Racial Differences in Prostate Cancer: Influence of Health Care Interaction and Host and Tumor Biology
Prostate Cancer in Caucasian vs African Americans - 2002

- Frequency of incidental prostate cancer the same
- In men < 65, CaP mortality rate is 3.1 times higher in African than Caucasian Americans
- In men > 65, CaP mortality rate is 2.3 times higher in African than Caucasian Americans
Reasons for Racial Disparity - 2002

Compared to Caucasian Americans, African Americans:

• Have more aggressive CaP
• Choose inferior treatments for CaP
• More often present with incurable CaP due to limited access to health care and/or decreased participation in early detection programs
Racial Differences in Health Care System Interaction

• African and Caucasian Americans desire clarity from their physicians but are often confused by the information received. Both lack of substance and poor sequence of information presented generate feelings of mistrust toward physicians.

• Among many characteristics studied (health-related attitudes, beliefs and experiences), African and Caucasian Americans differed in only one—religiosity.

• African Americans treatment decisions were influenced more by personal experiences; Caucasian Americans relied more on data and information.

Collins TC, Med Care, 2002
Barriers to Patient-Physician Communication

- race concordance improves satisfaction
- religious faith vs. medical care
- delay in care until symptoms severe
- fear of impotence and dependence
- mistrust of healthcare system

Mishel, Cancer, 2002
Benefits of Education/Outreach Intervention

- decreased rates and duration of incontinence and impotence
- improved CaP knowledge
- improved communication with physicians
- reduced depression, fatigue, anxiety, and confusion

Mishel, Cancer, 2002
Prostate cancer may be more common and aggressive in African Americans because higher levels of Androgen Receptor and SHBG in African Americans enhance the effect of racially similar levels of tissue androgens but clinical evidence for racial differences in prostate cancer behavior, once diagnosed, remains lacking.

PCaP Goal

To demonstrate whether public health resources should be focused upon altering critical patient-health care system interaction or altering patient or tumor biology to reduce CaP mortality, in general, and CaP mortality in African Americans, specifically.
Hypothesis

The mortality rate from prostate cancer is more than two-fold higher in African Americans compared to Caucasian Americans due to racial differences in:

1) interaction with the health care system;
2) diet and biology of the host; and/or
3) characteristics of the tumor.
Hypothesis Testing

Reasons for the disparity in prostate cancer outcome by race will be tested on 3 levels:

Level 1)

Racial differences in interaction with the healthcare system will be evaluated by examining early detection behavior; socioeconomic status; attitudes, beliefs and knowledge; health care access; patient-physician communication; patient decision-making; alternative treatment use and treatment choices.
Hypothesis Testing

Level 2)

Racial differences in host biology may affect CaP aggressiveness due to genetic, environmental or gene-environmental interactions. Racial differences will be sought in diet with an emphasis upon antioxidant and fat consumption; serum androgens; exposure to carcinogens; expression of CaP susceptibility genes such as androgen metabolism pathway, detoxification, DNA repair and hereditary CaP genes; and serum protein profiles associated with the aggressive CaP phenotype.
Hypothesis Testing

Level 3)

Racial differences in **tumor characteristics** will be examined in tumor extent (clinical stage and serum PSA, a tumor volume surrogate), tumor differentiation (Gleason grade) and tumor growth rate (apoptosis and cellular proliferation); expression of androgen receptor, androgen receptor co-activators and androgen-regulated genes; and stem-like cells.
Research Subjects

2000 men with newly-diagnosed CaP identified using Rapid Case Ascertainment (RCA)

- 1000 from LA (500 African Americans, 500 Caucasian Americans)
  - 32 Parishes
  - Among African Americans, one of the **LOWEST** CaP mortality rates in the US\(^1\)
- 1000 from NC (500 African Americans, 500 Caucasian Americans)
  - 42 Counties
  - Among African Americans, one of the **HIGHEST** CaP mortality rates in the US\(^1\)
  - Similar mortality rates in LA and NC among Caucasians\(^1\)

\(^1\)Based on rates available at the time of PCaP proposal

Mortality / 100,000

US: 47 (47 – 48)
LA: 42 (41 – 44)
NC: 55 (54 – 57)
North Carolina Study Area

>4,000,000 lbs. Tobacco

>100,000 Hogs
Louisiana Study Area
Participating Institutions

- Roswell Park Cancer Institute
- University of North Carolina
- Louisiana State University
- Natl. Inst. Environ. Health Sciences
- George Mason University
- University of South Carolina
- Harvard Medical School
- Boston University
- Johns Hopkins Medical Center
- Wake Forest University
- University of California-Irvine
- Duke University
PCaP Research Data Collection

Rapid Case Ascertainment

Physician Consent

In-Home Visit

Patient Contact-Enrollment Specialist

Subject Consent

Interview
- Diet
- Medication Use
  - NSAIDs
  - Alternative
- Care Access
- SES
- Early Detection Behavior
- Attitudes, Beliefs and Knowledge
- Treatment Choices

Adipose Tissue, Urine, Toenails
- Fatty Acids
- Tocopherols
- Carotenoids
- Heavy Metals

Blood
- CaP susceptibility genes
- Hereditary CaP genes
- Proteomics
- Carotenoids, tocopherols
- Serum androgens
- AR trinucleotide repeat
- DNA damage/repair

Diagnostic Biopsies
- Ki-67
- Apoptosis
- Androgen receptor
- AR co-activators
- Androgen-regulated genes
- Cell signaling molecules
- Growth factors
- Stem-like cells

Medical Records
- Clinical stage
- Medical History
- PSA
- Treatment Choices

HIPAA Coordinator

Hospital/Physician Office
Prostate Cancer Aggressiveness

- Tumor Extent (medical records and pathology review)
  - TNM stage
  - PSA (surrogate for tumor volume)
  - # and % Biopsies + CaP
- Tumor Differentiation (path report and pathology review)
  - Gleason grade (1-5) and sum (2-10)
- Tumor Growth Rate
  - Cellular proliferation (% Ki-67 +)
  - Apoptosis (programmed cell death) (% ACINUS +)
Prostate Cancer Aggressiveness: Clinical Classification

- **Low Aggressive**
  - Gleason sum < 7 and clinical stage ≤ T2 and PSA < 10

- **High Aggressive**
  - Clinical stage ≥ T3 and Gleason grade ≥ 7 or Gleason sum ≥ 8 or PSA > 20

- **Intermediate Aggressive**
  - All others

- Originally expected 20% low, 20% high, and 60% intermediate
PCaP End Products

• A repository for future use:
  • Clinical data
  • Epidemiological data
  • Biological specimens
  • Tissue Microarrays

• Coordinated characterization of racial differences in two geographical areas to maximize the chance of identifying factors that are important in CaP outcome
Core 1: Epidemiology

- Established Internet – II videoconferencing link between UNC and LSU
- PCaP participants spent 3 days reviewing every aspect of the PCaP study protocol
- Decisions made and action items generated
- Responsibilities assigned for start-up tasks
Nurse Training and Certification
Patient, Specimen and Data Tracking Systems

- Hardware and Software Developed
  - Joint effort of PCaP and several UNC School of Public Health Studies
  - Cores 1, 2 and 3 and PCaP database integrated
  - Specimens at RPCI, UNC and LSU linked
UNC-LSU Tracking System Training Session
Rapid Case Ascertainment
Pre-interview Communication
PCaP Questionnaires

- Uniform administration
  - NC vs LA
  - AA vs CA
  - Nurses
- Converted PCaP Questionnaires to Scannable Forms
Specimen Collection Kits
Pre-Labeled Forms

On-demand printing with bar-coded study ID

- Specimen collection forms and labels
- Consent forms
- Questionnaires
- Post-interview data form
  - Timing, problems, etc.
- Staff codes
- Date and time
Specimen Handling and Transport
Core 2: Blood and Tissue Procurement

- Samples from research subjects collected at the in-home visit and buccal swabs of those without DNA
- Specimens in biorepository include:
  - Plasma
  - Serum
  - RBCs
  - Immortalized WBCs
  - DNA
  - Urine
  - Adipose tissue
  - Toenails
PCaP Pilot
Transport of Biologic Specimens

Field Office

Local LSU Lab

Projects

Daily/Batch

PCaP Central Lab

TPF/TCF
Core 3: Tissue Microarray and ImmunoAnalysis

Tissue MicroArrays (TMAs) could not be constructed using paraffin blocks of community-acquired diagnostic prostate biopsies

Core 3: Diagnostic Biopsies

Based on pathology report from laboratory and medical record:

- If cancer present, cut seven 5 micron sections per block
- If cancer not present, cut 1 section per block
Core 3: Diagnostic Biopsies

- H&Es reviewed by Dr. Maygarden
- All cancer encircled and Gleason scored
- All sections digitally recorded
- % cancer determined from digital image of each slide
PCaP TMAs

0.6 mm core TMA block contains 600 RRP specimens
Core 3: Radical Prostatectomy TMA

Specimen tracking system for one quadrant of a TMA

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Width of array is 12mm
ml = mouse lung
Core 3: TMA Immunostaining

- Acinus (apoptosis)
- Ki-67 (proliferation)
- Androgen receptor
Core 3: Digital Color Quantitative Image Analysis

- Images acquired from regions of cancer circled by Core 3 pathologist for each immunostain
- Nuclei segmented
- % nuclei positive (apoptosis or proliferation)
- MOD for each positive nucleus (androgen receptor)
As of August 2007, Core 3 has received diagnostic biopsy blocks from 513 men (1707 blocks) and radical prostatectomy blocks from 251 men (2998 blocks). Core 3 has transferred QIA information for growth rate calculation on diagnostic biopsies from 250 men and constructed TMAs from radical prostatectomy specimens from 200 men.

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Pilot Study of Assigned Clinical Aggressiveness vs Calculated Growth Rate

- The data from the first 168 completed subjects were compared to the clinically assigned aggressiveness of either low, intermediate, or high.

- The subjects were divided into two groups: those above and below their median according to the growth rates.

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- Growth rate differs among aggressiveness groups (P = 0.04, one-sided scores test).
Core 4: PCaP Advisory Committees

- DoD Integration Panel-External Advisory Board
- Patient Advocate Committee
- Consortium Advisory Committee
- PCaP Consortium
  - Management Committee
  - Scientific Oversight Committee
PCaP Management Committee

Meets monthly after PCaP study-wide monthly meeting using videoconferencing between UNC and LSUHSC

- **Administrative**
  - Dr. James Mohler
  - Dr. Jeannette Bensen
- **Case Accrual**
  - Dr. Jane Schroeder
  - Dr. Elizabeth Fontham
  - Dr. Joseph Su
- **Community Relations and Clinical Advisors**
  - Dr. Paul Godley
  - Dr. James Mohler
- **Interview, Biological and Tumor Tissue**
  - Dr. Merle Mishel
  - Dr. Gary Smith
  - Dr. James Mohler
Scientific Oversight Committee

- Chair, Dr. H. Shelton Earp, UNC-LCCC Director
- Dr. Candace Johnson, RPCI Assoc. Director for Translational Research
- Dr. Augusto Ochoa, Stanley S. Scott Cancer Center Director
- Overall scientific direction of the Consortium and address any scientific issues that cannot be resolved by the Management Committee
PCaP Advisory Committee

- Drs. Litwin, Giovanucci and French
- Medical monitors
- Provide independent oversight in 3 areas of primary research focus for PCaP:
  - Androgen regulation
  - Nutritional epidemiology
  - Health outcomes research
Patient Advocate Committees

- 8 NC and 3 LA advocates
- Annual meetings
  - Update activities of committee members
  - Update PCaP progress in NC and LA
  - Advise on study accrual and logistics
NC Patient Advocate Committee

- Development of recruitment materials, brochure, family letter
- Distribution of brochures to MD offices
- Development of public website
- Liaison among PCaP, advocates and support groups
Core 4: PCaP Administrative Management Policies

• Ancillary Study Submission
  – Letter of Intent
• Data Sharing Agreement
• Abstract & Manuscript Submission
• Authorship Agreement
HIPAA Impact on PCaP

The Health Insurance Portability and Accountability Act (HIPAA) enacted by the US Congress in 1996 and the Privacy Rule took effect April 14, 2003

- Patient advocates prevented from assisting with enrollment
- All PCaP staff must receive HIPAA training
- All subjects must sign HIPAA document
- HIPAA document critical for contact with MDs and pathology labs and access to, and receipt of, clinical data (medical records, tumor blocks)
- Full-time coordinator hired for HIPAA and IRB compliance
Hurricane Katrina
PCaP Response:
Suspend then start over in LA
Expand study areas in both states
Seek additional funding

DoD Response:
Total support
PCaP Study Participation

- Good RCA reporting among urologists, pathologist & hospitals in study area
- 94% MD consent rate
- 63% study-wide cooperation rate
  - Typical of epidemiological studies enrolling older men
- 94 → 98% Biologics collection rates
- 99.8% Release of medical records
- 97% Consent to future contact
Prostate Cancer Aggressiveness: Clinical Classification

- **Low Aggressive (20% patients)**
  Gleason sum $< 7$ and
  clinical stage $\leq T2$ and
  PSA $< 10$

- **High Aggressive (20% patients)**
  Clinical stage $\geq T3$ and Gleason grade $\geq 7$ or
  Gleason sum $\geq 8$ or
  PSA $> 20$

- **Intermediate Aggressive (60% patients)**
  All others
Clinical Aggressiveness at Diagnosis

<table>
<thead>
<tr>
<th>Aggressiveness</th>
<th>#Subjects</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>429</td>
<td>50.2%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>268</td>
<td>31.3%</td>
</tr>
<tr>
<td>High</td>
<td>158</td>
<td>18.5%</td>
</tr>
<tr>
<td>Total</td>
<td>855</td>
<td>100%</td>
</tr>
</tbody>
</table>

Improved statistical power!
Race, Health Insurance and Radical Prostatectomy: Preliminary Data from PCaP

Jane Schroeder, DVM, PhD, UNC Core 1 Leader, et al.

Symposia Session 43-2

- As expected, RP is less common among:
  - Older (65+) than younger (<65) men
  - Gleason score > 7 than ≤ 7
  - Higher than lower co-morbidity
- Race: Little evidence of association with RP (2 - 4% difference)
- Poverty: Strong predictor of RP (16% less common after adjustment for race, age, grade, stage, co-morbidity)
### Completed In-Home Visits

Completed In-Home Visits by State (through August 31, 2007)

<table>
<thead>
<tr>
<th>State</th>
<th>African American</th>
<th>Caucasian</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Completed</td>
<td>Goal</td>
</tr>
<tr>
<td>North Carolina</td>
<td>464</td>
<td>500</td>
</tr>
<tr>
<td>Louisiana</td>
<td>122</td>
<td>…</td>
</tr>
<tr>
<td>Pre-Katrina*</td>
<td>119</td>
<td>500</td>
</tr>
<tr>
<td>Totals*</td>
<td>705</td>
<td>865</td>
</tr>
</tbody>
</table>

* includes 216 in-home visits pre-Katrina

Total In-Home Visits Completed = **1570** (of 2216 goal)
Department of Defense Funding

- Grant to prepare consortium proposal
  $150,000
- NC-LA Prostate Cancer Project (PCaP)
  $9,913,157
- Cost extension after Hurricane Katrina
  $4,177,369
- Total PCaP funding 2002-2009
  $14,240,526
Future Activities

Pending Grants
- Racial admixture
- Metabonomics
- Follow-up, treatment and survivorship

Pending Manuscripts
- Tumor growth rate as a measure of CaP aggressiveness
- Impact of insurance on CaP treatment
- Interaction and communication with health care system
PCaP Description

PCaP Website

http://www.ncla-pcap.org/
Acknowledgements

- Department of Defense
- UNC Lineberger Comprehensive Cancer Center
- LSUHSC Stanley F. Scott Cancer Center
- PCaP Cores and Projects
- NC and LA State Tumor Registries
- Advisory Committees
- 12 Participating Institutions
- And, most importantly, the PCaP Research Subjects