PCaP Snapshot

From the Guidelines for Use of Data and Biospecimens
North Carolina – Louisiana Prostate Cancer Project (PCaP)
Funded by the Department of Defense contract DAMD 17-03-2-0052
See Data Use Guide for more detail.

Baseline Data Collection

Participants were visited in their home by a trained Registered Nurse. The study nurse collected biologic samples, made anthropometric measurements and administered the questionnaire. For more information please see manual of procedures for specimen collection, body measurement, or questionnaire.

Overview of the North Carolina-Louisiana Prostate Cancer Project (PCaP)

The North Carolina-Louisiana Prostate Cancer Project (PCaP) is a multidisciplinary population-based case-only study designed to address racial differences in prostate cancer through a comprehensive evaluation of social, individual and tumor level influences on prostate cancer aggressiveness. PCaP enrolled approximately equal numbers of African Americans and Caucasian Americans with newly-diagnosed prostate cancer from Louisiana and North Carolina. The primary goals of the study are to investigate the factors associated with aggressive prostate cancer in the population as a whole, and compare risk factors for aggressive prostate cancer between the two racial groups. Geographic differences in aggressive prostate cancer within racial groups will also be evaluated to see if differences in race-specific prostate cancer mortality rates between North Carolina and Louisiana (specifically, higher mortality rates for African Americans in North Carolina (NC) versus Louisiana (LA), and higher mortality rates for Caucasian Americans in Louisiana versus North Carolina) can be explained.

For more detailed information please see the Data Use Guide.

PCaP Snapshot Sections (on the following pages)

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Table 1. Demographic and background characteristics of PCaP participants

	UNC						LSU Pre Katrina						LSU Post Katrina						Total	
	AA		CA		Total		AA		CA		Total		AA		CA		Total			
	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N
AGE GROUP AT DIAGNOSIS																				
40-49	5.9	30	4.2	22	5.0	52	3.4	4	2.1	2	2.8	6	3.8	19	2.4	12	3.1	31	3.9	89
50-59	39.2	198	24.0	126	31.4	324	33.6	40	20.2	19	27.7	59	32.2	163	26.8	136	29.5	299	30.2	682
60-69	36.8	186	45.8	241	41.4	427	42.0	50	43.6	41	42.7	91	44.1	223	43.1	219	43.6	442	42.5	960
70-79	18.0	91	26.0	137	22.1	228	21.0	25	34.0	32	26.8	57	20.0	101	27.8	141	23.9	242	23.3	527
MARITAL STATUS																				
Missing	0.2	1	0.0	0	0.1	1	0.0	0	0.0	0	0.0	0	0.2	1	0.0	0	0.1	1	0.1	2
Married	67.7	342	83.3	438	75.7	780	64.7	77	72.3	68	68.1	145	66.4	336	84.3	428	75.3	764	74.8	1689
Widowed	6.5	33	4.9	26	5.7	59	7.6	9	11.7	11	9.4	20	8.5	43	4.1	21	6.3	64	6.3	143
Divorced/separated	18.4	93	8.9	47	13.6	140	21.0	25	9.6	9	16.0	34	20.2	102	9.1	46	14.6	148	14.3	322
Never married	7.1	36	2.9	15	4.9	51	6.7	8	6.4	6	6.6	14	4.7	24	2.6	13	3.6	37	4.5	102
ANNUAL INCOME[1]																				
Missing	6.7	34	4.9	26	5.8	60	7.6	9	8.5	8	8.0	17	14.2	72	13.0	66	13.6	138	9.5	215
Less than $20,000	28.1	142	7.6	40	17.7	182	43.7	52	19.1	18	32.9	70	32.6	165	10.8	55	21.7	220	20.9	472
$20,001-40,000	25.3	128	20.7	109	23.0	237	31.1	37	28.7	27	30.0	64	23.9	121	17.7	90	20.8	211	22.7	512
$40,001-70,000	23.6	119	23.0	121	23.3	240	10.9	13	20.2	19	15.0	32	15.6	79	24.0	122	19.8	201	20.9	473
More than $70,000	16.2	82	43.7	230	30.3	312	6.7	8	23.4	22	14.1	30	13.6	69	34.4	175	24.1	244	26.0	586
EDUCATION[2]																				
Missing	0.2	1	0.0	0	0.1	1	0.0	0	0.0	0	0.0	0	0.2	1	0.0	0	0.1	1	0.1	2
Less than High school	26.9	136	8.4	44	17.5	180	47.1	56	14.9	14	32.9	70	36.2	183	11.6	59	23.9	242	21.8	492
High school	30.1	152	20.0	105	24.9	257	29.4	35	26.6	25	28.2	60	23.1	117	21.9	111	22.5	228	24.1	545
More than High school	42.8	216	71.7	377	57.5	593	23.5	28	58.5	55	39.0	83	40.3	204	66.5	338	53.5	542	53.9	1218
Don't know	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.2	1	0.0	0	0.1	1	0.0	1
FIRST DEGREE FAMILY HISTORY[3]																				
Missing	6.9	35	6.1	32	6.5	67	8.4	10	16.0	15	11.7	25	10.9	55	7.5	38	9.2	93	8.2	185
No	67.3	340	73.0	384	70.2	724	73.9	88	66.0	62	70.4	150	63.4	321	66.3	337	64.9	658	67.8	1532
Yes	25.7	130	20.9	110	23.3	240	17.6	21	18.1	17	17.8	38	25.7	130	26.2	133	25.9	263	24.0	541

	UNC						LSU Pre Katrina						LSU Post Katrina						Total	
	AA		CA		Total		AA		CA		Total		AA		CA		Total			
	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N
GENERAL HEALTH[4]																				
Missing	1.2	6	0.0	0	0.6	6	0.0	0	0.0	0	0.0	0	1.0	5	0.2	1	0.6	6	0.5	12
Fair/poor	24.0	121	11.6	61	17.7	182	35.3	42	25.5	24	31.0	66	30.2	153	18.1	92	24.2	245	21.8	493
Good	34.7	175	29.8	157	32.2	332	37.0	44	22.3	21	30.5	65	35.6	180	30.3	154	32.9	334	32.4	731
Very good, excellent	40.2	203	58.6	308	49.6	511	27.7	33	52.1	49	38.5	82	33.2	168	51.4	261	42.3	429	45.3	1022
SCREENING HISTORY[5]																				
Missing	4.6	23	2.3	12	3.4	35	7.6	9	1.1	1	4.7	10	5.9	30	1.8	9	3.8	39	3.7	84
PSA	2.2	11	3.2	17	2.7	28	5.0	6	5.3	5	5.2	11	5.1	26	5.3	27	5.2	53	4.1	92
DRE	26.5	134	12.9	68	19.6	202	22.7	27	11.7	11	17.8	38	18.6	94	8.1	41	13.3	135	16.6	375
PSA and DRE	53.3	269	77.4	407	65.6	676	42.0	50	72.3	68	55.4	118	56.9	288	78.1	397	67.6	685	65.5	1479
Neither	13.5	68	4.2	22	8.7	90	22.7	27	9.6	9	16.9	36	13.4	68	6.7	34	10.1	102	10.1	228
TREATMENT STARTED BEFORE THE VISIT[6]																				
Missing	7.9	40	5.9	31	6.9	71	13.4	16	2.1	2	8.5	18	10.9	55	3.7	19	7.3	74	7.2	163
No	12.9	65	14.3	75	13.6	140	26.9	32	18.1	17	23.0	49	16.6	84	16.1	82	16.4	166	15.7	355
Yes	79.2	400	79.8	420	79.5	820	59.7	71	79.8	75	68.5	146	72.5	367	80.1	407	76.3	774	77.1	1740
AGGRESSIVENESS OF TUMOR[7]																				
Missing	0.2	1	0.2	1	0.2	2	12.6	15	8.5	8	10.8	23	7.1	36	4.7	24	5.9	60	3.8	85
Low	44.8	226	57.6	303	51.3	529	44.5	53	43.6	41	44.1	94	42.7	216	51.8	263	47.2	479	48.8	1102
Intermediate	34.7	175	28.1	148	31.3	323	23.5	28	33.0	31	27.7	59	30.0	152	27.8	141	28.9	293	29.9	675
High	20.4	103	14.1	74	17.2	177	19.3	23	14.9	14	17.4	37	20.2	102	15.7	80	17.9	182	17.5	396
All	100.0	505	100.0	526	100.0	1031	100.0	119	100.0	94	100.0	213	100.0	506	100.0	508	100.0	1014	100.0	2258

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Medical Records Retrieval and Abstraction

Medical records were requested from the physician of consenting participants. Trained staff used a relational database designed specifically for PCaP to abstract information concerning comorbid conditions, family history of prostate cancer, urologic symptoms, indications for diagnostic examinations and biopsies, prostate cancer screening examinations, physical examinations and laboratory assays at or near diagnosis, imaging examinations used in staging, clinical stage and grade, and initial treatment information. The stage was derived for all subjects with medical records according to the algorithm described in Appendix 3. The clinical stage that was assigned by the physician was also abstracted when available. For more details see the Manual of Operations.

Biologic Sample Collection, Processing and Storage

Blood: Approximately 42ml of blood was obtained from consenting participants, including three 8.5ml yellow top (ACD) tubes, one 10 ml red top tube, and one 6.5ml lavender top (EDTA) tube. Red and lavender top tubes were wrapped in foil and were transported on ice prior to initial processing. Serum was removed from the red top tube and aliquoted into ten cryovials. Lavender top samples were processed into plasma (six aliquots) and packed red blood cells (two aliquots). Yellow top tubes were transported at room temperature, and Louisiana samples were shipped overnight to UNC for processing and lymphocyte immortalization. Immortalized lymphocytes were divided into 6 aliquots and cryopreserved in liquid nitrogen. Plasma was removed from yellow-top tubes and DNA was purified from white blood cells. DNA, plasma, serum and packed red blood cells were stored long-term at -80°C.

Buccal rinse: For participants whose DNA was unavailable from blood, a retrospective collection of buccal rinse samples was conducted in NC and LA. Beginning on September 4, 2007, LA participants who, at the time of the study visit, could not complete the blood draw for DNA were given the option to complete a buccal rinse instead.

Urine: A 20ml urine sample was requested from participants. The study nurse immediately aliquoted half of the sample into a 15ml conical centrifuge tube containing 20 mg of crystalline ascorbic acid (as a preservative) and placed the remainder into a second conical tube without preservative. Samples were wrapped in foil and transported on ice prior to long-term storage at -20°C.

Adipose tissue: Subcutaneous fat samples were obtained from the abdominal area of consenting participants who were not allergic to local anesthetics. After the overlying skin was anesthetized with 2% lidocaine solution, a 15-gauge needle was inserted into the subcutaneous fat and suction was applied using a 15ml vacutainer tube. Aspirated tissue was trapped in the needle and Luer lock adapter, which were placed in separate cryovials, transported on ice, and stored at -80°C.

Toenail clippings: Participants were asked to collect toenail clippings from each toe of one foot prior to the study visit. Toenails were stored in a cryovial at ambient temperature.

Anthropometric Measurements: Weight (to the nearest 0.1 kg), height, and waist and hip circumferences (in cm) were measured using standardized instruments.

Diagnostic and Radical Prostatectomy Tissue: See Tumor Block Retrieval and Tissue Microarray (TMA) Construction.

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Table 2a. Summary of Biologic Samples Collected from PCaP Subjects

Sample	Collection Vial	Description	Unit	Units/Subject	Vol. or Conc./Unit
Serum	Red Top*	No Additive	aliquot	10	~0.5 ml
Plasma	Lavender Top	EDTA	aliquot	6	~0.3 - 0.5 ml
	Yellow Top	ACD	aliquot	6	~1.0 ml
RBCs	Lavender Top	crude packed (WBCs)	aliquot	2	~1.0 ml
	Yellow Top	Ficol purified (RBCs only)	aliquot	2	~1.5 ml
Immortalized PBMCs	Yellow Top	EBV transformed B-cells	aliquot	6	1.0 ml 3-5 x 106 cells/ml
DNA	Yellow Top - PB	Genomic-peripheral blood	aliquot	7	50ul@100ng/ul [5ug]
				7	100ul@100ng/ul [10ug]
				1	stock
	Yellow Top - IC	Immortilized Cell (IDNA)	aliquot	18	100ul@100ng/ul [10ug]
				1	stock
	Mouth Rinse	Buccal Cell (bcDNA)	aliquot	7	50ul@100ng/ul [5ug]
				7	100ul@100ng/ul [10ug]
				1	stock
Adipose (abdominal)	Needle	needle and Luer-lock	aliquot	1	variable
Urine	conical	No Additive	aliquot	1	10 ml
		Preservative (ascorbic acid)		1	10 ml
Toenails	envelope	all toenails on 1 foot	cryovial	1	nail clippings
Diagnostic Tissue	paraffin blocks	4 micron sections	slides	21	4 micron
Prostatectomy Tissue	paraffin blocks	punched cores of CaP 4 micron	TMA slides	30 slides/TMA 47	up to 30 sections 4 micron

NOTE: In most cases biological samples were collected after initiation of treatment

* a portion of red top serum tubes were transported from the field at ambient temp at UNC through April 30, 2007; the remaining UNC red top tubes and all of LSU red top tubes were transported on ice

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Table 2b. Biospecimen repository: proportions of subjects with samples[2]

	UNC	Pre-K LSU	Post-K LSU	ALL
Serum[1] (10ml, no additive, no clot activator, uncoated interior). Proportion of subjects with 10 aliquots	0.92	0.85	0.92	0.92
Plasma (8.5ml tube-6ml draw ACD solution A). Proportion of subjects with 6 aliquots	0.89	0.94	0.90	0.90
Plasma (6.0ml K2 EDTA). Proportion of subjects with 6 aliquots	0.92	0.85	0.92	0.91
Packed RBCs. Proportion of subjects with 2 aliquots	0.92	0.85	0.92	0.91
Urine (with preservative)	0.98	0.86	0.98	0.97
Urine (without preservative)	0.98	0.86	0.98	0.97
Toenail Clippings	0.96	0.97	0.99	0.97
DENOMINATOR	1031	213	1014	2258

[1]There were 835 UNC subjects (395 AA, 440 CA) interviewed before May 1, 2007. Of these subjects, 772 (360 AA, 41 CA) contributed serum samples, which were transported at room temperature rather than on ice.

[2]For more detail on specimen preparation, see manual of operations.

Table 2c. Biospecimen repository: means (vol/aliquot)

	UNC	Pre-K LSU	Post-K LSU	ALL	DENOMINATOR
Serum (10ml, no additive, no clot activator, uncoated interior) out of >0	0.4	0.5	0.5	0.4	2084
Plasma (8.5ml tube-6ml draw ACD solution A)	1.3	0.8	1.5	1.3	2036
Plasma (6.0ml K2 EDTA)	0.4	0.5	0.5	0.5	2066
Packed RBCs	1.1	1.1	1.0	1.0	2066
Urine (with preservative)	10.0	10.0	10.0	10.0	2187
Urine (without preservative)	10.0	10.0	10.0	10.0	2185

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Appendix 3. PCaP essential variables

Name	Description	Possible Values
aggressive	**Aggressiveness of tumor** **High** • Any Gleason sum >= 8 or • Any PSA >20 or • Any Gleason sum = 7 & clinical stage T3-T4 **Low** • Gleason sum < 7 & clinical stage T1-T2 & PSA <10 **Intermediate** • Gleason sum = 7 & clinical stage T1-T2 & PSA <=20 or • Gleason sum < 7 & clinical stage T3-T4 & PSA <10 or • Any Gleason sum < 7 & PSA 10 - 20	1 low 2 intermediate 3 high . missing
formid	**PCaP subject ID**	1105-9999
age	**Age at Diagnosis** = Dx Procedure Date (the date of the biopsy as indicated in medical records) – Date of Birth (questionnaire) • Dx Procedure_Date from medical records: dxpath ○ if missing then from t_path_report in subject tracker ○ if dx date is missing in t_path_report then RP procedure date is used (all UNC subjects have Dx Procedure_Date in medical records, LSU still abstracting medical records) • Age is truncated: e.g. 42.75 yr >> 42 yr	40-79
bc6	**Race** • From questionnaire: Background Characteristics 6. • Race "other" (bc6=3) changed to "AA" in pc29.sas	1 (AA) 2 (CA)
site	**Site** • from questionnaire	'UNC' 'LSU'
surveydate	**Date of visit** • from questionnaire, page 1 • from Background Characteristics: "Today's Date"	9/10/2004 – LSU completion
stage	**Tumor stage** • from medical records: table dxpath ○ stage = 'DTNMT' (Derived Clinical Stage (Diagnostic) T) from	3A T1(NOS) T1C T1a

	table dxpath ○ if 'DTNMT' is missing, then stage = 'clistatnmt' (Clinical Stage (T)) from table dxpath	T1c T2 a or b T2(NOS) T2a T2b T2c T3/4(NOS) T3a T3b T4 NA blank = missing
stage_num	**Stage number** • derived from Stage • 1=T1a, T1c, T1(NOS), T1C 2=T2(NOS, T2a, T2b, T2 a or b, T2c 3=T3/4(NOS), 'T3b, T3a, 3A 4=T4	1-4 . missing
gleone_tbldxpath_mra	**Primary gleason grade** • always from medical records: table dxpath	0-5 . missing
gletwo_tbldxpath_mra	**Secondary gleason grade** • always from medical records: table dxpath	0-5 . missing
glesum_tbldxpath_mra	**Gleason sum or score: gleone_tbldxpath_mra + gletwo_tbldxpath_mra**	0-10 . missing
psaclosest365	**PSA value closest and within 1 year prior to diagnosis date.** • from medical records variable psatotal (table tblpsatest) • if psatotal = 'na' then it is set to a missing value • if psatotal had '>' or '<' instead of '=' then .003 is added or subtracted from psatotal (e.g. 'psatotal < .1' becomes 'psatotal = .097')	0.1 – 4520, . missing
bcstart_time242	• Time biological specimens taken • From questionnaire "After Consent Forms are Signed" • 24 hour time derived. e.g. 1:15, 19:35	00:01 – 23:59, . missing