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PETITION

Petition to the State Health Coordinating Council Regarding Special Need for Radiation Oncology – Linear Accelerator Service Area 20 2009 State Medical Facilities Plan

State Health Coordinating Council
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

August 1, 2008

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REQUESTED ADJUSTMENT

This petition requests inclusion of a special need for a multidisciplinary prostate health center in Service Area 20 that will offer a full range of services to treat men with urological and prostate cancer.

The adjusted need would appear on page 146 of Chapter 9 Radiation Oncology Services – Linear Accelerators the subsection, Adjusted Need Determination for a Linear Accelerator and would read as follows:

In response to a petitioner's request for an adjustment to the need determination for linear accelerators, there is an adjusted special need determination for one linear accelerator in Service Area 20 to be located in a dedicated prostate health center that is organized to provide multidisciplinary diagnosis, treatment and therapy by practicing urologists, oncologists and others; that has an organized outreach and advisory feedback program designed to address the special needs of African Americans and other high risk groups.

Table 9J would be adjusted to read as follows:

HSA	Linear Accelerator Service Area	Linear Accelerator Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
IV	20	1*	January 15,2009	February 1, 2009

*To be located in a dedicated Prostate Health Center that is organized to provide multidisciplinary diagnosis, treatment and therapy involving at least 10 urologists practicing in the service area and an organized outreach and feedback program to meet the needs of African Americans and other high risk groups.

- Services to be offered should include the disciplines of urology, oncology and biofeedback therapy, a focused prostate/ urological cancer tumor board, a linear accelerator, chemotherapy, brachytherapy, and post-treatment living skills therapy.
- Staffing should include the involvement of at least 10 urologists practicing in the service area who have treated prostate patients; a licensed pelvic rehabilitation specialist, radiation oncologist, a urologic pharmacologist and a hematologist/oncologist. It should care for approximately 200 prostate cancer cases a year
- Accessibility to high-risk populations should be a key feature of the center. To address the particularly high incidence of prostate cancer among North Carolina African Americans, the center should have an organized African American education/outreach program integrated with existing support groups. As the center develops, other special need groups may be identified.
- The center should have an Advisory Board composed of representatives of Prostate Cancer Advocacy groups, prostate cancer patients and survivors.
- The project should include evaluation by a third party researcher, and should provide the state with a report on outcomes of this disease-specific service and how the model could be extended to other parts of the state.

REASONS FOR THE PROPOSED ADJUSTMENT

Summary

This petition is based upon the need for and importance of a comprehensive multispecialty prostate health center in North Carolina to demonstrate the impact that such a structure can have on patient outcomes. It involves the critical role that a linear accelerator plays in treatment of prostate cancer and unique risks associated with linear accelerator treatment of prostate cancer. It responds to the imbalance in availability of linear accelerators in Service Area 20, and the high level of prostate cancer in North Carolina, particularly among African Americans, and the large number of African Americans at risk in Service Area 20. The following paragraphs explore each of these issues.

Prostate Cancer Incidence

Prostate cancer is extremely prevalent, with one in six men developing prostate cancer during his lifetime.¹ In a recent article in the NC Medical Journal, researchers at UNC reported that based on SEER data, North Carolina men had an age adjusted death rate from prostate cancer of 35.6/100,000. This exceeded the national average by 17.5 percent², a statistic that greatly concerns Cary Urology. North Carolina has one of the highest death rates from prostate cancer in the United States. See Attachment B.

Based on the 2007 projections from the North Carolina Cancer Registry, male urologic cancers represent 21.4 percent of all cancers diagnosed and eight percent of all cancer deaths in North Carolina. Prostate cancer accounts for the majority of urologic cancers (15.7 percent of total cancers). The disease itself is extremely prevalent and is second to lung cancer as a cause of death.

North Carolina has the undesirable attribute of having a very high prostate cancer death rate, statistically greater than national average. The rate is higher among African Americans. The disparity has the attention of the Prostate Cancer Research Program supported by the Department of Defense. Information from its Disparity Study shows that, regardless of similar socioeconomic status between the two states, African Americans in North Carolina have the highest prostate cancer death rates and in Louisiana have one of the lowest. The project has also found that few African Americans with prostate cancer participate in prostate cancer support groups. This limits screening and knowledge of the disease process. This phenomenon is presently being studied by a North Carolina-Louisiana study through a \$10 million grant from the Department of Defense. See Attachment C.

Unique Aspects of Prostate / Urological Cancer

The major issue associated with prostate cancer is who to treat and how aggressively. When this organ becomes cancerous, treatment choices involve preserving function in nearby organs. Prostate cancer rarely, if ever, involves a single tumor with well-defined margins; rather, it involves multiple cancerous cells dispersed throughout the organ. Prostate cancer often causes the prostate to enlarge enough to nestle within part of the bladder.

Prostate cancer treatment options include watchful waiting, surgery, hormonal ablation, radiation, chemotherapy, and combinations of these treatments. Age and health status of the patient play a significant role in the choice of treatment; patient preference is also involved. Because patients have the disease for 10 to 20 years, during which time they move around, results from studies are often not statistically significant. Patients in the studies are often lost during critical follow-up periods. This makes the physician's job of advising patients difficult. Overall, anyone who has investigated prostate cancer and searched the literature typically becomes more confused the more they learn.

¹ Source: DEVCAN Software, Probability of Developing or Dying of Cancer Software, Version 5.2. Statistical Research and Applications Branch, National Cancer Institute, 2005. <http://srab.cancer.gov/devcan>.

² Gaston, Kris, MD; Pruthi, Raj, MD. "Racial Differences in Prostate Cancer." North Carolina Medical Journal 67.2 (2006): 130-134.

The prostate is a soft tissue gland. It shifts around in the body, and is very close to the bladder and the rectum. A complex system of nerves and tiny valves governs flow of fluids through the prostate. The prostate gland is surrounded by a web of nerves and blood vessels that supply the bladder, prostate, penis, urethra, and seminal vesicles. See anatomy in Attachment A. Why is this so important? Disruption of any single tissue in this delicate network can cause major changes in physiologic function. Treating urologic cancers requires highly skilled and finely tuned techniques.

Where surgery is possible, removing the prostate has high potential for putting the prostate cancer in remission. Today, surgery on prostate cancer can preserve the delicate network of nerves, tissues, and connections of other organs that touch the prostate. We have Johns Hopkins' Dr. Patrick Walsh to thank for this nerve sparing radical prostatectomy technique.

Certain patients can have the same results with brachytherapy, a process of surgically implanting short half-life radioactive seeds in the affected gland. This technique requires collaboration between a surgeon and a radiation oncologist. One reviews the anatomy and guides the implant and the other reviews the cancer status and organizes the dosage and choice of seeds. Continuous follow-up by the surgeon while the radioactive seeds destroy the cancer assures preservation of the non-cancerous surrounding tissues.

Many patients benefit from combinations of external beam and brachytherapy, which can involve coordination of oncology services in two different locations.

About half of the people who can benefit from prostate cancer treatment need external beam radiation delivered by a linear accelerator. Linear accelerator treatments vary in dosage (grey) and in the degree to which they can be focused. Traditional external beam therapy involves lower dosages, up to 72 grey, but significant collateral tissue damage is an undesirable side effect. Conformal radiation can increase the dosage (grey). It also increases the collateral damage to healthy tissue. A linear accelerator with IMRT is more focused and permits use of higher dosage radiation (77 grey) that kills prostate and cancer cells by painting a tight, controlled beam of radiation across and through the prostate. In all of these, the external radiation beam must pass through the body to reach the prostate. The painting action of the beam, along with the high dosage is powerful in its ability to destroy the DNA in the cancer cells. However, during this treatment, non-cancerous tissue in the path of the radioactive high energy beam is at risk of injury. The same energy that kills the cancer can, and does, harm other healthy tissue.

During the two- to three-month linear accelerator treatment time, most patients are under the care of a radiation oncologist, whose focus is on the impact of radiation energy on cell death. Patients have little or no contact with the urologist, whose focus is on the anatomy and function of these organs and glands.

Benefits of Prostate Health Center

1. Prostate Health Center Vision

This proposal involves a center where patients with urologic and prostate cancer can expect individual, custom-tailored therapy, organized to meet their unique situations. To avoid bias in recommended patient treatments, it involves practicing urologists and oncologists as owners. It involves outreach and screening of patients at risk, as well as evaluation and feedback on the impact of clinical and outreach initiatives. Cary Urology is the official proponent for this petition. However, the proposed model involves participation of several urology practices and oncology practices.

Organizing such a prostate health center is not easy. It requires a multidisciplinary team of specialists whose skills complement each other. It involves breakthrough organization, rearranging silos of clinical specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing decisions. Reducing the impact of urologic cancers on the lives of patients involves complex treatment plans that consider how the whole body functions, how the whole body will respond to the treatment, as well as how the treatment will reduce the cancer. It requires specialists in the fields of anatomy, radiation, pharmacology, and chemotherapy.

The proposed Prostate Health Center provides counseling and care management; a full range of radiation oncology treatment including brachytherapy, external beam radiotherapy, and a combination of the two; and surgical and radiation together with biofeedback training, incontinence management, and sexual rehabilitation, its own tumor board, pharmaceuticals and psychological counseling. By statute, North Carolina requires a Certificate of Need for the linear accelerator.

The center makes a difference in individual care because of the way service is delivered. It makes a difference in health status because of the way it connects to the community. Hence, it has a strong, organized outreach component consisting of screening, support groups and advocacy.

The income from the Prostate Health Center's linear accelerator covers its own costs and provides the extra resources needed to cover treatment of all urological/ prostate cancer patients, regardless of their ability to pay. It also subsidizes the outreach and evaluation efforts and the tumor board.

2. Multidisciplinary Approach to Prostate/ Urological Cancer

Unfortunately, North Carolina's linear accelerator radiation oncology centers are designed such that a radiation oncologist must divide his/her time planning treatments for patients with lung, breast, kidney, cervix, stomach, prostate and other cancer types. In an urban area with multiple centers, the radiation oncologist will have limited contact with the prostate cancer patient's urologist. A single urologist can have patients being treated by five or six different centers at any given time. This dispersion of effort limits the ability for a radiation oncologist and a urologist to consult on the status of their patients during the two- to three-month radiation treatment period. If chemotherapy is also part of the treatment, the dispersion of care can reach even further. In

practice, the patient and urologist make a decision about the treatment option and if it involves radiation and/or chemotherapy, the patient is referred to those specialists to return only upon completion of the course of treatment.

These treatment silos result in preventable damage to nearby organs. The concept of a multidisciplinary approach to the treatment of prostate cancer is not new. The resolution, well developed at cancer centers outside North Carolina, is a multidisciplinary prostate health center. The MD Anderson Cancer Center, in Houston, Texas has a well-developed program. So do Dana Farber Cancer Institute in Boston, Massachusetts; Kirkland Prostate Center at the University of Alabama at Birmingham; The Center for Prostate Cancer at University of Minnesota Medical Center in Minneapolis, Minnesota; UC Davis Cancer Center/Prostate Cancer Clinic in Sacramento, California.

North Carolina does not have a true multidisciplinary prostate health center. No North Carolina provider focuses exclusively on the very complex issues associated with total treatment of prostate and urologic cancer. Yet, the numbers justify a focused approach. Approximately half of prostate cancers are treated with radiation therapy; 80 percent of which involves use of a linear accelerator. Prostate cancer treatment represents approximately 20 percent of all radiation treatments performed.

Changing the orientation of prostate/urological cancer treatment from medical-specialty to disease-specific orientation is the only practical way to address the many physiologic challenges that occur during prostate cancer treatment and management of prostate/urological health. Combining screening, diagnosis, treatment, and lifestyle management in a comprehensive, coordinated health care program involving oncologists, urologists, pharmacologists, pathologists and therapy specialists would require a linear accelerator.

Multidisciplinary approaches generally improve clinical outcomes and involve diminished morbidity. Common features include: the collaboration of multiple disciplines including urology, radiation oncology, hematology oncology, and a host of supportive professionals, a common medical record, a tumor board that focuses on contemporaneous review of cases. With the concentrated effort, the community of physicians and providers develop a deeper understanding of risk profiles of patients, impact of changes in treatment regimen on both elimination of the cancerous tissue and preservation of vital functions in nearby organs. Ready communication across the multidisciplinary approaches including incontinence nursing, behavioral therapy, and biofeedback, erectile dysfunction therapy, radiation injury/wound nurses, and pharmacology working together make a significant care difference. A single medical record diminishes redundancy of both laboratory radiography and paperwork. When medical care was primarily an inpatient service, this type of coordination occurred in the hospital. Technology has shifted care to the outpatient setting where services are dispersed to multiple locations. Today, we need new systems to accommodate the shift.

Radiation therapy involving IMRT on equipment that has on-board imagers produces valuable information for patient management. Today, that information is used only to position the patient for the treatment. In a focused center that has a single medical record, these images can be shared among disciplines, reduce the number of imaging studies done mid-treatment and have a significant impact on the total cost of care management. Because the urologists will be in the center, radiologists and urologists together will have the advantage of viewing real-time images while the patient is available to discuss how his body is reacting to treatment.

Cary Urology's two years of experience with brachytherapy confirms the patient outcome value of cooperation across medical disciplines. We now involve a urologic pathologist and have a urologist and radiation oncologist in our office cooperating on care regimens for our patients. Potential complications are, thus, carefully considered and advanced by both sets of clinical skills. Cary Urology staff also includes a registered nurse who has specialized training in bladder and sphincter rehabilitation post treatment. This multidisciplinary approach within the confines of the same office has dramatically improved the Cary Urology's efficiency, efficacy, and the patient satisfaction.

A model is working at MD Anderson Prostate Cancer Center. See Attachment E.

3. Development of Evidence-Based Protocols

Health care delivery is now sharply focused on repeatable best practices. Concentrating prostate cancer care in one location will provide more opportunities to organize, refine, and challenge assumptions about treatment approaches. A focused prostate health center will provide a continuous learning organization, which is one of the key recommendations of the NIH classic report, *Crossing the Quality Chasm*. The fifth platform of the document, Evidence-based Decision Making, is taking shape. To be effective, it requires continuous information on the same processes applied to people who have similar problems.

4. Value to North Carolina Cancer Registry

North Carolina has an excellent Central Cancer Registry. The Central Cancer Registry (CCR) collects, processes, and analyzes data on all cancer cases diagnosed among North Carolina residents. All health care providers are required by law to report cases to the CCR, but the primary data source is the hospitals of the state. The CCR supplements hospital data with reports from physicians who diagnose cases that are not seen in a hospital. Death certificates and pathology laboratory reports are used to help identify cases that are missed in the routine reporting. Duplicate reports are consolidated in the data editing process. This is primarily a cancer surveillance activity, monitoring the incidence of cancer among the various populations of the state. Finding and refining data for cases treated outside the hospital presents a challenge. With a dedicated prostate center, outpatient data quality should improve substantially.

5. Evaluation

We will soon initiate a database to record and measure at least three definable types of radiation injury to our prostate patients: radiation prostatitis, radiation cystitis and admissions to the hospital for hematuria or other surgical corrections. In just two of the involved practices, we will have a sizeable database by the time of the application. Within a year of operation, we should begin to see a measurable change in patient outcomes.

Shaw University's Daniel Howard, PhD, and the Institute for Health, Social and Community Research have expressed willingness to assist with the outreach and outcomes evaluation. See Attachment F for information.

Particular Need / Opportunity in Service Area 20

North Carolina has high prostate cancer rates, and rates are particularly high among African Americans. Service Area 20, which includes Wake, Harnett and Franklin Counties, is uniquely suited for a prostate health center with a linear accelerator.

- It is the only North Carolina Linear Accelerator Service Area in which the ratio of residents to linear accelerator exceeds 120,000. Page 152, the *Proposed 2009 State Medical Facilities Plan* shows a ratio of 129,000. Thus it meets one of the criteria in the Methodology on page 145 for showing need for an additional linear accelerator.
- Service Area 20 is approximately 22 percent African American, according to the State Demographer. One in five males in Service Area 20 is at high risk.
- Using SEER data, the State Center for Health Statistics estimates that Service Area 20 had approximately 500 new prostate cancer cases in 2007. With half of them candidates for linear accelerator treatment, the area has enough prostate cancer patients in its boundaries to satisfy the standard of 250 patients for a linear accelerator. In fact, fewer than 180 patients can make a program viable.
- The population of this area is also growing faster than the state average.

County	Estimated 2007 Prostate Cancer Cases
Wake	390
Harnett	65
Franklin	35
Total	490

<http://www.schs.state.nc.us/SCHS/CCR/proj07co.pdf>

At present, Service Area 20 has more than 20 urologists and eight radiation centers. In the three counties, chemotherapy is delivered in hospitals, radiation centers and in hematology/oncology offices. All of these providers have different medical record systems. Their service locations are scattered over a 1.5-hour travel radius. This presents more than 160 different possible medical records for prostate cancer patients. There is no practical way to have effective tumor boards and multidisciplinary approaches to this disease entity with such a structure. The sheer number of treatment locations works against any effective coordination among physician specialists treating the same patient.

The support of the vast majority of urologists in Service Area 20, along with radiation oncologists and medical oncologists provides a strong clinical infrastructure. Social support through churches and support groups will extend the outreach and feedback to clarify the value of treatment in the social network.

We have enthusiastic support from churches, prostate cancer support groups, and African American prostate support groups. No patient with cancer has ever been turned away from Cary Urology for lack of payment and the same policies will apply to this organization. For the proposed prostate health center, churches and support groups throughout the service area have pledged support and participation in continuous outreach. These groups play an essential role in maximizing exposure and education among people at risk.

Thus, Service Area 20 is an ideal location in which to demonstrate the effectiveness of multidisciplinary prostate health care.

ADVERSE EFFECTS ON THE POPULATION IF THE ADJUSTMENT IS NOT MADE

Service Area 20

Generally, the Radiation Oncology-Linear Accelerator Methodology has successfully provided statewide access to linear accelerators. However, access remains uneven. Urban centers like Areas 10 and 12 (Guilford and Forsyth) have 69,000 and 80,000 persons per operational linear accelerator, almost twice as much access as Area 20. According to the Proposed 2009 State Medical Facilities Plan, the Service Area 20 ratio is 129,000. Service Area 20 will continue to have the lowest access in the state.

Prostate Care

Focus of the equipment is a second problem. Application of the State's Methodology has produced centers that treat all types of cancers. In fact, the reviews favor the multispecialty centers, focusing on quantities of people served and unit cost per person served. Prostate cancer care is focused and involves more treatments per patient. Without a designated focus in the Plan, this densely populated area may never realize the benefits of a focused center.

It took multiple CON applications for replacement equipment for the state to approve stereotactic radiation therapy. Stereotactic radiation is far more expensive and benefits only a small proportion of cancer patients. By contrast, prostate cancer patients account for approximately 20 percent of radiation therapy patients and none of the approved equipment is dedicated to treatment of prostate or male urologic cancers.

Nationally, there is a shortage of urologists that was caused by closure of training programs a decade ago. Efficiently using the time of these specialists is an important feature of access to care. Access is one of the key reasons for late treatment of prostate cancer among high risk groups. Late stage

intervention has less probability of five-year survival, hence the likelihood that an area where one in five persons is African American will sustain above average death rates. North Carolina death rates from prostate cancer stay above the national norm. North Carolina ranks second nationally in prostate cancer in African-American men.

In Service Area 20, where cancer care is so disperse, prostate cancer patients whose optimal choice involves external beam radiotherapy may stay disconnected from their urologists during three crucial months. When treatment is complete, the patients will still return to the urologists, for aftercare of the effects of radiation treatment and of life without a prostate. Side effects of the harm to blood vessels will continue to show up months after the radiation treatment. Radiation damage to these tissues is not reversible; the body does not repair itself quickly enough. The community will lose the chance to reduce/eliminate the complications by involving the specialty that is trained to recognize small anatomical differences in the radiation treatment process.

Without a prostate health center as described here, patients getting combination therapies (surgery + external beam (linear accelerator) + brachytherapy) will continue to scuttle around, getting care at multiple locations. Medical records will remain fractionated in multiple non-compatible formats. Imaging studies will be repeated and pharmaceutical regimens will be at risk of coordination failures.

Information that could alter treatment approaches on the individual patient or across multiple patients will not be shared among the physicians who are treating them; patients may have images done by both the radiation oncologist and the urologist, which is not cost effective. Tumor boards will continue with a generalized focus on multiple types of cancers and local knowledge about prostate cancer will develop slowly.

Without specific ties to local advocacy groups, local treatment centers will have less impact on the information that is communicated to persons at high risk of prostate cancer and the physician community. Advocacy groups lack the resources to do this independently.

Male Health

Over its 20 years, Cary Urology has pioneered achievements in men's health including cutting edge services such as da Vinci prostatectomies, in-office prostate brachytherapy, and incontinence therapy, erectile dysfunction management, and counseling.

Notwithstanding multiple advances during the 21st century, male longevity continues to lag in comparison to the female counterpart and the divide is growing. In the 1900s, the average life expectancy was similar for males and females. Today, women are expected to live five to six years longer. Men's health issues are varied and complex and bridge physical and mental well being. Even with these achievements to protect against the current high death rate for male urologic cancers, more are needed. Without a focused center, advances will come more slowly.

ALTERNATIVES CONSIDERED AND REJECTED

Status Quo

Status quo fails to address the issues around prostate cancer treatment in North Carolina and specifically in Service Area 20. If it worked, the disparities would not exist and outcomes would be better.

Cary Urology is a multidisciplinary prostate health center within the limits of state statutes. Cary Urology offers four urologists, a radiation oncologist who provides brachytherapy in collaboration with the urologists, and a licensed pelvic rehabilitation specialist nurse and urologic pharmacologist. It successfully treats approximately 25 percent of its prostate cancer patients in its offices with excellent results. However, it is unable to directly treat the remaining majority, because state law requires a Certificate of Need to obtain a linear accelerator and none is available. Other urologists in Service Area 20 offer office consultation and surgical services. Attracting a hematologist oncologist to work specifically with prostate cancer patients requires a critical mass of patients. Organizing a critical mass requires a linear accelerator that can be shared among practicing physicians.

Work with Existing Radiation Therapy Providers

Sheer limitation of time prevents urologists from visiting every linear accelerator in Raleigh once a week, let alone once every day, to observe patient progress. Already in short supply, the 20 practicing urologists in Service Area 20 do not have the time to continuously observe individual patients among the eight (8) radiation treatment centers. For the medical records alone, this involves 160 different possible combinations of data formats. This is impossible to handle in a well-supplied discipline. It is unfathomable in a shortage specialty. Nationwide, almost half (47.21 percent) of practicing urologists are over 55. The supply of urologists is approximately 5 to 10 percent less than needed today and, at current trends, the shortfall will grow to approximately 20 percent in the next 15 to 20 years.

There is also no practical way to have effective tumor boards that focus on prostate cancer at eight separate locations involving the same urologists.

The urology workforce by the numbers

Number of active urologists (2006)	9,864
Number of people per urologist (2006)	30,200
Estimated percentage of urologists who are women	3.94% (389)
Estimated percentage of urologists age 55 years and older	47.21% (4,657)
Estimated percentage of urologists with foreign medical degrees	16.29% (1,607)
Estimated percentage increase in urologists, 1995 to 2004	7.73%

Source: Adapted from *Physician specialty data: a chart book*. Center for Workforce Studies, Association of American Medical Colleges. August 2006

Support and Sustain Existing Outreach Networks

The advocacy groups have an extensive network of prostate screening and awareness activities. These are important and are tied back to urologists in the service area. However, the screening effort is not directed back to a central treatment program. Hence, it becomes diluted; patients are individually separated and segregated, and the screening alone does not improve patient outcomes.

Wait for Need in a Future State Medical Facilities Plan

As noted earlier, the structure of the SMFP and review criteria favor linear accelerators in centers that treat all types of cancer and focus on optimizing the linear accelerator equipment. We filed a CON application for a focused center in 2007. That application was found fully conforming, but was denied because another center would reach more people faster. That center was an existing general radiation oncology center that had an organized base of patients. Moreover, while that approval is in litigation, and with the current formula requiring existing or approved CON's to be performing at 6,750 ESTV's each, it may take years to show additional need in Service Area 20.

Let Existing Providers Mature and Address Issue – Eventually

Effectively, this is the status quo option. It has failed. The Rex Prostate Cancer Center of Excellence funded by Jimmy Valvano Foundation to the Rex Hospital Foundation received \$500,000 over three years. The funding involves education and data collection. This center does not have a multidisciplinary care team of urologists and radiation oncologists. Outreach and Education, Community Screenings, Clinical Treatment and Follow up, and Survivorship are mentioned on the website, but there is no program description. The website describes a Support Group – second Thursday of each month. Free screening once a year. No urologists are involved in program.

Duke Prostate Research involves long waits, and lacks consistency. Service is not continuous or daily, is currently available only on Tuesday and Friday. Urologist and radiation oncologist are in the same building, but not an integrated team that practices together every day. Patients wait hours for consults among the specialists.

UNC-CH offers a support group on the first Wednesday of each month.

These efforts acknowledge the problem, but are making only minor inroads on changes in care delivery. They are not reaching the community physicians who care for large numbers of patients.

EVIDENCE THAT DEVELOPMENT OF PROPOSED SERVICE WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA

This project would not involve duplication.

- There is no existing comparable service in North Carolina.
- High rates of prostate cancer persist in the face of the number of available linear accelerators in Service Area 20.
- Even with the recent approved 2007 linear accelerator, there are more than 120,000 people per linear accelerator in Service Area 20, the only such high ratio in the state.
- Wake County alone is projected to have +200 cases of prostate cancer among non-white population and almost 400 recorded new cases overall in 2007, according to the NC Center for Health Statistics.
- Support Groups agree. Please see many letters of support from grassroots groups that are attached to this petition. (Attachment D)

CONCLUSION

This proposal involves a unique approach to a disease focus that affects more than 250,000 North Carolinians. Organized as proposed, the center would organize the energy and attention of all staff around that disease at all times. Appropriately executed, it should improve treatment for persons with prostate cancer, and promote an understanding of factors that facilitate the disease and help prevent prostate cancer. Its outreach arm should find patients earlier, when tissue preservation is easier.

This is the right time and Service Area 20 is the right place for a multidisciplinary center focused on a disease that affects one in six men. With 490 annual new prostate cancer cases, the service area has sufficient need and a large high risk population to justify a center. It has both urban and rural communities in which to test outreach approaches. It has willing community urologists.

Prostate cancer is a debilitating disease, whose treatment is typically intense and extends over long periods of time – months and even years. It involves the resources and energy of whole families. Studies have repeatedly shown that patients defer treatment when access to care is an issue. Quality studies also demonstrate over and over again the cost savings associated with doing things correctly the first time. A person who gets radiation burns from prostate cancer treatment cannot reverse that outcome. He will seek other treatments to address the side effects: wound therapy, surgery, biofeedback and counseling for sexual and urinary dysfunction, etc.

Men receiving treatment for urologic cancers can suffer from numerous side effects, including urinary, bowel and erectile dysfunction, loss of fertility, testosterone loss, and nerve damage. Ten percent to 25 percent of men with prostate cancer have bladder control problems two years after surgery or radiation therapy, according to research compiled by the Prostate Cancer Foundation. Impotence is even more common; up to 80 percent of men report problems after surgery or radiation. Some men's symptoms get better in time; most patients are never the same.

The management and treatment of these side effects can be more easily managed by a team that offers diagnosis, treatment, follow-up care and counseling at one location. The entire medical staff will have input into the treatment options and will have access to records regarding each patient's history when addressing individual responses to treatment. This will provide each patient convenient access to more individualized and comprehensive treatment from one staff with the optimum opportunity to confer on options.

We can measure the impact and test the outcomes statistically.

A linear accelerator is a key component and cannot be added unless one is made available in the 2009 State Medical Facilities Plan (SMFP). If the SMFP includes a linear accelerator and does not specify prostate health as the intended focus of that equipment, the area will have a low likelihood of getting a multidisciplinary prostate health care center.

Attachments: **A** – Prostate Gland Anatomy
B – North Carolina versus National Prostate Cancer Rates
C – Department of Defense Prostate Cancer Research Program
D – Support Letters
E – MD Anderson Prostate Cancer Center Process
F – Outcomes Research

Responses to questions we have been asked

Q How will you reach low-income persons at risk?

A See letters of support. We have expanded our already strong network of outreach to prostate support groups and community churches and they have responded enthusiastically. We would fund a position to translate clinical information to respond to community questions and concerns. Many people at risk are in the work force and have little spare time to participate in support groups, so we will focus on community communication techniques well developed by economic, political and social outreach organizations. Our research team from Shaw University is particularly experienced in this respect. We will conduct screenings in community clinics, as we do now. Cary Urology alone offers free screens to almost 1,000 men a year in rural and urban locations.

As we probe the issue, we are learning that cultural expectations, social norms and plain knowledge play a big role in men's willingness to get screened.

Health Departments in North Carolina play an active role in preventive health. We intend to share information with them, as well. Health departments have no specific funding for men's health.

Q How will you make it affordable?

A The resources provided by linear accelerator reimbursement will fund both charity care and protocol research and publication. A strong charity care policy will be mandatory.

Q This project represents a state precedent – what will prevent others from asking for a disease specific center?

A In an urban setting, where scarce specialty providers become separated from one another and have little time for essential collaboration, more disease specific centers are a good idea, one supported and endorsed by the National Institutes of Health in *Crossing the Quality Chasm*. The North Carolina CON statute and the State Medical Facilities Plan already encourage dedicated specialty gastroenterology centers.

The state's task will be to monitor appropriate distribution, to consider convenient location, a care delivery structure that supports collaborative care protocol development, to set the criteria for such centers and to assure sufficient organized volume to support a single disease focused program.

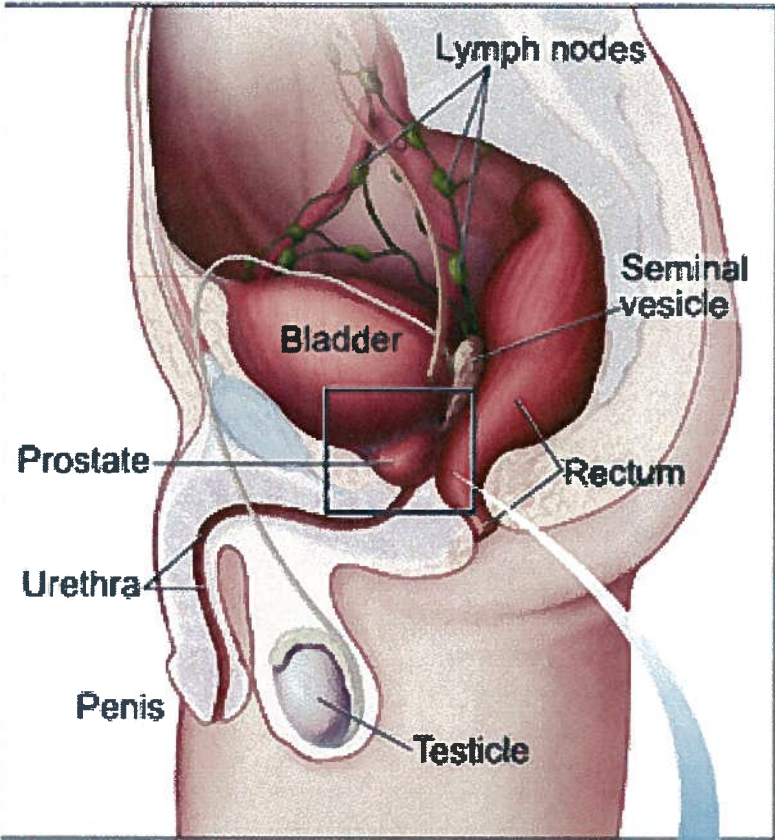
Q Can you measure the impact?

A Yes, we will be initiating a baseline database against which to measure the impact of this proposed approach. We will engage an outside evaluator and have a preliminary commitment from a team at Shaw University whose background is included in an Attachment to this Petition. (Attachment F)

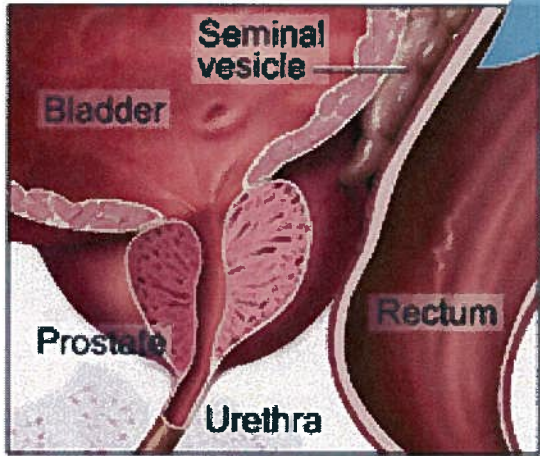
Q What this model share to benefit others statewide?

A This is a unique approach to care in North Carolina. Because we will be doing and evaluating, we will have results: clinical protocols that work or prove difficult, outreach approaches that do or do not increase contact with persons at risk, stage at which we find patients who have prostate cancer. We will learn what aspects of the multidisciplinary approach most benefit the patients we serve in terms of cost, satisfaction and clinical results. Over time, we expect to see an impact on cancer death rates. Near term we expect to see an improvement in quality of life.

**Attachment A
Prostate Gland Anatomy**



This shows the prostate and nearby organs.






















This shows the inside of the prostate, urethra, rectum, and bladder.

State Cancer Profiles



















Death Rates

Send to Printer (Choose Landscape) | Close Window

Death Rate Report for North Carolina by County, death years through 2004									
Prostate									
Healthy People 2010 Objective Number: 03-07									
Reduce the prostate cancer death rate.									
All Races (includes Hispanic), Male, All Ages									
Sorted by Rate									
County	Met Healthy People Objective of 28.8? ¹	Annual Death Rate over rate period deaths per 100,000 (95% Confidence Interval)	Average Deaths per Year over rate period	Rate Period	Recent Trend ²	Recent Annual Percent Change ² in Death Rates (95% Confidence Interval)	Recent Trend Period ²		
North Carolina (State)	No	32.4 (31.4, 33.4)	906	2000 - 2004	falling ↓	-4.3 (-5.0, -3.7)	1994 - 2004		
United States	Yes	27.9 (27.7, 28.0)	30,160	2000 - 2004	falling ↓	-4.1 (-4.2, -3.9)	1994 - 2004		
Northampton County	No	63.5 (43.9, 89.0)	7	2000 - 2004	**	**	**		
Hoke County	No	56.9 (32.7, 89.4)	4	2000 - 2004	**	**	**		
Martin County	No	56.7 (36.1, 83.9)	5	2000 - 2004	**	**	**		
Sampson County	No	54.5 (40.9, 70.7)	11	2000 - 2004	rising ↑	2.5 (0.5, 4.5)	1980 - 2004		
Vance County	No	50.9 (34.3, 71.8)	7	2000 - 2004	stable →	-0.4 (-2.9, 2.2)	1980 - 2004		
Warren County	No	48.5 (30.7, 72.9)	5	2000 - 2004	stable →	-0.1 (-3.5, 3.4)	1980 - 2004		
Richmond County	No	48.0 (33.5, 66.3)	8	2000 - 2004	stable →	1.3 (-0.9, 3.5)	1980 - 2004		
Duplin County	No	47.4 (33.5, 64.5)	8	2000 - 2004	stable →	-0.7 (-2.7, 1.3)	1980 - 2004		
Granville County	No	47.0 (32.1, 65.6)	7	2000 - 2004	stable →	-0.5 (-3.6, 2.7)	1980 - 2004		
Wayne County	No	46.8 (36.4, 59.0)	16	2000 - 2004	stable →	-1.1 (-2.6, 0.5)	1980 - 2004		
Pasquotank County	No	46.7 (31.4, 66.3)	6	2000 - 2004	stable →	-1.2 (-3.3, 1.0)	1980 - 2004		

Robeson County	No	46.6 (36.6, 58.2)	16	2000 - 2004	stable 	-1.0 (-2.8, 0.8)	1980 - 2004
Person County	No	46.5 (31.1, 66.3)	6	2000 - 2004	stable 	0.6 (-2.2, 3.5)	1980 - 2004
Hertford County	No	45.8 (27.9, 70.3)	4	2000 - 2004	falling 	-2.3 (-4.5, -0.1)	1980 - 2004
Pender County	No	44.7 (29.8, 63.6)	7	2000 - 2004	**	**	**
Nash County	No	43.3 (33.0, 55.5)	13	2000 - 2004	stable 	0.3 (-1.5, 2.1)	1980 - 2004
Halifax County	No	43.0 (31.5, 57.1)	10	2000 - 2004	stable 	-0.5 (-2.6, 1.8)	1980 - 2004
Lenoir County	No	42.4 (30.6, 56.8)	10	2000 - 2004	stable 	0.4 (-1.8, 2.8)	1980 - 2004
Edgecombe County	No	41.7 (28.6, 58.3)	7	2000 - 2004	stable 	-2.1 (-4.4, 0.3)	1980 - 2004
Harnett County	No	41.2 (30.0, 54.6)	10	2000 - 2004	stable 	-1.2 (-2.6, 0.2)	1980 - 2004
Scotland County	No	40.6 (24.2, 62.7)	4	2000 - 2004	stable 	0.2 (-3.1, 3.7)	1980 - 2004
Durham County	No	40.4 (33.6, 48.0)	26	2000 - 2004	stable 	-1.2 (-2.6, 0.2)	1980 - 2004
Caswell County	No	40.1 (23.5, 63.3)	4	2000 - 2004	stable 	1.4 (-2.1, 5.1)	1980 - 2004
Cumberland County	No	39.1 (32.0, 47.1)	24	2000 - 2004	stable 	-1.2 (-2.9, 0.6)	1980 - 2004
Bladen County	No	39.1 (24.3, 58.9)	4	2000 - 2004	stable 	1.3 (-1.8, 4.5)	1980 - 2004
Orange County	No	38.3 (28.4, 50.0)	11	2000 - 2004	stable 	-0.1 (-2.2, 2.1)	1980 - 2004
Pitt County	No	37.8 (28.8, 48.4)	13	2000 - 2004	falling 	-5.1 (-8.2, -1.8)	1989 - 2004
Chatham County	No	37.2 (27.0, 49.8)	9	2000 - 2004	stable 	-1.2 (-3.6, 1.2)	1980 - 2004
Franklin County	No	37.1 (23.8, 54.3)	5	2000 - 2004	stable 	0.9 (-2.7, 4.5)	1980 - 2004
Cleveland County	No	37.0 (28.5, 47.2)	13	2000 - 2004	stable 	-0.0 (-1.8, 1.8)	1980 - 2004
Anson County	No	36.9 (22.1, 57.3)	4	2000 - 2004	**	**	**
Wake County	No	36.3 (31.6, 41.4)	48	2000 - 2004	stable 	-1.0 (-2.0, 0.1)	1980 - 2004
Montgomery County	No	36.3 (20.9, 57.6)	4	2000 - 2004	**	**	**

Lee County	No	36.1 (24.5, 50.8)	7	2000 - 2004	stable	-0.9 (-3.4, 1.7)	1980 - 2004
Madison County	No	36.0 (21.2, 57.1)	4	2000 - 2004	**	**	**
Alexander County	No	36.0 (21.3, 55.8)	4	2000 - 2004	**	**	**
Bertie County	No	35.7 (20.1, 58.5)	3	2000 - 2004	**	**	**
Craven County	No	34.3 (25.7, 44.7)	12	2000 - 2004	stable	-1.4 (-3.8, 1.1)	1980 - 2004
Yancey County	No	33.4 (19.4, 54.1)	3	2000 - 2004	**	**	**
Wilkes County	No	33.2 (24.0, 44.5)	9	2000 - 2004	stable	-0.2 (-2.1, 1.8)	1980 - 2004
Ashe County	No	32.8 (20.6, 49.7)	5	2000 - 2004	**	**	**
Wilson County	No	32.6 (23.0, 44.4)	8	2000 - 2004	stable	-1.7 (-3.6, 0.1)	1980 - 2004
Stokes County	No	32.4 (20.5, 48.2)	5	2000 - 2004	stable	-0.3 (-3.1, 2.6)	1980 - 2004
Carteret County	No	32.0 (23.5, 42.5)	10	2000 - 2004	stable	-0.6 (-2.3, 1.2)	1980 - 2004
Cabarrus County	No	31.6 (24.2, 40.3)	13	2000 - 2004	rising	2.5 (0.1, 5.1)	1980 - 2004
Yadkin County	No	31.4 (19.7, 47.2)	5	2000 - 2004	**	**	**
Mecklenburg County	No	31.3 (27.5, 35.3)	54	2000 - 2004	falling	-2.1 (-3.2, -1.1)	1980 - 2004
Alamance County	No	31.2 (24.7, 38.7)	17	2000 - 2004	stable	-1.1 (-3.1, 0.8)	1980 - 2004
Columbus County	No	30.8 (20.7, 43.7)	6	2000 - 2004	stable	-19.8 (-37.5, 3.0)	1999 - 2004
Gaston County	No	30.4 (24.5, 37.3)	20	2000 - 2004	stable	-0.6 (-2.2, 0.9)	1980 - 2004
Forsyth County	No	29.9 (25.3, 35.1)	32	2000 - 2004	falling	-1.9 (-3.0, -0.8)	1980 - 2004
Guilford County	No	29.9 (26.0, 34.2)	43	2000 - 2004	falling	-10.8 (-19.8, -0.9)	1999 - 2004
Rockingham County	No	29.9 (22.6, 38.7)	12	2000 - 2004	stable	-1.1 (-3.7, 1.5)	1980 - 2004
Brunswick County	No	29.7 (21.3, 40.1)	10	2000 - 2004	stable	-0.5 (-3.3, 2.3)	1980 - 2004
Catawba County	No	29.5 (22.7, 37.5)	14	2000 - 2004	falling	-7.3 (-11.4, -2.9)	1994 - 2004
Johnston County	No	29.5 (21.5, 39.2)	10	2000 - 2004	stable	-1.7 (-3.9, 0.5)	1980 - 2004

Union County	No	29.3 (21.5, 38.8)	10	2000 - 2004	falling 	-7.8 (-11.8, -3.8)	1990 - 2004
Watauga County	No	28.9 (17.6, 44.4)	4	2000 - 2004	**	**	**
Stanly County	Yes	28.8 (19.8, 40.3)	7	2000 - 2004	stable 	-0.5 (-3.1, 2.1)	1980 - 2004
Caldwell County	Yes	28.3 (20.4, 38.2)	9	2000 - 2004	stable 	-1.4 (-3.7, 1.1)	1980 - 2004
Haywood County	Yes	27.3 (19.6, 37.1)	9	2000 - 2004	stable 	1.1 (-1.2, 3.4)	1980 - 2004
Onslow County	Yes	27.3 (18.3, 38.4)	8	2000 - 2004	stable 	-3.2 (-6.5, 0.2)	1980 - 2004
Davidson County	Yes	27.3 (21.2, 34.5)	15	2000 - 2004	stable 	-0.6 (-3.0, 1.8)	1980 - 2004
Randolph County	Yes	26.5 (20.0, 34.4)	11	2000 - 2004	stable 	0.2 (-1.9, 2.3)	1980 - 2004
New Hanover County	Yes	26.5 (21.0, 33.0)	17	2000 - 2004	falling 	-2.5 (-4.0, -1.0)	1980 - 2004
Buncombe County	Yes	26.4 (22.0, 31.5)	26	2000 - 2004	falling 	-5.5 (-8.6, -2.2)	1992 - 2004
Surry County	Yes	26.4 (18.8, 35.9)	8	2000 - 2004	stable 	-1.7 (-3.8, 0.5)	1980 - 2004
Rutherford County	Yes	26.2 (18.6, 35.9)	8	2000 - 2004	stable 	-0.4 (-2.8, 2.0)	1980 - 2004
Macon County	Yes	26.2 (17.5, 38.4)	6	2000 - 2004	**	**	**
Lincoln County	Yes	26.2 (17.2, 37.9)	6	2000 - 2004	stable 	-1.2 (-3.7, 1.5)	1980 - 2004
Iredell County	Yes	25.5 (19.2, 33.0)	12	2000 - 2004	stable 	-1.3 (-3.0, 0.4)	1980 - 2004
Beaufort County	Yes	25.4 (16.5, 37.4)	5	2000 - 2004	falling 	-4.0 (-7.1, -0.8)	1983 - 2004
Rowan County	Yes	25.2 (19.6, 31.9)	14	2000 - 2004	falling 	-8.0 (-12.5, -3.2)	1993 - 2004
Henderson County	Yes	24.9 (19.7, 31.2)	16	2000 - 2004	stable 	-0.9 (-2.7, 0.8)	1980 - 2004
Moore County	Yes	23.6 (18.0, 30.6)	12	2000 - 2004	falling 	-3.5 (-5.3, -1.6)	1980 - 2004
Davie County	Yes	23.4 (13.6, 37.2)	4	2000 - 2004	stable 	-2.6 (-5.9, 0.8)	1980 - 2004
Cherokee County	Yes	21.6 (12.4, 35.4)	3	2000 - 2004	**	**	**
Transylvania County	Yes	20.9 (12.6, 33.1)	4	2000 - 2004	**	**	**

County	Yes	20.1 (13.7, 28.3)	7	2000 - 2004	stable	-2.1 (-4.4, 0.2)	1980 - 2004
Burke County	Yes						
McDowell County	Yes	18.6 (10.5, 30.3)	3	2000 - 2004	**	**	**
Alleghany County	*	*	3 or fewer	2000 - 2004	**	**	**
Avery County	*	*	3 or fewer	2000 - 2004	**	**	**
Camden County	*	*	3 or fewer	2000 - 2004	**	**	**
Chowan County	*	*	3 or fewer	2000 - 2004	**	**	**
Clay County	*	*	3 or fewer	2000 - 2004	**	**	**
Currituck County	*	*	3 or fewer	2000 - 2004	**	**	**
Dare County	*	*	3 or fewer	2000 - 2004	**	**	**
Gates County	*	*	3 or fewer	2000 - 2004	**	**	**
Graham County	*	*	3 or fewer	2000 - 2004	**	**	**
Greene County	*	*	3 or fewer	2000 - 2004	**	**	**
Hyde County	*	*	3 or fewer	2000 - 2004	**	**	**
Jackson County	*	*	3 or fewer	2000 - 2004	**	**	**
Jones County	*	*	3 or fewer	2000 - 2004	**	**	**
Mitchell County	*	*	3 or fewer	2000 - 2004	**	**	**
Pamlico County	*	*	3 or fewer	2000 - 2004	**	**	**
Perquimans County	*	*	3 or fewer	2000 - 2004	**	**	**
Polk County	*	*	3 or fewer	2000 - 2004	**	**	**
Swain County	*	*	3 or fewer	2000 - 2004	**	**	**
Tyrrell County	*	*	3 or fewer	2000 - 2004	**	**	**
Washington County	*	*	3 or fewer	2000 - 2004	**	**	**

Notes:

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State Cancer Registries may provide more current or more local data. Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

Trend

Rising when 95% confidence interval of annual percent change is above 0.

Stable when 95% confidence interval of annual percent change includes 0.

Falling when 95% confidence interval of annual percent change is below 0.

* Data has been suppressed to ensure confidentiality and stability of rate estimates.

** Data are too sparse to provide stable estimates of annual rates needed to calculate trend.

1 Healthy People 2010 Objectives provided by the Centers for Disease Control and Prevention.

2 Recent trend in death rates were calculated using the Joinpoint Regression Program and are expressed as the annual percent change over the recent trend period. Recent trend period is the period since last change in trend as determined by Joinpoint.

Source: Death data provided by the National Vital Statistics System public use data file. Death rates calculated by the National Cancer Institute using SEER*Stat. Death rates are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). The Healthy People 2010 goals are based on rates adjusted using different methods but the differences should be minimal. Population counts for denominators are based on Census populations as modified by NCI.

"The U.S. Army's CDMRP is one of the best examples of direct action that is specifically dedicated to targeting prostate cancer and eliminating its tragic consequences ... the CDMRP is highly respected and is the example that other research programs should be modeled after. It was an honor to serve on the Integration Panel and to have the final review of, and vote for, the very best therapies specifically targeted against prostate cancer."

John Willey, Consumer Programmatic Reviewer, PCRCP

Program Focuses

To fill important research gaps, the PCRCP has focused on four broad areas:

- **Impacting Patients' Lives:** bringing new discoveries to patients through clinical research and trials
- **Eliminating Health Disparity:** eliminating the disparate burden of prostate cancer on the African-American community and other affected populations
- **Exploring Innovative, Groundbreaking Ideas and Technology:** funding high-risk and high-gain research of exciting new ideas
- **Training the Next Generation of Researchers:** inspiring and training prostate cancer researchers during their early career stages

Research Funding Strategy of the PCRCP

The PCRCP has implemented research and training award mechanisms that are specifically aimed at filling critical gaps and moving the field of prostate cancer research closer to finding a cure.

AWARD MECHANISM	FOCUS
• Clinical Consortium Award: provides resources to facilitate the rapid execution of collaborative Phase II or Phase II-linked Phase I clinical studies	Impact
• Clinical Trial Award: funds the rapid execution of novel Phase I, Phase I/II, or Phase II clinical trials	Impact
• Collaborative Undergraduate HBCU Student Summer Training Program Award: provides educational and training opportunities in prostate cancer research for undergraduate students at Historically Black Colleges and Universities (HBCU)	Training
• Consortium Award: funds major, coordinated goal- or product-driven research effort that is multi-institutional and national in scope and addresses overarching themes	Disparity & Impact
• Exploration—Hypothesis Development Award: supports initial exploration of untested, potentially groundbreaking concepts in prostate cancer	Innovation
• HBCU Collaborative Partnership Award: fosters collaborations between an HBCU and another institution that establish sustained HBCU prostate cancer research and training programs focused on disparity	Disparity & Training
• Health Disparity Research Award: supports research on the disparate burden of prostate cancer within affected populations and communities	Disparity
• Health Disparity Training Award: provides training opportunities to researchers early in their careers to study the disparate burden of prostate cancer within affected populations and communities	Disparity & Training
• Idea Development Award: supports innovative ideas and technology across all areas of laboratory, clinical, behavioral, and epidemiological research, including clinical trials	Innovation
• New Investigator Award: funds innovative research from newly independent investigators working in collaboration with experienced prostate cancer researchers	Innovation & Training
• Physician Research Training Award: prepares physicians for careers in prostate cancer research through a mentored training experience in a laboratory or clinical setting	Impact & Training
• Prostate Cancer Training Award: provides prostate cancer research training opportunities to individuals early in their careers	Training

two gene variants of IGF-1 that were strongly associated with prostate cancer risk across all ethnic groups. Dr. Freedman, now at the Dana-Farber Cancer Institute, is testing over 1,000 gene markers in an African-American population to identify gene variants that contribute to increased risk of prostate cancer, thereby leading to more effective screening, prevention, and treatment strategies.

HBCU Collaborative Partnership Award.

The goal of this partnership between Florida A&M University (FAMU) and the Moffitt Cancer Center (MCC) is for FAMU to create "The FAMU Minority Prostate Cancer Training and Research (FAMU MPC) Center." After FAMU researchers, led by Dr. Folakemi Odedina, received mentoring and training from MCC scientists led by Dr. Nagalakshmi Kumar, the FAMU and MCC scientists collaborated on studies focused on health disparity and prostate cancer. Studies to develop community outreach and education programs have been highly successful. Products include kiosks in drug stores, consumer forums, online training modules, and television programs.

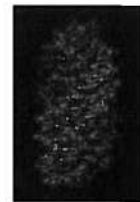
Exploring Innovative, Groundbreaking Ideas and Technology Idea Development Award.

Discovery of Gene Fusions. Dr. Arul Chinnaiyan of the University of Michigan discovered that gene fusions play a widespread role in the development of prostate cancer. Gene fusions, the accidental joining of the DNA in two genes, are commonly found in blood cancers but only rarely in solid tumors. Dr. Chinnaiyan's team found recurrent gene fusions between the prostate-specific androgen-regulated gene *TMPRSS2* and *ERG* or *ETV1* (two genes linked to leukemias) in approximately 80% of the prostate cancer tissue samples analyzed. These findings have broad implications for prostate cancer diagnosis and treatment, as the fused genes may provide both a novel biomarker and a therapeutic target in the majority of prostate cancers. Furthermore, these findings suggest a new model for cancer research: chromosomal rearrangements can occur in epithelial cancers.



New Investigator Awards.

Finding NEMO: A New Type of Cancer Therapy. Dr. Paula Bates and her colleagues at the University of Louisville discovered a class of synthetic molecules, called guanine-rich oligonucleotides (GROs), with a natural affinity for a protein (nucleolin) on the surface of cancer cells. After attaching to a tumor cell, GROs are drawn inside and trigger its death. This mechanism is different from any cancer therapy discovered thus far. Inside the cell, GROs target several proteins, including NEMO, a survival factor that helps cells become resistant to chemotherapy. A specific GRO (AGRO100/AS1411) showed promising antitumor activity with few adverse side effects in a recently conducted Phase I clinical trial.



Laser Technology to Improve Quality of Life. Urethral and bladder neck strictures (narrowing) occur as a consequence of prostate cancer surgery and result in urinary incontinence. In an effort to reduce scarring and recurrence of strictures, Professor Nathaniel Fried of Johns Hopkins University recently used a new laser technology (used in cosmetic wrinkle removal) to precisely incise the urethra and bladder neck during preclinical studies. Dr. Fried's laboratory showed that the Erbium:YAG laser is up to 30 times more precise than other lasers used in urology. These findings hold great promise for increasing the quality of life of thousands of men after prostate cancer surgery.

A New Genetic Link to Prostate Cancer in African Americans. Dr. Alex Lentsch of the University of Cincinnati College of Medicine suspected that there may be a link between the lack of a protein called DARC on red blood cells and the greater incidence and mortality of prostate cancer in the African-American



population. The absence of DARC on red blood cells is a genetic mechanism of protection against malaria. Approximately 70% of African Americans are missing DARC on their red blood cells. Dr. Lentsch's team found that red blood cells from DARC-deficient mice were unable to inhibit prostate tumor growth. Thus, the absence of DARC protein, which occurs in the majority of African Americans, may be a contributing factor to the increased mortality from prostate cancer in this population.

Exploration Hypothesis Development Awards.

Citrus Flavonoids and Prevention of Prostate Cancer. Dr. Susanne Henning of University of California, Los Angeles (UCLA) tested her hypothesis that nutrients in grapefruit and oranges called flavonoids have important biological functions besides their known effects as antioxidants. Dr. Henning and colleagues discovered that a particular citrus flavonoid called naringenin could stimulate DNA repair in prostate cancer cells. These data suggest that citrus fruits may have cancer-preventive effects that result from the prevention of gene mutations caused by environmental factors.



Training the Next Generation of Researchers

Prostate Cancer Training Awards.

Imaging. Dr. Baowei Fei of Case Western Reserve University envisions using imaging to create “before and after” treatment snapshots of the prostate to improve prostate cancer diagnosis and therapy. Dr. Fei's approach is to integrate structural and anatomical details with real-time, functional data from two or more different imaging techniques. Dr. Fei created novel image registration techniques that combine multiple imaging modalities for early detection and image-guided therapies for prostate cancer. These novel techniques could improve dosage planning for both external beam and brachytherapy treatments of prostate cancer.



New Blood Test. Dr. Xiaoju Wang and Dr. Arun Sreekumar of the University of Michigan developed a new blood test that is more accurate than the PSA test. This test is based on a panel of 22 biomarkers that together are more accurate than a single marker like PSA. These biomarkers generated false alarms only 12% of the time (compared to 80% for PSA). Importantly, the test was able to accurately identify prostate cancer in samples with intermediate PSA scores (2.5 to 10 ng/mL). This new prostate cancer test could potentially be used in combination with PSA screening and offers the hope of earlier and more accurate diagnosis.



Selenium-Induced Biomarkers. Dr. Yan Dong of the Roswell Park Cancer Institute identified a panel of biomarkers that respond to selenium. Selenium is a trace mineral found in seafood, grains, and vegetables that helps prevent cancer by protecting against the damaging effects of free radicals, boosting the immune system, and inhibiting tumor angiogenesis. Clinical trials testing selenium chemoprevention of prostate cancer are under way, and selenium-responsive biomarkers are needed to measure the effectiveness of selenium in these trials. Dr. Dong's team identified several candidate selenium-responsive biomarkers that provide exciting clues about selenium action and are potential diagnostic markers and therapeutic targets.

Physician Research Training Award.

Discovery of New Pathways in Hormone-Refractory Prostate Cancer. Dr. Ingo Mellinghoff of UCLA dissected signaling pathways that modulate function of the androgen receptor. He found the surprising results that a signaling pathway called the HER2/ERBB3 kinase pathway (and not the expected EGFR pathway) modulates androgen receptor function. These findings have clinical implication as they suggest that in hormone-refractory tumors the HER2/ERBB3 kinase pathway is a critical target for kinase inhibitor therapy.



Collaborative Undergraduate HBCU Student Summer Training Program Award.

Dr. Timothy McDonnell of The University of Texas M. D. Anderson Cancer Center and Dr. Debabrata Ghosh of Texas Southern University (TSU) lead a unique scientific training program with the ambitious goals of increasing the number of individuals with comprehensive training in prostate cancer and increasing the number of individuals from underrepresented populations in the scientific workforce. Undergraduate science majors from TSU attend courses and presentations at TSU and M. D. Anderson, perform intensive summer laboratory research at M. D. Anderson, present their work at local and national meetings, and receive follow-up training, mentoring, and career guidance.

Summary of PCRP Research Highlights

Basic Research. Basic research discoveries are critical in the fight against prostate cancer because they provide the foundation for the development of new diagnostic and therapeutic tools.

- Determining causes of health disparity and prostate cancer in African Americans (Dr. James Mohler)
- Discovery of the first gene fusions in prostate cancer (Dr. Arul Chinnaiyan)
- Discovery of biological functions in cancer of DARC (a protein implicated in health disparity of prostate cancer) (Dr. Alex Lentsch)
- Discovery of a signaling pathway that modulates androgen function (Dr. Ingo Mellingerhoff)



Prevention. One approach to fighting prostate cancer is to prevent the disease from occurring and decrease incidence rates.

- Discovery of mechanisms by which citrus flavonoids prevent prostate cancer (Dr. Susanne Henning)
- Identification of a panel of biomarkers that are responsive to selenium (Dr. Yan Dong)

Detection and Diagnosis. Men with early-stage prostate cancers have an excellent prognosis. Therefore, early detection and diagnosis of prostate cancer could greatly improve survival.

- Discovery of IGF-1 gene variants related to increased risk of prostate cancer (Dr. Matthew Freedman)
- Development of a new 22-biomarker blood test that is more accurate than the PSA test (Dr. Xiaoju Wang and Dr. Arun Sreekumar)

Treatment and Quality of Life. Once patients are diagnosed with prostate cancer, it is critical to provide effective treatments against the cancer and maintain a high quality of life.

- Creating an infrastructure to expedite multi-institutional clinical trials (Dr. Howard Scher)
- Developing new clinical therapeutics for late-stage prostate cancer (Dr. Jonathan Simons)
- Performing Phase I and II clinical trials of R.I.T.E. (Dr. Robert DiPaola)
- Discovery of a new class of cancer therapies called GROs (Dr. Paula Bates)
- Using laser therapy to reduce urinary incontinence (Dr. Nathaniel Fried)
- Development of new imaging techniques to guide therapies (Dr. Baowei Fei)



<http://cdmrp.army.mil/pcrp>

<http://cdmrp.army.mil>

CRESTVIEW BAPTIST CHURCH

1001 Plain View Highway • Dunn, NC 28334

(910) 892-2099

Don Davis ~ Pastor

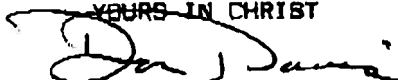
JULY 17, 2008

TO: STATE HEALTH COORDINATING COUNCIL AND
MEDICAL FACILITIES PLANNING SECTION
DIVISION OF HEALTH SERVICES REGULATION
2714 MAIL SERVICE CENTER
RALEIGH, NORTH CAROLINA 27699-2714

REF: LETTER IN SUPPORT OF PETITION REGARDING: RADIATION
ONCOLOGY-LINAC ACCELERATORS FOR THE 2009 STATE MEDICAL
FACILITIES PLAN.

I AM THE PASTOR AT CRESTVIEW BAPTIST CHURCH, DUNN
NORTH CAROLINA. PROSTATE CANCER AFFECTS ONE IN SIX MEN
NATIONALLY. NORTH CAROLINA, HOWEVER, HAS ONE OF THE HIGHEST
DEATH RATES IN THE COUNTRY FOR MEN, ESPECIALLY INDIGENT
AFRICAN-AMERICANS. WE ARE AWARE AND VERY CONCERNED ABOUT
THE DISEASE AND THE UNDERSERVED POPULATIONS INVOLVED. A
PROSTATE CANCER CENTER WILL HOPEFULLY HELP CHANGE THESE DEMOGRAPHYS.
WE LOOK FORWARD TO WORKING WITH THE PROSTATE CENTER AND
BRINGING THESE GENTLEMEN IN FOR SCREENING AND THERAPY. PLEASE
CONSIDER THIS LETTER OF SUPPORT FOR A PROSTATE CENTER IN
OUR AREA. THANK YOU.

YOURS IN CHRIST



DON DAVIS
PASTOR



*"Carrying the Sword Against Prostate Cancer for the
Next Generation"*

July 7, 2008

Kevin Khoudary, MD
Parkway Urology, P.A., d/b/a Cary Urology
105 SW Cary Parkway, Suite 300
Cary, NC 27511

Re: Proposed Prostate Cancer Center in Wake County

Dear Dr. Khoudary,

Thank you for taking the time to explain your vision for a prostate cancer center in Raleigh. I know from your commitment to the Action Team that you are passionate about reducing the morbidity and mortality of prostate cancer among African American males. The Action Team continues to see far too many men coming into treatment in the late stages of the disease. This is why we see screenings as a major tool in reducing the number of black men coming into treatment in the later stages of this disease. Many men still see this disease as a death sentence and this is far from the truth if the disease is caught early.

We must still overcome myths that are rooted in decade's old wrong information. We as an Action Team are vocal in our belief that black males must be part of clinical trials and the old concerns of harmful experimental treatments are not reality. We are particularly interested in your plans for active outreach that will aid our mission of getting accurate information into the community. Beyond the outreach, I am encouraged by your plans to offer a full range of options in one location: surgery, radiation and chemotherapy, along with post treatment therapies to help overcome some of the side effects of treatment. I particularly want our community to enjoy the benefits of having the radiation oncologist work directly with the urologist during radiation cancer treatment.

We support your efforts and we hope that the State Health Coordinating Council includes a Comprehensive Prostate Cancer Center in the 2009 State Medical Facilities Plan, allowing your vision to become a reality.

Sincerely,

James A. Smith, III / pp

James A. Smith, III, MD, DFAPA
President, NC Minority Prostate Cancer Awareness Action Team
"Carrying the Sword against Prostate Cancer for the Next Generation"

July 15, 2008

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Letter in support of Petition Regarding: Radiation Oncology – Linear
Accelerators For the 2009 State Medical Facilities Plan

I am the Pastor at Trinity A.M.-E Zion Prostate cancer affects one in six men nationally. North Carolina, however, has one of the highest death rates in the country for men, especially indigent African-Americans. We are aware and very concerned about the disease and the underserved populations involved. A prostate cancer center will hopefully help change these demographics. We look forward to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area. Thank you.

*always in chest
Pastor Ed*

515 S.E. BLVD
Greater Mt. Calvary

July 15, 2008

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Letter in support of Petition Regarding: Radiation Oncology – Linear
Accelerators For the 2009 State Medical Facilities Plan

I am the Pastor at Greater Mt. Calvary. Prostate cancer affects one in six men nationally. North Carolina, however, has one of the highest death rates in the country for men, especially indigent African-Americans. We are aware and very concerned about the disease and the underserved populations involved. A prostate cancer center will hopefully change these demographics. We look forward to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area. Thank you.

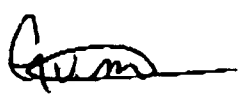
Sincerely in Christ,
Pastor Ruby T. Boykin
Pastor Ruby T. Boykin

July 15, 2008

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Letter in support of Petition Regarding: Radiation Oncology - Linear
Accelerators For the 2009 State Medical Facilities Plan

I am the Pastor at Faith Temple. Prostate cancer affects one in six men nationally. North Carolina, however, has one of the highest death rates in the country for men, especially indigent African-Americans. We are aware and very concerned about the disease and the underserved populations involved. A prostate cancer center will hopefully help change these demographics. We look forward to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area. Thank you.

Pastor Vincent 

February 1, 2008

Ms Lee Hoffman
Chief, CON Section
Division of Facility Services
701 Barbour Drive
Raleigh, NC 27603

RE: Letter in support of Parkway Urology, PA dba Cary Urology, PA (Cary Urology) proposed Certificate of Need application to acquire and operate a linear accelerator in Wake County

Dear Ms. Hoffman,

My name is Philip Newhal, M.D. I am a urologist and have been in practice in Raleigh for over 10 years. I am writing this letter to express support for Cary Urology's proposed Certificate of Need application to acquire and operate a linear accelerator at The Prostate Health Center in Wake County, for Service Area 20 (Wake, Harnett and Franklin County).

Cary Urology has been providing brachytherapy treatment services for prostate cancer in Wake County for two years and has a strong reputation for delivering quality services. External beam radiation therapy services will enhance the brachytherapy services allowing The Prostate Health Center to offer a full range of services for prostate health at one convenient location.

If The Prostate Health Center application is approved, I expect to direct 2 to 3 patients per month to The Prostate Health Center for prostate external beam radiation treatment.

Sincerely,



Philip Newhal, M.D.



**North Carolina National Association
For The Advancement Of Colored People**

Post Office Box 305
Clinton, NC 28329

June 25, 2008

To: State Health Coordinating Council and
Medical Facilities Planning Section
Division of Health Services Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Letter in Support of Petition Regarding: Radiation Oncology – Linear
Accelerators For the 2009 State Medical Facilities Plan

I am William T. Stokes, the President of the Sampson County NAACP Unit # 5446 and the Executive Committee of this Unit supports your cause. Prostate cancer affects one in six men nationally. We are aware that North Carolina has one of the highest death rates in the country for men, especially indigent African-Americans. We are aware and very concerned about the disease and the underserved populations involved. A prostate cancer center will hopefully help change these demographics. We look forward to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area. Thank you.

Sincerely,

William T. Stokes

William T. Stokes
President

Lisbon Street Missionary Baptist Church

501 Liston Street P O Box 271

Clinton, North Carolina 28329-0271

Rev H. R. Cogdell, Pastor

910 592-3554—Office

910-592-5692—(Pastor's Study)

910-592-5155--(Fax)

July 15, 2008

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: Letter in support of Petition Regarding: Radiation Oncology—Linear
Accelerators for the 2009 State Medical Facilities Plan

I am the Pastor at Lisbon St. Bap Church Prostate cancer affects one in six men nationally. North Carolina, however, has one of the highest death rates in the country for men, especially indigent African-Americans. We are aware and very concerned about the disease and the underserved populated involved. A prostate cancer center will hopefully help change these demographics. We look forward to looking to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area. Thank you.

Rev H R Cogdell, Pastor



*Compassionate Medical Care for
Our Working Neighbors*

ALLIANCE MEDICAL MINISTRY

May 30, 2008

Dear Dr. Khoudary,

I was excited to hear about your desire to develop a *prostate center* for both insured and uninsured men in downtown Raleigh and am thrilled to tender you my full support on behalf of Alliance Medical Ministry.

Our medical clinic serves working, uninsured adults throughout Wake County. Our providers statistically see a large number of patients with acute and chronic issues- including cancer. Men are less likely to come to our clinic than women; however, our goal is to eventually offer a well-man clinic that will focus on providing physicals and various screenings. To have a neighboring center such as yours to refer men to with prostate-related health needs would be a huge benefit to this population who often avoid medical care because of cost-related issues or pride.

In my role as Program Director, I am planning to provide a community prostate-testicular screening this fall targeting 100 underserved men over the age of 45 who have never been screened or have lapsed in being screened. In my 20 years of nursing (the past 17 in oncology and outreach), I know that such screenings can and do detect a number of prostate-related problems that men are often unwilling to talk about or seek medical attention for. Having a facility such as yours would lift a huge barrier because it is a community specialty center catered to men that is willing to accept men of all racial backgrounds, regardless of their ability to pay.

I hope to tap into your expertise for our fall screening and look forward to hearing more about future developments for your center. Do not hesitate to call me if I can be of any assistance or serve as a resource for your endeavor.

My best to you and your efforts!

Regina Heroux, RN, MS, OCN
Director of Programs & Outreach
Alliance Medical Ministry
101 Donald Ross Drive
Raleigh, NC 27610
Ph: 250-3582, ext. 422
Fax: 250-3322
www.alliancemedicalministry.org



Compassionate Medical Care for
Our Working Neighbors

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May 30, 2008

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My best to you and your efforts!

Regina Heroux, RN, MS, OCN
Director of Programs & Outreach
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www.alliancemedicalministry.org

101 Donald Ross Drive • Raleigh, North Carolina 27610 • (919) 250-3320 • Fax (919) 250-3322
www.alliancemedicalministry.org

POPLAR GROVE MISSIONARY BAPTIST CHURCH

P. O. BOX 746

FAISON, NORTH CAROLINA 28341

(910) 267-8411 Church

(910) 590-6483 Pastor

Senior Pastor: Rev. Willie C. Alford

Associate Ministers

Rev. Jackie Alford

Rev. Lenwood C. Pigford

Rev. Viva M. King

June 08, 2008

State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

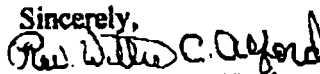
Re: Letter in support of Petition Regarding: Radiation Oncology – Linear
Accelerators for the 2009 State Medical Facilities Plan

To Whom It May Concern:

I greet you in the matchless name of my Lord and Savior Jesus Christ.

I am the Senior Pastor of Poplar Grove Missionary Baptist Church of Faison, North Carolina. Prostate cancer affects one in six men nationally. North Carolina, however, has one of the highest death rates in the country for men, especially indigent Black Americans. We are aware and very concerned about the disease and the underserved populations involved. A prostate cancer center will hopefully help change these demographics. We look forward to working with the prostate center and bringing these gentlemen in for screening and therapy. Please consider this letter of support for a prostate center in our area.

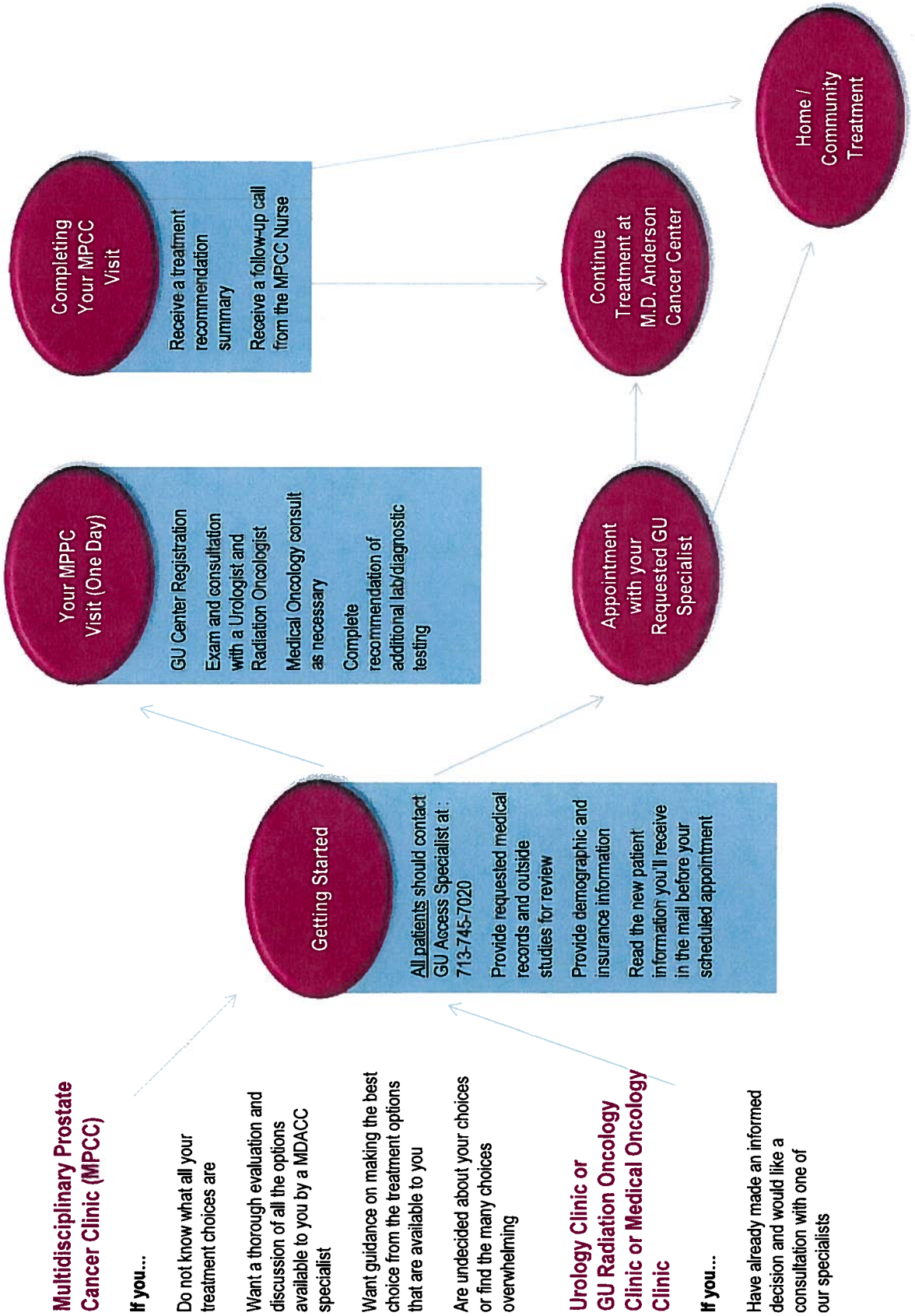
Sincerely,



Rev. Willie C. Alford

Senior Pastor

Visit Decision Map for a New Prostate Cancer Diagnosis



Daniel L. Howard, Ph.D. is a Professor of Health Policy and Director of the Institute for Health, Social, and Community Research at Shaw University www.ihscr.org. Dr. Howard received his Bachelor's Degree in Economics from the University of Michigan College of Literature, Sciences, and Arts in 1987 and his Ph.D. in Policy Development and Program Evaluation at Vanderbilt University Peabody College of Education and Human Development in 1992. He completed two-year postdoctoral training at the University of Michigan School of Public Health and School of Social Work as a Paul Cornely and Ford Foundation Postdoctoral Scholar in 1994. He also completed two-year postdoctoral training at the University of North Carolina at Chapel Hill (UNC-CH) Cecil G. Sheps Center for Health Services Research (Sheps Center) as a Health Services Research Postdoctoral Fellow funded by the Agency for Healthcare Research and Quality (AHRQ) National Research Service Award in 1998. He has been appointed (2002-2007) and re-appointed (2007-2012) as a Research Fellow at the UNCCH Sheps Center.

Dr. Howard's research interests include the examination of epidemiologic patterns of health outcomes that disproportionately affect African Americans; minority health and health disparities; health services; and, health policy. He has numerous scientific, peer-reviewed manuscripts in prominent journals such as *Academic Medicine*, *African American Research Perspectives*, *American Journal of Men's Health*, *American Journal of Obstetrics/Gynecology*, *American Journal of Public Health*, *Family Medicine*, *Harvard Health Policy Review*, *Health Services Research*, *Hispanic Journal of Behavioral Sciences*, *Humboldt Journal of Social Relations*, *Journal of Health Disparities Research and Practice*, *Journal of the Medical Library Association*, *Journal of the National Medical Association*, *Journal of Substance Abuse*, *Journal of Substance Abuse Treatment*, *Medical Care*, *Nursing Research*, *Public Health Reports*, *Research on Aging*, and *Substance Use and Misuse*.

Dr. Howard has actively participated as a Principal Investigator, Co-Principal Investigator, and Co-Investigator on grant research funded by the National Institutes of Health (NIH): National Center on Minority Health and Health Disparities (NCMHD), National Center for Research Resources (NCRR), National Institute on Drug Abuse (NIDA), and, National Institute on Aging (NIA); the United States Department of Health and Human Services (DHHS): Centers for Medicare and Medicaid Services (CMS), and, AHRQ; and, the United States Department of Defense (DOD), which pertain to health services, minority health, and racial health disparities research. He has received grant awards that have totaled over \$20 million dollars.

Dr. Howard is a founding member of the executive committee for the Academy for Health Equity www.academyforhealthequity.org, a national organization dedicated to creating a social movement designed to ensure equal opportunity for health. In 2008, he was invited to serve on the editorial board of the journal, *Risk Management & Healthcare Policy*. He was invited to serve on and elected chairman of the external advisory board of the Winston-Salem State University Center of Excellence for the Elimination of Health Disparities, funded by the NIH NCMHD P20 Project EXPORT, 2007-2012. In 2007, he was invited to serve on the editorial board of the *Journal of Multidisciplinary Healthcare*. In 2006, he received the *National Role Model Researcher Award* from Minority Access, Inc., a 501(c) (3) non-profit organization with a cooperative agreement with the U.S. DHHS to increase the pool of minority biomedical researchers by identifying individual and institutional role models. In 2001, he received the *Historically Black College and University Spotlight on Excellence Administrator/Faculty Award* from Black Voices Quarterly Magazine www.blackvoices.com and General Motors Corporation.

In 2002, Shaw University, with Dr. Howard as Principal Investigator, was the only university in the nation to hold two NIH NCMHD Project EXPORT grants (P60 and R24). It was noted by the 2004 P60 external scientific program advisory committee of national experts that the "*UNC-CH-Shaw Partnership should be viewed as the "showcase" model for addressing health disparities.*" In 2007, Shaw University, with Dr. Howard as Principal Investigator, was the only university in the nation to partner with two NIH NCMHD Project EXPORT P60 Centers of Excellence (UNC-CH and Johns Hopkins University).

Nancy M. Lane

From: khoudary@caryurology.com [cary004@nuvox.net]
Sent: Thursday, July 31, 2008 10:24 AM
To: nlane@pda-inc.net
Subject: Fw: Other members of the prostate cancer research team

----- Original Message -----

From: "Howard, Daniel" <howardd@SHAWU.EDU>
To: <khoudary@caryurology.com>
Sent: Thursday, July 31, 2008 9:51 AM
Subject: Other members of the prostate cancer research team

> Louie E. Ross, Ph.D., is a Chronic Disease (Cancer) Epidemiologist at the
> Institute for Health, Social, and Community Research at Shaw University.
> He received his Ph.D. in Sociology from North Carolina State University
> with concentrations in Social Psychology and Family Studies. He has taught
> at several universities including North Carolina Central University and
> Fayetteville State University. Dr. Ross currently serves as an adjunct
> professor at the University of Maryland (Adelphi Campus), and the
> Morehouse School of Medicine in Atlanta, GA. He has taught several courses
> to both undergraduate and graduate students that include the sociology of
> health (medical sociology), SPSS (Statistical Package for the Social
> Scientist), and quantitative research methods.

>
> More recently, he worked as a Research Behavioral Scientist in the
> Epidemiology and Applied Research Branch, Division of Cancer Prevention
> and Control at the Centers for Disease Control and Prevention, Atlanta,
> GA. He has initiated and managed several grants, cooperative agreements,
> and special interest projects. Two of the projects focus on primary care
> physicians' practices related to prostate cancer and screening, and
> attitudes and behaviors of African American and Jamaican men toward
> prostate cancer screening.

>
> Although his research is quite diverse and includes colorectal, breast,
> and cervical cancers, his major focus is prostate cancer. His primary
> research interests are in the areas of social and behavioral influences of
> health and disease (particularly prostate cancer) and health disparities
> research. He has authored and co-authored several publications, working
> papers, decision aids and pamphlets related to prostate and other cancers.

>
>
> Mary Anderson is the Associate Director for the Shaw UNC-CH Center for
> Prostate Cancer Research (SUCPCR), the Shaw Johns-Hopkins Center for
> Prostate Cancer Research (SJHPCR), and the Shaw UNC Undergraduate Program
> for Prostate Cancer Research and Training (SUUPRT). She is also the
> Executive Director of the Prostate Cancer Coalition of North Carolina
> (PCCNC), a 501(c)3 non-profit organization dedicated to the reduction and
> elimination of prostate cancer deaths in North Carolina.

>
> Ms. Anderson has been involved with various aspects of prostate cancer
> patient care, outreach, education and support since 1996. She aided in the
> formation and development of the PCCNC in 2001 and has expanded its

> statewide network of prostate cancer patient support, reaching into every
> major region of North Carolina. She is a Pilot Site Coordinator for the
> UsToo! International Minority and Underserved Populations Outreach and
> Awareness Program and is directly responsible for the development of the
> PCCNC Prostate Cancer Screening Guidelines, a reference piece for primary
> care medical professionals which captures recommendations for best
> practices prostate screening as defined by North Carolina's leading
> Urologists, and the PCCNC Partners Program, which works closely with
> breast cancer advocates in Western North Carolina to establish community
> and family awareness of both diseases. She is a member of the NC Minority
> Prostate Cancer Awareness Action Team (NCMPCAAT) and is directly
> responsible for the facilitation and expansion of the NCMPCAAT into Rocky
> Mount. She is also critical to establishing the vision and direction for
> the EMPOWER Men's Health Ministry, a pilot program in Rocky Mount, NC.

>
> In 2005 she received the Sword Bearer of Excellence Award by NCMPCAAT and
> in 2006 she was awarded the KnowledgeNet award for Family Advocacy and the
> Barbara Pullen-Smith Public Service Award for her work in minority and
> underserved communities.

>
>
>
> Yhenneko J. Taylor is a statistician for The Institute for Health, Social,
> and Community Research (IHSCR) at Shaw University. Currently she serves as
> statistician for the Shaw-UNC Center for Prostate Cancer Research
> (SUCPCR), Shaw-Duke Maternal and Infant Mortality Initiative and Shaw
> University M-RISP Minority Elderly Research (SUMMER) Center. She received
> the Bachelor of Science degree in Chemistry from Shaw University in
> Raleigh, North Carolina (2001) and the Masters of Statistics Degree from
> North Carolina State University (2004). She is trained in both research
> design and analysis methods. Her expertise includes analysis of
> longitudinal data, survival data and survey data analysis utilizing both
> small and large administrative and non-administrative databases. Ms.
> Taylor joined the staff at IHSCR shortly after completing her graduate
> studies and has contributed to several peer-reviewed manuscripts,
> abstracts and presentations.

Nancy M. Lane

From: khoudary@caryurology.com [cary004@nuvox.net]
Sent: Thursday, July 31, 2008 10:24 AM
To: nlane@pda-inc.net
Subject: Fw: Organizational information, capability, and capacity

----- Original Message -----

From: "Howard, Daniel" <howardd@SHAWU.EDU>
To: <khoudary@caryurology.com>
Sent: Thursday, July 31, 2008 9:59 AM
Subject: Organizational information, capability, and capacity

> IHSCR Mission

>
>

> The mission of The Institute for Health, Social, and Community Research is
> to become a national leader in the multidisciplinary empirical
> investigation of diverse issues that affect the health and well-being of
> minorities, particularly African Americans, and their families, and the
> communities in which they live. This mission will be accomplished through
> an interdisciplinary approach of intellectual exchange, research,
> education, consultation, technical assistance, and training that focuses
> on the discernment of timely and policy-relevant health issues with the
> goal of disseminating pertinent information to national, state, and local
> policy makers, the community at large, academic institutions, and funding
> agencies.

>

> The Institute

>

> 1) develops a collective of researchers involved in health-related
> areas of interest;

>

> 2) conducts scientifically sound and relevant minority health and
> health disparity research;

>

> 3) enhances collaborations with Research I level universities and other
> institutions; and

>

> 4) provides leadership to Shaw in developing a university focus toward
> public health.

>

>

>

>

>

> The Center for Survey Research

>

> The Center for Survey Research (CSR) within the IHSCR at Shaw
> University was developed from a core of the UNC-Shaw Partnership for the
> Elimination of Health Disparities (Project EXPORT) (grant P60 MD00239)
> funded by NIH NCMHD in 2002. The mission of the CSR is to support the
> IHSCR in its goal to become "a national leader in the multidisciplinary
> empirical investigation of diverse issues that affect the health and well

> being of minorities, particularly African-Americans, and their families,
> and the communities in which they live." The CSR has the capacity to
> design surveys, administer surveys by phone, and mail self-reported
> surveys to potential participants. The CSR uses the Win Cati4.2/Sensus
> software to administer computer-assisted telephone interviews and also has
> the capacity to conduct web-based surveys. The CSR has developed a
> pretesting laboratory for the evaluation of survey instruments for
> reliability and validity. Pre-testing techniques include focus groups,
> behavior coding, and cognitive interviewing.

>
> The CSR is composed of 12 calling stations and will expand to
> 24 calling stations in the new IHSCR facility, making the CSR the largest
> calling room at an HBCU in the nation. Each sound absorbent calling
> station is equipped with a personal computer, NEC Electra Elite IPK
> telephone, and a Plantronics Supra noise-canceling headset. Immediate
> plans include administering virtual surveys. The CSR has dedicated space
> for administrative staff to monitor SUCCEED activities and perform needed
> operations including production, duplication, and assembly of survey
> instruments; assembly and packaging of surveys for mail; receipt, sorting,
> and review of surveys for data entry; and secured storage of documents
> consistent with records retention protocol. University students and local
> community members are hired and trained as professional Interviewers. All
> interview staff participate in a comprehensive training, monitoring, and
> evaluation program.

>
>
>
> The Center for Biostatistics and Data Management

>
> The Center for Biostatistics and Data Management (CBDM) within the IHSCR
> at Shaw University was developed from funding by NIH NCMHD (grant R24
> MD00167) and DHHS AHRQ (grant R24 HS13353) in 2002. The purpose of the
> CBDM is to provide expertise in, data/database management, data quality
> control, statistical analysis, data entry and information technology for
> the IHSCR-funded research projects. The CBDM ensures that the security
> and integrity of the data is maintained throughout the processes of
> collection, managing, and analysis with the utilization of
> state-of-the-art statistical computing and information technology
> solutions. The CBDM provides a wide range of biostatistics support to
> members of the Shaw University community.

>
> The CBDM is comprised of three sub-cores: statistical analysis, data
> management and information technology. These sub-cores provide two levels
> of support to IHSCR investigators - consultation and implementation. The
> consultation level of support provides both general and specific advice to
> the IHSCR investigators on choosing the most appropriate statistical
> techniques for implementing research design, database development and
> management, and data analysis techniques. The implementation level of
> support provides in-depth support for the design of basic research
> studies, database management, analysis of complex data using SAS
> programming, and coordination of innovative web-based solutions to storing
> and disseminating project information.

Nancy M. Lane

From: khoudary@caryurology.com [cary004@nuvox.net]
Sent: Thursday, July 31, 2008 10:24 AM
To: nlane@pda-inc.net
Subject: Fw: our current prostate cancer research funding

----- Original Message -----

From: "Howard, Daniel" <howardd@SHAWU.EDU>
To: <khoudary@caryurology.com>
Sent: Thursday, July 31, 2008 10:16 AM
Subject: our current prostate cancer research funding

> PC060224 (W81XWH-07-1-0350)Howard and LaVeist (co-PIs)
> 7/1/07-6/30/10 1.2 Calendar Months
>
> U.S. DoD
> \$804,631.00
>
> Shaw-Johns Hopkins Center for Prostate Cancer Research (SJHPCR).
>
> The goal of SJHPCR is to further establish infrastructure support to Shaw
> University junior-level faculty to conduct prostate cancer research by
> providing training and mentorship through collaborative linkages with
> senior researchers at Shaw and the Johns Hopkins Bloomberg School of
> Public Health (SPH) and School of Medicine (SOM) and the Sidney Kimmel
> Comprehensive Cancer Center (SKCCC) at Johns Hopkins. This infrastructure
> support will allow a strengthened commitment to research aimed at reducing
> and eliminating disparities in prostate cancer, improvements in Shaw
> University's capacity to conduct quality multidisciplinary, and the
> provision of outreach and education regarding prostate cancer. The center
> will focus on prostate cancer research specifically in the fields of
> health services (outcomes) research and epidemiology.
>
> Role: Co-Principal Investigator
>
>
>
> PC061634 (W81XWH-07-1-0274)Godley and Howard (Co-PIs)
> 1/1/07-12/31/09 in kind
>
> U.S. DoD
> \$178,600.00
>
> Shaw-UNC-CH Undergraduate Program in Prostate Cancer Research and Training
> (SUUPPRT).
>
> At Shaw University, the training program would add to the critical mass of
> prostate cancer research activity developing in the Shaw-UNC-CH Center for
> Prostate Cancer Research. As Shaw University students matriculate in
> graduate schools, a synergistic effect would come from the presence of
> Shaw University graduates in UNC-CH graduate programs who would both
> generate more interest in prostate cancer research and expand diversity of
> the graduate students at UNC-CH.

>
> Role: Co-Principal Investigator
>
>
>
> PC060396 (W81XWH-07-1-0452) LaVeist (PI)
> 6/1/07-5/31/09 in kind
>
> U.S. DoD
> \$419,026.00 (Shaw \$89,719.00)
>
> Disparities in Prostate Cancer Treatment Modality and Quality of Life.
>
> The purpose of this project is to examine racial disparities in treatment
> decision-making and quality of life among white and African American
> prostate cancer patients. We will establish a racially diverse cohort of
> men recently diagnosed with prostate cancer. The cohort will be followed
> over a time to examine changes in their status. The baseline data
> collection for the study will be designed to explore factors that
> influence race differences in prostate cancer stage at diagnosis,
> selection of treatment modality, and quality of life. The current proposal
> seeks funding only to develop the cohort and collect the baseline data.
> The specific aims for this phase of the project are: Specific aim 1: to
> develop data collection instruments to conduct a survey of factors that
> influence treatment decision making and quality of life among white and
> African American prostate cancer patients. Specific aim 2: to establish a
> cohort of White and African American men to study factors that influence
> treatment decision making and quality of life among prostate cancer
> patients. Specific aim 3: to administer a questionnaire designed to
> assess factors that effect prostate cancer treatment decision making and
> quality of life as the baseline data collection to the cohort of white and
> African American prostate cancer patients.
>
> Role: Subcontract PI
>
>
>
> PC040907 (W81XWH-05-1-0208)Howard and Godley (Co-PIs)
> 7/1/05-6/30/09 1.2 Calendar Months
>
> U.S. DoD
> \$852,263.00
>
> Shaw-UNC Center for Prostate Cancer Research (SUCPCR)
>
> The goal of the proposed Shaw UNC-CH Center for Prostate Cancer Research
> (SUCPCR) is to establish infrastructure support to Shaw University
> junior-level faculty to conduct and sustain prostate cancer research with
> respect to racial disparities among the African Americans by providing
> training, resources, and mentorship opportunities through collaborative
> linkages with senior researchers at Shaw and the UNC-CH SOM, SPH,
> Lineberger and Sheps Centers.
>
> Role: Co-Principal Investigator
>
>
>

Nancy M. Lane

From: khouday@caryurology.com [cary004@nuvox.net]
Sent: Thursday, July 31, 2008 10:24 AM
To: nlane@pda-inc.net
Subject: Fw: Our current research on prostate cancer - you can pull the articles from our website www.ihsr.org

----- Original Message -----

From: "Howard, Daniel" <howardd@SHAWU.EDU>
To: <khouday@caryurology.com>
Sent: Thursday, July 31, 2008 10:13 AM
Subject: Our current research on prostate cancer - you can pull the articles from our website www.ihsr.org

> Prostate Cancer specific articles:

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>
> . Use of the Prostate-Specific Antigen Test among U.S. Men:
> Findings from the 2005 National Health Interview Survey Findings from
> the multivariate analyses indicated significantly higher PSA test use
> among younger non-Hispanic Black men than among non-Hispanic White
> men. These findings may indicate that healthcare providers are getting
> and conveying the message of increased risk of prostate cancer among
> African American men. (Cancer Epidemiol Biomarkers Prev
> 2008;17(3):636-44)

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>
> . Physician-Patient Discussions With African American Men About
> Prostate Screening
> Discussions
>
> African American men who were not having discussions with their
> physicians tended to be in fair or poor health, were not getting
> suggestions from their physicians to take the screening test, had not
> had a screening PSA test in the past 2 years, and had health insurance
> coverage. The borderline association between those men not covered
> with health insurance reporting more doctor discussions is somewhat
> surprising. However, this finding reflects a similar but
> non-significant pattern reported when examining men from the general
> population (McFall, 2006). Research by Stroud et al. (2006) reported
> that inasmuch as it is often more difficult for males in general (and
> African American males in particular) to interact with the health care
> system, physicians used "opportunistic counseling" to engage men into
> prostate cancer discussions during unrelated office and other rare
> visits. Possible interventions might focus on these groups to
> increase awareness and knowledge and possibly assist with their
> decision making regarding the PSA screening test. Some of the goals of
> Healthy People 2010 are to decrease risk and mortality for all cancers
> including prostate cancer, whereas an additional goal is to reduce
> health disparities among groups (U.S. Department of Health and Human Services, 2000).

>

> . Trends and Racial Differences in the Utilization of Androgen
 > Deprivation Therapy for Metastatic Prostate Cancer African-American
 > men were less likely than white men to receive any ADT following
 > diagnosis ($p < 0.001$). Differences were noted in the time to receipt of
 > ADT, with African-American men having a longer mean time to receipt of
 > orchiectomy (time ratio (TR)=1.50, 95% CI=1.03, 2.17) or LHRH agonist
 > (TR=1.42, 95% CI=1.06, 1.89) than white men.
 > (Under review: Pain)

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> . Patterns in Prostate-Specific Antigen Test Use and Digital
 > Rectal Examinations in the Behavioral Risk Factor Surveillance System,
 > 2002-2006
 > Overall differences for years 2002-2006 were: a significant increase
 > for PSA use only and a marginally significant decrease of PSA and DRE
 > combined for years 2002-2006. Having had a recent PSA test (within 2
 > years) only, a recent DRE only, or both tests varied by
 > sociodemographic and health-related variables including age,
 > race/ethnicity, marital status, levels of education and income, body
 > mass index (BMI), health insurance status and having a personal doctor or health care
 > provider.
 > (Pending submission/ in clearance with the CDC - will submit to
 > American Journal of Preventative Medicine (AJPM))

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> . Complementary and Alternative Medicine (CAM) use among Men with
 > a History of Prostate Cancer
 > The most frequently used types of CAM were: biologically-based
 > therapies
 > (72.6%) and mind-body therapies (70.4%). Within biologically-based
 > therapies, use of vitamins accounted for 71.3% of the total and within
 > mind-body therapies, prayer for health accounted for 78.0% of the total.
 > Use of mind-body therapies did not vary significantly by
 > socio-demographic characteristics, however, use of other types of CAM
 > was associated with higher levels of education, White race, and being
 > a veteran of the armed forces.

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> (Under review: Oncology Nurses Forum)

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> Related articles:

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> Healthcare Practices among Blacks and Whites with Urinary Tract
 > Symptoms Daniel L. Howard, PhD; Bennett G. Edwards, PhD; Kimberly
 > Whitehead, PhD; M. Ahinee Amamoo, MS; and Paul A. Godley, MD, PhD, MPP
 > Journal of the National Medical Association, VOL. 99, NO. 4, April
 > 2007 <http://www.ihscr.org/x/published/JNMA_Article.pdf>

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- >
- > Quality and Severity of Lower Urinary Tract Symptoms among, African
- > American Elders Daniel L. Howard, Bennet G. Edwards, Kimberly
- > Whitehead, M. Ahinee Amamoo, and Paul A. Godley Journal of Health
- > Disparities, Research and Practice, Volume 1, Number 2, Winter 2007,
- > page 73 <<http://www.ihsr.org/x/published/JHGRP-V1N2-2007-cs.pdf>>
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