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Award Number: W81XWH-06-1-0180

TITLE: ProCEED Pilot Study (Prostate Cancer Study of Ethnicity, Exercise and Diet)

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REPORT DATE: December 2006

TYPE OF REPORT: Annual Summary

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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Sylvia E. Furner, N	/IPH, Ph.D.			5e.	TASK NUMBER		
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INTRODUCTION:

Prostate cancer has a huge and growing burden of disease, yet its natural history has not been fully elucidated. Further, it is unknown why African-American men have the highest incidence rates in the world. The **overall goals of the ProCEED** *pilot study* are: 1) to advance the understanding of the IGF axis and its interplay with race/genetics and dietary/lifestyle risk factors for prostate cancer, 2) To elucidate modifiable risk factors which interact with genetics and possibly lead to a greater incidence of prostate cancer among African-Americans, and 3) to disseminate learned information in an effort to prevent disease. It is hypothesized that racial differences in prostate cancer risk are attributed, in part, to interactions between lifestyle factors and the IGF axis. This study examines subsets of African American and Caucasian men in an attempt to elucidate dietary and lifestyle risk factors which may operate/interact uniquely in African Americans. If there are lifestyle risk factors for prostate cancer which can be modified, this would be valuable information for primary and perhaps secondary prevention of prostate cancer.

BODY:

As the first year of the grant was dedicated to intensive study start-up activities and beginning subject enrollment, no results from the main study are yet available.

PUBLICATIONS:

A descriptive epidemiology study comparing racial trends in prostate cancer incidence rates in Illinois and the United States was undertaken during year one^{1,2}. The rationale for this descriptive analysis was that the ProCEED study is being undertaken in Illinois African-American and Caucasian populations, and there were no recent published reports of prostate cancer in these populations. A 1995 study reported that, compared to other US state/central cancer registries, Illinois has lower prostate cancer rates^{3,4,5}.

The objective of this descriptive study was to examine recent trends in Illinois and US prostate cancer rates, and to ascertain whether trends were similar by race. Incidence rates were obtained from Illinois State Cancer Registry and the Surveillance, Epidemiology and End Results (SEER) database. Hypothesizing that prostate cancer incidence followed the same pattern as the US, surrounding the availability of the prostate specific antigen (PSA) testing, rate ratios were estimated for three periods: 1986-1990 ("pre-PSA"), 1991-1995 ("PSA-uptake"), and 1996-2000 ("PSA-widespread use"). We found that incidence rates in both regions peaked in the mid-1990s, as expected, due to the artifact of PSA screening. Rate differences between Illinois and the US narrowed in 1994 and 1995. African-Americans had higher incidence rates in African-Americans declining and the racial disparities narrowing. This suggests more effective prostate cancer screening is taking place in Illinois African-American populations than US African-American populations, although differential risk profiles may also be operating.

The publication and the abstract/presentation are included as appendices A and B to this report.

FUNDING:

Additional funding was secured for the ProCEED Pilot Study from the following sources:

1) <u>Midwest Roybal Society for Health Promotion and Behavior Change (</u>\$5,000 award). This money was used to purchase a -70 freezer for the storage of ProCEED study blood samples. It was unknown at the time of grant writing that this freezer would be necessary.

2) <u>University of Illinois, Paul D. Doolen Award for the study of aging</u> (\$4,000 award). This award is only given to two students each academic year.

Katrine Wallace was one of two doctoral students featured in the 2005 University of Illinois, School of Public Health Sponsored Programs Report. This report is available online at: http://sph.uic.edu/manual/annualrpt2005/index.htm⁶

RESEARCH ACTIVITIES AND STATEMENT OF WORK:

Below is the approved statement of work with updates and changes described:

Task 1. Identification/recruitment of 328 participants (228 cases and 110 controls) - Ongoing until month 30

This study was moved from the Hines VA to the Jesse Brown VA Medical Center (JBVAMC) General Urology Clinic. This move was necessary for two major reasons: 1) the patient population at JBVAMC was more diverse and it would be easier to enroll African-American subjects, and 2) the JBVAMC had a relationship with UIC which more easily facilitated the clinic access necessary for this research.

This study took longer than planned to begin enrollment. The JBVAMC would not allow the collected serum samples be stored at the offsite central laboratory, as originally planned, due to their standard operating procedure for tissue banking. This procedure necessitated the purchase of a -70 freezer for onsite storage. Additional funding was secured, and the freezer was purchased.

Study enrollment began on 11/22/2006 and by the end of the annual reporting period (11/29/2006) there were two subjects enrolled, both cases. Enrollment has continued and Katrine Wallace attends the JBVAMC general urology clinic three times per week to enroll subjects.

Table 1. ProCEED Pilot Study Enrollment during the Annual Reporting Period: 11/30/2005- 11/29/2006

Subject ID	Date of enrollment	Case/Control Status	Race	Age
1101	11/22/2006	Case	African-American	50
1102	11/29/2006	Case	Caucasian	57

The recruitment strategy has also been streamlined. At JBVAMC, the MDs, residents, and medical students in the general urology clinic all have a 3x5" index card with the ProCEED inclusion/exclusion criteria written on it. When a patient meets criteria, they automatically ask the subject if they would be interested in study participation.

Task 2. Subject Recruitment and Data Collection, Months 2-29

When patients come in for a 60-minute study visit, the following tasks will take place:

- *i.* Informed consent
- ii. Demographic interview
- iii. Waist/hip circumference and Height/weight measurement
- iv. Blood sample
- v. 24-hour dietary recall
- vi. Work and social history questionnaire
- vii. IPAQ exercise questionnaire
- viii. Block Brief food frequency questionnaire
- ix. Patient incentive given

The dietary data collection has been streamlined and improved. The study employed a masters-level registered dietitian to complete the dietary assessments via phone call. Now the subjects complete everything on the above list except v and viii during the study visit, and the dietitian calls them at their home to assess the dietary information. This improved on the previous process because 1) we have a trained dietitian doing the assessments and 2) we are able to call them twice at their homes to assess the 24 food recall so that we can eliminate some variability by having repeated measures.

Task 3. Determination of serum levels of IGF-1, IGFBP-3, PSA and testosterone, Months 2-29 (for collections and storage), Months 29-31 (for assays and data entry)

As mentioned above, the serum samples will be stored now in a -70 freezer at the Jesse Brown VA Medical Center in the General Urology Research Lab. At the end of the study, the samples will be assayed at Quest in a batch at the end of the study. Thus far we had had no issues with the collection or storage of the serum samples.

Task 4. Statistical Analyses, Months 30-36

Will be done at the end of the study

KEY RESEARCH ACCOMPLISHMENTS:

- Prostate Cancer descriptive epidemiology publication in Journal of Registry Management, 4th Quarter, 2006
- Presentation at the American Public Health Association Annual Meeting in Boston, MA on 11/8/2006
- Additional funding for the study secured from two sources
- Serum bank for study established/approved at JBVAMC
- Study began enrolling subjects on 11/22/2006

I. Manuscript

"Racial Trends in Prostate Cancer Incidence in Illinois and the United States 1986-2000", Published in Journal of Registry Management (see appendix B for a copy of the paper)

II. Abstract / Presentation

"Racial Trends in Prostate Cancer Incidence in Illinois and the United States 1986-2000", Presented at the American Public Health Association (APHA) meeting on 11/8/2006 (see appendix A for a copy of the poster presentation handout)

III. Additional Funding / Scholarships

Katrine Wallace was one of two 2006-2007 recipients of the University of Illinois Paul D. Doolen scholarship award for the study of aging. This award was applied for based on this ProCEED research program. The amount of the award is \$4,000.

Katrine Wallace was a recipient of the Midwest Roybal Center for Health Promotion and Behavior Change dissertation pilot study award in 2005. The amount of the award was \$5,000 and was used to purchase a -70 freezer for the storage of the serum samples for the ProCEED study.

CONCLUSIONS:

As the first year of the grant was dedicated to intensive study start-up activities and beginning subject enrollment, no results from the main study are yet available.

Results from a descriptive epidemiology study suggest that decreases in health disparities exist in the state of Illinois that were not seen in the US. The recent prostate cancer incidence pattern in Illinois was unique with the rates in African-Americans declining into the most recent period and the racial disparities narrowing. This suggests that more effective prostate cancer screening is taking place in Illinois African-American populations than US African-American populations. Unfortunately, data on PSA screening was not collected by the BRFSS during the years under study. Whether the differences between African-Americans and Caucasians in Illinois were because of screening, case ascertainment or other risk factors requires further elucidation.

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UIC SCHOOL OF UNIVERSITY OF ILLINOIS PUBLIC HEALTH **Epidemiology and Biostatistics Division**

Racial trends in prostate cancer incidence rates for Illinois and the United States; 1986-2000

Katrine Wallace MA, Sylvia Furner PhD, Vincent Freeman MD MPH, Faith Davis PhD

INTRODUCTION

The 1988 introduction of PSA screening led to an increase and subsequent decrease in US prostate cancer incidence¹. Compared to other US cancer registries, Illinois has been reported to have lower prostate cancer rates². The objective of this study was to examine trends in Illinois and US prostate cancer rates to ascertain whether trends were similar by race.

METHODS

Incidence rates were obtained from Illinois State Cancer Registry³ and SEER⁴. Rate ratios were estimated for three periods: 1986-1990 ("pre-PSA"), 1991-1995 ("PSA-uptake"), and 1996-2000 ("PSA-widespread use"). 95% Confidence intervals were calculated using PEPI version 4.05. Age-adjusted rates are presented by year, race and region.

RESULTS

Incidence rates peaked in the mid-1990s. Illinois had lower rates for every time period under study in both race groups. Rate differences between the two regions narrowed in 1994 and 1995. African-Americans had higher incidence rates than Caucasians throughout. The post-1996 incidence pattern in Illinois. however, was unique with the incidence rates in African-Americans declining and the racial disparities narrowing.

Prostate Cancer Incidence Measures for Illinois and the United States: Pre-PSA (1986-1990), PSA-Uptake (1991-1995) and PSA-Widespread Use (1996-2000) Periods

Years	Caucasians RR (CI)*	African- Americans RR (CI)*	IL Caucasian Incidence Rates per 100,000 (CI)**	IL African- American Incidence Rates per 100,000 (CI)**	US Caucasian Incidence Rates per 100,000 (CI)***	US African- American Incidence Rates per 100,000 (CI)***
1986-1990	0.78 (0.6099)	0.76 (0.62-0.95)	110 (108-112)	148 (142-153)	142 (141-144)	193 (187-198)
1991-1995	0.82 (0.67-1.01)	0.75 (0.63-0.89)	163 (161–165)	231 (225-238)	198 (197-199)	308 (302-315)
1996-2000	0.86 (0.69-1.07)	0.81 (0.68-0.97)	145 (144-147)	227 (221-233)	169 (168-170)	280 (275-285)

*Sources: Illinois Department of Public Health, Illinois State Cancer Registry, SEER, National Cancer Institute

Source: Illinois Department of Public Health, Illinois State Cancer Registry, Incidence rates are adjusted for age * Source: SEER, National Cancer Institute, Incidence rates are adjusted for age



Prostate Cancer Incidence Rates by race for United States and the State of Illinois, 1986-2000



CONCLUSION

These results suggest that more effective prostate cancer screening is taking place in Illinois African-American populations than US African-American populations, although differential risk profiles may also be operating.

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ACKNOWLEDGEMENTS

Katrine Wallace is funded by: the National Institutes on Aging, Gerontological Public Health Training Program (Grant # T32-AG02050-01A1), and the United States Department of Defense. Congressionally Directed Medical Research Programs (CDMRP), Prostate Cancer Research Traineeship, (Grant # W81XWH-06-1-0180)

APPENDIX B – PUBLICATION

Original Article

Racial Trends in Prostate Cancer Incidence Rates for Illinois and the United States, 1986–2000

Katrine L. Wallace, MA^{ab*}; Sylvia Furner, PhD^b; Faith Davis, PhD^b; Vincent Freeman, MD, MPH^b

Abstract: The 1988 introduction of PSA screening led to an increase and subsequent decrease in US prostate cancer incidence. Compared to other US state/central cancer registries, Illinois has been reported to have lower prostate cancer rates. The objective of this study was to examine trends in Illinois and US prostate cancer rates to ascertain whether trends were similar by race. Incidence rates were obtained from the Illinois State Cancer Registry (ISCR) and from the Surveillance, Epidemiology and End Results (SEER) Program. Rate ratios (RRs) were estimated for 3 periods: 1986–1990 ("pre-PSA"), 1991–1995 ("PSA-uptake"), and 1996–2000 ("PSA-widespread use"). Incidence rates peaked in the mid-1990s. Rate differences between the 2 regions narrowed in 1994 and 1995. African-Americans had higher incidence rates in African-Americans throughout. The post-1996 incidence pattern in Illinois, however, was unique with the incidence rates in African-Americans declining and the racial disparities narrowing. This suggests more effective prostate cancer screening is taking place in Illinois African-American populations as compared with US African-American populations, although differential risk profiles may also be operating.

Key words: incidence, prostate cancer, race, state cancer registry data

Introduction

Adenocarcinoma of the prostate is the most common cancer among men in the United States, and the third most common cancer among men globally.1-3 Incidence rates in the United States and globally are systematically highest (75% of cases) in men over the age of 65,²⁻⁴ and thus prostate cancer is more prevalent in areas where the age distribution includes greater numbers of men over the age of 65, such as in the United States and other developed countries. The United States has an extremely high overall incidence rate at 165.5 cases per 100,000 persons (1992–1999)⁵ and prostate cancer accounts for 33% of all cancer diagnoses among men in the United States.1 Additionally, enormous racial disparities exist with respect to this disease. Incidence rates are highest among African-Americans, at 257.3 per 100,000, and Caucasian men are the second most commonly diagnosed at a rate of 158.7 per 100,000.5

The incidence rate trends for prostate cancer in the United States were altered with the introduction of the PSA (prostate-specific antigen) test in 1986.⁶ The recorded incidence of prostate cancer in the United States doubled between the years of 1984 (111.6 per 100,000) and 1992 (235.9 per 100,000). The incidence rates are thought to have declined again in 1992 as the number of unscreened individuals was exhausted.² After the surge in incidence subsided (between 1992 and 1999), rates in the United States declined and then leveled off.

Compared to other cancer registries across the United States, Illinois has been previously reported to have lower prostate cancer incidence rates.⁷⁻⁹ Whether this is due to increased/decreased screening, case ascertainment, or differential risk factor profiles is currently not known. In the most recently published report on the status of cancer in Illinois (2001), prostate cancer was noted as having the highest age-adjusted incidence rates among Illinois males for the years 1994–1998. Rates were 129.4/100,000 overall, 119.1/100,000 for whites, and 60% higher for African-Americans, at a rate of 198.7/100,000.⁸

The objective of this descriptive study was to further examine Illinois and US prostate cancer incidence trends for the years 1986–2000 by race to ascertain whether the trends over time by race are similar between the Illinois and US populations.

Methods

Illinois prostate cancer incidence rates over time for African-Americans and Caucasians for the years 1986–2000 were derived from the ISCR.^{10,11} The ISCR has been collecting cancer data from various sites across the state each year since 1986 and has received gold certification from the North American Association of Central Cancer Registries (NAACCR) for each year of data collected since 1996,^{12,13} reflecting both completeness of the registry and death certificate clearance. This is the highest rating granted by

[&]quot;Racial Trends in Prostate Cancer Incidence Rates for Illinois and the United States, 1986-2000"

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^{*}Katrine Wallace is funded by: the National Institutes on Aging, Gerontological Public Health Training Program (Grant # T32-AG02050-01A1), and the United States Department of Defense, Congressionally Directed Medical Research Programs (CDMRP), Prostate Cancer Research Traineeship, (Grant # W81XWH-06-1-0180)

the association, which began certifying registries for data collected in the year 1995. US 1986–2000 incidence rates over time were derived from the SEER Program.⁵ SEER currently collects and publishes cancer incidence and survival data from population-based cancer registries covering approximately 26% of the US population.⁵ Incidence rates are presented in Figure 1 by year, race, and region, adjusted by age.

To ascertain differences in prostate cancer incidence rates by race between Illinois and the United States, rate ratios (RRs) were estimated. This measure enables the direct comparison of rates between the 2 regions. RRs were calculated by dividing rates for Illinois by rates from the United States for each time period of interest, by race. The RRs were estimated for 3 time periods that reflect the prevalence of PSA test use for the screening of prostate cancer: 1986–1990 ("pre-PSA" phase, before PSA screening was routinely used), 1991–1995 (the "PSA-uptake" phase) and 1996–2000 (after "PSA-widespread use"). Ninety-five percent confidence intervals (CI) for the RRs were calculated using PEPI version 4.0.¹⁴

Results

Figure 1 illustrates the prostate cancer incidence pattern expected in the United States, based on previous reports. In the pre-PSA period (1986–1990), trends by race in prostate cancer incidence rates were similar for both the United States and Illinois, although lower rates were apparent in Illinois. Table 1 shows that RRs for prostate cancer in Illinois compared with the US population were significantly lower at 0.78 (95% CI, 0.60–0.99) for Caucasians and 0.76 (95% CI, 0.62–0.95) for African-Americans.

During the PSA-uptake period (1991–1995), Figure 1 shows that prostate cancer incidence rates increased for all groups. Caucasians in the United States and Illinois experienced incidence peaks in 1992. African-Americans experienced later incidence peaks in the United States (1993)

and in Illinois (1994). Incidence rates among Illinois and US Caucasians decreased similarly between the years 1992 and 1995. US African-Americans followed the pattern of the Caucasian groups, but the decrease had a later onset – from 1993–1995. Illinois African-Americans demonstrated a unique trend to the other 3 groups, with an increase that leveled off late in this period. Table 1 shows that RRs for the PSA-uptake period demonstrate lower incidence in Illinois than in the United States, by race: 0.82 for Caucasians (95% CI, 0.67–1.01) and 0.75 for African-Americans (95% CI, 0.63–0.89). The RR for prostate cancer among African-Americans in Illinois relative to the United States remained statistically significantly lower during this period.

By 1997, prostate cancer rates in the PSA-widespread use phase (1996–2000) were relatively stable among all groups with the exception of the Illinois African-Americans, whose rates have continued to decline through 1999 (Figure 1). Comparing the rates between the United States and Illinois, the RRs for African-Americans and for Caucasians were 0.81 (95% CI, 0.68–0.97) and 0.86 (95% CI, 0.69–1.07), respectively, during this period. The RRs for both Caucasians and African-Americans increased, indicating less of a difference between Illinois and US incidence rates. However, the RR for African-Americans still demonstrate significantly lower incidence in Illinois as compared to the United States during this period.

Discussion

The objective of this descriptive study was to examine Illinois and US prostate cancer incidence trends for the years 1986–2000, to ascertain whether the trends were similar in these 2 populations, by race. Prostate cancer incidence trends in the United States between 1986 and 2000 can be classified into 3 distinct phases in the United States: pre-PSA from 1986–1990, PSA-uptake from 1991–1995, and PSAwidespread use from 1996–2000. Illinois prostate cancer rates also mirrored these 3 distinct incidence phases. The



RRs for all 3 phases reflect lower rates of prostate cancer in Illinois in both race groups, agreeing with published data on Illinois prostate cancer incidence.⁷⁻⁹

The trends in incidence rates over time were similar between United States and Illinois Caucasians. Additionally, the rate difference between the 2 Caucasian groups is shrinking, as evidenced by RRs becoming closer to 1.0 and narrowing trends in incidence rates. African-Americans in the United States, while demonstrating much higher incidence rates than Caucasians, followed the similar, expected incidence patterns over time. Illinois African-Americans however, demonstrated a unique incidence pattern from the other 3 groups with rates continuing to decline in the most recent time period. This decline represents a decrease in disparities, as evidenced by lower rates among African-Americans in Illinois compared to other parts of the country.

In this study, we found decreases in health disparities in the state of Illinois that were not seen in the United States as a whole. The recent prostate cancer incidence pattern in Illinois was unique with the rates in African-Americans declining into the most recent period and the racial disparities narrowing. This suggests that more effective prostate cancer screening is taking place in Illinois African-American populations than in US African-American populations. Unfortunately, the Behavioral Risk Factor Surveillance Study did not collect data on PSA screening during the years under study. Whether the differences between African-Americans and Caucasians in Illinois were because of increased/ decreased screening, case ascertainment, or other risk factors requires further elucidation.

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(1991–199	(1991–1995), and PSA-Widespread Use (1996–2000) Periods							
Years	Caucasians RR (CI)*	African-Americans RR (CI)*	IL Caucasian Incidence Rates per 100,000 (CI)**	IL African-American Incidence Rates per 100,000 (CI)**	US Caucasian Incidence Rates per 100,000 (CI)***	US African-American Incidence Rates per 100,000 (Cl)***		
1986–1990	0.78	0.76	110	148	142	193		
	(0.60–.99)	(0.62–0.95)	(108–112)	(142–153)	(141–144)	(187–198)		
1991–1995	0.82	0.75	163	231	198	308		
	(0.67–1.01)	(0.63–0.89)	(161–165)	(225–238)	(197–199)	(302–315)		
1996–2000	0.86	0.81	145	227	169	280		
	(0.69–1.07)	(0.68–0.97)	(144–147)	(221–233)	(168–170)	(275–285)		

Table 1. Prostate Cancer Incidence Measures for Illinois and the United States: Pre-PSA (1986–1990), PSA-Uptake

*Sources: Illinois Department of Public Health, Illinois State Cancer Registry, SEER, National Cancer Institute

**Source: Illinois Department of Public Health, Illinois State Cancer Registry; incidence rates are adjusted for age

*** Source: SEER, National Cancer Institute; incidence rates are adjusted for age