Technology and Equipment Committee

Radiation Oncology Services - Linear Accelerators

Material Related To

Linear Accelerator Petition: Cary Urology, PA

April 21, 2008

Technology & Equipment Committee
Linear Accelerator Petition
Regarding the Proposed 2009 SMFP

Agency Analysis:

Petitioner:
Cary Urology PA
Cary, Wake County, North Carolina

Request

The petitioner requests a change in the basic policies and methodologies of the State Medical Facilities Plan (SMFP) for Radiation Oncology Services - Linear Accelerators. The change would add the following language to Chapter 9 Radiation Oncology – Linear Accelerators, subsection Methodology for Determining Need:

Any area that has a ratio of 120,000 persons per approved or operational linear accelerator or higher and a minimum population of 600,000 shall have a need for one IMRT/IGRT -capable linear accelerator, provided that the linear accelerator is offered at an organized prostate center staffed by urologists, as well as medical and radiation oncologists and urologic rehabilitation therapists; and the center agrees to provide a report demonstrating the impact of this arrangement on patient health status, cost and patient quality of life, within three years of the date the project becomes operational.

"Approved linear accelerator" shall include any linear accelerator approved for inclusion in the State Medical Facilities Plans of 2006, 2007 or 2008 for which CON applications were filed.

Background Information

In the Final 2008 SMFP, there are 66 hospitals and freestanding oncology treatment centers statewide in North Carolina with 112 linear accelerators that are operational, have a CON in hand, or for which there is a prior year need determination.

The methodology incorporates a geographic accessibility criterion (population base of 120,000),. a criterion aimed at assuring efficient use of megavoltage radiation facilities (when ESTV Procedures divided by 6,750 minus the number of present linear accelerators equals .25+), and a patient origin criterion that when a service area has 45% or more of the patients coming from outside the service area. A need determination is generated when two of the three criteria are met within a service area

In the last several years, there have been a number of need determinations. In the 2006 SMFP, there was one need determination through the first part of the need determination methodology. It

was determined that there was a need for an additional linear accelerator in Service Area 7, which includes Anson, Mecklenburg, and Union Counties.

Additionally in the 2006 SMFP, any county that had a population of 120,000 or more and did not have a recognized linear accelerator had a need for one linear accelerator and the county became a separate Linear Accelerator Service Area. It was determined that there was a need determination for one linear accelerator for each Linear Accelerator Service Area of Davidson (Service Area 11), Johnston (Service Area 21), Onslow (Service Area 24) and Randolph (Service Area 13) Counties.

Governor Easley determined that the 2007 State Medical Facilities Plan should recognize a need for one additional linear accelerator in Service Area 20, to be awarded to an existing provider of radiation oncology services in Service Area 20 which meets applicable policies in the State Medical Facilities Plan, and applicable criteria in the Certificate of Need Law and Administrative Rules.

In the 2008 SMFP, there is an adjusted need determination, based on a petition, for one linear accelerator for Linear Accelerator Service Area 18, comprised of Bladen, Cumberland, Robeson, and Sampson Counties.

Analysis/Implications

The petitioner indicates that application of the state's methodology has produced centers that treat all types of cancers. Only stercotactic radiation therapy has received attention; and that service benefits a very 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.

The petitioner states that prostatc cancer is extremely prevalent, with one in six men developing prostate cancer during their lifetimes. 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 percent. North Carolina has one of the highest death rates from prostate cancer in the United States.

The petitioner continues that 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 at 15.7 percent of total cancers. Approximately half of prostate cancers involve radiation therapy; 80 percent of which involves use of a linear accelerator. Prostate cancer treatment represents approximately 20 percent of all radiation treatments (ESTVs) performed. Yet, North Carolina does not have a prostate cancer center comparable to Atlanta, Georgia; Denver, Colorado; or Akron, Ohio. No North Carolina provider focuses exclusively on the very complex issues associated with total treatment of prostate and urologic cancer.

The petitioner says that tailoring linear accelerator treatment beams to individual patient tumors is called conformal therapy. The radiation beam from the linear accelerator can be more precisely controlled with the advances provided by Intensity Modulated Radiation Therapy (IMRT) and Intensity Gated Radiation Therapy (IGRT). IGRT optimizes dose to the target organ to minimize

opportunities for undesired radiation of healthy tissues. With IMRT, the radiation oncologist and physicist can control the placement, as well as shape and intensity of the beam, adjusting it to the tumor dimensions while minimizing normal tissue exposure. Together, the techniques optimize control for the best possible long term patient outcomes. They permit the clinical team to use high, carefully controlled doses to reduce the tumor(s). Not all linear accelerators have these capabilities.

The petitioner states that the technology is so important because urologic cancers are located in areas of the body that involve intricate networks of organs, blood vessels, nerves and muscles. Disruption of any single tissue can cause major changes in physiologic function. 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, physiology, radiation, pharmacy and chemotherapy.

Lastly, the petitioner indicates that organizing a prostate cancer center is not easy. It requires a multidisciplinary setting and a multidisciplinary team of specialists whose skills complement each other. It involves breakthrough organization, rearranging the silos of single specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing adjustments during the course of patient treatments. It requires assembling professionals who currently work in different settings into a single setting. Today, surgeons generally work in operating rooms and in their offices. Radiation oncologists and medical oncologists sometimes work together, but their conferences and their focus is on a wide range of cancers: prostate, breast, lung, cervix, stomach, soft tissue, etc. Optimal prostate cancer radiation treatment occurs when the urologist and the radiation oncologist cooperatively plan dosage and approach during the course of radiation therapy. It is enhanced when physical therapists and urologic therapy nurses caring for those patients provide immediate real time feedback to the treatment planning team for use in dose planning.

The Agency notes that it has reservations about a separate need methodology for linear accelerators with stereotactic treatment capabilities. There are a growing number of specialized linear accelerators with stereotactic treatment capabilities. Each of these units approaches the problem of delivering a tightly tailored radiation dose to a precisely localized target in a different way, but in the final analysis, they are all capable of precise targeting and elegant dose distributions. Each linac has some unique features and capabilities, but as yet no one machine has been proven to provide superior curability vs. its competitors.

The Agency notes that the petitioner could request an adjusted need determination during the Summer 2008 review period for the Proposed 2009 SMFP.

Agency Recommendation

The Agency recommends denial of the petition in its request for a change to the methodology. The Agency suggests that the petitioner consider a petition for an adjusted need determination in the Proposed 2009 SMFP for a linear accelerator in Service Area 20 addressing the issue of access to some of the underserved population in the service area and demonstrating the medical advantage of the proposed need determination.

PETITION

Petition to the State Health Coordinating Council
Regarding Change Methodology for Radiation Oncology – Linear Accelerators
For the 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

March 4, 2008

Petitioner and Contact:

Kevin Khoudary, MD
Parkway Urology, PA, d/b/a Cary Urology, PA (Cary Urology)
105 SW Cary Parkway, Suite 300
Cary, NC 27511
khoudary@caryurology.com
Ph: 919-467-3203

STATEMENT OF REQUESTED CHANGE

Cary Urology requests a change in the basic policies and methodologies of the State Medical Facilities Plan for Radiation Oncology Services - Linear Accelerators. The change would add the following language to Chapter 9 Radiation Oncology – Linear Accelerators subsection Methodology for Determining Need.

Any area that has a ratio of 120,000 persons per approved or operational linear accelerator or higher and a minimum population of 600,000 shall have a need for one IMRT/IGRT -capable linear accelerator, provided that the linear accelerator is offered at an organized prostate center staffed by urologists, as well as medical and radiation oncologists and urologic rehabilitation therapists; and the center agrees to provide a report demonstrating the impact of this arrangement on patient health status, cost and patient quality of life, within three years of the date the project becomes operational.

"Approved linear accelerator" shall include any linear accelerator approved for inclusion in the State Medical Facilities Plans of 200, 2007 or2008 for which CON applications were filed.

The SMFP would reflect these changes:

HSA	*Linear Accelerator Service Area*	*Fixed IMRT Capable Linear Accelerator*	*Certificate of Need Application Due Date*	*Certificate of Need Beginning Review Date*
IV	*20*	*1**		

** Restricted to applicants proposing a multidisciplinary prostate cancer center staffed by urologists as well as radiation oncologists, medical oncologists and rehabilitation urologic therapists; and providing a structured written evaluation to the Division within three years of project initiation.*

REASONS FOR THE PROPOSED CHANGES

Summary

The statute governing Certificate of Need defines a new institutional health service to include: linear accelerator (GS 131E-176(16)f1.5a) and simulator (GS 131E-176(16)f1.9). Of these, the *State Medical Facilities Plan* contains a Methodology for only linear accelerators. The State Health Coordinating Council has focused on access and used the *Plan's* Methodology to distribute access to linear accelerators across the state, including a statement in the current Methodology that :

> *Any county that has a population of 120,000 and does not have a linear accelerator shall have a need for one linear accelerator and the county shall become a separate Linear Accelerator Service Area."*

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 79,000 persons per operational linear accelerator, almost twice as much access as Area 20

Focus of the equipment is a second problem. Application of the State's Methodology has produced centers that treat all types of cancers. Only stereotactic radiation therapy has received attention; and that service benefits a very 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.

Prostate cancer is extremely prevalent, with one in six men developing prostate cancer during their lifetimes.[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

[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.

35.6/100,000. This exceeded the national average by 17.5 percent[2], a statistic that greatly concerns Cary Urology. North Carolina has one of the highest death rates from prostate cancer in the United States

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 at 15.7 percent of total cancers. Approximately half of prostate cancers involve radiation therapy; 80 percent of which involves use of a linear accelerator. Prostate cancer treatment represents approximately 20 percent of all radiation treatments (ESTV's) performed. Yet, North Carolina does not have a prostate cancer center comparable to Atlanta, Georgia, Denver, Colorado; or Akron, Ohio. No North Carolina provider focuses exclusively on the very complex issues associated with total treatment of prostate and urologic cancer.

Tailoring linear accelerator treatment beams to individual patient tumors is called conformal therapy. The radiation beam from the linear accelerator can be more precisely controlled with the advances provided by Intensity Modulated Radiation Therapy (IMRT) and Intensity Gated Radiation Therapy (IGRT). IGRT optimizes dose to the target organ to minimize opportunities for undesired radiation of healthy tissues. With IMRT, the radiation oncologist and physicist can control the placement, as well as shape and intensity of the beam, adjusting it to the tumor dimensions while minimizing normal tissue exposure. Together, the techniques optimize control for the best possible long term patient outcomes. They permit the clinical team to use high, carefully controlled doses to reduce the tumor(s). Not all linear accelerators have these capabilities.

Why is this so important? Urologic cancers are located in areas of the body that involve intricate networks of organs, blood vessels, nerves and muscles. Disruption of any single tissue can cause major changes in physiologic function. 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, physiology, radiation, pharmacy and chemotherapy.

Organizing a prostate cancer center is not easy. It requires a multidisciplinary setting and a multidisciplinary team of specialists whose skills complement each other. It involves breakthrough organization, rearranging the silos of single specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing adjustments during the course of patient treatments. It requires assembling professionals who currently work in different settings into a single setting. Today, surgeons generally work in operating rooms and in their offices. Radiation oncologists and medical oncologists sometimes work together, but their conferences and their focus is on a wide range of cancers: prostate, breast, lung, cervix, stomach, soft tissue, etc. Optimal prostate cancer radiation treatment occurs when the urologist and the radiation oncologist cooperatively plan dosage and approach during the course of radiation therapy. It is enhanced when physical therapists and urologic therapy nurses caring for those patients provide immediate real time feedback to the treatment planning team for use in dose planning.

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

North Carolina is a state known for excellent health care and for innovative thinking in general. In Service Areas with a high ratio of population per linear accelerator, and eight or more linear accelerators, it is reasonable and necessary to focus new resources on groups with special needs to encourage excellence in patient care

Any need that is accorded special focus should be evaluated and documented; and results should be shared with the State, for consideration in future *Plans*. To assure such a report, the *2009Plan* should require an applicant for such a focused project to provide for a systematic evaluation of the investment for its impact on cost, quality and access, in addition to meeting high standards of care delivery. The literature has several well-developed clinical indices to measure patient outcomes. One is the SOMA-LENT measures of skin toxicity in normal tissue; this was developed by the European Organization for Research in Therapy and the Radiation Therapy Oncology Group.[3] The International Index of Erectile Function has standardized measures of impotence.[4] Together, these provide a developed and structured basis for evaluating the value of a focused service. The measures have been tested and panels of experts have refined the definitions.

Service Area 20 has more than 600,000 people and more than 120,000 persons per linear accelerator. Updated with 2008 population from the State Demographer, the attached Table 9H from the *2008 Plan* shows population and ratios in other Radiation Oncology Service Areas.

Service Area 20 Linear Accelerators – Count In Service Only

Location	County	Pop 2008(a)	Linear Accelerators 2008 SMFP
2007 SMFP	NA		1
CCNC Raleigh Hematology	**Wake**	853,260	1
Duke Raleigh	Wake		1
Rex Hospital (b)	Wake		4
Wake Radiology	Wake		1
	Franklin	57,866	0
	Harnett	107,961	0
Total		1,019,087	8
Population per LINAC		127,386	

a Source: State demographer http:// www.state.demog.nc.us 2/27/08

b Rex has approval to move one to Wakefield and has filed a CON application to move another that is out of service to Panther Creek

[3] Cancer Radiother. 1997;1(6):622-68.Scoring system of late effects of radiations on normal tissues: the SOMA-LENT scale

[3] R C Rosen[1], J C Cappelleri[2] and N Gendrano III[1] International Journal of Impotence Research .August 2002, Volume 14, Number 4, Pages 226-244 The International Index of Erectile Function (IIEF): a state-of-the-science review

Counties in Service Area 20 and its periphery have high rates of prostate cancer relative to both North Carolina and the US.

Age Adjusted Death Rates from Prostate Cancer 2000-2004
SEER Data

Location	Prostate Death Rate*	Percent ABOVE US Avg
U.S.	27.9	
North Carolina	32.4	16
Wake County	36.3	30
Harnett County	41.2	48
Franklin County	37.1	33
Johnston County	29.5	6
Lee County	36.1	29

Rates per 100,000
http://statecancerprofiles.cancer.gov/cgi-bin/deathrates/deathrates.pl?37&066&00&1&001&1&1&1

Statement of Adverse Effects if the Change is Not Made

Failure to make the proposed changes will have multiple adverse effects.

- Linear accelerator services in general will remain unevenly distributed in the state of North Carolina, rewarding providers who have equipment that is not in service and that has not been in service for a year or more, but making service less accessible for patients.
- North Carolina will not have an organized multidisciplinary program for treating urologic and prostate cancer. As a result, cancer patients who understand the value of such a program and want it will travel out of state or do without Others who do not understand the options will be deprived of the alternative.
- Clinical treatment of prostate cancer in North Carolina, will trail behind states like Colorado, Georgia, and Ohio. North Carolina has the 11th highest incidence of prostate cancer in the United States Of the states mentioned, only Ohio has a higher incidence.

Costs of health care have three sources:

- Cost of associated with having disease in a population.
- Cost of the unit service delivered, and
- Total cost of the care treatment.

This proposal involves a unique approach to a disease focus that affects more than 250,000 people statewide. Organized as proposed, the center would provide a setting in which prostate and urologic cancer care quality and outcomes would absorb the energy and attention of all staff at all

times. Appropriately executed, it should improve treatment for persons with prostate cancer, promote an understanding of factors that facilitate progression of disease, and help prevent prostate cancer.

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 distance 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.

In North Carolina, approximately 3,000 men will qualify for prostate cancer treatment for new cancers in 2009 alone. They will use approximately 112,000 ESTV's. They deserve an alternative choice. A study funded by the Department of Defense indicates that even when controlled for race, North Carolina black men have higher incidence rates than Louisiana black men.

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; other 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.

Even the United States Department of Defense has recognized that prostate cancer merits special attention, and has organized a major initiative to understand its prevention and treatment. http://cdmrp.army.mil/pcrp/default.htm

Statement of Alternatives to the Proposed Change

1. Do Nothing Status Quo

Not changing the methodology sustains misdistribution of services and fails to challenge service delivery approaches for 20 percent of the radiation oncology users.

2. One statewide demonstration

The initial egalitarian appeal of such an approach, would address only one of the issues addressed above. It would give the state one prostate cancer center However, such an approach would risk placing another linear accelerator in a community that already has excess capacity. Doing so would risk low utilization of the demonstration and could jeopardize the viability of existing resources.

3. Multiple sites

This option offers broader geographic choice, but risks the same problem of low utilization and excess capacity described in 2 above.

4. Program emphasis for new linear accelerators

Encouraging existing radiation oncology – linear accelerator programs to develop special initiatives in prostate cancer would be an improvement on the current situation. It would highlight a major issue in men's health that has received little attention by the general health care community. However, the State Health Coordinating Council does not have a mechanism to monitor or challenge such programs There is no guarantee that the encouragement would be accepted or converted to a high-focus program. Such encouragement might increase educational efforts and even support some multi-disciplinary conferences. However, in communities with multiple linear accelerators, it could even further fragment the services by pulling the urologists in multiple directions to multiple programs. Such an organization would still risk duplication of efforts.

By contrast, the proposed alternative uniquely responds to the basic principles of the *State Medical Facilities Plan* for a service that affects enough people to justify its viability

1. Promote Cost Effective Approaches

With radiation oncologists and urologists working separately, both may order the same lab or imaging studies to measures outcomes associated with therapy. In an organized prostate cancer center, radiation oncologists and urologists will share one medical record containing the same set of laboratory and imaging data. Savings on diagnostic testing resulting from the proposed organization of care delivery can be significant. Shared consult using exactly the same data will enhance clarity of communication among clinicians and between clinician and patient.

2. Expand Health Care Services to Medically Underserved

Above average death rates from prostate cancer in North Carolina make a clear statement. Men with urologic cancers are poorly served. A prostate cancer center would organize urological resources to expand the community prostate cancer screening. According to the North Carolina Center for Health Statistics[5] in 2005, prostate cancer death rates, age adjusted, were almost 2.5 times higher for non-whites than for whites, 52 compared to 21 per 100,000. North Carolina black men are a group consistently with one of the highest death rates from prostate cancer in the country. The disparity is so great the Department of Defense provided a 9.9 million dollar grant to study different prostate cancer incidences between North Carolina black men and those from Louisiana. We anxiously await the preliminary results.

3. Encourage Quality Health Care Services

With prostate representing 20 percent of cancers, clearly the proposed services will benefit a significant portion of the population "dealing with chronic conditions." Specializing in one disease process will enable a prostate cancer center to provide high quality care in a cost effective manner.

NON-DUPLICATION OF SERVICES

We have clearly established the need for and absence of an organized prostate cancer center in North Carolina. Restricting the need to an area with a ratio of more than 120,000 persons per approved linear accelerator will assure that the center is established in an area that can reasonably absorb additional linear accelerator capacity.

Requiring a structured evaluation report, will provide the State Health Coordinating Council with feedback on the value of a disease focused service.

[5] http://www.schs.state.nc.us/SCHS/CCR/mort2005r.pdf

CONCLUSION

It is reasonable and timely for the 2009 State Health Facilities Plan to include a change in methodology that emphasizes a change in care delivery structures. This fits well with the landmark recommendation number 2 of the National Institutes of Health Quality Recommendations for the 21st Century:

> *2. Customization based on patient needs and values. The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.*

Attachments
State Cancer Profiles NC (cancer.gov)
Department of Defense Prostate Cancer Study
Table 9H 2008 State Medical Facilities Plan
Clinical Measures

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

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]
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

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]
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

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]
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

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]
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	**	**	**

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]
Transylvania County	Yes	20.9 (12.6, 33.1)	4	2000 - 2004	**	**	**
Burke County	Yes	20.1 (13.7, 28.3)	7	2000 - 2004	stable →	-2.1 (-4.4, 0.2)	1980 - 2004
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:

Table 9H: 2008 State Medical Facilities Plan
LINEAR ACCELERATOR SERVICE AREAS and CALCULATIONS

Service Area	2007 Civilian Population	Accelerators	Population within Service Area Per Accelerator	Percentage of Patients from Outside the Service Area	2005-2006 ESTV Procedures	Procedures Per Accelerator	ESTV Procedures Divided by 6750 Minus # of Accelerators	NEED Determination
Area 1	129,510	2	64,755	7.14%	6,780	3,390	-1.00	*
Area 2	378,179	7	54,026	20.29%	34,671	4,953	-1.86	*
Area 3	87,469	1	87,469	26.47%	4,491	4,491	-0.33	*
Area 4	151,110	3	50,370	10.60%	8,945	2,982	-1.67	*
Area 5	357,995	6	59,666	10.20%	25,146	4,191	-2.27	*
Area 6	430,542	5	86,108	7.50%	23,406	4,681	-1.53	*
Area 7	1,043,447	11	94,859	21.76%	57,307	5,210	-2.51	*
Area 8	281,981	4	70,495	10.24%	16,994	4,249	-1.48	*
Area 9	217,483	3	72,494	25.33%	17,436	5,812	-0.42	*
Area 10	614,782	9	68,309	16.59%	52,597	5,844	-1.21	*
Area 11	157,450	1						
Area 12	547,202	7	78,172	14.14%	43,678	6,240	-0.53	*
Area 13	141,054	1						
Area 14**	183,745	4	45,936	49.86%	22,224	5,556	-0.71	*
Area 15	166,305	2	83,153	8.73%	7,991	3,996	-0.82	*
Area 16**	405,732	7	57,962	54.70%	47,595	6,799	0.05	*
Area 17	295,396	3	98,465	13.28%	27,886	9,295	1.13	*
Area 18	537,003	5	107,401	12.68%	37,115	7,423	0.50	*
Area 19	389,616	4	97,404	11.69%	22,755	5,689	-0.63	*
Area 20	970,558	8	121,320	14.62%	38,391	4,799	-2.31	*
Area 21	155,874	2	77,937		2,648	1,324	-1.61	*
Area 22	228,888	2	114,444	21.75%	13,099	6,550	-0.06	*
Area 23	181,417	3	60,472	6.86%	16,430	5,477	-0.57	*
Area 24	159,097	1						
Area 25	301,606	4	75,402	12.36%	15,526	3,882	-1.70	*
Area 26	301,751	5	60,350	34.64%	27,392	5,478	-0.94	*
Area 27	153,608	2	76,804	0.96%	9,380	4,690	-0.61	*
Totals	8,968,800	112	80,079		579,883	5,178	-26.09	0

* Service Area does not have 120,000 base population per accelerator
** Areas 14 and 16 have more than 45% of its patients coming from outside its service area

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News Release

July 12, 2004 -- No. 350

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Department of Defense funds consortium's research on racial, other disparities in prostate cancer death rates

CHAPEL HILL -- Researchers are preparing to begin a new study focused on why prostate cancer deaths are more than twice as common in black men as in white men and why such deaths also vary significantly from state to state.

A new consortium of top U.S. cancer researchers is leading the study, which is funded by a three-year, $9.9 million grant from the U S. Department of Defense Prostate Cancer Research Program

"Prostate cancer is the most common cancer in men and the second leading cause of cancer mortality in the United States," said Dr. James L. Mohler, consortium director.

Mohler is professor and chairman of the department of urologic oncology at Roswell Park Cancer Institute in Buffalo, N.Y. He remains a member of the University of North Carolina at Chapel Hill Lineberger Comprehensive Cancer Center and adjunct associate professor of surgery and pathology at UNC's School of Medicine, where he led the prostate cancer research program for 16 years.

"In men younger than age 65, the prostate cancer death rate for African Americans is 3.1 times that of Caucasian Americans. In men 65 and older, the prostate cancer mortality rate for African Americans is 2.3 times that of Caucasian Americans. Why that's true is an intriguing medical mystery that likely will hold clues to treating the deadly illness more successfully," said Mohler.

To try to solve it, investigators at Louisiana State University Health Sciences Center; Harvard, Johns Hopkins, Boston and Wake Forest universities; the universities of South Carolina and California at Irvine; and Roswell Park Cancer Institute will join Mohler and other scientists at the National Cancer Institute, the National Institute of Environmental Health Sciences and the U.S. Food and Drug Administration as one of the two newly funded Prostate Cancer Consortiums.

"One of our goals is to study 2,000 patients with newly diagnosed prostate cancer," said Mohler. "We will interview 500 African-American men and 500 Caucasian-American men in both North Carolina and Louisiana and collect and analyze both blood and fat samples from the subjects.

"Men will be recruited for this study," he added, "so we are not asking for volunteers, but we hope that if a man is called to take part, he will agree to help us with this important study."

The team is focusing on the two states because North Carolina often has the highest prostate cancer incidence and death rates nationwide for black men, while Louisiana has one of the lowest, said Dr. Elizabeth T. Fontham, leader of Louisiana's consortium efforts. Fontham is dean of the school of public health, professor of pathology and associate director of the Stanley Scott Cancer Center at Louisiana State University Health Sciences Center.

The two states have similar incidence and mortality rates for white men, however.

Three reasons have been suggested for the disproportionate mortality between the two races, Mohler said. "First, African Americans may present more often with advanced, incurable prostate cancer because of more limited access to health care. African Americans have been reported more likely to just let the disease follow its course, which doctors often advise in men over age 75."

Second, biological differences between the two races may cause prostate cancer to develop at a younger age or grow and spread more rapidly in blacks, Mohler said. "Finally," he added, "the prostate cancers that occur in African Americans may be inherently more aggressive. These studies will help pinpoint which of these three categories are important."

Researchers at the participating institutions have particular expertise they can bring to bear on the questions, he said, and that's why they are working together. One major result will be an invaluable central resource of clinical and research data on prostate cancer patients, Mohler said, eventually including what happens to patients following various treatments.

Another result should be a better understanding of what can be done to reduce prostate cancer deaths in general and in the African-American population specifically. "These studies should demonstrate whether public health resources should be focused on altering interactions between patients and the health-care system, changing diets or altering patient or tumor biology," Mohler said.

The other consortium is based at Emory University in Atlanta.

This year, more than 30,000 men nationwide will die from prostate cancer, American Cancer Society statistics show, and close to 190,000 new cases will be diagnosed.

The prostate gland is a chestnut-shaped male organ surrounding the urethra just below the bladder. Its purpose is to produce secretions that keep the lining of the urethra moist and others that form part of the seminal fluid. The prostate grows during puberty and begins to enlarge further in most men after age 50, sometimes interfering with urination.

Cancers increase in frequency as men age, research shows. Early detection using prostate examination and blood tests for prostate-specific antigen, or PSA, can detect the disease before symptoms develop when the cancer is most curable. Treatment options include "watchful waiting," radiation, operation and hormonal therapies.

Note: Mohler will be in Chapel Hill today (July 12) and available for interviews. To arrange an interview, contact Dianne Shaw at (919) 966-5905 or dgs@med.unc.edu. He may be reached by phone, (716) 713-6700, after that date. Dr. Jeannette Bensen, study coordinator, also is available for interviews and may be reached at (919) 843-1017. Study participants and advocates are available for interviews.

UNC Lineberger contact: Dianne Shaw, (919) 966-5905 or dgs@med.unc.edu

1: Cancer Radiother. 1997;1(6):622-68.

[Scoring system of late effects of radiations on normal tissues: the SOMA-LENT scale]

[Article in French]

Mornex F, Pavy JJ, Denekamp J, Bolla M.

Département d'oncologie-radiothérapie, EA 643, centre hospitalier Lyon-Sud, Pierre-Bénite, France.

Radiation tolerance of normal tissues remains the limiting factor for delivering tumoricidal dose. The late toxicity of normal tissues is the most critical element of an irradiation: somatic, functional and structural alterations occur during the actual treatment itself, but late effects manifest months to years after acute effects heal, and may progress with time. The optimal therapeutic ratio ultimately requires not only complete tumor clearance, but also minimal residual injury to surrounding vital normal tissues. The disparity between the intensity of acute and late effects and the inability to predict the eventual manifestations of late normal tissue injury has made radiation oncologists recognize the importance of careful patient follow-up. There is so far no uniform toxicity scoring system to compare several clinical studies in the absence of a "common toxicity language". This justifies the need to establish a precise evaluation system for the analysis of late effects of radiation on normal tissues. The SOMA/LENT scoring system results from an international collaboration. European Organization Treatment of Cancer (EORTC) and Radiation Therapy Oncology Group (RTOG) have created subcommittees with the aim of addressing the question of standardized toxic effects criteria. This effort appeared as a necessity to standardize and improve the data recording, to then describe and evaluate uniform toxicity at regular time intervals. The current proposed scale is not yet validated, and should be used

cautiously.

PMID: 9614880 [PubMed - indexed for MEDLINE]

Note: Performing your original search, ***European organization for Research Therapy rtog***, in PubMed will retrieve *43* citations.

1: Int J Radiat Oncol Biol Phys. 1995 Mar 30;31(5):1341-6.

ELSEVIER FULL-TEXT ARTICLE

Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC)

Cox JD, **Stetz J**, **Pajak TF**.

Publication Types:

- Editorial
- Research Support, U.S. Gov't, P.H.S.

PMID: 7713792 [PubMed - indexed for MEDLINE]

August 2002, Volume 14, Number 4, Pages 226-244

Paper

The International Index of Erectile Function (IIEF): a state-of-the-science review

R C Rosen[1], J C Cappelleri[2] and N Gendrano III[1]

[1] *Department of Psychiatry, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, Piscataway, New Jersey, USA*

[2] *Pfizer Inc, Global Research and Development, Groton, Connecticut, USA*

Correspondence to: R C Rosen, Department of Psychiatry, UMDNJ-Robert Wood Johnson Medical School, 675 Hoes Lane, Piscataway, NJ 08854, USA. E-mail: rosen@umdnj.edu

Abstract

The International Index of Erectile Function (IIEF) is a widely used, multi-dimensional self-report instrument for the evaluation of male sexual function. It is has been recommended as a primary endpoint for clinical trials of erectile dysfunction (ED) and for diagnostic evaluation of ED severity. The IIEF was developed in

conjunction with the clinical trial program for sildenafil, and has since been adopted as the 'gold standard' measure for efficacy assessment in clinical trials of ED. It has been linguistically validated in 32 languages and used as a primary endpoint in more than 50 clinical trials. This review summarizes early stages in the psychometric validation of the instrument, its subsequent adoption in randomized clinical trials with sildenafil and other ED therapies, and its use in classifying ED severity and prevalence. The IIEF meets psychometric criteria for test reliability and validity, has a high degree of sensitivity and specificity, and correlates well with other measures of treatment outcome. It has demonstrated consistent and robust treatment responsiveness in studies in USA, Europe and Asia, as well as in a wide range of etiological subgroups. Although only one direct comparator trial has been performed to date, the IIEF is also sensitive to therapeutic effects with treatment agents other than sildenafil. A severity classification for ED has recently been developed, in addition to a brief screening version of the instrument. This review includes the strengths as well as limitations of the IIEF, along with some potential areas for future research.

International Journal of Impotence Research (2002) **14**, 226–244.
doi:10.1038/sj.ijir.3900857

Keywords

erectile dysfunction; sexual dysfunction; psychometric validation; diagnostic classification; self-report questionnaire

Received 5 January 2002; accepted 16 January 2002

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Start Application Here

Prostate Cancer

Vision

Conquer prostate cancer

Mission

Support research that will eliminate prostate cancer

Prostate cancer is the most commonly diagnosed cancer in men, accounting for 30 percent of all cancers in men. In 2008, approximately 186,320 men in the United States will be diagnosed with prostate cancer and an estimated 28,660 will die from the disease. Prostate cancer is second only to lung cancer as a leading cause of cancer deaths in men. During the period of 2000 to 2003, the average annual incidence of prostate cancer among African American men was 60 percent higher than among Caucasian men. Since 1980, the average annual death rate among African American men has been more than twice that of Caucasian men. Currently, there is no cure for locally advanced or metastatic prostate cancer.

- Funding Opportunities
- Search Awards
- Integration Panels
- Peer Review Participants
- Related Prostate Cancer Links

Prostate Cancer

Congressional Appropriations

- $810 million in FY97–07
- $80 million in FY08
- Research Program Fact Sheet

Innovative Minds in Prostate Cancer Today (IMPaCT)

- 2007 IMPaCT Meeting
- First Ten Years (Adobe PDF)

Funding Summary

Prostate Cancer News

FY08 PCRP Funding Opportunities Now Available!

New PC Diagnostic Test Beats PSA (external link)

FY07 PCRP Proposals Recommended for Funding

More News...

Research Highlights

Training the Next Generation of HBCU Scientists as Prostate Cancer Researchers

Previous Highlights...

- 1,648 awards in FY97–06
- approximately 160 awards in FY07
- Previous Proposals Recommended for Funding

Response to Petition from Cary Urology
For Change in Methodology for Radiation Oncology – Linear Accelerator
For the 2009 State Medical Facilities Plan

Response Contact: John F. Reilly, MD
Raleigh Hematology Oncology Associates, PC
d/b/a Cancer Centers of North Carolina
4000 Westchase Blvd
Suite 300
Raleigh, NC 27607

INTRODUCTION

Cary Urology has submitted a petition requesting that the 2009 State Medical Facilities Plan (SMFP) recognize a need for a dedicated prostate cancer linear accelerator, specifically in Service Area 20. Raleigh Hematology Oncology Associates, PC d/b/a Cancer Centers of North Carolina (CCNC) opposes this petition because it is based on inaccurate and incomplete information and does not represent sound health planning.

CCNC supports the overall concept that there is a need for additional linear accelerator capacity in Service Area 20 based upon the current availability of linear accelerators per 120,000 area residents, particularly in densely populated areas of the state with a minimum of 600,000 residents. However, to limit this expanded capacity to the treatment of prostate cancer fails to recognize the broader need for greater access to radiation therapy services to address cancer incidence and mortality rates for all types of cancer in North Carolina. The proposed petition as written also fails to recognize that the benefits of an organized prostate cancer center can easily be achieved and have been achieved by other providers without a dedicated linear accelerator limited only to the treatment of prostate cancer. For these reasons, CCNC recommends that any requested change in the 2009 SMFP to recognize greater need for linear accelerator services reflect a broader need for such specialized equipment.

COMMENTS

The 2008 SMFP does show that in Service Area 20, the ratio of existing and approved linear accelerators to the population is just over the level of one accelerator per 120,000 persons. However, even if one accepts the assertion that this data shows a quantitative need for additional linear accelerator capacity in Service Area 20, there is no valid basis to suggest that such need should be limited to treating prostate cancer only nor does Cary Urology provide any basis that there is enough incremental demand to support a dedicated linear accelerator.

Cancer Statistics Support the Need for General Purpose Linear Accelerator

Cary Urology's petition points to the high age-adjusted death rate from prostate cancer in North Carolina as a basis for a dedicated prostate cancer linear accelerator. In fact, the National Cancer Institute's (NCI's) official website www.statecancerprofiles.cancer.gov classifies prostate cancer in North Carolina as "Similar to U.S. Rates" based on age-adjusted cancer death rates. Only lung and bronchus cancer in males is classified as "Above the U.S. Rate" for North Carolina as a

whole. Please see Attachment A for an excerpt from the NCI website comparing age-adjusted cancer death rates by site for North Carolina to U.S. rates.

Cary Urology identifies a prostate cancer death rate of 35.6 per 100,000 population, which may represent outdated statistics. The NCI website identifies a 2004 age-adjusted death rate from prostate cancer of 32.4 representing a recent annual decline of 4.3 percent.[1] Thus, according to NCI prostate cancer death rates in North Carolina are not only comparable to the U.S. on an age-adjusted basis but also are declining. In fact, the death rate from prostate cancer in North Carolina is declining at a greater rate than almost all other cancers. According to NCI data, the North Carolina death rate from prostate cancer declined by 5.3 percent over the five-year period 2000-2004. Only cervical cancer death rates declined at a greater rate. During this same period, at least 7 other cancer sites experienced increasing death rates in North Carolina. Please see Attachment B for a graphic presentation of this comparison. These data suggest that there are numerous other cancer types that bear greater concern than prostate cancer in terms of addressing increasing death rates.

A linear accelerator dedicated solely to prostate cancer will not begin to address the numerous other cancer types that take a much greater toll on North Carolina residents. As shown below, Cary Urology fails to recognize that deaths due to prostate cancer represent roughly five and a half percent of all cancer deaths both in North Carolina and in Service Area 20, for which Cary Urology proposes an additional linear accelerator in the 2009 SMFP. To the extent that additional linear accelerator capacity is needed in North Carolina or in Service Area 20, it is much more appropriate to recognize the need for a linear accelerator that will meet the need for treating all cancer types.

Comparison of Average Annual Deaths by Cancer Site*

	All Cancers	Prostate	Percent of All Cancers
North Carolina	16,136	906	5.6%
Wake	881	48	5.4%
Franklin	100	5	5.0%
Harnett	177	10	5.6%
Total Area 20	1,158	63	5.4%

Source: National Cancer Institute, State Cancer Profiles

** Average deaths per year 2000 - 2004*

[1] www.statecancerprofiles.cancer.gov/

Cary Urology also focuses on the higher death rates for African Americans due to prostate cancer. Again, Cary Urology fails to recognize that African Americans in both the U.S. and North Carolina face a disparity in cancer death rates for most cancer types. Data from NCI demonstrates that age-adjusted death rates for all cancer types reflect a significant disparity between White and African Americans. This is true at the national level, within North Carolina, and within Service Area 20, as shown below.

Comparative Age Adjusted Death Rate by Race

	Total Death Rate*		
	White	African American	Percent Difference
US	190.7	238.8	25.2%
North Carolina	192.5	238.4	23.8%
Service Area 20			
Wake	173	224	29.5%
Harnett	216.6	261.4	20.7%
Franklin	220.7	236.3	7.1%

Source: National Cancer Institute, State Cancer Profiles

**Age adjusted death rate for all cancer types.*

Cary Urology's proposal to serve only prostate cancer patients will address only a fraction of the existing disparity in death rates by race. The data above would also suggest that White residents of Harnett and Franklin Counties in Service Area 20, when compared with the rest of North Carolina and the country as a whole, face a significant disparity in cancer death rates for all cancer types (not just prostate cancer). Thus, should additional need for linear accelerator capacity in Service Area 20 be recognized in the 2009 SMFP, this need should not be limited to serving only prostate cancer.

Cary Urology may argue that having a linear accelerator dedicated to the treatment of prostate cancer will "free up" existing linear accelerator capacity to treat other cancers, but this argument is flawed because this can only happen if all or most of the urologists in Service Area 20 refer exclusively to the proposed prostate cancer center. There are two flaws in this thinking. First, it would be extremely disruptive to established referral relationships and treatment sources for other urology practices to redirect all of their patients to the proposed dedicated prostate linear accelerator. Second, it also is unlikely that other urology practices will refer all of their patients to a radiation therapy practice operated by a competing urology group, particularly without any documentation of improved quality or outcomes. To assume that any capacity would be "freed-up" would in essence require all Service Area 20 urology patients to be referred to the proposed prostate cancer center. This assumption would limit patient choice and actually reduce accessibility to cancer treatment services in the Service Area.

Continuity of Prostate Care Can Be Provided without a Dedicated Linear Accelerator

Cary Urology claims that North Carolina lacks a center with a linear accelerator that is dedicated for the treatment of prostate cancer. [2] In its Petition, Cary Urology mentions three prostate cancer centers in Atlanta, Georgia; Denver, Colorado; and Akron, Ohio but does not specifically name any of these centers. It is more than likely that the reference to a prostate cancer center in Atlanta, Georgia is a reference to Radiotherapy Clinics of Georgia (RCOG), which serves prostate patients from throughout Georgia, the southeast region, the U.S. and even foreign countries. What Cary Urology fails to recognize is that at least one of these centers, RCOG in Atlanta, does not operate any linear accelerators that are dedicated to prostate patients only.[3] RCOG, which is the closest prostate cancer center of excellence to North Carolina, has a highly developed program of prostate cancer treatment including a wide variety of adjunct therapies, emotional support, and wellness-related activities for prostate cancer. RCOG, however, also provides services to all cancer types in each of its 7 locations throughout Metro Atlanta, demonstrating that a prostate cancer center of excellence can be developed within a general oncology program and without a linear accelerator dedicated to only prostate cancer.

RCOG's centers have also been actively involved in prostate cancer research and have done so without a dedicated linear accelerator. RCOG's radiation oncologists have published, in peer-reviewed journals, better cure rates for prostate cancer with fewer side effects than Johns Hopkins as summarized below.

Principal Investigator/Institution	Treatment	Ten Year Cure Rates	Medical Journal Reference
Critz/RCOG	ProstRcision® (simultaneous irradiation)	83%	Updated from Journal of Urology (169:179,2003)
Walsh/Johns Hopkins	Radical Prostatectomy	80%	Updated from Urologic Clinic North America (24:395,1997)
Ragde/Seattle	Seed Implant Only and Irradiation plus seeds	55%	Cancer (83:989,1998)

Furthermore, RCOG has made significant progress in narrowing the disparities in prostate cancer death rates faced by African Americans. RCOG's radiation oncologists published a study in the peer-reviewed The Prostate Journal (Vol. 2, No. 2, 2000), which is provided in Attachment C. This study showed no significant difference in the cancer-free rates between White men and

[2] Cary Urology's claim that North Carolina lacks resources focused on the treatment of prostate cancer ignores the substantial achievements of CCNC physicians in this area. It also fails to recognize that Wake Forest University Baptist has established The Prostate Cancer Center of Excellence as part of its Comprehensive Center Program. This center fosters multidisciplinary research and treatment including the collaborative efforts of experts in genitourinary medical oncology, radiation oncology, urologic oncology, pathology and radiology. See-http://www1.wfubmc.edu/cancer/Research/Centers+of+Excellence/Prostate+Cancer+Center+of+Excellence

[3] Georgia Department of Community Health, Division of Health Planning

African American men who were treated by simultaneous seed implant and external beam irradiation as provided by RCOG. These findings were in spite of the fact that African American men presented with a higher average PSA than did White men. This study was conducted collaboratively between RCOG's radiation oncologists and local Atlanta Urology Group; however, neither a dedicated prostate linear accelerator nor a linear accelerator owned by a urology practice was required to conduct such research or to achieve the documented and highly successful patient outcomes.

RCOG provides a clear example that the development of an organized prostate cancer center in North Carolina can be achieved without a dedicated linear accelerator and that Cary Urology's petition for a dedicated linear accelerator to treat prostate cancer is without merit. RCOG is but one such example. The Texas Prostate Institute at the Texas Cancer Clinic represents an additional example of organized prostate cancer treatment without a dedicated linear accelerator and operated by appropriately trained radiation oncologists, not urologists.[4]

CONCLUSION

Cary Urology's petition is not supported by the facts. Yes, prostate cancer death rates are a concern in North Carolina. However, there are many cancer types that are just as concerning and should be addressed by any linear accelerator added to the 2009 SMFP. Yes, African American men face disparities in death rates from prostate cancer. However, a dedicated linear accelerator is not needed to develop a highly specialized approach to treating prostate cancer across all races with comparable outcomes. Most importantly, the petition proposed by Cary Urology is so narrow in its focus that the only possible applicant approved in Service Area 20 would be Cary Urology. As such, the petition does not represent appropriate health planning for the state which is concerned with accessible and appropriate healthcare for all of its residents. The petition as submitted is self-serving and not in the best interest of the residents of North Carolina. Furthermore, there is no published data to show that treatment in a dedicated prostate cancer center is superior in terms of outcome compared to a quality, state-of-the-art general oncology practice.

CNCC urges the Technology and Equipment Committee of the State Health Coordinating Council to deny Cary Urology's petition to modify the 2009 SMFP or at minimum to recognize the need for additional "general" linear accelerator capacity in Service Area 20 to meet the needs of all cancer patients. We appreciate the opportunity to present these comments and would welcome the opportunity to participate in a discussion of the petition and to address any questions that the committee may have about the information in these comments.

[4] www.texascancerclinic.com

Attachment A

NCI Comparison of Age Adjusted Death Rates by Site for North Carolina and U.S.

State Cancer Profiles

Rate/Trend Comparison by State/County

Death Rate/Trend Comparison by State/County, death years through 2004
North Carolina versus United States

All Races, Both Sexes

	Above US Rate	Similar to US Rate	Below US Rate
Rising Trend	Priority 1: rising ↑ and above ↑ [none]	Priority 2: rising ↑ and similar = Kidney & Renal Pelvis (Females) Lung & Bronchus (Females) Melanoma of the Skin (Males) Pancreas (Females)	Priority 3: rising ↑ and below ↓ Liver & Bile Duct (Females) Liver & Bile Duct (Males)
Stable Trend	Priority 4: stable → and above ↑ [none]	Priority 6: stable → and similar = Bladder (Females) Bladder (Males) Esophagus (Females) Esophagus (Males) Kidney & Renal Pelvis (Males) Leukemia (Males) Non-Hodgkin Lymphoma (Females) Non-Hodgkin Lymphoma (Males) Oral Cavity & Pharynx (Males) Ovary (Females) Thyroid (Males) Uterus (Females)	Priority 7: stable → and below ↓ [none]
Falling Trend	Priority 5: falling ↓ and above ↑ Lung & Bronchus (Males)	Priority 8: falling ↓ and similar = Brain & ONS (Females) Brain & ONS (Males) Breast (Females) Cervix (Females) Childhood (Ages <15, All Sites) (Females) Childhood (Ages <15, All Sites) (Males) Childhood (Ages <20, All Sites) (Females) Childhood (Ages <20, All Sites) (Males) Colon & Rectum (Females) Colon & Rectum (Males) Leukemia (Females) Melanoma of the Skin (Females) Oral Cavity & Pharynx (Females) Pancreas (Males) Prostate (Males) Stomach (Females)	Priority 9: falling ↓ and below ↓ [none]

Stomach (Males)

Created by statecancerprofiles.cancer.gov on 03/24/2008 11:27 pm.

Trend[2]

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.

Rate Comparison

Above ↑ when 95% confident the rate is above and Rate Ratio[3] > 1.10
Similar = when unable to conclude above or below with confidence.
Below ↓ when 95% confident the rate is below and Rate Ratio[3] < 0.90

[1] Priority Indices were created by ordering from rates that are rising and above the comparison rate to rates that are falling and below the comparison rate.
[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.
[3] Rate ratio is the county rate divided by the US rate.

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+). Population counts for denominators are based on Census populations as modified by NCI.

Note: When the population size for a denominator is small, the rates may be unstable. A rate is unstable when a small change in the numerator (e.g., only one or two additional cases) has a dramatic effect on the calculated rate. Suppression is used to avoid misinterpretation when rates are unstable.

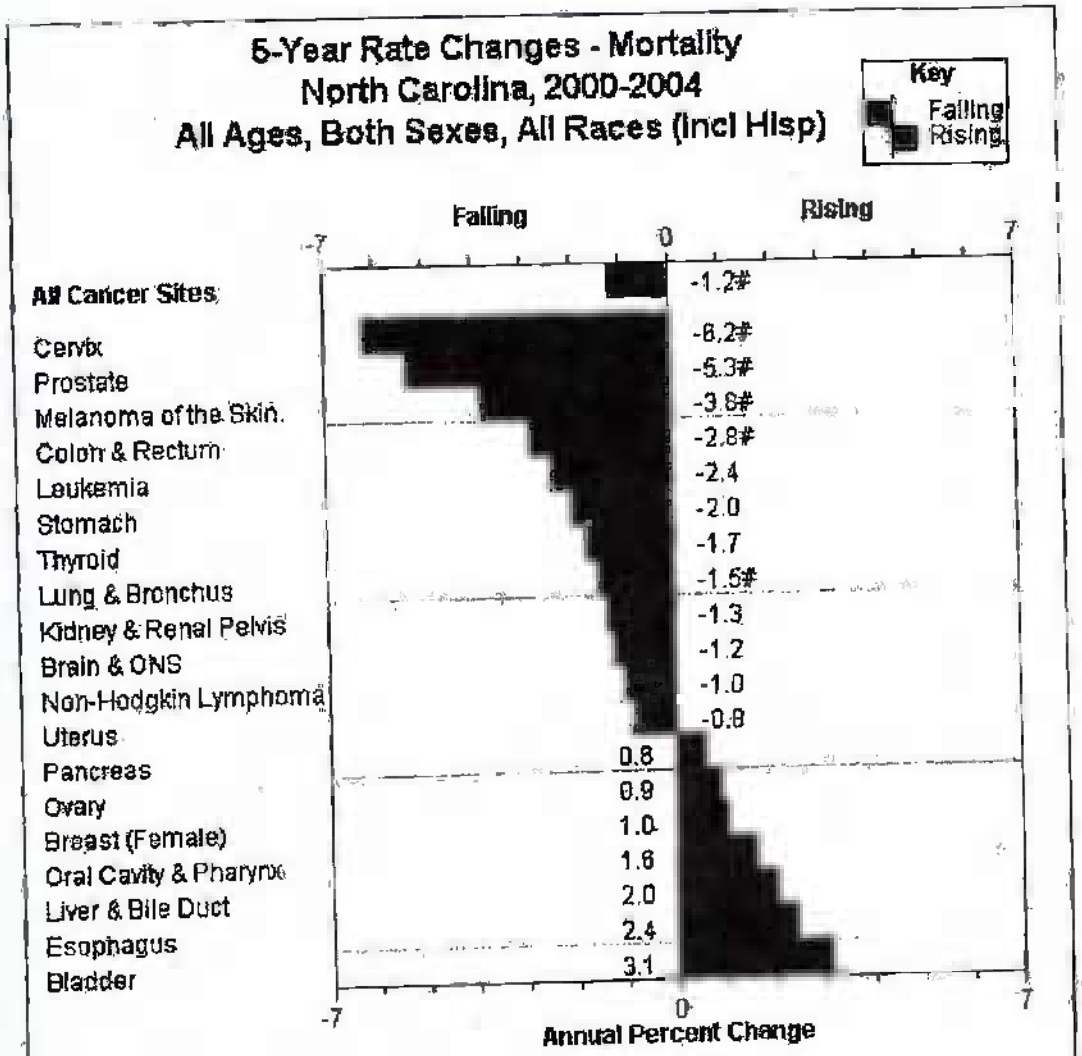
State Cancer Registries may provide more current or more local data. Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

Data for the following has been suppressed to ensure confidentiality and stability of rate estimates:
Thyroid (Females)

Attachment B

Comparison of 5-year Mortality Rate Changes by Cancer Site in North Carolina, NCI

5-Year Rate Changes - Mortality
North Carolina, 2000-2004
All Ages, Both Sexes, All Races (Incl Hisp)



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Annual Percent Change (APC) over the 5-year period calculated by SEER*Stat.
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 (deaths per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ... , 80-84, 85+). Population counts for denominators are based on Census populations as modified by NCI.

- The annual percent change is significantly different from zero (p<0.05).

Attachment C

The Prostate Journal (vol. 2, No. 2, 2000)

African American Men with Prostate Cancer Treated by Simultaneous Irradiation

W. Hamilton Williams, MD,* Frank A. Critz, MD,*
James B. Benton, MD,* Keith Levinson, MD,†
Walter Falconer, MD,* Emerson Harrison, MD,*
Clinton T. Holladay, MD,* and David A. Holladay, MD‡
*Radiotherapy Clinics of Georgia, Decatur, Georgia, U.S.A.
†Georgia Urology, Decatur, Georgia, U.S.A.
‡Atlanta Urological Consultants, Atlanta, Georgia, U.S.A.

ABSTRACT

Objectives: Reportedly, African American men (AAM) with prostate cancer present with more advanced disease and have worse outcomes than white men (WM). We evaluate this concept in our series of men with prostate cancer treated with modern simultaneous irradiation in a busy private practice.

Materials and Methods: From 1993 to 1998, 1270 men with clinical stage T1T2N0 prostate cancer were treated by ultrasound-guided transperineal implantation of I-125 in the prostate and seminal vesicle (median dose 12,000 cGy) followed by external-beam radiation therapy (4500 cGy) including an additional 750 cGy seminal vesicle boost in men with adverse prognostic factors. None received neoadjuvant or adjuvant hormone therapy. The median pretreatment prostate specific antigen (PSA) level for 141 AAM and 1129 WM was 8.6 ng/ml and 7.1 ng/ml, respectively, a significant difference ($p = 0.0001$). Disease freedom is defined as achievement and maintenance of a PSA nadir of ≤ 0.2 ng/ml. The median follow-up is 24 months (range 12–66 months).

Results: Disease-free survival for the entire group is 89% (± 3%) at 5 years. Overall, or when analyzed by stage, Gleason score, or age, AAM present with higher pretreatment PSA levels than WM. However, according to pretreatment PSA groups of ≤ 4.0 ng/ml, 4.1–10.0 ng/ml, 10.1–20.0 ng/ml, and > 20.0 ng/ml, the 5-year disease-free survival rates for AAM and WM in these groups are 100% and 95%, 85% and 92%, 67% and 80%, 76% and 83%, respectively. No significant difference in disease freedom is observed within the above PSA groups or by analysis of Gleason score or stage. With disease freedom as an end point, race is not a significant factor on multivariate analysis.

Conclusions: AAM present with higher pretreatment PSA levels than WM both overall and when stratified by stage, Gleason score, or age. In this series, however, disease-free survival rates of AAM and WM are not significantly different overall or according to pretreatment variables. Thus, race does not appear to be an adverse prognostic factor after simultaneous irradiation.

INTRODUCTION

Multiple reports have documented that, in comparison with white men (WM), African American men (AAM) have a higher incidence of prostate cancer (1,2), present with more advanced disease at initial diagnosis (2–4), and appear to have a worse prognosis than WM (5–7). Explanations for these differences include both a lack of equal access to healthcare (8) and the possibility that prostate cancer in AAM is more virulent than in WM (6,7). Additionally, some reports have noted younger AAM have a poorer disease freedom than older AAM, the opposite of the finding in WM (8,9). However, there is no consensus, because other studies have not found a difference in outcome (10–14). To date, most studies, regardless of finding, were conducted in the pre-prostate specific antigen (PSA) era or have overall survival or disease-specific survival as an end point, not a PSA-defined end point (2–6,8–10,12,13).

Since the introduction of PSA for clinical use in 1987, virtually all reports on treatment results for localized prostate cancer use PSA end points to define disease freedom. PSA is the most powerful pretreatment predictor of successful prostate cancer treatment in most series, regardless of the technique used. However, of the six surgery or radiotherapy reports describing freedom from

Address correspondence and reprint requests to: Frank A. Critz, MD, 2349 Lawrenceville Highway, Decatur, GA 30033, U.S.A.

cancer using a PSA-based end point (7,11,14–17), only Zagars et al. (17) and Waterhouse et al. (16) (a study that has appeared in abstract form only) reported results with complete pretreatment PSA information. The study by Zagars et al. (17) evaluated disease freedom with a simple rising PSA level, while Waterhouse et al. (16) required two rises above 1.0 ng/ml. In this study, with complete pretreatment PSA information, we evaluate the concept of whether AAM with prostate cancer have a worse outcome than WM when treated with modern simultaneous irradiation. However, unlike other radiotherapy series, disease freedom is defined by the achievement and maintenance of a PSA nadir level of 0.2 ng/ml, the identical definition used after radical prostatectomy.

MATERIALS AND METHODS

From February 1993 to April 1998, 1276 men with clinical stage T1T2N0 prostate cancer were treated by simultaneous radiation implantation of I-125 in the prostate followed by external-beam radiotherapy). According to race, 141 (11%) were AAM, 1129 (88.5%) were WM, and 6 (< 1%) were of other races. For this analysis, these latter six men are excluded. All men had biopsy-proven prostate adenocarcinoma. Staging evaluation was by digital rectal exam. Twenty-seven (2%) of the 1270 men had a pretreatment staging lymphadenectomy (N0); otherwise, pretreatment planning computed axial tomography scans were negative for lymphadenopathy (NX). Table 1 documents the clinical characteristics of all men according to race. All 1270 men underwent ultrasound-guided transperineal implantation of I-125 in the prostate and seminal vesicle. The median prostate implant dose, calculated at the capsule, was 12,000 cGy (range 8,000–18,000 cGy). Three weeks postimplant, the prostate, seminal vesicles, and periprostatic tissue were treated with 4500 cGy of external-beam irradiation at 150 cGy per treatment, 5 days per week, via a combination of bilateral arc and conformal beam technique. Two hundred sixty-seven men with adverse prognostic factors also received a 750-cGy external beam boost to the

TABLE 1. Clinical characteristics[a]

Characteristics	Overall	AAM	WM	p Value
N:	1270	141 (11%)	1129 (89%)	
Median age (range) (years)	65 (40–88)	63 (44–73)		<0.001
Follow-up (months)				
Median	24			
Range	12–72			
Pretreatment PSA, ng/ml				
Median (mean)	7.10 (9.0)	8.3 (11.3)	7.05 (8.7)	<0.001
Range	0.3–87	2.8–72.8	0.3–87	
0–4.0	96 (7%)	5 (3%)	91 (8%)	
4.1–10	830 (65%)	80 (57%)	750 (66%)	
10.1–20	274 (22%)	38 (27%)	236 (21%)	
>20.0	70 (6%)	18 (13%)	52 (5%)	
Stage				
T1	584 (46%)	70 (50%)	514 (46%)	
T2	686 (54%)	71 (50%)	615 (54%)	NS
Gleason score[b]				
2–6	939 (74%)	104 (74%)	835 (74%)	
7–10	311 (26%)	37 (26%)	274 (26%)	NS

[a] NS, not significant.
[b] Gleason scores were unavailable on 20 patients.

seminal vesicles. No man received hormonal therapy before recurrence.

Disease freedom is defined as the achievement and maintenance of a post-treatment PSA nadir level of ≤ 0.2 ng/ml. Treatment failure is defined by a PSA nadir level of > 0.2 ng/ml or a subsequent rise in PSA above this level. Follow-up was performed every 6 months, with a median follow-up of 24 months (average 27 months; range 12–72 months). Disease-free survival rates are calculated by the Kaplan-Meier life table estimates method from the month of implantation, including 95% confidence intervals. Comparison between survival curves is performed by the Wilcoxon Rank-Sum Test. Comparisons of normally distributed pretreatment characteristics are performed with the chi-square test. Tests of PSA distribution are performed with the Mann-Whitney *U* test. Multivariate analysis was performed by the Cox proportional hazards model.

TABLE 2. Distribution of pretreatment PSA by clinical factors[a]

Factors	AAM	WM	*p* Value
Stage			
T1	7 (2.82–38)	7.1 (0.3–42)	0.56
T2	10.5 (3.9–72.8)	7 (0.8–87.8)	<0.001
Gleason score			
2–6	8 (2.82–38)	6.7 (0.3–60.4)	<0.004
7–10	15.1 (4.2–72.8)	7.8 (0.86–87.8)	<0.002
Age (years)			
<65	7.8 (2.82–41)[b]	6.5 (0.8–87.8)[c]	<0.002
≥65	10.5 (4.4–72.8)	7.3 (0.3–87.8)	<0.001

[a]Values given (ng/ml range).
[b] $p < 0.005$ between age groups.
[c] $p < 0.001$ between age groups.

RESULTS

A comparison of the pretreatment clinical characteristics between AAM and WM is given in Table 1. The median pretreatment PSA level for AAM was 8.5 ng/ml (range 2.8–72.8), and for WM it was 7.05 ng/ml (range 0.3–87), a significant difference ($p < 0.001$). We also analyzed PSA distribution according to race in the following pretreatment subgroups: Stage T1 or T2, Gleason scores 2–6 or 7–10, and age < 65 years or ≥ 65 years. Table 2 demonstrates that in all comparisons except for Stage T1 disease, AAM presented with a significantly greater PSA burden than WM. In the case of Gleason score of 7–10, AAM had nearly double the PSA level of WM (15.1 versus 7.8 ng/ml, respectively). According to age distribution within race, both AAM and WM who were ≥ 65 years presented with significantly higher pretreatment PSA levels than their younger counterparts ($p < 0.005$ and $p < 0.001$, respectively). Both younger AAM and older AAM had higher PSA levels than their WM counterparts ($p < 0.002$ and $p < 0.001$, respectively). AAM were significantly younger when they received their diagnoses than WM, with median ages of 63 and 67 years, respectively ($p = 0.001$). No significant difference was noted in the distribution of Gleason score or stage.

Overall disease freedom for the entire group of 1270 men is 89% (± 3%) at 5 years with no significant difference in disease-free survival observed between AAM and WM (Fig. 1). In addition, when men were stratified according to pretreatment PSA groups, no difference in disease-free survival was observed (Fig. 2 A–D). To minimize the effect of sample size, we additionally analyzed all men with PSA levels of ≥ 10.1 ng/ml according to race. The 5-year disease-free survival rates for AAM and WM were 72% and 80%, respectively ($p = 0.18$), a nonsignificant difference. At the 5-year follow-up, no difference in disease freedom was noted according to clinical stage or Gleason scores (Table 3). When AAM

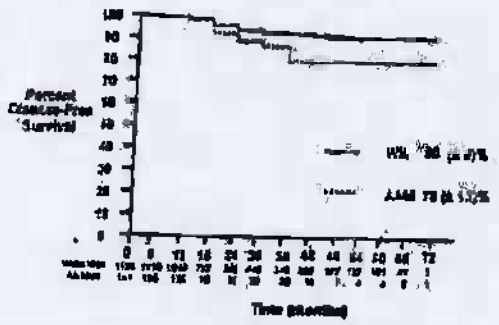

FIG 1. Comparison of disease-free survival rates for AAM versus WM. Disease freedom is defined as the achievement and maintenance of a PSA nadir level of ≤ 0.2 ng/ml. No significant difference is noted in disease-free results ($p = 0.69$). The overall disease-free survival rate for all 1270 men at 5 years is 89% (± 3%).

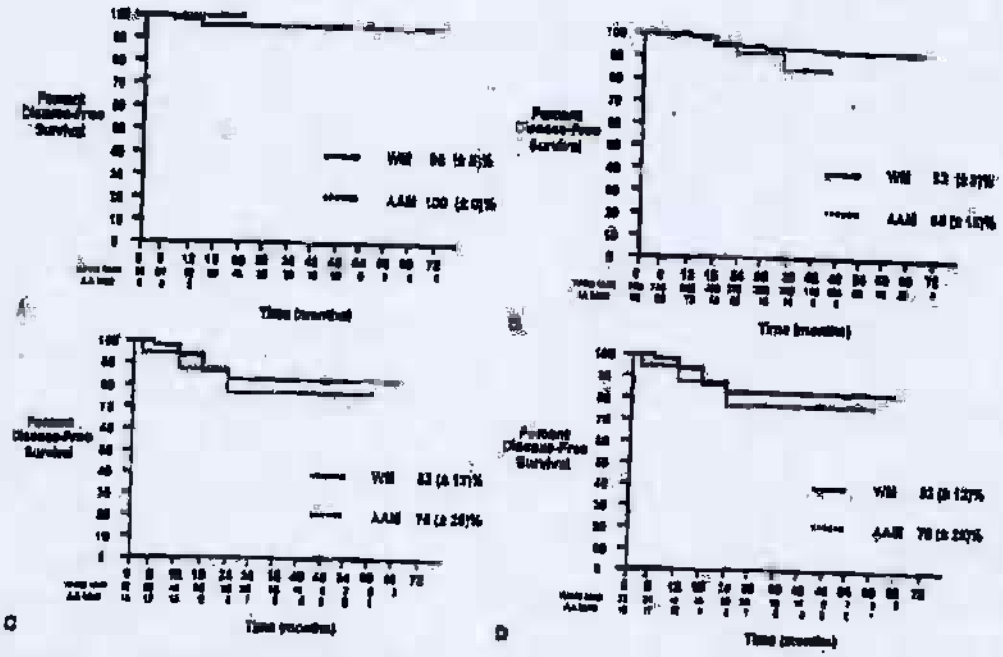

FIG. 2. PSA-monitored disease freedom of AAM versus WM based on stratification of pretreatment PSA level groups of ≤ 4.0 ng/mL, 4.1–10.0 ng/mL, 10.1–20.0 ng/mL, and > 20.0 ng/mL respectively. No significant difference is appreciated in disease-freedom among these groups ($p = 0.76$, 0.59, 0.37, and 0.49, respectively).

and WM were stratified within race according to age groups of < 65 years or ≥ 65 years, no difference in the disease-free survival rate was noted. In addition, no differences were noted when comparing older AAM to older WM and younger AAM to younger WM. (Table 3).

On multivariate analysis, pretreatment PSA level and Gleason score were significant predictors of subsequent disease freedom, whereas clinical stage, age, and race were not significant (Table 4).

DISCUSSION

Our finding that AAM with prostate cancer present with significantly higher pretreatment PSA levels than do WM is similar to observations by other investigators. Moul et al. (3) reported that AAM with clinical stage T1T2N0 prostate cancer before radical prostatectomy had significantly higher pretreatment PSA levels than did WM, even when the pretreatment PSA level was simultaneously controlled for stage, grade, and age. After surgery, Moul et al. (7) correlated pretreatment PSA levels with microscopic examination of the prostatectomy specimens, demonstrating a direct correlation of PSA levels with tumor volume for both races. Importantly, these investigators noted that AAM and WM had similar PSA values per unit of tumor volume. The mean tumor volume for AAM was 8.1 cc, which was significantly greater than the mean 4.68 cc tumor volume for WM. Moul et al. (7) concluded that pretreatment PSA level is a reasonable surrogate for the higher tumor volume of AAM. In a separate radical prostatectomy study, Powell et al. (5) also noted that AAM have a higher chance of capsular penetration and a significantly higher rate of positive margins than WM.

In men without prostate cancer, Eastham et al. (18) found that PSA levels are higher in AAM than in WM. After an evaluation of screening prostate biopsy specimens, these authors also discovered that AAM have a higher incidence of prostatic inflammation and suggested this as the cause of the elevated PSA level in AAM relative to WM without prostate cancer. Thus, there may be more than one cause for the difference in PSA level presentation between the two races.

After radical prostatectomy, Moul et al. (7) observed a 62% 5-year disease-free survival rate for WM (mean pretreatment PSA level 9.9 ng/

TABLE 3. 5-year disease-free survival rates of AAM versus WM according to pretreatment clinical factors[a]

Factors	AAM	WM	p Value[b]
Stage			
T1 (n)	78 (70)[c]	91 (514)	0.16
T2 (n)	77 (71)	88 (615)	0.24
Total	(141)	(1129)	
Gleason score[d]			
2–6 (n)	82 (104)	92 (835)	0.34
7–10 (n)	62 (37)	83 (274)	0.12
Total	(141)	(1109)	
Age (years)			
<65 (n)	78 (80)[e]	91 (482)[f]	0.38
	p = 0.76	p = 0.37	
≥65 (n)	78 (61)	89 (647)	0.14
Total	(141)	(1129)	

[a]Values are given as percentage (No.).
[b]Chi-square analysis used.
[c]For 48 months.
[d]Twenty men did not have Gleason scoring.
[e]p = 0.76 between age groups for AAM.
[f]p = 0.37 between age groups for WM.

ml), which was significantly better ($p = 0.018$) than the 38% 5-year disease-free survival rate for AAM (mean pretreatment PSA level 15.8 ng/ml). This significant difference in treatment outcome is particularly impressive because the median follow-up time was only 13.9 months in the study by Moul et al. (3) and only 45 WM and 4 AAM were at risk for 5-year follow-up. Furthermore, this study was conducted in the U.S. Military, which provides equal access in healthcare.

TABLE 4. Multivariate analysis of pretreatment factors

Factor	p Value
Pre-PSA	<0.001
Gleason score	<0.002
Stage	0.587
Age	0.184
Race	0.173

In contrast, Iselin et al. (14) studied 115 AAM and 1204 WM after radical prostatectomy, finding no difference in pathologic stage or PSA-defined disease-free survival rates, although the latter data were not shown. In specimen-confined tumors, AAM had a greater tumor volume than WM, which is similar to the findings of Moul et al. (7). Interestingly, AAM and WM in the specimen-confined group had similar disease-free survival rates, which suggests that complete removal of the cancer can equalize outcome despite the greater tumor burden. However, because AAM with positive margins tended to fail earlier than WM with positive margins, the authors believe that AAM may have biologically more aggressive tumors (14).

After monotherapy by transperineal implantation of radioactive iodine or palladium in the prostate, Waterhouse et al. (16) noted a 66% 3-year disease-free survival rate for 158 WM compared with a 39% 3-year disease-free survival rate for 38 AAM with clinical stage T1T2N0 prostate cancer. AAM had a higher pretreatment PSA level than did WM, but Gleason score and clinical stage were similar for both groups. Recurrence was defined as two consecutive PSA increases above 1.0 ng/ml. According to the authors, the treatment outcome was not statistically different between the races because of the small number of AAM.

After monotherapy with external beam radiation, Kim et al. (15) noted a significantly higher disease-free survival rate for WM (median pretreatment PSA level 15.8 ng/ml) than AAM (median pretreatment PSA level 68.4 ng/ml). Because of the very high pretreatment PSA levels in AAM, it is likely that most of these men had metastatic disease when treated. Zagars et al. (17) also evaluated treatment outcome after external-beam irradiation alone in a study of 116 AAM and 1085 WM with clinical stage T1–T4 prostate cancer. In contrast to the report by Kim et al. (15), the pretreatment PSA levels were much lower: the median for AAM was 14.0 ng/ml and that for WM was 9.5 ng/ml, a significant difference. With disease freedom defined as a rising PSA regardless of the nadir achieved, no significant difference was observed between AAM and WM when stratified by pretreatment PSA levels, Gleason scores, or stages of disease.

However, postradiotherapy PSA nadir level is the most important predictor of subsequent disease freedom after prostate cancer radiotherapy (19–21). Further, Horwitz et al. (22) have shown that varying the definition of disease

freedom after radiotherapy can enhance the reported disease-free survival rate. Because the study by Zagars et al. (17) included a disproportionate number of AAM who received hormonal therapy and lacked a strict PSA nadir-based definition of disease-free survival, the treatment results may be overstated.

Similar to Moul et al. (3), we found that AAM have a significantly greater PSA level than WM even after stratification of pretreatment clinical factors (Table 2). However, in the present study, no difference was observed in disease freedom between AAM and WM overall (Fig. 1), by pretreatment PSA groups (Fig. 2 A–D), or when men were stratified by stage, Gleason score, or age (Table 3). Also, we found no evidence that young AAM fare worse than older AAM or young WM. On multivariate analysis, race is not a significant prognostic factor when men are treated by simultaneous radiation (Table 4).

Therefore, whether comparing disease-free survival rates overall or according to various pretreatment clinical characteristics, or when evaluating race by multivariate analysis, AAM have the same treatment outcome as WM when treated by simultaneous radiation even though AAM present with significantly higher pretreatment PSA levels. These observations may be of greater interest because this study was conducted in a community-based private practice where most men with prostate cancer will be treated, whereas the study by Moul et al. (3) was conducted in a single U.S. tertiary-care military institution.

Assuming that the higher PSA levels of AAM reflect more extensive disease, simultaneous radiation may be one reason that AAM have outcomes equal to WM. An I-125 implant that has a 60-day half-life initially is placed in the prostate. Three weeks after the implantation, external-beam radiation is started and given daily for 6 weeks. Thus, organ-confined malignant and benign prostate epithelium is irradiated simultaneously, which intensifies the intraprostatic radiation dose. Extracapsular disease is not treated by seed implantation alone. Because extracapsular disease is present subclinically in at least half of all men with clinical stage T1T2N0 prostate cancer, and even in 25% of men with a pretreatment PSA level of ≤ 4.0 ng/ml (23), all men in this study had irradiation of microscopic extracapsular disease by the follow-up external beam radiation. Therefore, although AAM present with higher pretreatment PSA levels than WM, which is indicative of greater intraprostatic tumor volume and more extensive extracapsular disease, simultaneous radiation may equalize the treatment outcomes for both races.

These observations correlate with the findings of Waterhouse et al. (16), Moul et al. (7), and Iselin et al. (14). Because prostate implantation alone does not effectively treat extracapsular disease, and because AAM present with higher pretreatment PSA levels than WM, AAM should have a failure rate greater than WM when treated by prostate implantation alone, as observed by Waterhouse et al. (16). In the radical prostatectomy study by Moul et al. (7), > 80% of both AAM and WM had a nerve-sparing radical prostatectomy, almost always a bilateral nerve-sparing procedure. Because AAM presented with more extensive disease than WM but had the same rate of nerve-sparing radical prostatectomies, more AAM would be expected to have disease recur. While no comment is made in the report of Iselin et al. (14) regarding the use of nerve-sparing surgical techniques, the concept of comprehensive treatment for AAM is supported because all men with specimen-confined tumors in their series had similar outcomes despite larger tumor volumes for AAM.

The findings in this study are encouraging but should be interpreted cautiously. This study is similar to those of Moul et al. (7) and Iselin et al. (14) in terms of the number of AAM at risk as well as in length of follow-up for those patients treated in the PSA era; nonetheless, the follow-up is short. The PSA levels for AAM in this report are lower than those reported by Moul et al. (7), perhaps reflecting a lower disease burden. Additionally, some investigators have suggested that because of educational and economic differences between the races, PSA screening efforts have not been as effective among AAM as WM (24,25). Twenty-seven percent of the Georgia population is African American (26), whereas only 11% of men in this report were AAM. Therefore, through educational or economic selection measures, AAM treated in our private-practice clinic may not reflect the overall AAM population.

On the other hand, the results achieved in the treatment of AAM in this report may reflect the current status of prostate cancer management relative to race better than other published reports. Vijayakumar et al. (27) noted that the average pretreatment PSA level in AAM has declined sharply, even more than in WM, over the periods 1988 to 1995, reflecting increased use of PSA screening. In this study, AAM were treated

between 1993 and 1998 when PSA screening was performed even more intensively. Thus, through more extensive PSA screening was conducted during the years covered by this study, earlier detection of prostate cancer in AAM may be responsible for the lack of a significant difference in treatment outcome between AAM and WM.

CONCLUSION

In this study of race and prostate cancer, AAM with clinical stage T1T2NX prostate cancer treated in private practice present with higher pretreatment PSA levels than WM. Nonetheless, after the evaluation of treatment outcome, AAM have the same disease-free survival rates as WM when treated by simultaneous radiation. If their higher pretreatment PSA levels reflect greater tumor burden and, thus, more locally advanced disease, simultaneous irradiation appears to compensate for the more extensive rates of prostate cancer in AAM.

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Timothy E. Cloninger, M.D.
Robert W. Fraser, III, M.D., F.A.C.R.
Mark Kirsch, M.D., F.A.C.R.
Steven R. Plunkett, M.D.
Mark J. Liang, M.D.
John B. Konefal, M.D.
Michael R. Haake, M.D.
Donna J. Girard, M.D.
Timothy H. Seymore, M.D.
Scott McGinnis, III, M.D.
Charles J. Meakin, III, M.D.
Bradley T. McCall, M.D.
Yvonne Mack, M.D.
Thomas G. Trautmann, M.D

SOUTHEAST RADIATION ONCOLOGY GROUP, P.A.

200 Queens Road, Suite 400 • Charlotte, N.C. 28204
Phone (704) 333-7376 • Fax (704) 333-7386 • www.treatcancer.com

Stuart H. Burri, M.D.
Arthur W. Chaney, III, M.D.
Gregory C. Mitro, M.D.
Helen R. Maddux, M.D.
William B. Warlick, M.D.
William E. Bobo, M.D.
Kevin S. Roof, M.D.
Anthony J. Crimaldi, II, M.D.
Vipul V. Thakkar, M.D.
M. Maddie Sharma, M.D.
Roger F. Anderson, Jr., M.D.

Paul A. Williams, M.S.P.H.
Administrator

April 10, 2008

Dr. Christopher G. Ullrich, Chair
SHCC Technology Committee
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Chris:

At the Discussion Group on Radiation Oncology Issues, which we attended yesterday in Raleigh, Dr. Kevin Khoudary of Cary Oncology noted that his group had filed a certificate of need for a new center focused on the treatment of prostate cancer, which he said would apply a 'multidisciplinary approach', involving both urologists and radiation oncologists.

We feel strongly that this petition should not be granted, for several reasons:

1) there is no evidence that a radiation treatment center devoted solely to the treatment of cancers of one specialty disease site achieves results superior to those of a typical full service radiation oncology department. You do not need to have a devoted center in order to have excellent multidisciplinary input for cancer patients. In particular, the Research Triangle area is well supplied with radiation oncology centers, many of which have well established multidisciplinary programs;

2) the American College of Radiology, American College of Radiation Oncology and the American Society for Therapeutic Radiology and Oncology have all petitioned the Center for Medicare and Medicaid Studies (CMS) to exclude radiation oncology as an in-office ancillary services (IOAS) provision under the Stark physician self-referral regulations. These national organizations have concluded that ownership of a linear accelerator by referring physicians, e.g. urologists, creates an undue financial incentive for self-referral for this costly treatment. CMS has indicated that it could issue clarifications regarding the IOAS later this year, which would make centers, such as the one proposed by Dr. Khoudary, illegal. Whether or not CMS acts this year, we agree with these national organizations that the ownership of linear accelerators by referring physicians creates an inappropriate financial incentive to self-refer;

3) the majority of radiation treatments at a urology linac center would be intensity-modulated radiation treatments (IMRT) for prostate cancer. IMRT treatments are

currently very well compensated by Medicare and private insurers. Allowing single organ specialty centers to selectively capture those highly reimbursed IMRT treatments would have a significant negative financial impact on any nearby radiation oncology centers; and,

4) the Medical Facilities Planning Section has worked hard to create and appropriately update a linac needs methodology for North Carolina. If the CON Section were to grant the request of Dr. Khoudary's group for an organ-specific linac center, it would create an unfortunate precedent. Other North Carolina physicians, who routinely refer cancer patients for radiation therapy, e.g. medical oncologists, breast surgeons, other urologists, would similarly petition the state. This would not only undermine the present carefully crafted needs methodology currently in place, it would also threaten the current collegial and multidisciplinary approach to cancer care which now routinely applies across North Carolina, to the detriment of our patients.

In summary, we feel that the needs of prostate cancer patients in the Research Triangle area – as well as state-wide - are already being very well addressed by the existing radiation oncology service providers. Accordingly, we strongly recommend that you not grant this request for a 'specialty' linac center, which would surely open a regulatory 'Pandora's box'.

Sincerely,

Bob Fraser

Robert W. Fraser, III, M.D., FACR
President

NCHA
PO Box 4449
Cary, NC 27519 - 4449

919 / 677-2400
919 / 677-4200 fax
www.ncha.org

April 11, 2008

MEMORANDUM

TO: Tom Elkins, DHSR Planner
Elizabeth Brown, DHSR Chief of Budget & Planning

FROM: Mike Vicario, Vice President of Regulatory Affairs
919-677-4233 <mvicario@ncha.org>

SUBJECT: Comment: Cary Urology Petition for a methodology to establish need for an IMRT/IGRT – capable linear accelerator

The Cary Urology petition proposes a separate linear accelerator methodology for a prostate cancer center. The petition reports that 20% of linear accelerator pts are there for prostate cancer, and that NC men have higher prevalence rates. The petition argues that many NC counties have high death rates, perhaps attributable to a very high incidence in non-white males. It focuses on the need for appropriate conformal therapy and suggests that a more integrated care team (including urology and oncology) approach would be used.

North Carolina's approach to establishing need for linear accelerators considers that patients seek treatment locally for therapies like radiation oncology that require multiple visits. Most likely an existing linear accelerator facility will be closer to a patient with the disease than the proposed new center and therefore more likely to seek services locally. Each of the three existing centers mentioned in the petition are located in metropolitan areas with populations over 2.5 million persons, more than twice the population of the Raleigh-Durham metropolitan area.

2000 Metropolitan Population Estimates	
Atlanta, GA MSA	4,112,198
Denver--Boulder--Greeley, CO CMSA	2,581,506
Cleveland--Akron, OH CMSA	2,945,831

The petitioner reports that there are now 7 operational linear accelerators in Wake County and an additional linear accelerator from last year's SMFP. The petitioners expressed need for more widespread education on prostate disease and more integrated treatment approaches has merit. However an approach that establishes new equipment need for disease-based clinics in addition to the existing utilization-based methodology is potentially duplicative to the existing process and should not be considered as a supplement to the existing methodology.

NCHA recommends that the Council support the existing need methodology and encourage the petitioner to work with existing linear accelerator providers.