

Technology and Equipment Committee
May 9, 2018
Multidisciplinary Prostate Health Center Demonstration Project
Agency Discussion Paper

Executive Summary

- The 2009 SMFP established a “demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.”
- The CON required an evaluation of the “efficacy of the mode” and development of “recommendations regarding whether the model should be replicated in other parts of the state.”
- The criteria, however, did not define the goals of the demonstration nor how efficacy should be assessed. Therefore, the evaluator examined what he referred to as an “apparent gap” in the treatment of African American prostate cancer patients.
- The breakdown of African American patients at the Prostate Health Center (PHC) generally reflects their proportion of prostate cancer patients in the service area.
- The PHC evaluation interpreted the results as indicating success of the demonstration. The Agency’s review of the evaluation noted that it is not possible to determine whether this model is successful unless data is available on the patient profile of other treatment centers in the service area. PHC’s patient characteristics could simply be like those of other centers.
- If PHC served a larger proportion of African American patients than other cancer treatment centers, siting the center in a predominantly minority section of the city and near a large hospital may have achieved this result, apart from any other characteristics of PHC or the demonstration project requirements.
- The evaluation directly or indirectly addressed only four of the 11 demonstration project requirements in the 2009 SMFP. It is, therefore, not possible to determine whether the project adhered to most of the requirements.
- The Agency does not recommend expansion of the demonstration.

Background

The 2009 State Medical Facilities Plan (SMFP) included a statewide need determination for “one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men” because of their comparatively high rate of the disease. Parkway Urology (d/b/a Cary Urology) received a certificate of need (CON) on February 23, 2011 to develop the project (CON J-008331-09). The Prostate Health Center (PHC) opened on May 1, 2013 at 117 Sunnybrook Road in Raleigh. Although the facility focused on prostate cancer, it treated other types of cancer as well.

Among the conditions of the CON are the following:

- Develop an organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives, such as the NC Minority Prostate Cancer Awareness Action Team.
- Develop an Advisory Board that meets regularly and provides feedback about effective practices or about changes that need to be made.
- Prepare an annual report at the end of the first three operating years that shall include (1) the total number of patients treated; (2) the number of African Americans treated; (3) the number of other minorities treated; and (4) the number of insured, underinsured and uninsured patients served by type of payment category.
- Make arrangements with a third party researcher (preferably a historically Black university) to evaluate the efficacy of the model during the fourth operating year and to develop recommendations regarding whether the model should be replicated in other parts of the state.

In addition to CON conditions, the demonstration project was required to adhere to requirements described in the 2009 SMFP (see Appendix).

In April of 2016, Rex Radiation Oncology (RRO), a wholly owned subsidiary of Rex Hospital, Inc., acquired PHC. The facility is now UNC REX Cancer Care of East Raleigh; it is required to adhere to the conditions of the CON and the demonstration project.

During the fourth year of the demonstration, Paul Godley, MD, PhD, MPP, of the UNC School of Medicine, conducted the required evaluation. Healthcare Planning staff presented Dr. Godley’s evaluation report at the September 13, 2017 meeting of the Technology and Equipment Committee¹. After discussion of the report, Dr. Jordan asked staff to add this topic to the committee’s 2018 agenda for further evaluation and discussion.

¹ https://www2.ncdhhs.gov/dhsr/mfp/pdf/2017/tec/0906_la_evaluation.pdf

Review of the Evaluation

Two conditions of the CON were to develop an outreach program and to create an Advisory Board. Presumably, such activities would enhance PHC's ability to treat patients from the minority community. These activities could also address how PHC might make its services and facility more attractive and/or accessible to minority patients. The evaluation report did not address these requirements, but an online article published soon after PHC's opening noted that the center had an event that offered free prostate cancer screening². The center is located in a largely minority section of the city, but it is unknown whether PHC conducted any ongoing activities to target minority patients.

As mentioned above, the conditions of the CON required a third party researcher to "evaluate the efficacy of the model" and to "develop recommendations regarding whether the model should be replicated in other parts of the state." The SMFP included no further information or direction on this requirement. Hence, evaluating the power of the project to produce an effect (i.e., efficacy) required the evaluator to infer the project goal(s). The evaluation report stated that the goal of the center was to "help address an apparent gap in the care of African Americans and other minorities with prostate cancer." The "gap" referred to in the evaluation report appears to be that African American men are less likely to initiate and/or receive treatment than would be expected based on their proportion of the population of men with prostate cancer³.

The first step in evaluating an "apparent" gap is to determine whether a gap, in fact, exists. Doing so requires examination of the racial/ethnic breakdown of prostate cancer patients in light of the racial/ethnic breakdown of men in the service area who have prostate cancer. If this analysis finds that fewer patients from racial/ethnic minority groups receive treatment than their incidence of prostate cancer would suggest, then a gap can be said to exist. An analysis of this issue requires two types of data: (1) prevalence data (the number of men currently living with prostate cancer) in the service area by race/ethnicity; and (2) the racial/ethnic breakdown of men in the service area who received treatment for prostate cancer during a given timeframe.

Prevalence data is not available, but incidence data (the number of persons who received a new prostate cancer diagnosis within the past 12 months) can be used as a proxy. Prevalence data is preferable to incidence data, however, because cancer patients often continue to receive treatment long after they receive a diagnosis. This situation may be especially true for prostate cancer, given the common practices of "watchful waiting" (seeking treatment only if symptoms change) and "active surveillance" (periodic monitoring with tests and/or biopsies)⁴. Comparative data from cancer treatment centers in the service area is available from the North Carolina Central Cancer Registry (CCR), but access requires a special process due to privacy regulations.

² <http://healthandhealingonline.com/new-prostate-health-center-offers-free-psa-screening/>

³ In addition to receipt of treatment generally, one aspect of health disparity is the issue of racial/ethnic differences in the receipt of appropriate diagnosis and/or treatment. While these are crucial issues, especially in understanding health outcomes, their examination is beyond the scope of the demonstration and evaluation.

⁴ <https://www.cancer.org/cancer/prostate-cancer/treating/watchful-waiting.html>

If a gap does not exist, a man's or race/ethnicity would not be associated with whether, and if so where, he receives treatment. That is, it would be expected that the proportion of African American men receiving treatment would reflect their prostate cancer incidence. A treatment center that focuses on treating African American men would, therefore, be expected to have a higher proportion of African American patients than the average across other treatment centers in the area.

The evaluation did not obtain comparative data from other treatment centers, but rather, compared the racial/ethnic breakdown of PHC patients to the racial/ethnic breakdown of annual prostate cancer incidence in Wake County separately and in the 10 counties of residence of 95% of PHC's patients⁵. This type of analysis can provide a partial examination of whether a treatment gap exists.

Agency's Analysis

Like the UNC evaluation, the Agency also used data from the CCR. It differed from the analysis presented in the evaluation report in two ways, however. First, with the RRO acquisition of PHC in April 2016, the center no longer focused on prostate cancer treatment. Therefore, the Agency's analysis considers only the time period that PHC operated the center (2013 through 2015). Second, although the Agency used the same data source as the evaluation report (CCR), consultation with CCR indicated that the evaluation's use of annual data is problematic. At the county-level the number of males of each race and ethnicity⁶ is too low to yield valid age-adjusted incidence data⁷. Rather, CCR calculates incidence data by county for combined years (2011-2015) and for limited race/ethnicity categories (Non-Hispanic White and Non-Hispanic African American). Therefore, the Agency's analysis did not consider other minorities in its evaluation because the numbers were too low to provide valid incidence estimates. The number of other minorities treated at PHC from 2013-2015 was also very low (33, or 4% of total patients), so their exclusion is unlikely to affect overall results. Table 1 shows the most recent four-year prostate cancer incidence for Wake County and for PHC's 10-county service area.

⁵ The evaluation did not identify these counties, but other PHC documents indicate that the counties were most likely Chatham, Duplin, Durham, Franklin, Harnett, Johnston, Lee, Sampson, Wake, and Wayne. There may have been some fluctuation from year to year.

⁶ The groups reported by CCR are Non-Hispanic Whites, Non-Hispanic African Americans, Non-Hispanic American Indians, Non-Hispanic Other Races, and Hispanics (of any race).

⁷ It is standard practice to report age-adjusted disease incidence. It is especially important in prostate cancer because the incidence by age is inverse to the population by age. That is, as men age, their incidence of prostate cancer increases dramatically, but their share of the overall male population decreases.

Table 1. 2011-2015 Prostate Cancer Incidence and Incidence Rate*

		Wake County		10-County Service Area	
Non-Hispanic White	Incidence	1,857		3,641	
	Incidence Rate		117.6		106.1
Non-Hispanic African American	Incidence	663		1,760	
	Incidence Rate		194.0		180.4
Total**	Incidence	2,520		5,401	
	Incidence Rate		129.9		Not available

* Age-adjusted incidence of prostate cancer diagnosis within the past 12 months among males 18 and older.

** The Total includes other races/ethnicities. The number of prostate cancer cases in other races/ethnicities can be obtained by subtracting the number of White and African American cases from the Total Number. However, it is not accurate to subtract the White and African American incidence rate to arrive at the separate incidence rate for other races/ethnicities.

Source: North Carolina Central Cancer Registry, State Center for Health Statistics.

The Agency’s examination shows that for the 10-county service area, African Americans represent 32.6% of the incidence of prostate cancer and 32.3% of PHC patients, based on the limited race/ethnicity categories available in the CCR (see Table 2). Generally, the results here and in the evaluation report show that PHC served about the proportion of African American patients in the 10-county area as would be expected based on the racial/ethnic breakdown of the incidence of prostate cancer in the service area.

Table 2. PHC Patient Population Compared to Local Prostate Cancer Incidence*

		2013	2014	2015	Total
PHC	African American Patients Treated	83	95	81	259
	Total Patients Treated	219	320	263	802
	African American % of Treated	37.9%	29.7%	30.8%	32.3%
Wake County Incidence 2011-2015	African American Incidence				663
	Total Incidence				2,520
	African American % of Incidence				26.3%
10 Counties Incidence 2011-2015	African American Incidence				1,760
	Total Incidence				5,401
	African American % of Incidence				32.6%

* The analysis excludes other minority groups.

Source: PHC evaluation, Central Cancer Registry.

It is not possible to perform the same analysis for Wake County because the number of PHC patients from Wake County is not available⁸. Although the incidence rate in Wake County is higher than the 10-county service area for both Whites and African Americans, the difference between the rates is almost identical; the rate for African Americans in Wake County is 76.4 persons higher per 100,000 population, while the rate for African Americans in the 10-county area is 74.3 persons higher. As indicated in Dr. Godley's evaluation, the difference is likely related to the fact that African American males comprise a smaller proportion of males of a racial/ethnic minority in Wake County than in the 10-county service area. It is not likely to be indicative of differential treatment.

Conclusions and Recommendations

Nationally, the rates of both the incidence of and deaths from prostate cancer have decreased greatly among African American men over the past 20 years⁹. Even so, both rates remain substantially higher among African American men than all other racial and ethnic groups¹⁰. Therefore, the need to engage and sustain African American men in treatment is clear. The first question for the Agency is whether a treatment gap exists based on race/ethnicity. Second, if a treatment gap exists, the Agency would ask whether the PHC demonstration has been successful in addressing this gap. Without additional data especially on characteristics of the local treatment center population, it is not possible to know the answer.

It is also important to know why PHC is no longer owned by the entity that applied for the CON. The evaluation report provided no information about the reasons UNC REX acquired the facility. It is reasonable to ask whether the number of patients served was sufficient for financial viability. The original petition (from PHC's parent company) that formed the basis of the demonstration project stated that a center with a LINAC could be financially viable with as few as 180 patients, even though the application noted that the standard is 250 patients. PHC served an average of 267 patients annually from 2013 to 2015, and applied for a CON in 2014 to acquire an additional LINAC. PHC's 2014 CON application projected 7,996 equivalent simple treatment visits (ESTV) for CY 2014 and 9,231 ESTVs for CY 2015. In FFY 2013-2014, PHC performed 7,271 ESTVs. As of FFY 2015-2016, the ESTVs had reduced to 4,187¹¹. Clearly, utilization did not increase as projected in the CON application. The 2014 CON application was initially approved, but UNC REX appealed the

⁸ Although the evaluation compares Wake County prostate cancer incidence to the PHC patient population, this comparison is not informative because the number of PHC patients from Wake County is unknown. PHC's Registration and Inventory Form for the 2013-2014 reporting year shows that 57% of patients were from Wake County, but this form uses a different reporting period from the evaluation data.

⁹ <https://www.cdc.gov/cancer/prostate/statistics/race.htm>

¹⁰ Nationally, the incidence of prostate cancer is higher for African Americans than for Whites. It is higher for Whites than for all other racial and ethnic groups (i.e., Asian/Pacific Islander, American Indian/Alaskan Native, Hispanic) (<https://www.cdc.gov/cancer/prostate/statistics/race.htm>).

¹¹ 2015 and 2017 Registration and Inventory Forms.

decision. The parties and the Agency reached a settlement agreement in which UNC REX would acquire PHC and receive a CON for an additional LINAC.

Finally, if the demonstration were to be expanded, the criteria should clearly spell out the goals of the project, the questions to be answered in an evaluation, and the data required to conduct the evaluation.

In summary, PHC served African American patients commensurate with their incidence of prostate cancer. On the one hand, this result may indicate that the center is serving African American men as expected. On the other hand, the lack of data on other treatment centers leaves open the question of whether PHC's prostate cancer patient population differs from any other cancer treatment center.

Given this and other the factors discussed above, the Agency recommends that the demonstration be concluded, that the LINAC acquired by PHC and now owned by RRO and its associated procedures be included in the regular inventory in the SMFP, and that RRO no longer be required to adhere to the conditions of the demonstration. Further, the Agency recommends that the demonstration project not be replicated.

Appendix

Excerpt from Chapter 9 of the 2009 North Carolina 2009 State Medical Facilities Plan

In response to a petition, there is included in this North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.

The Linear Accelerator Demonstration Project shall include the following components:

- Development of a multidisciplinary prostate health center to provide urology services, medical oncology services, biofeedback therapy, chemotherapy, brachytherapy and living skills counseling and therapy in the same building.
- Location of prostate health center in close proximity to minority communities.
- A medical director who shall be either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology.
- Commitment to sponsor regular case conferences and tumor boards.
- Written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.
- Written strategies that include specific activities designed to assure the services will be accessible by indigent patients without regard to their ability to pay.
- Written description of patient selection criteria, including referral arrangements for high-risk patients.
- An organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives such as the NC Minority Prostate Cancer Awareness Action Team.
- An Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.
- Commitment to prepare an annual report at the end of each of first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
 - The total number of patients treated;
 - The number of African-Americans treated;
 - The number of other minorities treated; and
 - The number of insured, underinsured and uninsured patients served by type of payment category.
- Documentation of arrangements made with a third party researcher (preferably a historically black university) to evaluate the efficacy of the model 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 Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project.