

Urologic Oncology Outcomes Data Sets: Study Details

DATA CATEGORY	CHARACTERISTIC/VARIABLE	CaPSURE	UODB Prostate
A. General study characteristics	Principal Investigator (PI)	Carroll	Carroll
	Co-investigator	Cooperberg	Chan
	Director, Data Procurement & Quality Assurance	Broering	Broering
	Year of study's inception	1995	2001
	UCSF Study Only		x
	National multisite study coordinated by UCSF	x	
	Longitudinal design, not a clinical trial	x	x
	Clinic/physician-reported data	x	x
	Patient-reported data	x	x
B. Patient characteristics	Date of birth	x	x
	Race/ethnicity	x	x
	Gender	n/a	n/a
	Primary language		
	Marital/relationship status at diagnosis	x	x
	Education level at diagnosis	x	
	Household income at diagnosis	x	
	Weight	x	
	Height	x	
	Appointment scheduling information		
	Insurance coverage	x	
C. Clinical	Physician		x
	Hospital/clinic site	x	x
	PSA at diagnosis	x	x
	Digital rectal exam/TNM staging (2002) at diagnosis	x	x
	Diagnostic biopsy Gleason grade, tumor locations	x	x
	Number of biopsy cores taken and positive at diagnosis	x	x
	Biopsy core tissue length at diagnosis		x
	D'Amico Clinical Risk Group	x	x
	CAPRA (Cancer of the Prostate Risk Assessment)	x	x
	Kattan Nomogram score	x	x
D. Diagnostic imaging & repeat testing	Diagnostic and repeat TRUS findings, tumor locations	x	x
	Diagnostic and repeat MRI/MRSI findings	x	x
	Diagnostic and repeat CT scan/bone scan/x-ray findings	x	x
	Repeat biopsy Gleason grade, tumor locations	x	x
E. Lab test results	PSA history & follow up (pre- and post-treatment)	x	x
	Testosterone level		x

Urologic Oncology Outcomes Data Sets: Study Details

	Creatinine	x	
	Other hematology/blood chemistry	x	
F. Family history of prostate cancer	Number, relationship of family member(s) diagnosed		
	Age of family member(s) diagnosed		
G. Pre- & post-treatment comorbidities/previous med history	Cardiovascular (hypertension, heart disease, stroke, lung)	x	
	Other cancer diagnosis	x	
	Kidney disease	x	
	Diabetes	x	
	Other comorbid conditions	x	
	Total burden of Illness (TIBI-CaP)	Substudy	
H. Pre- & post-treatment quality of life (QOL) (patient reported)	Expanded Prostate Cancer Index Composite (EPIC)		x
	UCSF Prostate Cancer Index (PCI)	x	
	General health questionnaire	SF-36	SF-12
	IIEF-5/Sexual Health Inventory for Men (SHIMS)		x
	Kornblith Fear of Cancer Recurrence scale	x	
	Satisfaction with Treatment & Care scale	x	
	General Anxiety & Depression (GAD-7) scale		
	Pain assessment (pixels)		
	Treatment- & hormonal-related symptom checklist	x	
	General health-related checklist	x	
I. Pre- & post-treatment quality of life (QOL) (physician reported)	International Prostate Symptom Score (I-PSS)/AUA Score	x	x
	Continence	x	x
	Erectile dysfunction management	x	x
	IIEF-5/Sexual Health Inventory for Men (SHIMS)		x
	Treatment-related symptom checklist	x	
	General health-related checklist	x	
	ECOG performance status		
J. Treatment types & dates	Karnofsky score	x	
	Active surveillance	x	x
	Radical prostatectomy	x	x
	Cryotherapy	x	
	Brachytherapy	x	
	External beam radiation	x	
	Androgen deprivation/hormonal medications	x	
	Hormone refractory and chemotherapy agents	x	
	Nephrectomy		
K. Neoadjuvant/adjuvant	Other treatment medications	x	
	External beam radiation	x	x

Urologic Oncology Outcomes Data Sets: Study Details

treatments & dates	Androgen deprivation/hormonal medications	x	x
	Hormone refractory and chemotherapy agents	x	x
L. Other or non-treatment related medications	Erectile dysfunction	Posttx	
	Post-op/other (pain, antibiotics, diabetes, statins, others)	Posttx	
M. Surgery	Surgeon		x
	Open or laparoscopic procedure	x	x
	Nerve-sparing prostatectomy procedure	x	x
	Lymphadenectomy	x	x
	Transplant/donor details	n/a	n/a
	Operating time		Limited
	Estimated blood loss		Limited
	Transfusion		x
	Ischemia type, times	n/a	n/a
	Length of stay	x	x
N. During or post-surgical complications	Concurrent/other surgical procedure(s)		Limited
	Continence	x	x
	Erectile function	x	x
	Anastomotic leak, fluid collection, wound, urinary infection		x
	Hematoma, abdominal mass, fever, anemia, erythrocytosis		
	Other complications		x
O. Surgical pathology	Tumor histology	x	x
	TNM staging (2002) at pathology	x	x
	Pathologic Gleason/tumor grade	x	x
	Estimated tumor volume/size	x	x
	Prostate or specimen weight	x	x
	Tumor location(s)	x	x
	Surgical margin status, extent, location	x	x
	Number of lymph nodes dissected and positive	x	x
	ECE/EPE, SVI, perineural inv; adrenal, IVC, other extent	x	x
	Prostatic intraepithelial neoplasia (PIN)		x
P. Clinical and survival outcomes	Biochemical/PSA recurrence	x	x
	Second treatment (not adjuvant)	x	x
	Bone metastasis	x	x
	Other metastasis		x
	Mortality and cause of death	x	x
Q. Complementary & Alternative medicine/ Health behaviors	Smoking	Limited	
	Nutrition questionnaire	Substudy	
	Type, duration of CAM treatments	x	

Urologic Oncology Outcomes Data Sets: Study Details

	Exercise		
	Alcohol use	x	
	Marijuana or narcotic use		
R. Resource utilization	Number, type of treatment related office visit	x	
	Number, type of non-treatment related office visit	x	
	Employment & school status and return to work	x	
S. Hospitalization/ previous surg history	Non-disease related hospitalization details	x	
	Transurethral resection of prostate (TURP)	x	x
	Other related surgeries	x	