

July 19, 2017

NC Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
Martha J. Frisone, Section Chief
Mike McKillip, Project Analyst
2704 Mail Service Center
Raleigh, NC 27699



RE: Annual Report for Project ID# J-8331-09, Original Owner being Parkway Urology, PA (also known as the Prostate Health Center) for acquisition of a linear acccelerator and development of a multidisciplinary prostate health center demonstration project in Raleigh (Wake County).

Dear Ms. Frisone and Mr. McKillip:

On February 23, 2011, Parkway Urology, PA received its Certificate of Need for Project ID# J-8331-09, which entailed the acquisition of a linear accelerator and development of a multidisciplinary prostate health center demonstration proejct in Raleigh ("The Prostate Health Center"). On May 1, 2013, The Prostate Health Center began operation at its newly constructed facility at 117 Sunnybrook Road in Raleigh.

As part of the CON application, Parkway Urology submitted a letter of commitment (Exhibit 57 of the original CON application) to adhere to special rule 10 NCAC 14C.1902(c)(13) Information Required of Applicant which states:

- (c) An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide the following information:
 - (13) commitment to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
 - (A) the total number of patients treated
 - (B) the number of African American persons treated;
 - (C) the number of persons in other minority populations treated; and

(D) the number of insured, underinsured and uninsured patients served by type of payment category.

On April 28, 2016, Rex Radiation Oncology, LLC ("RRO"), a wholly owned subsidiary of Rex Hospital, Inc., acquired the assets of the Prostate Health Center.

Additionally, on October 12, 2016 the CON Section requested that as a result of a September 14, 2016 meeting of the Technology and Equipment Committee of the State Health Coordinating Council, RRO provide additional annual reports at the end of the fourth and fifth operating years. As current owner and operator, RRO files this report, which is now compiled by RRO. Consequently, the fourth operating year's annual report is attached for the time period May 1, 2016 through April 30, 2017.

Furthermore, condition 7 on the certificate of need for the above referenced project requires the certificate holder or its successors "to make arrangements with a third party researcher...to evaluate the efficacy of the mode during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the [the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency)] in the first quarter of the fifth operating year of the project."

Also attached is the report and recommendation evaluating the efficacy of the mode, prepared by a nationally recognized researcher in prostate cancer epidemiology, Paul A. Godley, MD, PhD, MPP.

If you have any questions, or require further information, please do not hesitate to contact me.

Sincerely

Steve Burriss

President

ee: Paige Bennett, Ass). Chief Healthcave Planning

Annual Report Statistics

May 1, 2016 through April 30, 2017

The total number of patients treated		188
The number of African American patients treated	62	
The number of persons in other minority populations treated		6
	Aetna	5
	Blue Cross	60
The number of insured patients served by type of Payment category	Cigna	7
	Commercial	6
	Medicaid	4
Medicare B/Medicare	80	
	Tricare	3
	United	6
The number of underinsured patients served by type of	Free Care	4
Payment category	Bad Debt	4
The number of uninsured patients served by type of payment of	ategory	3
The number of other patients served previous	Free Care	4
to the date range that received	Bad Debt	4
free care or bad debt write offs during the date range		

Evaluation of the Prostate Health Center Demonstration Project

Author: Paul Godley MD, PhD, MPP
Vice Dean for Diversity and Inclusion,
Rush S. Dickson Distinguished Professor,
Division of Hematology/Oncology,
Department of Internal Medicine,
University of North Carolina at Chapel Hill School of Medicine.

Adjunct Professor in the Department of Epidemiology, UNC Gillings School of Global Public Health.
Member, UNC Lineberger Comprehensive Cancer Center.
Senior Fellow at the UNC Sheps Center for Health Services Research.

Report date: June 30, 2017

I. Background:

The Prostate Health Center (PHC) was created in order to help address an apparent gap in the care of African Americans, and other minorities, with prostate cancer. The present analysis was performed to quantitatively assess if the PHC was successful in meeting this goal, and to develop recommendations as to whether or not the model should be replicated in other parts of the State.

II. Methods

To assess the progress toward achieving this goal, this analysis examined data comparing the racial breakdown of patients treated for prostate cancer at the PHC vs. the racial breakdown of patients in the area diagnosed with prostate cancer. In other words, addressing if the PHC was treating a disproportionate number of African American, and other minority, patients. The racial breakdown of the PHC patients was obtained from data collected internally at the PHC. The racial breakdown of patients in the area diagnosed with prostate cancer was extracted from the North Carolina Central Cancer Registry. From this registry, two reference populations were considered. First, the examination focused on PHC's primary service area, Wake County, where the preponderance of PHC's patients resides. Second, we also examined the ten immediately adjacent/proximal counties where ≈ 95% of the PHC's patients reside.

Separately, in order to characterize the broader prostate cancer environment, additional data and information are considered from the American Cancer Society, the United States Preventive Services Task Force, and the National Cancer Institute, and others.

III. Results

A. Racial breakdown of the PHC patients compared to the reference groups

The racial breakdown for the patients treated at the PHC is shown in the upper-most portion of table 1. Comparison data from Wake county are shown in the middle section of table 1. Between years 2011 and 2016 – the most recent years for which data are available – African American men comprised 31% of the patients with prostate cancer treated at the PHC, compared to 24% of the patients with prostate cancer throughout Wake county. Further, 35% of the patients with prostate cancer treated at the PHC were from racial minorities (African American, American Indian, Asian/Pacific Islander, etc.), compared to 27.5% of the patients with prostate cancer throughout Wake county. Thus, the PHC cares for a disproportionate number of African American, and other minority, patients with prostate cancer.

While the majority of PHC's patients are from Wake County, it also provides care to prostate cancer patients from nearby counties where racial minorities comprise an even greater proportion of the prostate cancer population than in Wake County. Data from the comparison group from the ten immediately adjacent/proximal counties is shown in the bottom portion of table 1. Again, the fraction of the PHC's patients that are African American exceeds the fraction of prostate cancer patients who are African American in the broader ten county area. Similarly, the fraction of the PHC's patients that are from any minority is again higher than the fraction of prostate cancer patients who are minority in the broader ten county area.

Thus, as presented in Table 1, PHC has demonstrated a consistent pattern of treating a disproportionally-high fraction of African American and other minority patients who historically were underserved not only in its primary service area (Wake County) but also the surrounding region.

During years 2013-2016, 103 (10%) of PHC's patients were uninsured or underinsured, and 179 patients were provided care free of charge or had bad-debt that was forgiven.

Table 1. PHC Patient population compared to local prostate cancer burden.

		2011	2012	2013	2014	2015	2016	2011-2016
PHC	AA Patients Treated	-		83	95	81	62	321
	Other Minorities Treated	-	-	8	19	6	6	39
	Total Patients Treated	-	-	227	339	269	188	1,023
	AA % of Treated	-	Ξ.	36.6%	28.0%	30.1%	33.0%	31.4%
	All Minorities as % of Treated	-	-	40.1%	33.6%	32.3%	36.2%	35.2%
Wake County	AA Incidence	149	119	101	137	153	140	659
	Other Minority Incidence	12	15	19	18	15	19	79
	Total Incidence	608	487	439	568	584	547	2,686
	AA % of Incidence	24.5%	24.4%	23.0%	24.1%	26.2%	25.5%	24.5%
	All Minorities as % of Incidence	26.5%	27.5%	27.3%	27.3%	28.8%	28.9%	27.5%
10 Counties*	AA Incidence	382	337	290	320	364	323	1,693
	Other Minority Incidence	21	24	25	26	22	25	118
	Total Incidence	1,296	1,031	935	1,114	1,192	1,076	5,568
	AA % of Incidence	29.5%	32.7%	31.0%	28.7%	30.5%	30.0%	30.4%
	All Minorities as % of Incidence	31.1%	35.0%	33.7%	31.1%	32.4%	32.3%	32.5%

^{*}The 10 contiguous/proximal counties where ~95% of PHC's patient population resides.

^{*2016} data for Wake County and Ten-County cancer incidence is estimated based on prior 5 years.

B. The Broader Prostate Cancer Environment

The impact of race on incidence: Prostate cancer has long been the most common cancer among men, and it has also yielded one of the highest numbers of cancer deaths. The problem of racial disparities in prostate cancer remains substantial. Nationally, African American men are 1.6 times more likely than Caucasian men to be diagnosed with prostate cancer and nearly 2.5 times more likely to die from it. In North Carolina, African American men are 1.75 times more likely to be diagnosed with prostate cancer than Caucasian men, and they are 2.4 times more likely to die from it. Between years 2011 and 2016 – the most recent years for which data are available – African American men comprised approximately 19% of the male population in Wake County, yet account for a disproportionate 24.5% of new prostate cancer.

The impact of screening on incidence: In 2012, the United States Preventive Services Task Force (USPSTF) issued guidance that recommended against prostate cancer screening. As presented in Table 2, the use of screening dropped nationally and in North Carolina overall, as did rates of prostate biopsy and prostate cancer incidence. Importantly, this analysis did not find evidence of a corresponding downturn in prostate cancer incidence in central North Carolina (See Table 1, incidence measures). This is likely due at least in part to the ongoing substantial population growth.

In May, 2017, the USPSTF reissued draft guidance and, in sum, will no longer recommend against prostate cancer screening. It is anticipated that prostate cancer screening will increase, and the rate of diagnosis of new cases of prostate cancer will grow. This growth may yield a disproportionately large number of prostate cases representing not only the ongoing prostate cancer case detection amidst a growing population, but also a short-term increase due to "catch-up" diagnosis of those that had otherwise gone undetected in the prior few years of lower screening utilization.

Table 2. Trends in prostate cancer incidence, USA and North Carolina (statewide).

		2011	2012	2013	2014	2015	2016
USA	Overall Incidence Rate	153.5	152.9	151.4	146.6	142.1	131.5
	Overall Incidence	240,890	241,740	238,590	233,000	220,800	180,890
NC	Overall Incidence Rate	154.9	144.2	134.3	125.0	115.5	105.4
	AA Incidence Rate	238.5	223.3	207.0	191.0	176.5	160.4
	Overall Incidence	36,371	35,161	33,984	32,878	31,462	30,341
	AA Incidence	9,149	9,033	8,802	8,548	8,255	8,076

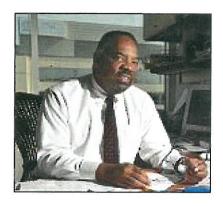
IV. Conclusion

The above data demonstrates that the PHC is addressing the problem of racial disparities through its treatment of a disproportionate share of the prostate cancer burden experienced by African Americans and other minority patients in Wake County and surrounding counties. Therefore, the facility is likely having a continued positive impact on the ability of community members to access necessary radiation oncology services. Further, it could be reasonably concluded that a similar project in other settings might be helpful if there is evidence of racial disparities in access to health care among these at-risk populations.

References¹⁻⁶

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Paul A. Godley, MD, PhD, MPP



Paul A. Godley, MD, PhD, MPP, became the inaugural Vice Dean for Diversity and Inclusion in February 2017. He is a Rush S. Dickson Distinguished Professor in the Division of Hematology/Oncology at the University of North Carolina at Chapel Hill School of Medicine, Adjunct Professor in the Department of Epidemiology at the UNC Gillings School of Global Public Health, member of the UNC Lineberger Comprehensive Cancer Center, and a Senior Fellow at the UNC Sheps Center for Health Services Research. Previously

Dr. Godley held the positions of Vice Dean for Finance and Administration and Executive Associate Dean for Faculty Affairs. In 2001 Dr. Godley became Director of the Program on Ethnicity, Culture, and Health Outcomes (ECHO), a university initiative to advance understanding and elimination of racial health disparities through multidisciplinary research, education and training, and community partnerships.

Dr. Godley is a graduate of Yale University and Harvard Medical School, and holds a PhD in epidemiology from the UNC School of Public Health. He has also earned a master's degree in public policy from Harvard's John F. Kennedy School of Government. He completed his internship and residency at Case Western Reserve University Hospitals, University Hospitals of Cleveland, and the Cleveland VA Medical Canter. He came to UNC in 1987 for a research fellowship in cancer epidemiology, earning his PhD from UNC in 1993 as well as completing his subspecialty training in hematology and oncology.

In addition to leading prostate cancer clinical trials he has federally funded research experience in the epidemiology of prostate cancer, determinants of treatment choice, and treatment outcomes of this common condition that disproportionately affects African-Americans. Dr. Godley is PI of the NCI-funded, "Carolina Community Networks," which utilizes community-based participatory research to develop cancer prevention interventions.

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Paul A Godley

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2017

Association between choice of radical prostatectomy, external beam radiotherapy, brachytherapy, or active surveillance and patient-reported quality of life among men with localized prostate cancer

Chen, R. C., Basak, R., Meyer, A. M., Kuo, T. M., Carpenter, W. R., Agans, R. P., Broughman, J. R., Reeve, B. B., Nielsen, M. E., Usinger, D. S., Spearman, K. C., Walden, S., Kaleel, D., Anderson, M., Stürmer, T. & Godley, P. A. Mar 21 2017 In: JAMA - Journal of the American Medical Association. 317, 11, p. 1141-1150 10 p.

Research output: Contribution to journal > Article

(Brachytherapy	Prostatectomy	Prostatic Neoplasms	Radiotherapy	Quality Of Life

2016

Racial Differences in Diffusion of Intensity-Modulated Radiation Therapy for Localized Prostate Cancer

Cobran, E. K., Chen, R. C., Overman, R., Meyer, A. M., Kuo, T. M., O'Brien, J., Sturmer, T., Sheets, N. C., Goldin, G. H., Penn, D. C., Godley, P. A. & Carpenter, W. R. Sep 1 2016 In: American Journal of Men's Health. 10, 5, p. 399-407 9 p.

Research output: Contribution to journal > Article

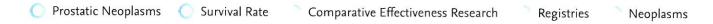
C	Prostatic Neoplasms	Radiation	African Americans	Neoplasms	Medicare

2015

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Research output: Contribution to journal > Article



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Neoadjuvant chemotherapy administration and time to cystectomy for muscle-invasive

African American Churches

Odulana, A. A., Kim, M. M., Isler, M. R., Green, M. A., Taylor, Y. J., Howard, D. L., Godley, P. A. & Corbie-Smith, G. Jan 2014 In: Health Promotion Practice. 15, 1, p. 125-133 9 p.

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Research output: Contribution to journal > Article

Research output: Contribution to journal > Article

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Androgen Receptors
Comparative effectiveness of intensity-modulated radiotherapy and conventional conformal radiotherapy in the treatment of prostate cancer after radical prostatectomy
Goldin, G. H., Sheets, N. C., Meyer, A. M., Kuo, T. M., Wu, Y., Stürmer, T., Godley, P. A., Carpenter, W. R. & Chen, R. C. Jun 24 2013 In: JAMA Internal Medicine. 173, 12, p. 1136-1143 8 p.
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Conformal Radiotherapy
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Research output. Contribution to journal > Article
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Guideline-discordant androgen deprivation therapy in localized prostate cancer: Patterns of use in the medicare population and cost implications
Kuykendal, A. R., Hendrix, L. H., Salloum, R. G., Godley, P. A. & Chen, R. C. May 2013 In : Annals of Oncology. 24, 5, p. 1338-1343 6 p., mds618
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Long-term survival of participants in the prostate cancer prevention trial
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Research output: Contribution to journal > Article
Prostatic Neoplasms Tinasteride Placebos Survival Rate Confidence Intervals

Racial differences in time from prostate cancer diagnosis to treatment initiation: A Population-Based Study Stokes, W. A., Hendrix, L. H., Royce, T. J., Allen, I. M., Godley, P. A., Wang, A. Z. & Chen, R. C. Jul 1 2013 In: Cancer. 119, 13, p. 2486-2493 8 p. Research output: Contribution to journal > Article Prostatic Neoplasms
African Americans Recurrence Mortality Epidemiological Monitoring Receipt of national comprehensive cancer network guideline-concordant prostate cancer care among african american and caucasian american men in north carolina Ellis, S. D., Blackard, B., Carpenter, W. R., Mishel, M., Chen, R. C., Godley, P. A., Mohler, J. L. & Bensen, J. T. Jun 15 2013 In: Cancer. 119, 12, p. 2282-2290 9 p. Research output: Contribution to journal > Article African Americans
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How does health literacy affect quality of life among men with newly diagnosed clinically localized prostate cancer?: Findings from the North Carolina-Louisiana Prostate Cancer Project (PCaP)
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Research output: Contribution to journal > Article
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Intensity-modulated radiation therapy, proton therapy, or conformal radiation therapy and morbidity and disease control in localized prostate cancer
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Research output: Contribution to journal > Article
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Is primary prostate cancer treatment influenced by likelihood of extraprostatic disease? A surveillance, epidemiology and end results patterns of care study

Holmes, J. A., Wang, A. Z., Hoffman, K. E., Hendrix, L. H., Rosenman, J. G., Carpenter, W. R., Godley, P. A. & Chen, R. C. Sep 1 2012 In: International Journal of Radiation Oncology Biology Physics. 84, 1, p. 88-94 7 p. *Research output: Contribution to journal > Article*

Prostatic Neoplasms Depidemiology Radiotherapy Surgery Prostatectomy
Patient Satisfaction Influenced by Interpersonal Treatment and Communication for African American Men: The North Carolina–Louisiana Prostate Cancer Project (PCaP)
Moore, A. D., Hamilton, J. B., Knafl, G. J., Godley, P. A., Carpenter, W. R., Bensen, J. T., Mohler, J. L. & Mishel, M. 2012 In: American Journal of Men's Health. 6, 5, p. 409-419 11 p.
Research output: Contribution to journal > Article
Patient Satisfaction African Americans Communication Prostatic Neoplasms Men's Health
Phase i study of concurrent weekly docetaxel, high-dose intensity-modulated radiation therapy (IMRT) and androgen-deprivation therapy (ADT) for high-risk prostate cancer
Chen, R. C., Rosenman, J. G., Hoffman, L. G., Chiu, W. K., Wang, A. Z., Pruthi, R. S., Wallen, E. M., Crane, J. M., Kim, W. Y., Rathmell, W. K., Godley, P. A. & Whang, Y. E. Dec 2012 In: BJU International. 110, 11 B Research output: Contribution to journal > Article
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Research output: Contribution to journal > Article
Urinary Bladder Neoplasms Prostatic Neoplasms Urinary Bladder Kidney Urologic Neoplasms
Assessing the readiness of black churches to engage in health disparities research
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Research output: Contribution to journal > Article
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Community-Based Participatory Research

Phase III Clinical Trials

HealthNeoplasms

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