Published in final edited form as:

Urol Oncol. 2012 January ; 30(1): 102–108. doi:10.1016/j.urolonc.2011.09.001.

PROSTATE CANCER SURVIVORSHIP: LESSONS FROM CARING FOR THE UNINSURED

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Abstract

Since 2001, UCLA has operated IMPACT: Improving Access, Counseling and Treatment for Californians with prostate cancer. Funded by the California Department of Public Health, with a cumulative budget of over \$80 million, the program provides comprehensive care for low-income, uninsured Californian men with biopsy-proven prostate cancer. Health services research conducted with program enrollees, through the UCLA Men's Health Study, yields an opportunity to perform qualitative and quantitative assessments of patient-reported outcomes in these men, all members of historically underserved, primarily minority populations. This review summarizes data from several studies in which validated instruments were administered longitudinally in 727 participants, prospectively measuring health-related quality of life (HRQOL), self-efficacy in interactions with physician interactions, social and emotional health, symptom distress, satisfaction with care, and other patient-reported outcomes.

BACKGROUND

Ideologically axiomatic to the principles of social justice is a society's commitment to caring for its poor. However, widespread implementation of this precept in American health care has recently come under scrutiny.

Medicaid—the most recognizable safety net for the indigent in the US—was enacted in 1965 under the same federal legislation that established Medicare. Prior to its passage, health services for the poor were mediated through an *ad hoc* patchwork of programs sponsored by state and local governments, charities, and community hospitals.¹ Since its

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inception, Medicaid has offered three types of health protection: 1) health insurance for low-income families with children and people with disabilities, 2) long-term care for the elderly and those with disabilities, and 3) supplemental coverage for low-income Medicare beneficiaries for non-covered services. Medicaid enrollment and expenditures have grown substantially since inception—currently providing care to 56 million vulnerable Americans with an annual budget of \$374 billion.² Medicaid eligibility requires that individuals below 133% of the the Federal Poverty Level have a coverage link (e.g., those who are pregnant, disabled, caring for young children). Notwithstanding the Medicaid expansion inherent in the Affordable Care Act of 2010, there is little appetite in the current political climate for including those who fall through the openings in society's safety net. County and city hospitals have long served as the provider of last resort, but recent budgetary constraints have seen significant contraction in this commitment. Fifty years ago, California operated 66 public hospitals nested within 50 of its 58 counties. Today, this has dropped to only 17 public hospitals within 16 counties; yet these facilities provide care for 45% of all uninsured patients in the state. The retrenchment of the county safety net system has not been associated with a corresponding increase in alternative measures to improve access to care.³⁻⁶

IMPACT PROGRAM

In the context of a receding county safety net system and insufficient Medicaid coverage for those lacking a coverage link, several years ago the California Department of Public Health embarked on a 3-year demonstration project to provide care for uninsured men with prostate cancer. During a fiscally propitious period in 2001, the State initiated the Improving Access, Counseling and Treatment for Californians with prostate cancer (IMPACT; www.californiaimpact.org) program for uninsured and underinsured Californians with biopsy-proven prostate cancer with household incomes under 200% of the Federal Poverty Level. IMPACT was the first program of its kind in the nation. While there was significant interest from prostate cancer advocates in establishing similar programs in other states, the economic downturn proved to be too great of a barrier. Notable exceptions include the Delaware Cancer Treatment Program which has successfully provided cancer screening and up to two years of treatment to all state residents without health insurance and with incomes under 650% of FPL. Missouri in 2011, passed Senate Bill 38, which established a prostate cancer screening, treatment, education and outreach pilot program through grants to local health departments in four counties for uninsured or economically challenged men with incomes under 150% of FPL.

Provision of coordinated and timely cancer care for this vulnerable population is vital, particularly given the historical barriers in health care access and the disparate disease aggressiveness in this population. For example, Parsons *et al.* reported that participants treated by private providers had higher odds of undergoing radiotherapy (OR 2.36; 95% CI 1.37–4.07) and androgen deprivation therapy (OR 4.71; 95% CI 2.15–10.36) than those treated in public settings, despite controlling for sociodemographic and tumor characteristics.¹⁰ While significant reductions in the incidence of advanced and aggressive prostate cancer have been noted in other large cohorts,^{7, 8} IMPACT has not seen meaningful decreases in the incidence of metastatic disease, prostate specific antigen (PSA), clinical stage, Gleason score, or tumor risk in its vulnerable population.⁹ Miller *et al.* reported that nearly 1 in 5 men enrolled in IMPACT present with metastatic disease—more than 4 times that of comparison populations.

IMPACT partners with community providers, local health departments and other community based health organizations who refer participants to the study. Individuals access the program via a toll-free 800 number or the program website and are screened for eligibility

and enrollment. The program is administered by the UCLA Department of Urology under the direction of Dr. Mark S. Litwin, Program Director, Dr. James R. Orecklin, Medical Director, and Dr. William Aronson, Associate Medical Director. Full prostate cancer treatment and services are available at no cost to eligible patients, irrespective of time from diagnosis, and include a wide variety of options provided by community physicians and health care facilities. The program funds prostate cancer-related treatments including surgery, radiation therapy (IMRT and Brachytherapy), palliative radiation therapy, hormone therapy, active surveillance, and chemotherapy. For each enrollee, the program provides access to a prostate cancer care provider, nurse case management, clinical care coordination, counseling, translation, nutritional information, as well as assistance with transportation services, and culturally-competent literacy-sensitive education materials in several languages. Central to the success of the IMPACT program is the nurse case manager, acting as navigator, supporter, advocate, and muse for men negotiating the byzantine health care system. When qualitatively describing the role of the nurse case manager, themes such as assessment, coordination, advocacy, facilitation, teaching support, collaborative problem solving, and keeping track emerge from the clinical record.¹¹

UCLA MEN'S HEALTH STUDY

Patients enrolled in the IMPACT Program are offered an opportunity to voluntarily participate in the UCLA Men's Health Study. The UCLA Men's Health Study is a prospective longitudinal project that quantifies knowledge, attitudes, educational needs, health-related quality of life (HRQOL), self-efficacy, symptom distress, satisfaction with care, and a variety of other patient-reported outcomes among low-income men receiving various prostate cancer treatments in the IMPACT Program. The Institutional Review Board at UCLA granted approval to conduct these studies. Table 1 presents multivariate associations of interest.

Telephone interviews and self-administered questionnaires are administered in English or Spanish by trained language-matched interviewers to collect HRQOL measures at baseline and every 6 months thereafter. Of the 1,581 men receiving care under IMPACT, 1,421 men were eligible, 1069 consented to participate, of whom 727 men have completed baseline telephone interviews and self-administered questionnaires and are engaged in long-term follow-up.

1. HRQOL Instruments

General HRQOL is measured using the RAND Medical Outcomes Study Short Form 12-Item Health Survey, version 2 (SF-12). The SF-12 measures general HRQOL in 2 composite scores (physical and mental composite scores) and 8 multi-item subscales: physical and social functioning, emotional well-being, role limitations from physical and emotional problems, pain, energy, and general health perceptions. The 2 composite scores are normalized to a mean of 50 and a standard deviation of 10. The 8 subscales are scored from 0–100, with higher scores denoting improved outcomes. In addition to the mental composite score, emotional well being was measured with all 5 Mental Health Inventory items (MHI-5) from the RAND 36-Item Health Survey.

Disease-specific HRQOL is measured using the UCLA Prostate Cancer Index short form (PCI-SF). The PCI-SF includes 15 items across 6 domains, urinary, sexual, bowel function and bother. Function scales assess incontinence, proctitis, and erectile difficulties, while the bother scales quantify how much the patient is troubled by the corresponding symptoms. The 6 domains are each scored from 0–100, with higher scores denoting improved outcomes.

Fear of cancer recurrence is assessed with the Memorial Anxiety Scale for Prostate Cancer. Each of the 5 items is scored on a 5-point Likert scale, with raw scores being reversed and transformed to 0–100 scales. Higher scores represent better function and less fear. Treatment decision regret was measured using a validated 2-item scale that assessed how often a man wished in the past 4 weeks that he could have changed the kind of treatment he received, or the feeling that he would have been better off with an alternative treatment.

The McCorkle and Young's Symptoms and Degrees of Distress in Patients with Cancer Scale (SDS) is a validated instrument that measures the degree of distress perceived by patients for 10 cancer-specific symptoms. Responses are scored from 1–5 and summed, with higher scores denoting more symptom-related distress.

Perceived self-efficacy in obtaining medical information and physicians' attention to medical concerns is measured with the 5-item Perceived Efficacy in Patient-Physician Interaction (PEPPI) questionnaire. The responses are scored 1–5 and then summed, with higher scores denoting lower self-efficacy.

Spirituality is assessed using the Functional Assessment of Chronic Illness Therapy Scales Spirituality subscale (FACIT-Sp). The FACIT-Sp is a 12-item survey with a Peace/Meaning component (8 items) that assesses participants' sense of purpose and meaning in life, and a Faith component that quantifies the level of comfort and strength participants derive from their spiritual beliefs. Responses are scored 0–4 and then tallied, with higher scores denoting higher level of spirituality.

2. Findings

2a. Cost of care—In 2001, the Program was established with a \$50 million award for a 3-year demonstration project. It has since been extended and competitively renewed several times for a cumulative total budget of more than \$88 million. At the outset, IMPACT reimbursed physicians at Medicare rates, an approach that was shown to be cost-effective, with an incremental cost-effectiveness ratio of less than \$50,000 per additional quality-adjusted life year.¹²

2b. Access to care—In the context of Andersen's Behavioral Health Services Research Model,¹³ Miller *et al.* quantified health services utilization—1) non-emergent emergency department (ED) visits and 2) post-treatment PSA surveillance—among 357 participants.¹⁴ The Program was found to be successful since it minimized non-emergent ED visits (18%) and inadequate PSA surveillance (28%) in this vulnerable population. While, Hispanics had higher odds (OR 5.15; 95% CI 1.17–22.60) of being completely satisfied with the health care received, the authors did not discover any racial or ethnic differences in health services utilization. In 2005, the IMPACT Program experienced budgetary cuts and endured enrollment suspensions. Using the natural experiment of a state-mandated enrollment suspension in 2005, Anger *et al.* accrued a control group of waitlisted patients to measure the significance of access to the IMPACT Program on HRQOL.¹⁵ Eighty-three men in each group (waitlist vs enrolled) were matched on age, race, and tumor stage. Wait-listed men had worse symptom distress and less perceived efficacy than those actively enrolled. These two studies demonstrate the role of the IMPACT Program in cultivating patient self-efficacy to successfully navigate the healthcare system and minimize distress, irrespective of any disparities in access to resources and baseline knowledge.

2c. Quality of care—In 2003, RAND Health developed 44 quality-of-care indicators for early-stage prostate cancer.¹⁶ Krupski *et al.* measured adherence with these quality indicators in 84 men diagnosed with early-stage prostate cancer with at least 6 months of follow-up.¹⁷ Men treated with radiation therapy, when compared with surgery, were more

likely to have documented 1) communication with the primary care physician (77% vs 45%) and 2) pretreatment urinary, sexual and bowel function (90% vs 73%). Furthermore, patients treated in a private setting, compared with public hospital, were more likely to have 1) at least 2 follow-up visits with the treating physician/institution within 1 year (93% vs 63%) and 2) documentation of communication with the primary care physician (90% vs 40%). They did not find a statistically significant difference in disease-specific HRQOL when stratified by treatment setting.

Against a backdrop of rising healthcare costs, the utility of hospice for end-of-life care has emerged as a quality metric.¹⁸ Bergman and colleagues measured the quality and frequency of hospice use among participants who died while enrolled in IMPACT.¹⁹⁻²¹ They found that 28% (16 of 57) of all men who died were enrolled in hospice,²⁰ which is within the 18%–43% range reported in the literature.²²⁻²⁵ Furthermore, end-of-life care in disadvantaged men dying of prostate cancer was of high quality.²¹ Only 11% were enrolled in hospice for fewer than 7 days, and none were enrolled for more than 6 months. Chemotherapy was never initiated within 3 months of death and in only 6% of cases was the final chemotherapeutic regimen administered within 2 weeks of death. During the last 3 months of life virtually none of the men were admitted to the intensive care unit (3%). Taken together, men in the IMPACT Program appear to be receiving high-quality care that spans the disease spectrum—from localized disease to end-of-life care.

2d. HRQOL Outcomes

General quality of life: Krupski *et al.* compared general and disease-specific HRQOL of men enrolled in the Men's Health Study to normative age-matched men without prostate cancer.²⁶ Participants were found to have lower generalized HRQOL in every domain (Mental and Physical Composites and all 8 subscales) than a normative cohort without prostate cancer. Multivariate analyses were performed to identify predictors of worse quality-of-life (QOL) outcomes.^{26, 27} Hispanics had worse physical composite scores while men with multiple comorbidities had lower mental composite scores. Brar *et al.* identified factors associated with changes in QOL from baseline among 184 participants. Men with less than a high school education and lower Gleason scores had improved mental and physical composite scores, respectively.²⁸ The improved mental composite score finding was surprising since educational attainment is closely linked with prostate cancer knowledge and expectations.²⁹ While it may appear counterintuitive that less advanced education was associated with improved mental composite scores, the authors attribute this to IMPACT service benefits, including nurse case manager oversight and individual counseling sessions, which improve mental well being.

Gore *et al.* compared emotional well being among participants of the Men's Health Study with those suffering from congestive heart failure, diabetes mellitus and chronic obstructive pulmonary disease.³⁰ Participants in the Men's Health Study had lower mental health inventory scores than those with the aforementioned chronic conditions. Furthermore, Hispanic ethnicity, unpartnered men, those with significant urinary and bowel distress, poor physical health and low spirituality were all independently associated with worse mental health outcomes.^{30, 31}

These studies demonstrate that participants enrolled in the Men's Health Study have significantly worse HRQOL measures than those with chronic conditions and the general public. Predictors of general HRQOL include ethnicity, partnership status, comorbidity, Gleason score, and underlying urinary and bowel distress.

Disease-specific quality of life: Krupski *et al.* compared disease-specific HRQOL (PCI-SF) among 286 participants in the Men's Health Study with an age-match cohort without

prostate cancer.²⁶ Study subjects had lower disease-specific HRQOL in all 6 domains when compared with an age-matched cohort without prostate cancer. The authors then performed multivariate analyses to identify predictors of HRQOL.^{26, 27} Hispanics had worse bowel function and bother scores. Also, men who underwent radical prostatectomy, when compared with watchful waiting, had worse sexual and urinary function. Others noted that partnered men and those who underwent radiation or hormone therapy (when compared with radical prostatectomy) had less urinary bother,³¹ while those with a college education had less bowel distress.³² Zavala *et al.* surveyed 357 men in the Program, and found that those exposed to the Program's supportive and educational interventions for longer periods of time reported less severe declines in post-operative urinary and bowel HRQOL than those with shorter exposure to the Program's benefits.³³

These studies demonstrate that participants enrolled in the Men's Health Study have significantly worse disease-specific HRQOL measures than the general public. Predictors of general HRQOL include ethnicity, partnership status, education, and treatment type.

Regret, Anxiety, and Symptom Distress: In an era when all management options offer similar survival rates for men with localized prostate cancer, patient preferences and QOL should be the principal arbiters of treatment choice. Patients enrolled in the IMPACT program have a wide range of viable treatment choices. With that thought in mind, Hu *et al.* examined associations of treatment-related regret among 195 men, of whom 46% underwent radical prostatectomy, 28% underwent radiation therapy, and 26% received androgen deprivation therapy.³⁴ Eighteen percent regretted their treatment choice. In multivariate analysis, non-white men were more likely to experience treatment-related regret. Conversely, a lower odds of treatment-related regret was found among men confident of cancer cure (OR 0.19; 95% CI 0.04–0.86), with greater spirituality levels (OR 0.91; 95% CI 0.87–0.96), and those with acute treatment effects (OR 0.34; 95% CI 0.12–0.93).

Gore and colleagues discovered that partnership status was associated with less symptom distress, while the presence of metastatic prostate cancer portended worse distress and anxiety.³¹ Surprisingly, African Americans experienced less anxiety related to fear of recurrence than white men, which is concordant with another study.²⁷ The authors hypothesized that the public campaign to raise awareness of increased prostate cancer risk among African Americans may have alerted these men to the benefits of screening and treatment.^{35, 36} Of note, the authors discovered that decreased anxiety was evident despite African-American men having more advanced disease.

These studies demonstrate an association between ethnicity and extent of disease influence, regret, anxiety, and symptom distress. Spirituality, acute treatment effects, and confidence in cure attenuate treatment-related regret.

Self-efficacy and Spirituality: Maliski *et al.* examined the confidence of 286 participants in interacting with their physicians when facing treatment decisions and symptom management.³⁷ They discovered that 23% of participants had low self-efficacy scores. These participants were more likely to be depressed and have worse general (physical, role-emotional, and social functioning) and disease-specific detriments (all domains of the PCI-SF) in HRQOL. Men who had confidence and were satisfied with their healthcare providers, and those with improved symptom distress experienced more self-efficacy in the patient-physician interaction.

Maliski *et al.* conducted a qualitative analysis examining the role of spirituality of prostate cancer survivorship in 60 Hispanic and 18 African-American men with prostate cancer.^{38, 39} The diagnosis of prostate cancer made participants aware of their mortality.

Faith and spirituality subsequently empowered men to develop an alliance of support between the patient, the doctor, the religious leader, and God. From this alliance, they drew strength, gratitude for the gift of life, hope for the future and new meaning. It is not surprising then, that spirituality, while associated with minority status and low educational attainment, was associated with improved general and disease-specific HRQOL.⁴⁰

Gore *et al.* noted that partnered and non-white men were more likely to be spiritual than unpartnered or white men, respectively.³¹ Moreover, men with metastatic disease as well as those undergoing watchful waiting had lower spirituality scores than men with localized prostate cancer, or those undergoing radical prostatectomy, respectively. Krupski *et al.* demonstrated that the Peace/Meaning subscale of the FACIT-Sp was associated with improved physical and mental composite scores, emotional well being, symptom distress, anxiety, urinary bother, bowel function and bother, and sexual function scores.⁴¹ The Faith subscale, which reflects one's spiritual beliefs, was not associated with HRQOL measures.

CONCLUSION

Low-income, uninsured men in California benefit significantly from a state-funded comprehensive program that offers each patient a sundry of healthcare services. Voluntary participation of this cohort in the longitudinal Men's Health Study has helped cultivate our understanding of prostate cancer survivorship in this vulnerable population. While this cohort may not be representative of the general population, it has identified measures that help minimize distress and improve patient self-efficacy and HRQOL.

Acknowledgments

FUNDING SOURCE: This work was supported by the Ruth L. Kirschstein National Research Service Award Extramural (1 F32 CA144461-01 (Principal Investigator: KC)); American Cancer Society (117496-PF-09-147-01-CPHPS (Principal Investigator: KC)); and Jonsson Comprehensive Cancer Center Seed Grant (Principal Investigator: MSL))

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Table 1
Summary of multivariate statistically significant associations between covariates and outcomes in the UCLA Men's Health Study.

Variables	PF	EWB	Pain	PCS	MCS	MHI-5	UF	UB	SF	SB	BF	BB	Regret	Anxiety	SDS	PEPPI
Advancing Age						+34			- 36	- 36						
Race																
Hispanic	- 41	- 41		- 26,27,31		- 30,31	- 41	- 41	- 33,41		- 26,27,33,41	- 27,33,41	- 34		- 41	
African American									- 33		- 33	- 33	- 34	+27,31		
Other									- 26,33,41	- 41	- 33,41	- 33	- 34			
Partnership Status																
Partnered				+33	+33	+31		+31,33				+33			+31,41	
Stage																
Regional													- 31			
Metastatic	- 41			- 31										- 31	- 31,41	
Gleason Score																
≥6				- 28	- 28					- 28						
Education																
< HS				- 33	+28								- 32			
Comorbidity																
Charlson >1				- 33	- 26											
Treatment																
Surgery					- 26,33		- 26,33	- 33	- 33	- 33						
Radiation						- 41		+31								
Hormone Therapy				- 33			+31		- 33	- 33	- 33	+41				

Variables	PF	EWB	Pain	PCS	MCS	MHI-5	UF	UB	SF	SB	BF	BB	Regret	Anxiety	SDS	PEPPI
Spirituality																
Peace/Meaning	+ ⁴¹		+ ⁴⁰	+ ^{40,41}	+ ^{40,41}			+ ⁴¹	+ ^{40,41}		+ ^{40,41}	+ ^{40,41}	+ ⁴¹		+ ⁴¹	
High	+ ⁴¹			+ ⁴¹	+ ⁴¹	+ ³⁰		+ ⁴⁰	+ ⁴¹		+ ⁴¹	+ ^{40,41}	+ ³⁴	+ ⁴¹	+ ⁴¹	
Time since treatment																
Time (continuous)				+ ³³					– 33			+ ³³				
IMPACT status																
Waitlisted															– 14	– 14

Abbreviations: Physical functioning (PF); Emotional well being (EWB); Physical composite score (PCS); Mental composite score (MCS); Urinary bother (UB); Sexual function (SF); Sexual bother (SB); Bowel function (BF); Bowel bother (BB); Symptom distress scale (SDS); and Perceived Efficacy in Patient–Physician Interaction (PEPPI).

Referent Groups: Race (white); Partnership status (unpartnered); Stage (localized); Gleason score (<6); Education (college education); Comorbidity (Charlson score <1); Treatment (watchful waiting); Spirituality (low); and IMPACT status (enrolled).

Multivariate outcomes: + denotes statistically significant improved outcomes (p<0.05); – denotes statistically significant worse outcomes (p<0.05). Numbers refer to corresponding references in the manuscript.