

Annual Report & Recommendations

2014



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FLORIDA PROSTATE CANCER ADVISORY COUNCIL ANNUAL REPORT & RECOMMENDATIONS

SUBMITTED TO

THE GOVERNOR
THE PRESIDENT OF THE SENATE
THE SPEAKER OF THE HOUSE OF REPRESENTATIVES
THE STATE SURGEON GENERAL

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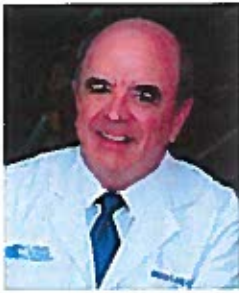
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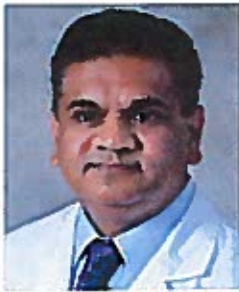
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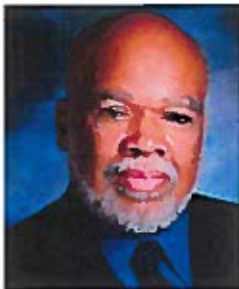
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MISSION

To be the reliable source of prostate cancer information that is accessible to patients, advocates, physicians, care providers, researchers and Florida's governing officials.

VISION

To improve the outcomes and reduce the ethnic/racial disparities related to prostate cancer.

MESSAGE FROM THE CHAIR

On behalf of the Florida Prostate Cancer Advisory Council, I am pleased to present our 2014 Annual Report. Prostate cancer remains the most commonly diagnosed cancer among men in Florida and across the nation. In 2014, an estimated 16,590 Floridian men were diagnosed with prostate cancer, and 2,170 are expected to die from this disease.¹

The Florida Prostate Cancer Advisory Council, also known as PCAC, is the state council responsible for advising the Legislature, Governor and Surgeon General on how to enhance awareness and reduce prostate cancer incidence, mortalities and health disparities in Florida. PCAC was established in state statute in 2004 and is governed by Florida Statute 381.911. The Council is housed at, and administratively and fiscally supported by, the University of Florida Prostate Disease Center, but operates as an independent, multidisciplinary group of recognized leaders in health care, education, research, advocacy and the Florida government.

PCAC monitors prostate cancer trends and disparities in our state, evaluates and promotes effective health interventions and develops screening and treatment recommendations that specifically address the needs of populations at high risk for developing the disease.

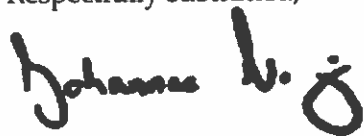
Florida continues to attract national interest for its prostate cancer activities, including recent initiatives in the following areas:

- Novel academic-community collaborations designed to improve the quality of prostate cancer care.
- Evidence-based prostate cancer screening and treatment recommendations and their dissemination.
- Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.
- Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

PCAC's collective expertise, combined with the support and assistance of others working to reduce the burden of prostate cancer in Florida, has produced significant results. I am confident that, working together, we can build on these successes in the months ahead.

Updated information on PCAC's activities and progress can be obtained online at our website www.prostatecanceradvisorycouncil.org. For additional copies of this report, or any additional information about PCAC and its activities, please contact the Council office.

Respectfully submitted,



Johannes Vieweg, MD, FACS
Chairman, Florida Prostate Cancer Advisory Council
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EXECUTIVE SUMMARY

The Florida Legislature recognized that prostate cancer is a major public health problem and that promoting awareness and improving care of this highly prevalent and costly disease is in the public interest of this state. In 2004, the Florida Legislature enacted the Florida Prostate Cancer Awareness Program, Section 381.911, Florida Statutes. The bill, amended in 2006, mandates formation of the Florida Prostate Cancer Advisory Council (PCAC).

PCAC is charged with recommending strategies for enhancing awareness and reducing incidence and mortalities of prostate cancer. PCAC's scope of work includes, but is not limited to, developing health quality improvement initiatives, providing position statements on screening and treatment recommendations, aiding in collaborative research and collaborating with industry to reduce the burden of prostate cancer in Florida. PCAC is statutorily mandated to provide the Governor, Speaker of the Florida House of Representatives and Florida Senate President an annual report of PCAC's progress and recommendations.

The following report outlines PCAC's accomplishments during 2014 and our direction for the future with a focus on continuing to advance the following target areas:

- Novel academic-community collaborations designed to improve the quality of prostate cancer care.
- Evidence-based prostate cancer screening and treatment recommendations and their dissemination.
- Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.
- Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

In summary, PCAC has made major progress in addressing the critical shortcomings that affect prostate cancer incidence, health disparities and disease mortality in Florida. Over time, we expect that PCAC activities will reduce death and suffering from prostate cancer in our state through improvements in the quality and safety of care and through the development of new cures and treatments for men affected with prostate cancer.

2014 ACCOMPLISHMENTS

Following is a summary of PCAC's progress and cooperative efforts in the development of the following target areas:

- Target Area 1: Novel academic-community collaborations designed to improve the safety and quality of prostate cancer care.
- Target Area 2: Evidence-based prostate cancer screening and treatment recommendations and their dissemination.
- Target Area 3: Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.
- Target Area 4: Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

PROGRESS IN TARGET AREA 1:

Establish novel academic-community collaborations designed to improve the quality of prostate cancer care.

1.1. Development of the Quality Improvement Collaborative (QIC) Network

In 2014, we have begun to develop the first physician-led prostate cancer Quality Improvement Collaborative (QIC) in Florida. This collaborative effort involves teams of academic and community physicians seeking to improve the care process and the outcomes of men diagnosed with prostate cancer.

Specifically, this quality network seeks to achieve these objectives:

- Reduce unwarranted variations of prostate cancer care including the use of diagnostic imaging.
- Facilitate informed decision-making by patients diagnosed with prostate cancer.
- Educate participating providers in "best care" practices, screening and treatment guidelines.
- Decrease medical errors and reduce cost of care.

At present, we have successfully secured the participation of more than 60 physicians with expertise in prostate cancer care from the following practice sites (see also Figure 1):

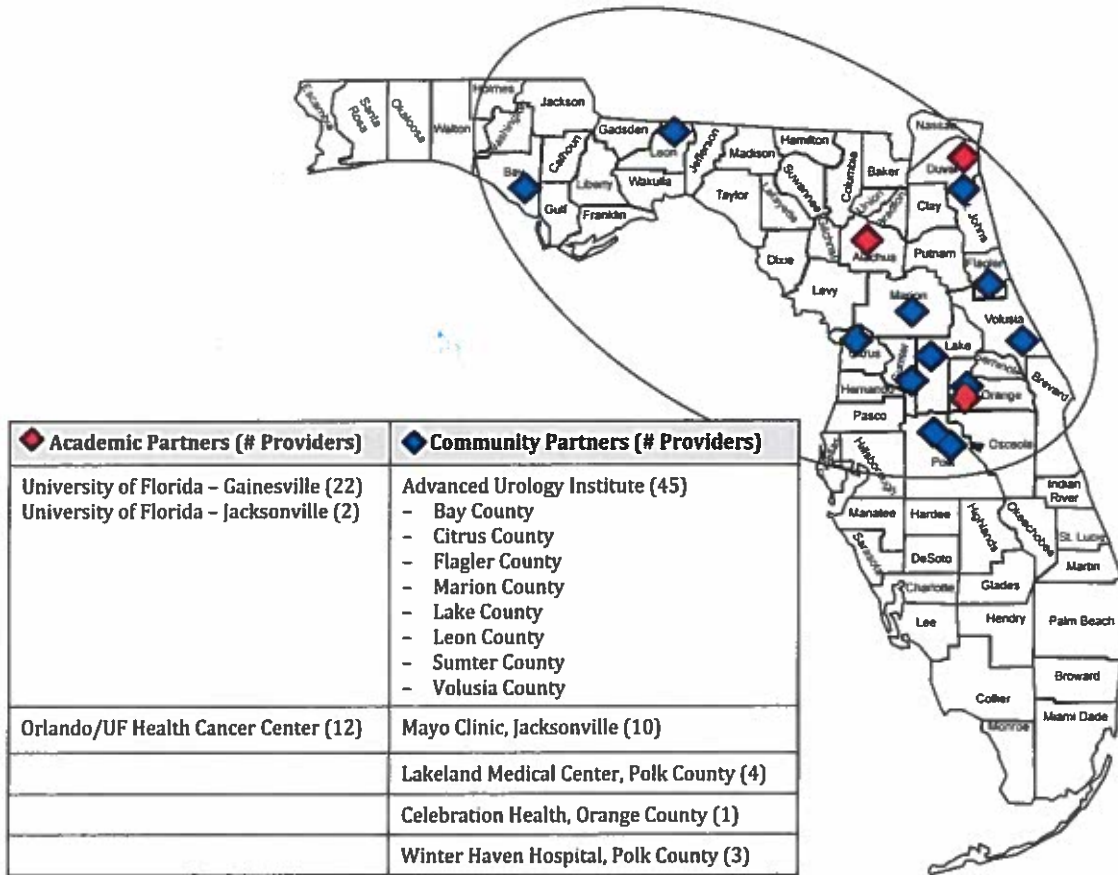
- Academic sites: UF Health, Gainesville and Jacksonville campuses and UF Health Cancer Center at Orlando Health
- Community Hospitals and Large Community Practice Sites: Mayo Clinic Jacksonville; Lakeland Regional Medical Center; Florida Hospital Celebration Health, Orlando; Winter Haven Hospital, Winter Haven; and Advanced Urology Institute in Bay, Citrus, Flagler, Marion, Lake, Leon, Sumter, and Volusia Counties

According to data provided by the Florida Division of Health Statistics and Performance, approximately 7,800 men will be diagnosed with prostate cancer in the indicated QIC network area each year, representing approximately 47% of the new prostate cancers diagnosed in the entire state.²

The PCAC Leadership team is responsible for coordinating the operations, directions and communications of the quality network, and reports to the PCAC bi-annually.

The long-term objective is to expand the quality network further to include other practice sites with the goal of improving the quality of prostate cancer care and reducing cost in Florida.

Figure 1 – The Florida Prostate Cancer Quality Network



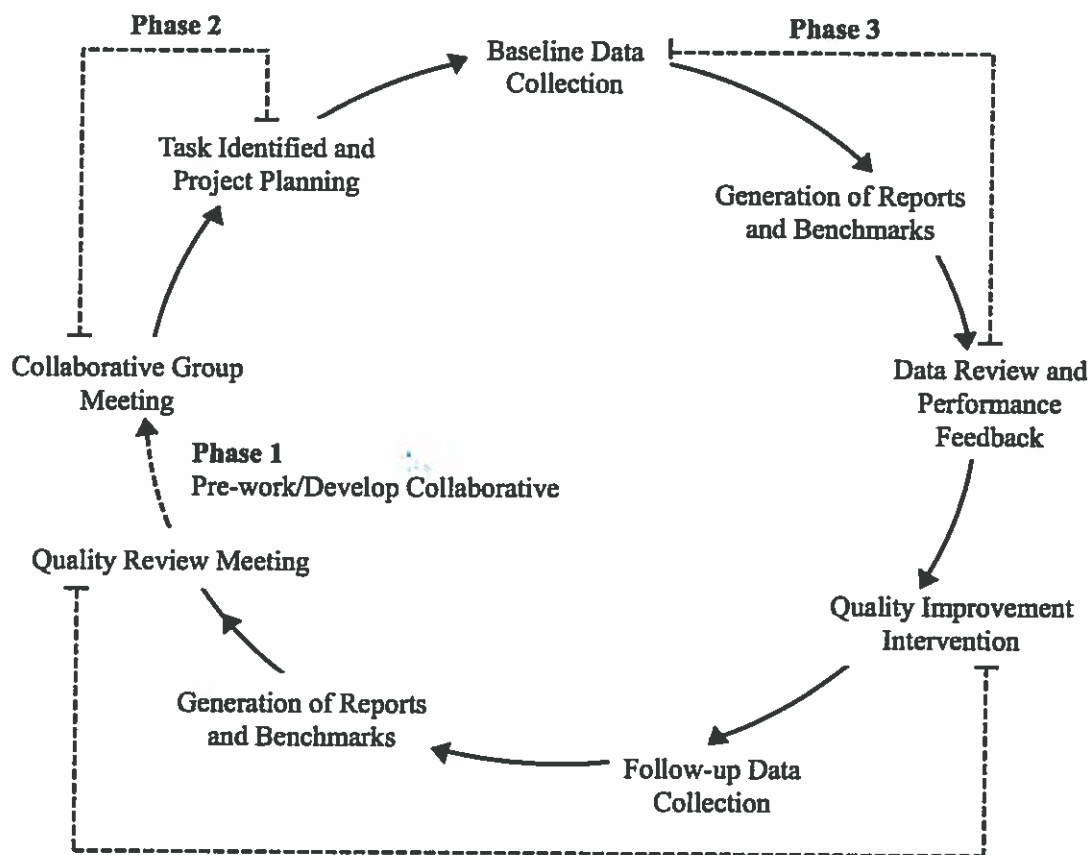
Strategy:

The QIC will be implemented in four distinct phases as shown in Figure 2.

- Phase I: involves aligning and organizing the participating practices and formalizing the QIC network.
- Phase II: involves developing and testing the data registry using the CTSI-based REDCap research database and data repository, designing the data collection instruments and methods, determining the exact data variables and definitions, determining the level of burden and resource needs for individual practices, site training and ongoing database support.
- Phase III: involves assessing baseline practice patterns for each practice against the established pathways, identifying key factors contributing to variation, providing specific feedback to each practice that compares and contrasts practice patterns among participating sites.
- Phase IV: involves re-assessing practice patterns for each practice after early detection and treatment pathways have been discussed, then providing feedback and comparison data.

This structured process will ensure seamless data entry and analysis and that data will be shared appropriately among physicians in order to receive real time feedback regarding their adherence to established practice guidelines.


Figure 2 – Four Phases of the QIC Process



1.2. Development of a Clinical Registry

In collaboration with the University of Florida Clinical and Translational Science Institute (CTSI), we have initiated efforts to design a clinical registry that captures practice-specific patterns of prostate cancer care and clinical outcomes within the QIC network area. Specifically, we are interested in addressing the following goals:

- Improve prostate cancer care in the staging of men with newly diagnosed prostate cancer.
- Reduce prostate biopsy-related morbidity and establish standards for secondary biopsies.
- Improve outcomes after primary prostate cancer therapy, including functional outcomes.
- Reduce treatment variation and correlate treatment within the quality network with existing screening and care guidelines.
- Analyze patient-centered decision-making among men considering therapy for localized prostate cancer.
- Through collaboration with organizations, enhance enrollment of underserved or vulnerable populations.



Data collected in the QIC registry will capture clinically important events relevant to newly diagnosed or recurrent prostate cancer patients within the QIC service area. Collectively, these data allow analyses on regional service patterns, processes and patient outcomes. Participating sites will begin to contribute data in a protected, HIPPA-compliant environment under the auspices of the UF CTSI. According to known patient volumes at participating sites, we project enrollment of more than 5,000 subjects for abstraction over a 3- to 4-year data collection period. This sample size is consistent with other quality initiatives and will provide adequate power for comparative analyses.

Impact

Data derived from the QIC registry will allow us to accomplish the following:

- Receive feedback from physicians to understand the variation in prostate cancer screening and treatment in Florida communities.
- Use such feedback to review quality of care periodically and analyze patient treatment choices and outcomes.
- Work with participating QIC sites and PCAC members to create a formal process for evaluating prostate cancer research opportunities (health services analyses, clinical trials, etc.).
- Intensify ongoing research collaborations with the Florida Cancer Data System to link epidemiologic data with the quality registry and to analyze associations of the quality of care on actual outcomes.

1.3. Other Academic Partnerships

PCAC leadership has reached out to other health organizations and societies to raise awareness of and capitalize on new technologies in the healthcare sector that are designed to mitigate Florida's prostate cancer problem. For example, PCAC membership has actively participated with the Society for Immunotherapy of Cancer (SITC) to examine exciting new developments in cancer immunology.

PROGRESS IN TARGET AREA 2:

Evidence-based prostate cancer screening and treatment recommendations and their dissemination.

In 2014, PCAC established a workgroup to develop Florida-specific screening and treatment guidelines that not only conform with existing best practice principles, but also address the specific needs of those patients at high risk of disease progression and mortality (i.e., African Americans and first degree relatives of patients with prostate cancer). In order to develop evidence-based screening and treatment recommendations for the State of Florida, we developed a two-step approach to analyzing strengths and weaknesses of existing guidelines (e.g., AUA, ASCO, ASTRO) and implementing these insights into PCAC's final recommendations.

Step 1:

As an initial step to develop Florida-specific prostate cancer screening and practice recommendations founded on a high level of evidence, we performed meta-analysis on a total of 13 existing guidelines to evaluate validity, applicability and the transparency of individual care recommendations. We used the validated Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument to identify specific strengths and weaknesses of existing screening and care recommendations that will be considered when developing PCAC's Florida-specific screening and care recommendations. The results of the meta-analysis have recently been accepted for publication in the Journal of Urology.³

Step 2:

A multi-disciplinary physician team from the University of Florida and Orlando Health have created a working document on treatment recommendations, which includes recommendations throughout the entire prostate cancer disease continuum, ranging from early detection to advanced disease. Recommendations developed by the workgroup are presently being vetted internally prior to presenting them for discussion and revisions at the upcoming PCAC meeting in May 2015.

Impact

- PCAC's screening and treatment recommendations will provide guidance to Florida physicians and their patients regarding "best practice" in prostate cancer screening and care.
- The inventory of the workgroup's early detection and treatment recommendations will be presented to PCAC members for review and acceptance.
- Established results will be implemented into the QIC network, and deviations will be tracked to improve quality performance.
- The expertise of the PCAC members will be used to draft and approve a statewide announcement and FAQ (frequently asked questions) that underscore the screening and treatment recommendations.
- Results will be communicated to stakeholders throughout Florida, including physicians, physician societies, patients, insurance companies and advocacy groups.

PROGRESS IN TARGET AREA 3:

Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.

In 2014, PCAC has continued our dialogue with advocates and support groups to address this target area. PCAC is deeply concerned with the widening gap in health disparities and the alarmingly low enrollment of African Americans in clinical trials on preventing prostate cancer. Future research and educational outreach efforts must include strategies for including more African Americans as participants. To raise awareness of these issues, a Patient Advocacy Round Table meeting was created to serve as a forum for enhanced collaboration among Florida's prostate cancer advocates, prominent prostate cancer organizations that serve as resources, and the Prostate Cancer Advisory Council. On May 2, 2014, PCAC initiated a Prostate Cancer Advocacy Round Table with the following institutions participating:

- 100 Black Men of America, Inc.
- Alachua County Prostate Cancer Alliance
- American Urological Association
- Florida Department of Health
- Health Information Research
- Jim West Prostate Cancer Foundation
- Ocala Prostate Cancer Support Group
- Roswell Park Cancer Institute
- Willie J. Greer Kimmons Educational Consulting

Impact and Outcomes

The initial interaction produced a number of subsequent meetings and dialogues among PCAC representatives and the 100 Black Men of America, Inc. (International Health & Wellness Committee Summit meeting in Fort Lauderdale, FL) and meetings with the leadership of the Ocala Prostate Cancer Support Group. **Both groups stressed the need for prostate cancer education and health intervention in rural communities.** PCAC will continue to promote statewide knowledge and resource sharing by making the Patient Advocacy Round Table an annual event.

PROGRESS IN TARGET AREA 4:

Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

PCAC's activities have generated considerable interest from the biomedical industry. Several industry partners expressed interest in supporting collaborative research initiatives that collect biospecimens linked to treatment outcomes using the QIC registry (see Target Area 1). Biotech companies or not for profit research institutes, such as Opko Health, Inc.; the Translational Genomics Research Institute, Phoenix, AZ; Genomic Health, Inc.; and Myriad Genetics have requested information regarding PCAC's capability in the validation of new proprietary biomarkers. Also, all partners recognized that prognostic or therapeutic markers for African American and Hispanic populations have been deficient because these groups were only sporadically included in clinical trials. Based on these recommendations, PCAC is currently evaluating the feasibility of implementing the following strategies:

- Identifying collaborative grant opportunities to support tissue collection and establishing a clinical trials infrastructure throughout Florida through PCAC's network and partners.
- Collaborating with industry partners in developing and supporting pilot studies for drug development, imaging and biomarker validation.
- Organizing a forum to enhance inclusion of underserved populations into clinical trials.

Impact

PCAC views research partnerships formed by academic and industrial investigators as a key for future success and enabling translation. Aside from engaging in collaborative clinical trials, there are opportunities for joint submissions of NIH or other research grants that will enhance academic-community participatory research and foster translational development of new diagnostics and treatments to improve the outcomes of prostate cancer patients within our state and beyond.

RECOMMENDATIONS

As highlighted in the 2013 Annual Report, the work of the Council and its bi-annual meetings have been sponsored through the host institution, the University of Florida Prostate Disease Center, College of Medicine, with additional support from the H. Lee Moffitt Cancer Center & Research Institute. PCAC will focus on securing peer reviewed grant funding and other sources of income in support of our proposed scope of work. A grant to support the quality initiative has been submitted, and other means of funding have been communicated with the Florida Department of Health. This past year, our mission was furthered through the generous support of Cure on Wheels, who donated the profits raised from an important outreach event promoting awareness of PCAC's objectives.

The work completed to date has been in pursuit of achieving the national precedent of establishing the first physician-led quality initiative and developing state-specific screening and treatment recommendations for prostate cancer. The following recommendations were drafted in an effort to establish the pragmatic "next steps" required to accomplish these groundbreaking objectives and, ultimately, to improve the care for all Floridian men who will be diagnosed with this devastating disease in the months to come.

Target Area 1: Novel academic-community collaborations designed to improve the quality of prostate cancer care.

- Support and commence the QIC network and the registry to all Florida communities affected by prostate cancer.
- Communicate results of the quality initiative to all stakeholders in our state involved in prostate cancer care, research and education.
- Provide education to community physicians regarding best practice screening and care recommendations.
- Track deviations of recommended screening and care pathways throughout the state through the QIC model.
- Work with participating QIC sites, PCAC and CCRAB members to create a formal process of evaluating prostate cancer research opportunities.
- Consider the QIC model as a template for other diseases to improve the quality of care and improve outcomes.

Target Area 2: Evidence-based prostate cancer screening and treatment recommendations and their dissemination.

- Complete the internal review process of PCAC's screening and treatment recommendations by May 2015.
- Present the screening and treatment recommendations to statewide stakeholder groups for review and, if necessary, revisions.
- Present the screening and treatment recommendations to council members during the Spring PCAC meeting.
- Develop an effective communication strategy to promote PCAC's screening and treatment recommendations throughout the state.
- Utilize the expertise of the PCAC members to draft and approve a statewide announcement and FAQ (frequently asked questions) that further clarify PCAC's position and recommendations on prostate cancer screening, early detection and treatment.

Target Area 3: Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.

- Support enhancing education and treatment of underserved populations by developing analytic and interventional strategies in Florida Counties in need.
- Intensify our ongoing dialogue with advocacy and patient support groups on recommended screening and treatment guidelines.
- Continue ongoing work in promoting statewide knowledge and resource sharing through PCAC's Annual Patient Advocacy Round Table event.
- Enhance participation of underserved populations in clinical trials through education and communication.

Target Area 4: Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

- Support collaborations with the private sector to develop new diagnostic tools and treatments for prostate cancer.
- Extend the QIC registry towards developing the capacity for the procurement of tissue and other biospecimens in collaboration with academic centers in Florida.
- Develop the organizational capacity to conduct investigator and industry-sponsored clinical trials.
- Investigate grant opportunities or other funding sources to provide infrastructure support for tissue collection and clinical trials, as well as other PCAC activities designed to promote more positive outcomes for patients, the State of Florida and beyond.

PLAN OF WORK 2015

The following list comprises the Prostate Cancer Advisory Council's plan of work for 2015. Based on the Council's recommendations, the plan of work is designed to address the following target areas:

Target Area 1: Novel academic-community collaborations designed to improve the quality of prostate cancer care.

- Test and validate the data registry.
- Create a process for data entry at various practice sites.
- Monitor project and regulatory compliance and conduct quarterly site visits.
- Collect baseline data related to the following objectives:
 - Perform statistical analyses and identify areas for improvement (community interventions, early detection, treatment, decision-making, etc.).
 - Create a communications plan that includes all QIC processes and activities.
- Produce an annual report to the Governor, President of the Senate, Speaker of the House and State Surgeon General.

Target Area 2: Evidence-based prostate cancer screening and treatment recommendations and their dissemination.

- Utilize the work of the interdisciplinary PCAC working group to finalize the draft screening and treatment recommendations by May, 2015.
- Review the draft recommendations at the May 2015 PCAC meeting and provide further review and revisions.
- Present the final recommendation draft pathways to the State Surgeon General by July 15, 2015.

Target Area 3: Collaboration with underserved and vulnerable populations to raise awareness and enhance education of the prostate cancer problem.

- Promote statewide knowledge and resource sharing by developing the Patient Advocacy Round Table on an annual basis.
- Continue the dialogue with stakeholders and patients on screening and treatment recommendations to address the needs of high-risk and underserved populations.
- Intensify outreach and education of high-risk and underserved populations, including those in rural counties within the Panhandle, Central Florida and other areas of our state.

Target Area 4: Research collaborations with the private sector with the objective of creating new jobs and establishing the State of Florida as a destination for prostate cancer care in the United States and abroad.

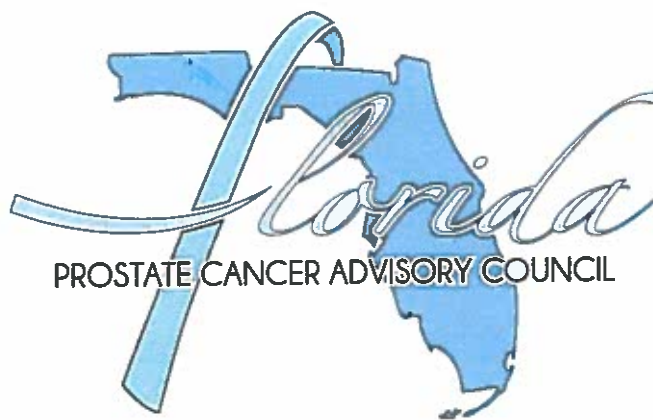
- Expand collaborations with the private sector with the goal of developing new diagnostic tools and treatments for prostate cancer.
- Extend the QIC registry to develop the capacity to procure tissue and other biospecimens in collaboration with academic centers in Florida.
- Build the organizational capacity necessary for conducting investigator and industry-sponsored clinical trials.
- Identify and pursue grant opportunities or other funding sources to support the quality initiative.

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