

# 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

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- 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

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- 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

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- 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

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## 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

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- Bivariate analysis was used to examine the association between the four major treatment options and patient and tumor characteristics. Two-sided  $\chi^2$  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

|       |       |
|-------|-------|
| <60   | 18.1% |
| 60-64 | 16.9% |
| 65-69 | 22.0% |
| 70-74 | 21.3% |
| 75-79 | 13.7% |
| 80+   | 7.9%  |

### Race/ethnicity Distribution

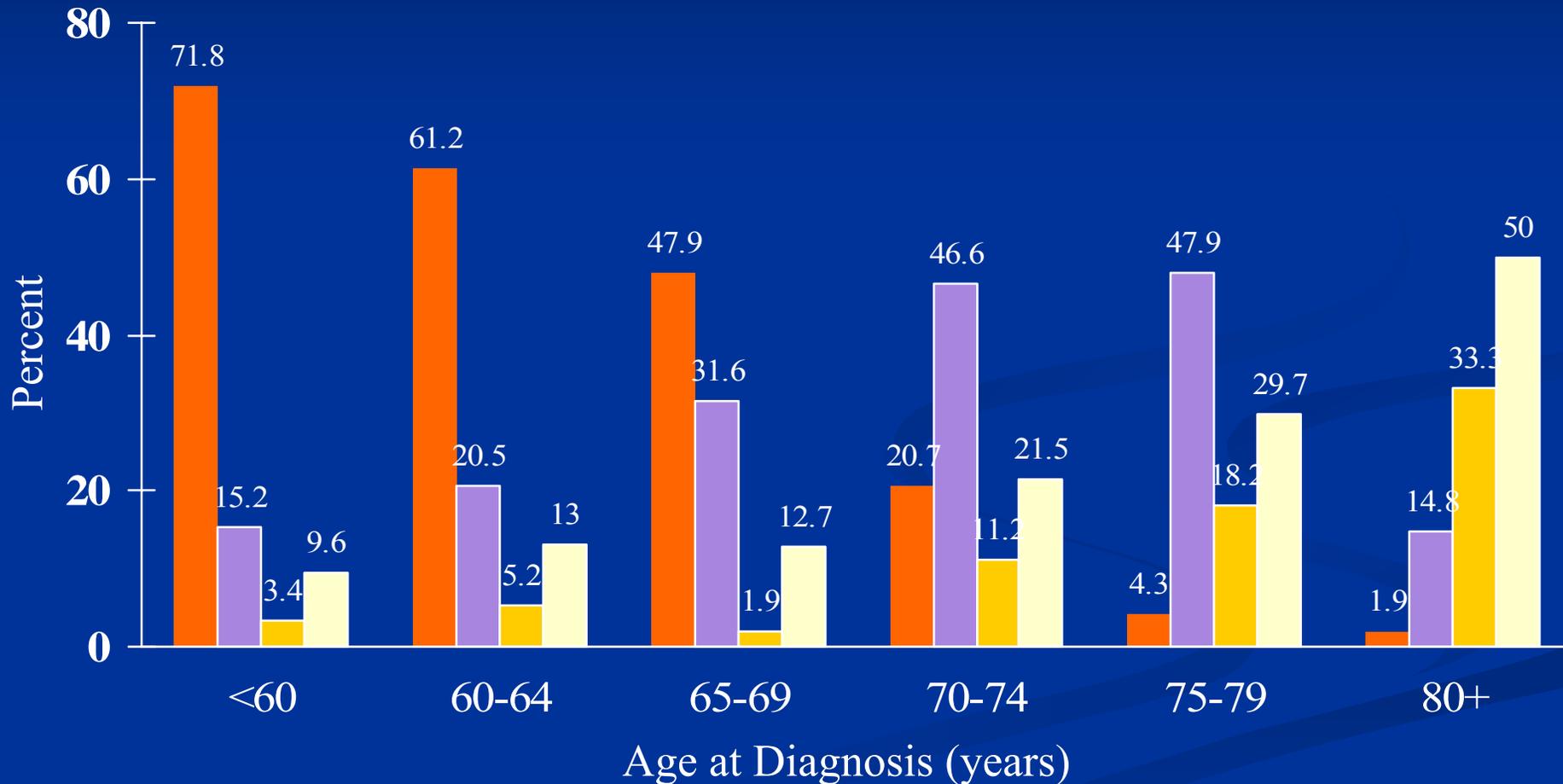
|                    |       |
|--------------------|-------|
| White Non-Hispanic | 80.2% |
| Black Non-Hispanic | 14.0% |
| Hispanic           | 3.5%  |
| Other Non-Hispanic | 1.7%  |
| Unknown            | 0.7%  |

## Results

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- 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



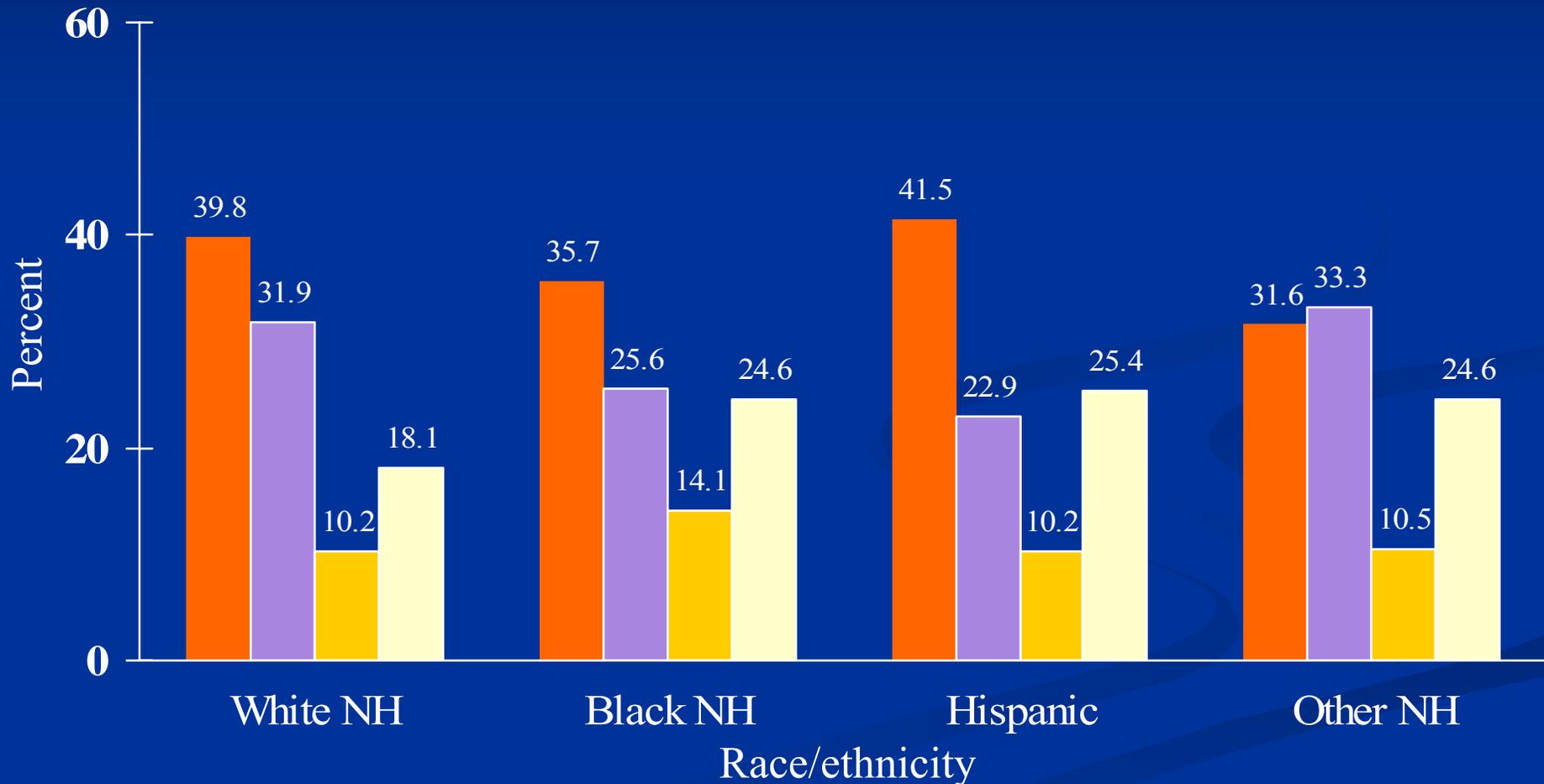
Radical Prostatectomy

Radiation

Hormone

WW

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



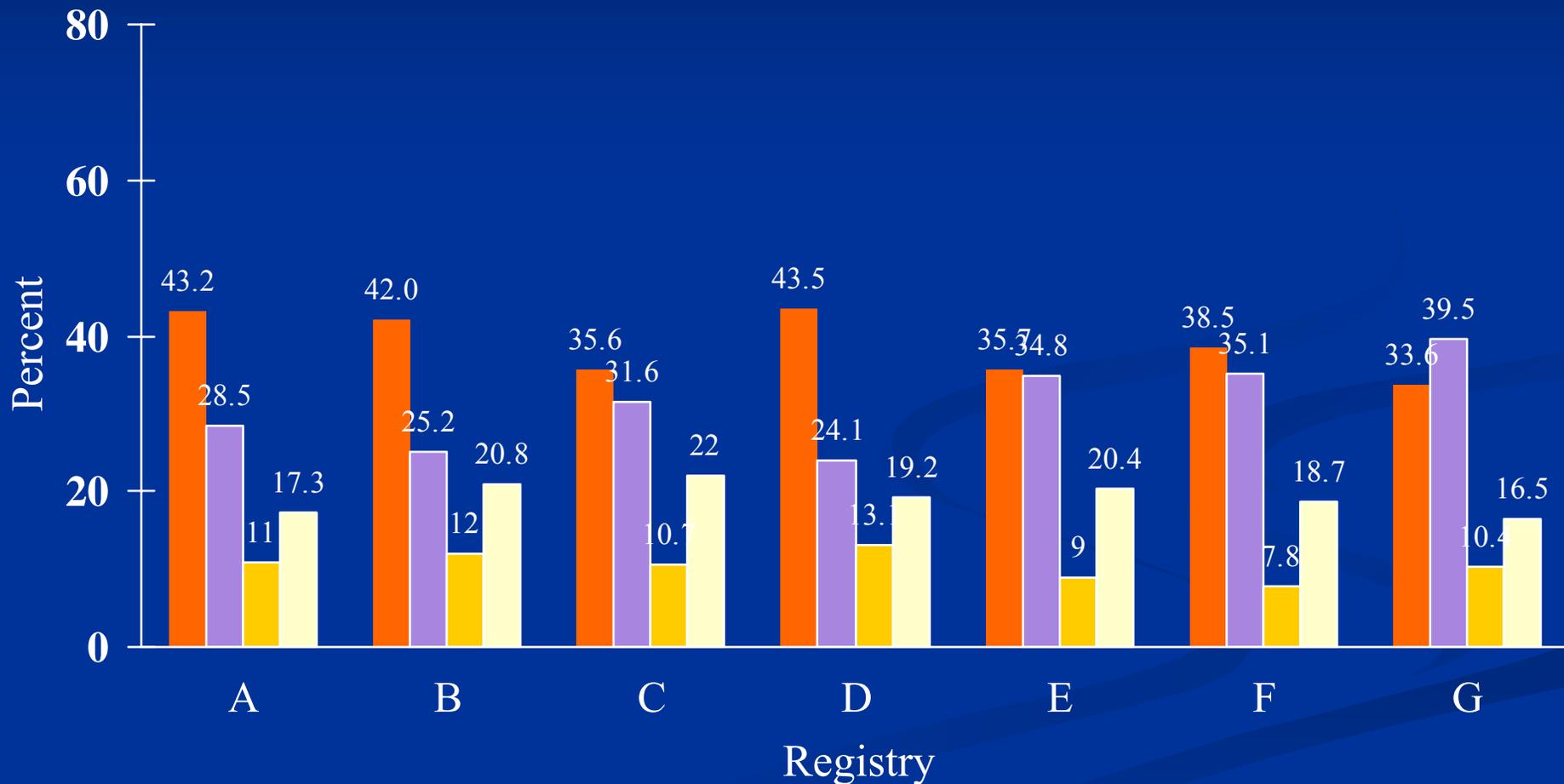
Radical Prostatectomy

Radiation

Hormone

WW

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



Radical Prostatectomy

Radiation

Hormone

WW

# 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:<br>Yes vs. No | 0.44 (0.35-0.55)*  |
| DRE Results:<br>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.