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TITLE: Study of Prostate Cancer Screening and Mortality in Black
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PRINCIPAL INVESTIGATOR: Nabih R. Asal, Ph.D.

CONTRACTING ORGANIZATION: University of Florida
Gainesville, Florida 32611

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13. ABSTRACT (Maximum 200 Words) We are implementing a case-control study of prostate cancer screening and mortality in 5 Metro Atlanta & 23 North Central Florida counties to determine if screening with the PSA/DRE reduces mortality from prostate cancer in black and white men. 566 Prostate cancer deaths (221 Black and 345 Whites Men) occurring to residents of Metro Atlanta during 1998-2001 were identified, reviewed, and linked to the hospital(s) of prior treatment. IRB approval and access to medical records have been requested from most of the institutions and IRBs. About 119 medical charts of 219 available from the 5 largest hospitals in Atlanta were reviewed. Records of the Georgia Cancer Registry are available for review. Last annual Report dated 10/23/2002 includes detailed information. The Post-Doctoral fellow (11/01-09/03) completed her training. Similar efforts are underway in Florida. IRB approvals have been obtained from the U of Florida to access Shands/VA Hospitals in north central Florida. 2866 prostate cancer death records were obtained from the Florida Department of Health occurring to residents in the 23 counties during 1998-2001. A request has been submitted to the Florida Dept of Health IRB and Bureau of Epidemiology to access the Florida Cancer Data System (cancer registry). No further project activities are planned until all outstanding IRB issues are resolved.				
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Study of Prostate Cancer Screening and Mortality in Black and White Men in the Five Atlanta SEER and Twenty Three North Central Florida Counties

I. Introduction

Prostate cancer is the leading cause of cancer morbidity and the second leading cause of cancer mortality among U.S. men, and is projected to account for an estimated 232,090 new cases and 30,350 deaths in the year 2005. The significant changes in incidence and mortality that occurred since 1988 (significant rise between 1988-92, decreased between 1992-95, and increase between 1995-2004 in men <65 years of age, have been attributed to increased awareness of the disease and efforts at early diagnosis with the Prostate-Specific Antigen (PSA). African American men have the highest incidence and mortality rates in the world and continue to experience significantly higher incidence and twice as high death rates as whites in the U.S. The disparity in morbidity and mortality between African American men in the U.S. has not been adequately studied or explained, although it is generally believed that a number of factors are responsible, including stage at diagnosis and accessibility to health care (American Cancer Society Facts and Figures, 2005).

There is a great deal of controversy surrounding the interpretation of existing epidemiological and clinical evidence. Expert recommendations regarding the age, frequency and the necessity for the use of the Prostate Specific Antigen (PSA) and the Digital Rectal Examination (DRE) for mass screening in the general population as a public health policy remain conflicting and controversial. Results from large scale randomized controlled trials conducted by the National Cancer Institute and the European Union, necessary to document the benefits of screening through reduction in mortality, will be available in few years. Meanwhile, a number of case-control studies, including the present study, are underway to determine if screening with the PSA and DRE reduce mortality from prostate cancer.

II. Body

Objectives/Hypothesis: The objective of this study is to provide much needed data on the efficacy of screening for prostate cancer using observational case-control methodology while awaiting the results of randomized controlled trials and to explain the black white disparity in mortality from prostate cancer. The hypothesis to be tested is that the frequency of screening tests (DRE and PSA) should be higher in the general population than in the group of men who die from prostate cancer.

Specific Aim: Is to determine if screening with PSA and DRE reduces prostate cancer mortality.

Study Design: To accomplish this aim and test the hypothesis, a case-control study is being implemented in the 5 SEER Atlanta, Georgia and 23 North Central Florida counties with access to or with an automated linkage to death certificates. The frequency of PSA and DRE screening prior to the diagnosis of prostate cancer will be compared between a sample of 450 men (170 black & 280 white) who died/will die of prostate cancer in the 5 counties during the 4 year 1998-2001 period and a sample of 450 control men (170 black & 280 white) (sample size with adequate power) who did not die from prostate cancer. Deaths will be ascertained directly from the SEER Registry in Atlanta and the State Cancer Registry in Florida as well as the Georgia and Florida Departments of Public Health. The cases and controls will be frequency matched by race, age, sex and county of residence. Given the long and poorly understood natural history of prostate cancer, the favorable five-year relative survival rates for early stage disease, the advent of PSA utilization (1986), and to allow for the longer possible retrospective assessment interval of exposure data from date of diagnosis, the prostate cancer deaths during 1998-2000 (2001 added if needed) will be included as cases. Death records will be systematically linked to hospital records using seven identifiers: name, social security #, date of birth or age, date of death, race and county of death and

residence. Linkage and review of hospital records will be limited to the following hospitals in Atlanta: Grady Health System, Emory Hospitals, Piedmont Hospital, Crawford Long, Dekalb Medical Center, and V.A. Hospital, and in Florida to Shands Hospital and the North Florida South Georgia V.A. Medical Center. Hospital, physician and laboratory records will be reviewed to assess the frequency of DRE and PSA tests in cases and controls for a period of 12 to 14 years prior to the date of death of the case and to include the exposure period prior to the reference date of diagnosis of the case. The odds ratio with 95% C.I. will be used for overall comparisons and within subgroups defined by risk factors and adjusted for co-morbidity. Logistic regression will be used to generate summary odds ratios adjusted for co-variates.

III. Key Research Accomplishments

Key research accomplishments are based on progress made relative to each of the items listed under Task 1-5 in the Statement of Work that follows and submitted as part of the revised Proposal.

Statement of Work

Task 1. Personnel Recruitment/Arrangements, Months 1-2:

a. Prepare paper work, position description and advertisement.

Completed for the Atlanta Site. In Progress at the Florida Site.

b. Hire and train data abstractor(s) at Morehouse School of Medicine and the University of Florida.

The hiring of personnel was completed at Morehouse School of Medicine from the inception of the Project. Yassa Nadjakani, MD, MPH has been associated with the project since the beginning (10/1/2001) although funding was not available for a considerable period of time during the transfer of the Project from MSM to UF. He continues to the present to be the Project Coordinator for the Atlanta area. We have not hired any new personnel in Florida, however, Ryan Theis, MPH, who coordinates a Kidney Cancer Case-Control Project (Asal, P.I.) currently provides administrative support for the project. He assists the P.I. with IRB issues with the Florida Department of Health, the University of Florida, the VA Hospital and Shands Medical Center, all are in Florida..

Celestine Kiki, M.D., M.P.H. was hired as a Post doctoral fellow on 11/5/2001. Dr. Kiki completed her two year Post Doctoral fellowship in December 2003 and returned to her Native Country of Benin, Africa. She is affiliated with the Department of Health in her Native land.

c. Finalize arrangements with the Tumor Registries, the Health Departments, Hospitals, Laboratories, Urologists, and Primary Care Providers in Georgia and Florida.

Arrangements have been made with the Tumor Registries at the Georgia Department of Health and at the Florida Department of Health as well as the Offices of Vital Statistics in both Health Departments. Mortality records in the form of listings by year, have been provided for prostate cancer deaths during 1988-2001. Approval from the Georgia Department of health and the SEER Registry in Atlanta has been received. Application to access the Florida Cancer Registry has been submitted but awaits approval of the Florida Department of Health IRB (Pending).

Approval has been received from all of the University/Hospital IRBs in both Florida and Atlanta. Consent Forms with HIPPA language approved by the Army IRB has been forwarded to each of the hospital IRBs in Florida and Atlanta. (work in progress). Several of the hospitals have provided approval by a stamp on the Consent Form. Once received the approved consent forms will be forwarded to the Army IRB for final approval.

It is too early to begin contact with laboratories, urologists, and primary care providers. This process will begin once all cases have been identified, the records abstracted, controls identified through a match,

approval is received from control subjects, medical records abstracted, then laboratories contacted.

d. Obtain death certificate lists and all other materials from the State Health Departments and Tumor Registries in Atlanta and Florida.

This task has been completed.

Task 2. Sample Size Determination and Power Calculations, Months 1-4:

a. Review Georgia/Florida State Departments of Health mortality records and Registry data for 1998-2000 (2001) to determine the number of men dying from prostate cancer.

This activity has been completed. See tables 1 and 2 below.

b. Determine the adequacy of sample size projected in the proposal.

The following Tables (1 and 2) summarize the prostate cancer mortality data obtained from the Georgia and Florida Departments of Health (Georgia Department of Human Resources/Georgia Cancer Registry).

**Table 1
Prostate Cancer Mortality in the 5 Metro Atlanta SEER Counties
1998, 1999, 2000, 2001* By Race**

Counties	1998		1999		2000		2001		Total		Grand Totals
	Black	White	Black	White	Black	White	Black	White	Black	White	
Clayton	4	11	4	1	1	4			9	16	25
Cobb	3	33	6	21	5	26			14	80	94
Dekalb	24	32	17	22	17	27			58	81	139
Fulton	58	33	57	45	19	20			134	98	223
Gwinnett	1	23	3	26	2	21			6	70	76
Total	90	132	87	115	44	98			221	345	566

*Data for 2001 will be added to the table

**Table 2
Prostate Cancer Mortality In 23 North Central Florida Counties
By Race 1998-2000**

County	White Male Cases			Black Male Cases		
	1998	1999	2000	1998	1999	2000
St. Johns	16	14	9	0	1	2
Nassau	2	7	4	1	3	2
Duval	53	73	58	32	36	24
Clay	15	9	15	1	3	1
Baker	1	2	0	0	1	0
Flagler	11	10	11	4	1	3
Volusia	71	73	84	7	6	11
CHPA4 Jacksonville	169	188	181	45	51	43
Putman	12	9	3	4	4	2
Alachua	17	16	16	8	5	8
Hamilton	0	0	2	4	0	0
Columbia	10	8	4	1	2	3

Union	2	1	0	0	1	0
Dixie	1	3	2	0	0	0
Lafayette	0	0	0	0	0	0
Suwannee	4	4	4	5	4	0
Marion	70	52	47	5	6	6
Sumter	5	7	6	1	3	0
CHPH3 Gainesville	121	100	84	28	25	19
Pasco	73	66	55	1	0	0
Pinellas	132	144	134	8	12	11
Tampa-St. Petersburg-Clearwater	205	210	189	9	12	11
Orange	60	61	52	20	16	30
Seminole	28	26	32	11	2	4
Osceola	11	16	13	2	2	3
Orlando/Other	99	113	97	33	20	37
Tallahassee/Leon	17	14	18	11	7	11
Total per year	307	302	283	83	84	73
Three Year Total		892			240	

Florida Division of Vital Statistics

The 461 black deaths from prostate cancer between 1998-2000 (221 deaths in Atlanta and 240 in North Central Florida) and 1236 white deaths from prostate cancer 1998-2000 (345 white deaths in Atlanta and 891 in North Central Florida) exceed the needed sample of 170 blacks and 280 whites projected as a minimum sample for adequate Power.

Inclusion of mortality for 2001 will provide additional 100 black deaths and 350-400 white deaths. The needed sample will then be selected randomly.

Task 3. Modify and Pre-test Medical Record Review Form, Months 2-4:

a. Modify, pre-test, refine, and finalize the medical record review forms.

Forms have been modified, pre-tested, finalized, used, and continue to be used in both Atlanta and Florida (when IRB approval is received from the Army)

Telephone screening forms to select controls have been modified, approved by the Army IRB, and ready to be used to select controls.

b. IRB packages will include the final medical record review forms and protocol with sampling and data collection strategies and final sample size estimates.

Since receiving the tentative approval from the Army on April 1, 2005. A process has begun to secure final approval of the protocol and IRB Consent forms from each of the participating hospitals in Atlanta and North Central Florida.

Task 4. Access Hospital Lists/Select Controls, Months 4-6:

a. Identify list of hospitals where cases were diagnosed in Georgia and Florida

Completed for Atlanta, But has not begun for Florida.

b. Finalize arrangements with Florida hospitals for in-site visit

Not Applicable For This Report

c. .Selection of Controls at each hospital in Georgia and Florida.

Not Applicable For This Report

Task 5. Conduct Medical Record Review/Computerize Data Set for Analysis, Months 6-20:

a. Begin Data collection on cases and controls from hospitals, clinics, physicians and laboratories.

A total of 219 charts have been identified in the Atlanta area hospitals. (Appendix A)

b. Conduct the medical record review on 450 black and white male prostate cancer deceased cases and their 450 frequency matched age and race male controls.

A total of 119 have been reviewed and included in the initial report submitted October 20, 2002. No charts have been requested or reviewed in Florida. (Appendix A)

b. Ongoing quality control, cleaning, and completeness of data.

Not Applicable For This Report

c. Computerize completed, cleaned, and validated data and translate into ASCII file format with a data dictionary.

Not Applicable For This Report

Task 6. Data Analysis, Months 20-22:

Comprehensive analyses of collected data according to the statistical procedures outlined in the statistical section of the proposal.

Not Applicable For This Report

Task 7. Final Report/Manuscript Preparation, Months 22-24:

a. Preparation of the final report to funding agency and manuscript prepared for publication.

Not Applicable For This Report

IV. Reportable Outcomes.

Work In Progress no Outcomes to Report.

V. Conclusions.

The study was progressing fine until the Principal Investigator relocated from Morehouse School of Medicine in Atlanta to the University of Florida in Gainesville, Florida on July 1, 2002. The process of transferring the proposal and funding from MSM to UF is still ongoing. Once final Army IRB approval is completed the project will begin anew at the University of Florida and through a sub-contract at Morehouse School of Medicine.. We anticipate this date to be May 1, 2005.

VI. References.

Not Applicable

VII. Appendices

Appendix A : Medical Record Abstracting of Cases (Progress Report October 20,2002)

Appendix A

Study of Prostate Cancer Screening and Mortality In Black and White Men
 In Five Atlanta Area SEER Counties
 Medical Record Abstracting of Cases
 Progress Report
 October 20, 2002

Hospital	# of Charts Reviewed	Charts Reviewed Blacks	Charts Reviewed Whites	Number of Charts Requested	Number of Charts Pending Review	Estimated Total Number of Charts
V.A. M.C.	ASAP	-	-	-	-	-
Crawford Long Hosp	24	21	3	16	17	60
	-	-	-	-	-	-
	-	-	-	-	-	-
Dekalb Med Center	7	3	4	27	-	34
Emory University Hospital	49	4	45	-	-	49
	-	-	-	-	-	-
Grady H.S.	45	44	1	10		55
	-	-	-	-	-	-
	-	-	-	-	-	-
	-	-	-	-	-	-
Piedmont Hospital	13	5	8	-	1	21
		-	-	-	-	-
	-	-	-	-	-	-
	-	-	-	-	-	-
Totals	138	77	61	53	18	209