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

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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 Determ-ination	
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

For immediate use

July 12, 2004 -- No. 350

Local angles: Alamance, Caswell, Chatham, Cumberland, Duplin, Durham, Edgecombe, Franklin, Granville, Guilford, Halifax, Harnett, Hoke, Johnston, Lee, Nash, Orange, Person, Rockingham, Sampson, Vance, Wake, Warren, Wayne and Wilson counties

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

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Paper

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

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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

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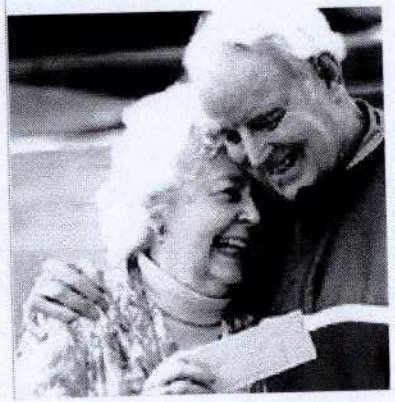
Prostate Cancer

Start Application Here

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**