 65 years) with newly diagnosed PCa, from the urology clinic of an academic urban medical school. Matched controls were identified from the same institution. The institutional review board approved the study and all subjects provided informed consent and HIPAA forms.

Participants and Recruitment: Young (< 65 years) African American or Caucasian Men with newly diagnosed PCa between 2000-2001 were identified, recruited prior to their treatment and followed up prospectively for two years. Patients unwilling to participate unable to communicate in English and/or those who visited urology clinic for second opinion only were excluded. A control group of men without cancer, matched by age and ethnicity were identified using Pennsylvania Integrated Clinical Administrative and Research Database (PICARD) and recruited. Upon completion of written consent and HIPAA forms, cases and controls were enrolled into the study.

Data Collection: Health resource utilization and direct medical care cost (DMC) data were obtained from PICARD for four years (one year pre-diagnosis, one year during treatment and two years post-treatment). Medical care costs are defined as reimbursements for specific services by any part of the health care organization. Clinical data such as diagnosis date, treatment type (radical prostatectomy, radiation, brachytherapy, or hormone therapy), histologic tumor grade, other illnesses, Gleason score, TNM cancer stage, Prostate Specific Antigen (PSA) level and demographics (insurance status, ethnicity and age) were obtained via structured medical chart review. Annual Charlson comorbidity index (CHS) (6) was computed using PICARD.

***Measures*:** Cases completed generic and prostate specific HRQoL questionnaires at baseline and at, 3, 6 12 and 24 months follow-up. Controls completed similar questionnaires at baseline only. Generic HRQoL was measured using the Medical Outcome Study Short Form (SF-36) (5). This reliable and validated instrument was designed for use in clinical practice (self administered or by a trained interviewer), research and general population surveys and assesses eight health concepts: physical limitation caused by health, limitations on social activities caused by physical or emotional problems, role limitations caused by physical and emotional

problems, bodily pain, general mental health, vitality, and general health perceptions. The range of possible score for each sub- scale is 0% to 100%, higher score indicates a better HRQoL (5). The UCLA Prostate Cancer Index (PCI) is a comprehensive, validated, self-administered 20-item questionnaire that quantifies prostate-specific HRQoL in six domains (urinary function and bother, sexual function and bother, bowel function and bother) (4).

***Statistical* Analysis:** T-test and chi-square were used to compare demographic and clinical variables. Individual item responses were reported as cross tabulation over time for urinary, bowel and sexual domains of the PCI. Composite scores were presented for SF-36 and PCI domains, a change of 5-10 points in scales score is considered clinically significant (5). Mean DMC and HRQoL were compared between cases and controls. Multivariate log-linear regression was used to compute the incremental cost of PCa. Independent variables were age, ethnicity and CHS. Multivariate backward elimination log-linear regression was used to determine the predictors of 24-month prostate-specific HRQoL for three domains: sexual function, sexual bother and urinary function. Covariates were age, ethnicity, income, CHS, marital status, education, employment and baseline score.

III. RESULTS

Demographics, signs and symptoms of the study population are presented in Table-1. Majority of the participants were Caucasian, college-educated, currently working fulltime, married with an annual income level of $40,000 or more. Mean age of cases was 58.7 years and that of controls was 60.4 years. Demographics were comparable between two groups, mean CHS was higher for cases, indicating higher prevalence of co-existing morbidity. Higher percentage of cases had difficulties or discomfort with urination and weak urinary stream. Significantly higher percentage of controls experienced pain in back, hips or legs. There were no significant differences with having to urinate too often, infection of bladder, blood in urine and tiredness.

Table-2 presents the clinical characteristics of cases at diagnosis and treatment type. Clinical and pathologic stages ranged from T1N0M0 (clinically in-apparent tumor not palpable or visible by imaging [T1], no regional lymph node metastatsis [N0], and no distant metasis [M0]) to T3bN0M0 (tumor extends through prostate capsule [T3], no regional lymph node metasis [N0], and no distant metastasis [M0]). Tumors were moderately differentiated with a mean Gleason score of 6.42 (sd=.5). Mean PSA level was 6.27 (sd=3.65). Majority of the men received radical prostatectomy alone as primary treatment with a mean length of stay of 3.31days.

In table-3, DMC comparison is presented (pre-diagnosis, treatment and post-treatment). For the treatment phase we found significant difference in mean inpatient, outpatient and total medical care cost. However, the groups showed no differences in medical care cost in pre-diagnosis and post-treatment phases. This indicates that PCa patients achieve normalcy in resource utilization after treatment. The incremental cost analysis for PCa showed that cost of care for PCa patients was 3 times greater than that for controls (table-4).

Baseline HRQoL: A comparison of baseline generic and prostate specific HRQoL by groups is presented in Table-5. There was no difference between groups with respect to role physical, role emotional, vitality, mental health and social function. Controls were physically less functional, had greater bodily pain and expressed lower general health than cases. They were also sexually less functional and experienced higher bowel and sexual bother.

Changes in Generic HRQoL: Figure-1 presents the post treatment progression of mean scores for cases for: bodily pain, social function, mental health and general health. Mental health score remained mostly constant between baseline and 24 months and was comparable to controls at 24 months post-treatment. After initial worsening, bodily pain returned to baseline level by 24 months, and social function was higher than its baseline

level. By 24 months, general health too returned to baseline level. In Figure-2, post-treatment progression for physical role and function, role emotional and vitality for the cases is presented. After declining at 3 months, scores on these four domains improved by 24 months. Emotional role showed the highest improvement compared to baseline level with a clinically significant change of 13 points. All other domains of generic HRQoL were at least equal to their baseline values by 24 months.

Urinary Function and Urinary Bother: Score on urinary function scale (Figure-3) at 24 months was 16.7 points lower than baseline value. However, it should be noted that by 24 months urinary function had improved significantly after a steep decline of 38.4 points at 3 month. Urinary bother at 24 months was 11 points lower than its baseline value (Figure-4). Urinary function consists of 5 items and urinary bother consists of one item. At the item level, after one year post treatment, majority of patients reported their urinary function has either not been a problem or very small problem. This number hadn't changes much by 24 months. At 12 months, 97% had total urinary control or occasional dribbling; at 24 months 96% reported so.

Bowel function and Bowel Bother: At 3 months post-treatment, bowel function (Figure-3) and bowel bother (Figure- 4) returned to baseline level and remained constant or improved at 24 months. No clinically significant change over time was observed in these domains. Bowel function consists of 4 items (rectal urgency, loose stools, distress with bowel movement and abdomen pain) and bowel bother has one item. At baseline, about 90% of participants reported no problems with these items and this number either stayed constant or improved at 24 months.

Sexual Function and Sexual Bother: Sexual function scale score declined at 3 months and improved thereafter (Figure-3), whereas sexual bother began to improve at 24 months. However, both scales showed clinically and statistically significant decline at 24 months compared to their baseline values. PCI measures sexual function by combining eight items and sexual bother by one item. At baseline, 74% had either good/very good ability to function sexually, and 28% reported so at 24 months. At baseline 73% were sexually active and 35% continued to be so at 24 months. Compared to baseline, at 24 months, majority of patients reported poor ability to have erection, poor quality of erection and poor level of sexual desire. At baseline 79% reported that they had good/very good ability to reach an orgasm, by 24 months 53% reported so.

The result of backward elimination, multivariate, log-linear regression indicated that age, income, marital status and sexual function score at baseline were significant predictors of 24 -month sexual function score (Table-6). For 24- month urinary function, marital status and education were the only significant predictors. Bowel function at baseline and marital status were significant predictor of bowel function at 24

months. Detectable PSA after radical prostatectomy may be a source of anxiety for patients, and the decision to institute adjuvant therapy is often based more on emotion than scientific rationale. Correlation between post treatment level of PSA and HRQoL domains were weak, indicating lack of significant relationship between PSA level and generic and prostate-specific HRQoL.

IV DISCUSSIONS

Preliminary findings of this study indicated that: a) younger patients with early stage of PCa and receiving radical prostatectomy as their primary treatment, returned to their baseline generic HRQoL by 6 months; b) normalcy in cost and health resource utilization was achieved by end of first year of treatment; c) significant improvements in prostate-specific HRQoL domains such as bowel function, bowel and urinary bother were observed; d) reduced urinary and sexual function and sexual bother was observed at 24 months; and e) marital status was an important predictor of sexual, urinary and bowel functions at 24 months.

Several studies have addressed the issues surrounding HRQoL in PCa patients using retrospective and prospective cohort study designs using various valid instruments (SF-36, UCLA-PCI, EPIC, EORTC-QLQ and FACT-p) (3,5-20). Studies have shown treatment-derived differences in both short and long term HRQoL (8-15,18-20). In the immediate short run after treatment, HRQoL declined significantly in localized PCa patients receiving prostatectomy (8). Using CaPSURE longitudinal database, Litwin et al., showed that PCa patients who underwent surgery exhibited improved urinary function in the first year that remained fairly constant by second year. Though age, ethnicity and comorbidity were not associated with urinary function or bother, being married was (18). In another study using CaPSURE database, Hu et al., showed that younger patients receiving prostatectomy were more likely to regain baseline continence, potency and physical health (19). Clinical stage, PSA and Gleason sum were not predictors of returning to baseline HRQoL. In a recent study by Potosky et al., men receiving prostatectomy continued to show declined sexual and urinary function at five years after diagnosis (20). Demographic, social and psychosocial factors were identified as important predictors of HRQoL (5,11,18). In a study of population based longitudinal cohort with up to 24 months of follow-up, Stanford et al., concluded that radical prostatectomy was associated with significant erectile dysfunction and some decline in urinary function (14). Steineck et al. evaluated symptoms and HRQoL in men randomized to either radical prostatectomy or watchful waiting. Erectile dysfunction and urinary leakage were more common with radical prostatectomy group. Bowel function, prevalence of anxiety, well-being and subjective HRQoL were similar in both groups (17). At 12 months post-treatment, men who underwent radical prostatectomy experienced significant decline in urinary and sexual function and bother (10). Lubeck et al., used CaPSURE database to

show that prostatectomy patients had improved HRQoL at 1 year compared to just after surgery (15). Using SEER database, Penson, et al., showed that urinary and sexual function, and urinary and sexual bother were independently associated with worse general HRQoL (16). Our results confirm the general longitudinal trend in both generic and prostate-specific HRQoL noted by these studies. We observed that while most generic and prostate-specific HRQoL domains declined at 3 months of post treatment, except for sexual and urinary function, and sexual and urinary bother, all other domains showed an improving trend by 12 months. Wide ranges of cost estimates associated with PCa across different stages of cancer were derived, initial cost of PCa decreased with age and varied significantly by treatment type (1).

There are several limitations to our study. (1) Small sample size and homogeneity due to recruitment from a single medical center may limit generalizability. However, our study results are in accordance with the trend noted by earlier studies; (2) potential bias for inconsistency in the reported (PICARD) and actual services provided; (3) indirect costs (caregivers, loss of productivity, early morality, etc) of PCa not used in our analysis, could affect cost estimates. Our future research addresses some these limitations.

V. Conclusion

The widespread use of PSA testing has resulted in dramatic increases in the number of men diagnosed at both a younger age and at an earlier stage of disease (1-3). Radical prostatectomy may benefit patients with localized PCa, however, effects on HRQoL continue to be a puzzle in the overall care of PCa. Our study suggests that in the short run (3 months post-treatment) except for mental health, other seven health domains of generic health declined. So did other measures of prostate-specific HRQoL, except for bowel bother and bowel function. However, in the long run (24 months), most generic HRQoL related domains were either equal to or higher than baseline level. Except for bowel function and bowel bother, other domains of prostate-specific HRQoL (sexual and urinary function, and sexual and urinary bother) remained significantly lower than their baseline values. Although our control group was cancer-free, matched by age, income and ethnicity, this group had lower mean CHS, indicating better health. However, cases had better generic and prostate-specific HRQoL at baseline, thus, a cross sectional approach of comparing cases and controls to determine treatment effects can lead to biased conclusion than that from a longitudinal cohort approach. There exists a tremendous opportunity to enhance post treatment HRQoL of younger men diagnosed with early stage PCa. Multiple factors (demographics, environmental, clinical, social, and economic) influence the HRQOL and must be addressed by adopting multidisciplinary approach during diagnosis, treatment and post-treatment phase.

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Table 1: Demographic Characteristics (n=80)

Covariates	Prostate cancer cases (n= 40)	Controls (n=40)	p value
Mean age (std)	58.7 (6.5)	60.4 (4.9)	.2395
Mean Charlson Score (std)	3.8 (2.9)	0.79 (1.6)	<.0001
Race (%)			
Caucasian	91.4	91.2	.9704
African American	8.6	8.8	
Education (%)			
HS or less	26.47	17.65	.3803
College or more	73.53	82.35	
Marital Status (%)			
Single/Widowed/Div	11.76	23.53	.2032
Married	88.24	76.47	
Employment Status (%)			
Full-time	76.47	48.48	.0179
Part-time/other	23.53	51.52	
Income Level (%)			
> $40,000	84.85	75.86	.3715
• $40,000	15.15	24.14	
Signs and symptoms (%)			
Difficulty or discomfort urinating	26.5	6	.044
Having to urinate too often	27.3	20.6	.57
Weak urinary stream	29.4	5.9	.023
Infection of bladder or prostate	3	2.94	.51
Blood in urine	0	2.94	.5
Pain or aches in back, hips or legs	11.76	50	.0003
More tired or worn out than usual	18.2	20.6	.23

Table 2: Clinical characteristics and type of treatment received for prostate cancer patients

	Mean	Std	Min	Max
PSA (at the time of diagnosis) ng/ml	6.27	3.65	0.7	17.4
PSA (post treatment, %)				
0.0	86.0			
0.1	9.0			
0.2	5.0			
Gleason score (total)	6.42	0.5	6.0	7.0
TNM stage				
T1a – T2a	54.55%			
T3a – T3b	45.45%			
Treatment received				
Prostatectomy	93.75%			
+Radiation therapy	13.33%			
+Hormonal Therapy	6.45%			

Table 3: Comparisons of Direct Medical Care cost in $

	Pre-diagnosis		Treatment		Post-treatment	
	Cases (n=40)	Controls (n=40)	Cases (n=40)	Controls (n=40)	Cases (n=40)	Controls (n=40)
Inpatient						
Mean	122.4	0	3384.4*	0.04	0	0
Std	679.0	0	2772.3	0.2	0	0
Median	0.0	0	3739.8	0	0	0
Mean Length of stay (sd)			3.31 (1.01)			
Outpatient						
Mean	102.4	179.7	776.4*	142.5	180.4	149.8
Std	353.6	327.7	1861.6	377.5	321.1	239.6
Median	1.0	48.6	0	1.0	56.5	8.0
Total						
Mean	224.8	179.7	4160.8*	142.5	180.4	149.8
Std	749.1	327.7	2395.1	377.5	321.1	239.6
Median	1.0	48.0	3976.7	1.0	56.5	8.0

* significant at .05 level

Table 4: Incremental cost

Covariates	Estimate	SE	P value
Intercept	74.3	2.13	0.04
Prostate cancer (1=yes)	3.09	0.479	0.01
Age	0.97	0.03	0.37
Race	1.78	.686	0.39
Charlson comorbidity score	1.10	0.08	0.24
R^2	.58		

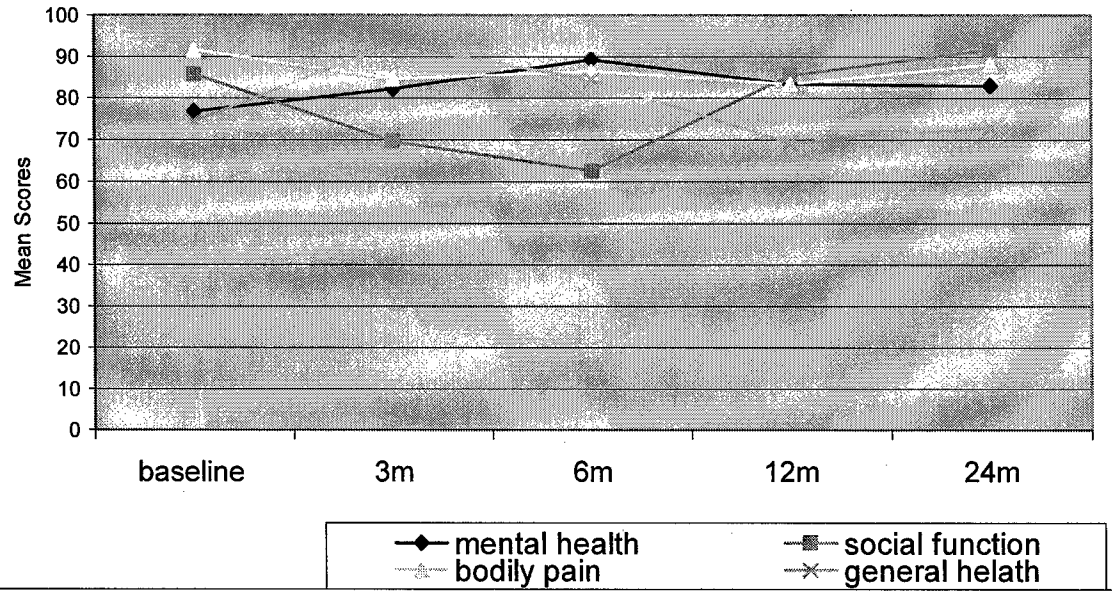
Table 5: Baseline Health Related Quality of Life

Sub-scale	Prostate cancer (n= 40)	Controls (n= 40)	P value
Mean Generic HRQoL			
Physical function	72.6 (13.7)	61.0 (21.7)	.0107
Role physical	86.8 (26.9)	83.3 (29.1)	.6183
Role emotional	77.1 (38.3)	85.9 (30.1)	.3072
Vitality	71.7 (17.9)	70.9 (22.3)	.8814
Mental health	76.8 (16.4)	81.9 (15.9)	.1931
Social function	85.7 (29.9)	84.9 (29.8)	.9066
Bodily pain	91.5 (16.7)	76.9 (24.0)	.0054
General health	74.3 (21.6)	64.4 (24.6)	.0838
Prostate cancer specific HRQoL			
Urinary function	93.9 (13.4)	96.3 (11.4)	.4311
Bowel function	92.3 (9.4)	88.3 (17.4)	.2381
Sexual function	71.5 (21.9)	48.7 (31.1)	.0009
Urinary bother	94.1 (13.8)	94.9 (14.8)	.8331
Bowel bother	96.9 (8.3)	86.0 (28.9)	.0411
Sexual bother	89.1 (26.9)	69.4 (35.8)	.0160

Table 6: Predictors of twenty-four month HRQoL subscales

Covariates	Sexual function			Urinary function			Bowel function		
	PE	SE	P	PE	SE	P	PE	SE	P
Intercept	.005	2.2	.02	17.2	.55	<.0001	54.5	.13	<.0001
Age	1.06	.02	.04	0.98	.009	.064			
Married	25.3	.76	.0004	11.8	.26	<.0001	1.26	.06	.0007
Income	3.45	.45	.012						
Education				1.38	.12	<.015	1.06	.027	.0521
Charlson comorbidity	.90	.04	.03						
SF at baseline	1.03	.006	.0009						
UF at baseline									
BF at baseline							1.003	.127	.0234
R^2	0.69			.82			.57		

Figure 1:Progression of Generic Quality of Life



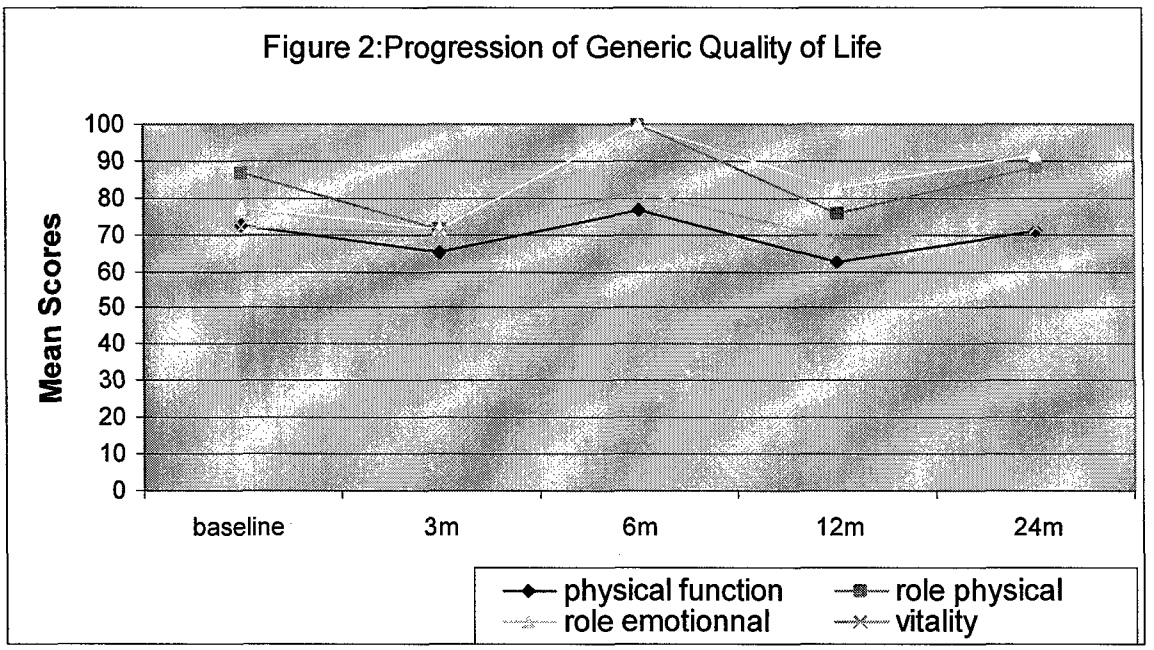


Figure 2:Progression of Generic Quality of Life
Mean Scores
100
90
80
70
60
50
40
30
20
10
0
baseline
3m
6m
12m
24m
physical function
role physical
role emotionnal
vitality

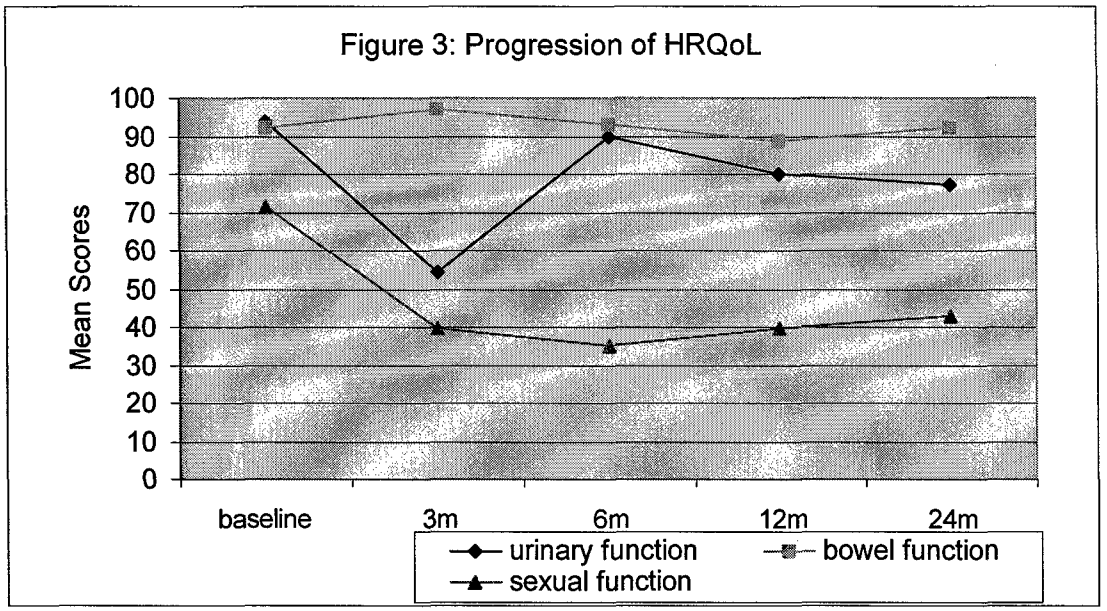


Figure 3: Progression of HRQoL
Mean Scores
100
90
80
70
60
50
40
30
20
10
0
baseline
3m
6m
12m
24m
urinary function
bowel function
sexual function

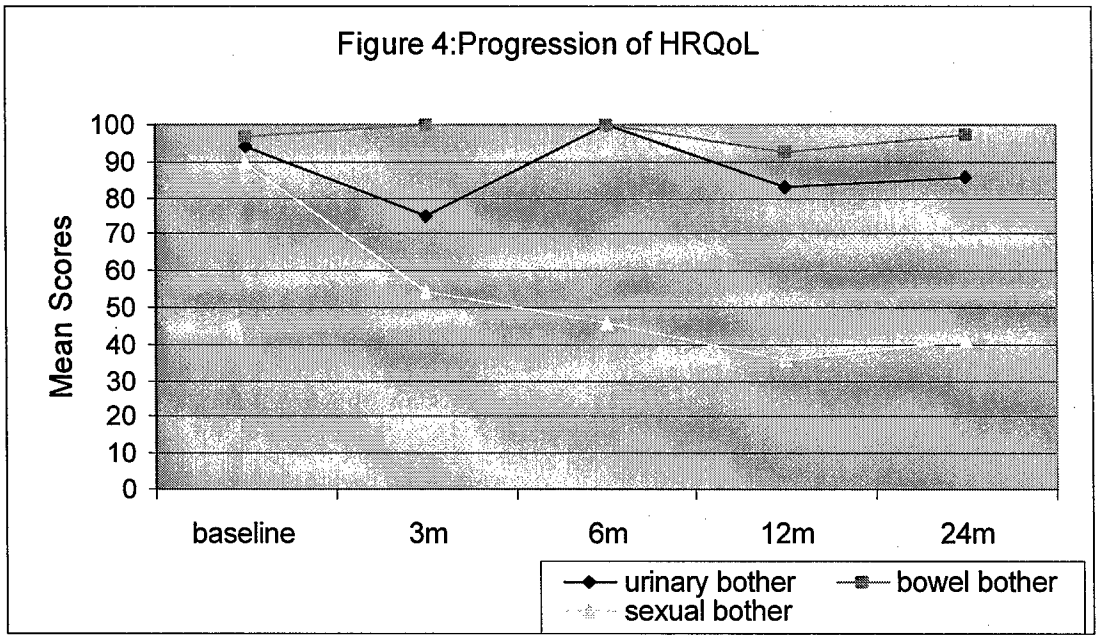


Figure 4:Progression of HRQoL
Mean Scores
100
90
80
70
60
50
40
30
20
10
0
baseline
3m
6m
12m
24m
urinary bother
bowel bother
sexual bother

PROSTATE CANCER PROJECT

MEDICAL RECORDS ABSTRACTION SHEET

Date of Record Abstraction ----/----/----

(1) Medical Record #_____

(2) Patient Name: _____

(3) Patient unique ID # _____

(4) Date of Birth __/__/_____

(5) Marital status: 1= married • 2 = single • 3 = widowed • 4 = divorced•

(6) Ethnicity: 1 = African American • 2 = White • 3 = Hispanic • 4 = other • ----------

(7) Mortality (Last progress note): Yes____ No_____

(8) Pre-hospital living arrangement

1 = Nursing home • *2 = Care facility other than nursing home •*
3 = In Community with wife/husband • and/or care giver •
4 = Lives alone • *5 = Don't know •*

(9) Post-hospital living arrangement

1 = Nursing home • *2 = Care facility other than nursing home •*
3 = In Community with wife/husband • and/or care giver •
4 = Lives alone • *5 = Don't know •*

(10) Health Insurance

1 = Medicaid *Yes •* *No •* *2 = Medicare* *Yes •* *No •*
3 = Managed Care *Yes •* *No •* *4 = Private* *Yes •* *No •*
5 = None •

(11) Date of First Prostate Cancer Diagnosis ___/___/____

(12) PSA Score Before Diagnosis _____ and after treatment_____

(13) TNM Stage _____

(14) Indicate histological score on Gleason (2-10)_____

PRE-TREATMENT DIAGNOSTIC STUDIES

(15) Bone scan: 1=Yes • 2 = No •
If yes, 1 = + for bone mets • 2 = neg • 3 = not done •

(16) CT Scan of Pelvis: 1=Yes • 2 = No •
If yes, 1 =+ for lymph node mets • 2 = neg • 3 = not done •
4 = Local invasion to seminal vesicle(s) or bladder • 5 = other •

(17) Are pelvic lymph nodes involved? 1 = Yes • 2 = No • 9 = unknown •

(18) Stage this patient on the MD Anderson Staging
Staging Classification (use highest grade listed) A_____ B_____

(A) 1 = Group I
2 = Group II
3 = Group III
4 = Group IV

(B) 1 = well diff.
2 = Mod. Diff.
3 = Poorly diff.

(19) Stage this patient on the American Urological Staging scale _____

1 = Stage A1 Focal
2 = Stage A2 Diffuse
3 = Stage B1 confined to prostate, small Discrete nodule
4 = Stage B2 confined to prostate, nodule > 1.5 or multiple nodules
5 = stage C1 tumor 70g or less, locally advanced disease; no involvement of seminal vesicles
6 = stage C2 tumor >70g; involvement of seminal vesicles
7 = stage D1 pelvic lymph node metastases or urethral obstruction causing hydronephorosis
8 = stage D2 Bone or distant lymph node or organ or soft tissue metastases

PROCEDURES (TYPE OF TREATMENT)

(20) Radiation 1=Yes • 2 = No • ***If yes, specify***
Tx –Type:
1 = external beam • 2 = interstitial • 3 = extended filed •

(21) Amount of RADS _____

(22) Surgery: 1=Yes • 2 = No •
If yes, specify

1 = Pelvic LN dissection • 2 = TURP •
3 = Orchiectomy • 4 = Radical Prostatectomy •

(23) Hormone therapy: 1=Yes • 2 = No • ***If yes, specify*** _____

(24) Watchful waiting 1=Yes • 2 = No • ***If yes, specify*** _____

(25) Other procedures or treatments: 1=Yes • 2 = No • ***If yes, specify*** _____

POST-TREATMENT DIAGNOSTIC STUDIES

(26) Change in PSA score and Stage: 1 = Yes • 2 = No • 9 = unknown/not recorded •

If Yes, What is the current PSA score: _____
PSA Score and stage at subsequent diagnosis: _____and_____
PSA score and Stage at 3 months (after diagnosis): _____and_____
PSA score and Stage at 6 months (after diagnosis): _____and_____
PSA score and Stage at 9 months (after diagnosis): _____and_____
PSA score and Stage at 12 months (after diagnosis) _____and_____
PSA score and Stage at 15 months (after diagnosis) _____ and _____
PSA score and Stage at 18 months (after diagnosis) _____and _____
PSA score and Stage at 21 months (after diagnosis) _____and_____
PSA score and Stage at 24 months (after diagnosis) _____and_____

(27) TNM Stage _____

(28) Indicate histological score on Gleason (2-10)_____

(29) Bone scan: 1=Yes • 2 = No •
If yes, 1 = + for bone mets • 2 = neg • 3 = not done •

(30) CT Scan of Pelvis: 1=Yes • 2 = No •
If yes, 1 =+ for lymph node mets • 2 = neg • 3 = not done •
4 = Local invasion to seminal vesicle(s) or bladder • 5 = other •

(31) Relevant Medical Diagnosis: Yes • No • ***If yes check all that apply:***

1 = Depression • 2 = Stroke • 3 = Parkinson's • 4 = Dementia •
5 = UTI • 6 = Asthma • 7 = Arthritis of knees or hips •
8 = Diabetes mellitus • 9 = CHF/MI heart troubles angina •
10 = COPD • 11 = Cancer • 12 = Other (e.g., M.S., neurological) •
Other(s)_____

(32) Relevant medications at the time of review: Yes • No • ***If yes check all that apply***
List all the Prescribed Medications (at baseline):

_____

_____

List all the Prescribed Medications (After):

_____

_____