Factors Associated with Initial Treatment for Clinically Localized Prostate Cancer

Preliminary Results from the
National Program of Cancer Registries
Patterns of Care Study (PoC1)

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Background

- In 1989 the American Urological Association convened the Prostate Clinical Guidelines Panel to conduct a comprehensive analysis of published outcomes data for different methods of treating clinically localized prostate cancer and to make treatment recommendations.

- The panel analyzed data on radical prostatectomy, external beam radiation, brachytherapy and surveillance (a.k.a. expectant management, watchful waiting or observation).

- Androgen deprivation was categorized as investigational (i.e., not enough existing data to allow adequate evaluation).

- "For overall survival, any differences between treatments may be explained by patient selection factors. For progression-free and disease-specific survival at 10 years data are too variable to permit conclusions about relative treatment effectiveness." (Middleton, RG et al. J. of Urology 1995; 154:2144-2148).

Background

- A randomized clinical trial comparing RP to WW in men with early stage disease in the pre-PSA screening era showed a statistically significant difference in overall survival at 10 years (73% vs. 68%).

- Results from an ongoing randomized trial in the US comparing RP to WW (PIVOT: Prostate Intervention Versus Observation Trial) have not been reported.

- To date, there is lack of definitive evidence favoring one treatment approach over another.

Objectives

- Describe the initial treatment patterns for localized prostate cancer in a population-based sample.

- Determine the clinical and patient characteristics associated with initial treatment.
  - Conservative vs. Definitive Treatment
  - Radiation Therapy vs. Radical Prostatectomy

Methods – eligibility criteria

- Invasive Prostate Cancer (ICD-O-2: C61.9; Behavior=3)
- Diagnosed in 1997
- Adenocarcinomas
- Microscopically confirmed
- Clinically localized disease
  - cT1 or cT2 with no clinical evidence of nodal involvement and no evidence of metastasis
  - Or if cT missing, pT1 or pT2 with no clinical evidence of nodal involvement and no evidence of metastasis
  - Or if cT and pT missing, SEER summary stage 1977 = localized
- Sequence number=00 or 01
- Non-missing treatment information including treatment dates*.

Methods – definition of initial treatment

- Initial treatment was defined as treatment received within the first 6 months following diagnosis.

- A hierarchical variable was created to categorize treatment, ranging from the most aggressive to the least aggressive.

- Men who received radical prostatectomy were assigned to radical prostatectomy, whether or not they received any other therapy.

- Men who received radiation therapy (external beam or interstitial) were assigned to radiation therapy, whether or not they also received hormone therapy.

- The hormone therapy category was comprised of men who only received hormone therapy (medical or surgical) .

- Men who had no record of any therapy within the first 6 months following diagnosis were assigned to the watchful waiting category.

Methods – definition of initial treatment

- Whether or not cases with missing treatment data were excluded from analysis depended on what treatment data were missing relative to the treatment hierarchy.
- Cases with missing surgery information were excluded.
  - Two radical prostatectomy cases with missing surgery dates were included because >95% of radical prostatectomies occur within six months of diagnosis.
- Cases with missing hormone information were still eligible for inclusion in the radical prostatectomy or radiation therapy categories but not in the hormone or WW categories.
- 64 cases were excluded due to missing RX information or RX dates.
- 11 cases that had either a simple prostatectomy or a less than total prostatectomy were excluded (3 would have fallen into the hormone and 8 into the WW categories) .

Methods – Variables included

Patient Characteristics:

Age

Race/ethnicity

Marital Status

Health Insurance

Comorbidity

Census tract SES indicators

    Working Class

    Poverty

    Education

Census tract Urban/rural indicator

Registry

Clinical Characteristics:

Whether tumor was screen detected

DRE results

PSA value

Gleason score

Methods – Statistical Analysis

- Bivariate analysis was used to examine the association between the four major treatment options and patient and tumor characteristics. Two-sided χ^2 tests were used to compare the distribution of treatments across the predictor variables.

- Variables found to be significantly associated in the bivariate analysis, were included in the multiple logistic regression models.

  - Conservative vs. Definitive Treatment
  - Radiation Therapy vs. Radical Prostatectomy

Description of study sample

3,405 cases met eligibility criteria.

Age Distribution		Race/ethnicity Distribution	
<60	18.1%	White Non-Hispanic	80.2%
60-64	16.9%	Black Non-Hispanic	14.0%
65-69	22.0%	Hispanic	3.5%
70-74	21.3%	Other Non-Hispanic	1.7%
75-79	13.7%	Unknown	0.7%
80+	7.9%		

Results

- 39.0% received radical prostatectomies
- 30.9% received radiation therapy
- 10.8% received hormone therapy
- 19.4% underwent watchful waiting

- Except for the urban-rural indicator, all other variables considered in the bivariate analysis were found to be statistically significantly associated with mode of initial treatment.

Distribution of Initial Treatment
for Clinically Localized Prostate Cancer by Age
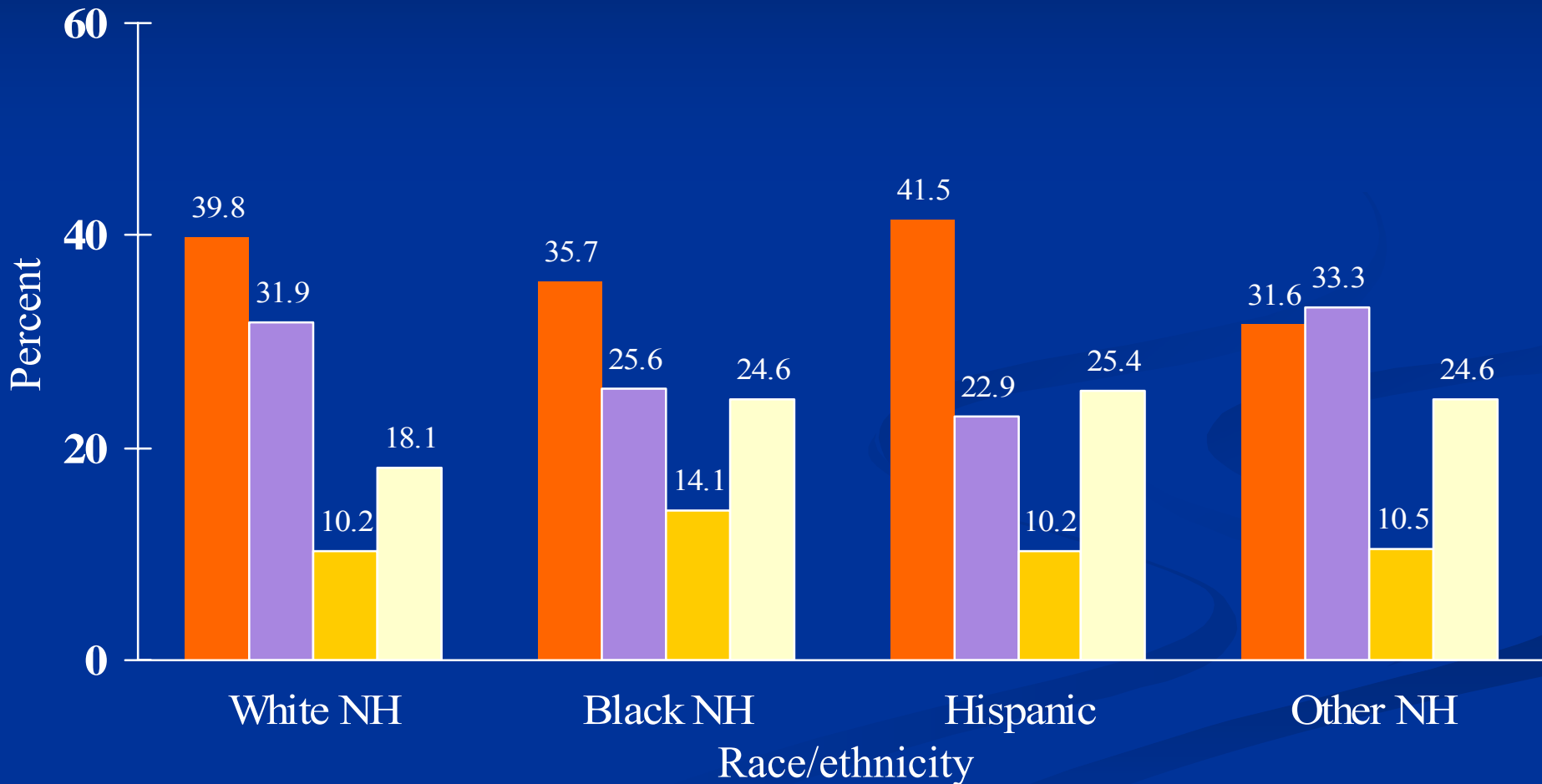for Selected U.S. Areas, 1997
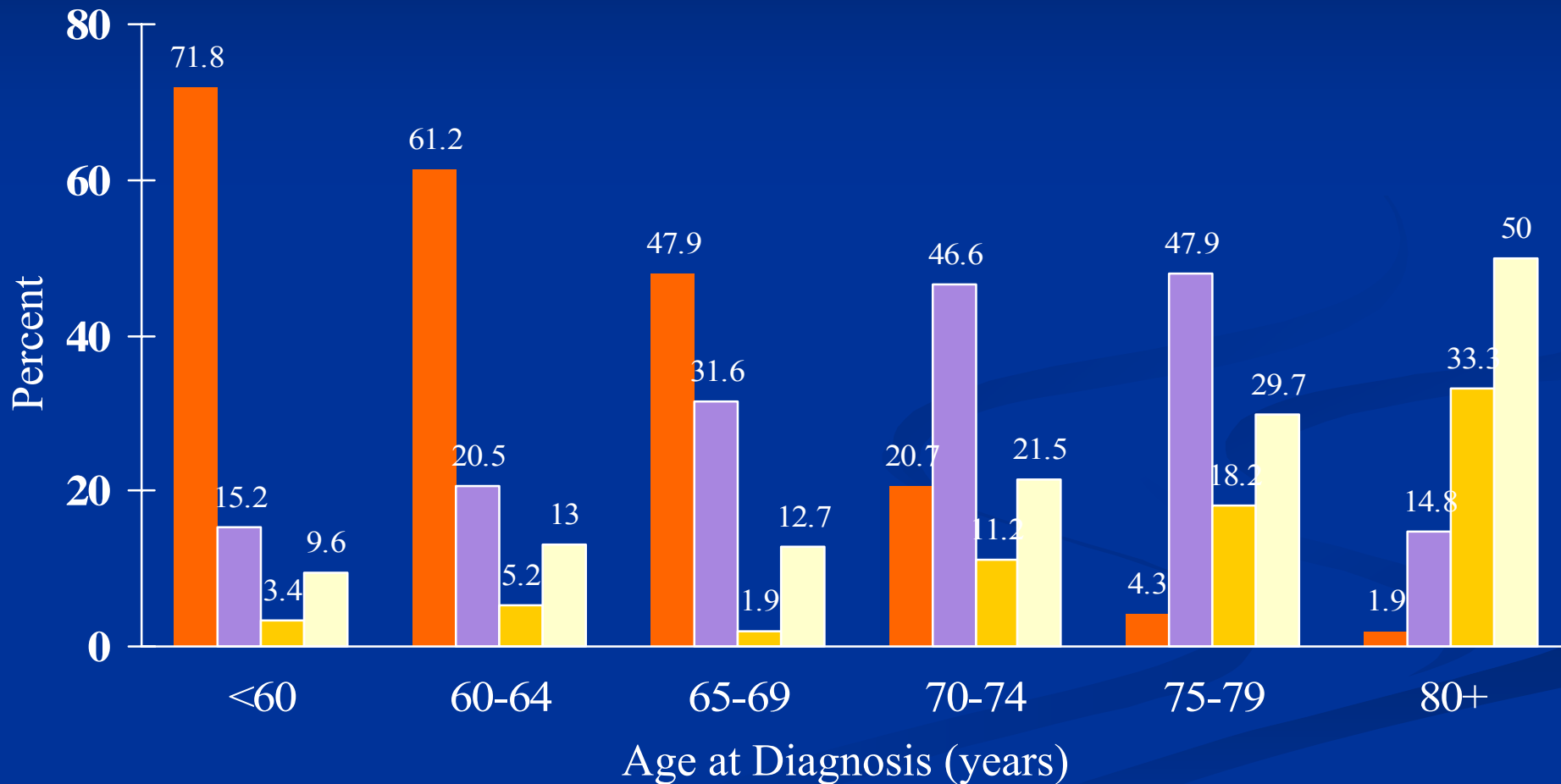
Distribution of Initial Treatment for Clinically Localized Prostate Cancer by Race/ethnicity Selected U.S. Areas, 1997

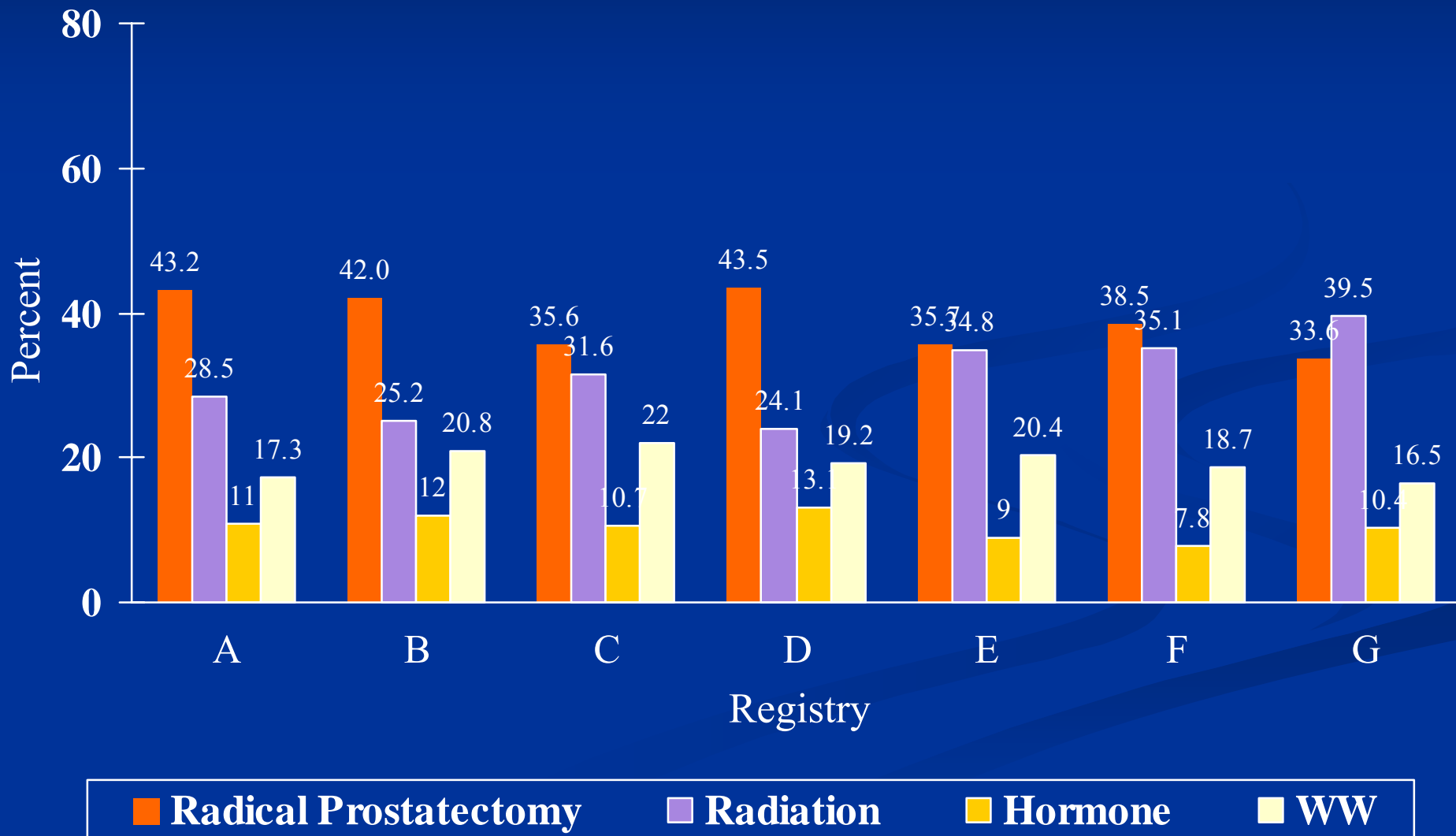Distribution of Initial Treatment
for Clinically Localized Prostate Cancer by Registry, 1997

Logistic Regression Results
Conservative vs. Definitive Treatment

- Outcome – Conservative Treatment

- The following factors were found to be statistically significantly associated with receipt of conservative treatment: age at diagnosis, race/ethnicity, marital status, health insurance, registry, comorbidity, whether cancer was screen detected, DRE results, PSA value and Gleason score.

- Census tract SES and urbanicity indicators were not associated with receipt of conservative treatment.

Logistic Regression Results
Conservative vs. Definitive Treatment

Factor	Odds Ratio (95%CI)
Age 60-64 vs. Age <60	1.5 (1.1-2.2)*
Age 65-69 vs. Age <60	1.7 (1.3-2.4)*
Age 70-74 vs. Age <60	3.0 (2.3-4.1)*
Age 75-79 vs. Age <60	6.4 (4.7-8.9)*
Age 80+ vs. Age <60	25.9 (17.0-40.1)*

Logistic Regression Results
Conservative vs. Definitive Treatment

Factor	Odds Ratio (95%CI)
Black NH vs. White NH	1.7 (1.3-2.1)*
Other NH vs. White NH	1.3 (0.7-2.5)
Hispanic vs. White NH	1.4 (0.9-2.2)
Not Married/Unk. vs. Married	1.7 (1.4-2.1)*
Public vs. Private Insurance	1.5 (1.2-1.9)*
Unk./Not insured vs. Private	1.7 (1.3-2.3)*

Logistic Regression Results
Conservative vs. Definitive Treatment

Factor	Odds Ratio (95%CI)
Comorbidities: 1 vs. 0	1.5 (1.2-2.0)*
2+ vs. 0	2.7 (1.8-4.2)*
Cancer screen detected:	
Yes vs. No	0.44 (0.35-0.55)*
DRE Results:	
Abnormal vs. Normal	0.68 (0.55-0.85)*

Logistic Regression Results
Conservative vs. Definitive Treatment

Factor	Odds Ratio (95%CI)
PSA value: >4-10 vs. 0-4	0.73 (0.53-1.0)
>10-20 vs. 0-4	0.83 (0.58-1.2)
>20-50 vs. 0-4	1.5 (1.0-2.2) ~
50+ vs. 0-4	1.8 (1.1-3.1)*
Gleason Score: 5-7 vs. 2-4	0.44 (0.34-0.58)*
8-10 vs. 2-4	0.46 (0.32-0.68)*

Logistic Regression Results
Radiation Therapy vs. Radical Prostatectomy

- Analysis restricted to cases with definitive treatment.

- Outcome – Radiation Therapy

- The following factors were found to be statistically significantly associated with receipt of radiation treatment: age at diagnosis, race/ethnicity, marital status, health insurance, registry, education, poverty, DRE results, PSA value and Gleason score.

- Comorbidity, whether cancer was screen detected, working class and urbanicity were not associated with receipt of radiation treatment.

Logistic Regression Results
Radiation Therapy vs. Radical Prostatectomy

- Age-Race/ethnicity Interaction

White Non-Hispanic	Odds Ratio (95%CI)
Age 60-64 vs. Age <60	1.7 (1.2-2.5)*
Age 65-74 vs. Age <60	7.2 (5.3-10.0)*
Age 75+ vs. Age <60	65.6 (39.0-115.2)*

Logistic Regression Results
Radiation Therapy vs. Radical Prostatectomy

- Age-Race/ethnicity Interaction

OR (95% CI): Black NH, Hispanics vs. White NH by age

	Black NH	Hispanic
<60	2.4 (1.4-4.2)*	0.66 (0.15-2.1)
60-64	1.3 (0.68-2.5)	0.62 (0.03-3.6)
65-74	0.81 (0.52-1.3)	0.64 (0.31-1.3)
75+	0.74 (0.21-3.5)	----

Logistic Regression Results
Radiation Therapy vs. Radical Prostatectomy

Factor	Odds Ratio (95%CI)
Not Married/Unk. vs. Married	1.5 (1.2-1.9)*
Public vs. Private Insurance	1.0 (0.75-1.3)
Unk./Not insured vs. Private	1.7 (1.2-2.6)*
In poverty vs. not in poverty	0.68 (0.50-0.93)*
Undereducated vs. educated	1.3 (1.0-1.7)~

Logistic Regression Results
Radiation Therapy vs. Radical Prostatectomy

Factor	Odds Ratio (95%CI)
PSA value: >4-10 vs. 0-4	1.0 (0.70-1.4)
>10-20 vs. 0-4	1.6 (1.1-2.3)*
20+ vs. 0-4	2.2 (1.4-3.5)*
Gleason Score: 5-7 vs. 2.4	0.77 (0.54-1.1)
8-10 vs. 2.4	1.6 (1.0-2.6)*
Unk. vs. 2.4	5.5 (3.0-10.2)*

Summary

- Factors found to be associated with receipt of conservative treatment included age at diagnosis, race/ethnicity, marital status, health insurance, registry, comorbidity, whether cancer was screen detected, DRE results, PSA value and Gleason score.

- Among patients receiving definitive treatment, factors found to be associated with receipt of radiation therapy included age at diagnosis, race/ethnicity, marital status, health insurance, registry, education, poverty, DRE results, PSA value and Gleason score.

Conclusions/Discussion

- We observed statistically significant variation in treatments for localized prostate cancer across the seven registries.
  - 26.4%-32.8% for conservative RX
  - 33.6%-43.5% for radical prostatectomy
  - 24.1%-39.53% for radiation RX
- Observed differences in geographic treatment patterns may be biased by differences in case ascertainment across registries.
- Race/ethnic distribution varies by state. Part of observed race/ethnic differences may be attributable to geographic differences.
- Results of the analyses are preliminary.
  - Analyses will be repeated when SES information for 81 cases with missing census tract information is obtained.
  - Evaluate additional interactions

Conclusions/Discussion

- Strengths:
    - Included population-based samples from seven states, several of which had not conducted any previous patterns of care studies.
    - Study included large number of localized prostate cancer cases.

- Limitations:
    - Did not over sample minorities. Therefore, the number of non-White and Hispanic cases was still relatively small.
    - Had no information on patients' symptoms nor on the patient and MD decision making process.
    - Time lag between cancer diagnosis and PoC data collection resulted in difficulty retrieving some medical information.
    - Reliance on hospital face sheets for comorbidity information probably resulted in under-identification of comorbidities.