

ANNUAL REPORT & RECOMMENDATIONS

2011

FLORIDA PROSTATE CANCER ADVISORY COUNCIL ANNUAL REPORT & RECOMMENDATIONS

MAY 31, 2011 - DECEMBER 31, 2011

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

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The Honorable Rick Scott, Governor
The Honorable Mike Haridopolos, Senate President
The Honorable Dean Cannon, House Speaker
Dr. H. Frank Farmer, State Surgeon General

Dear Governor Scott, President Haridopolos, Speaker Cannon, and Surgeon General Farmer:

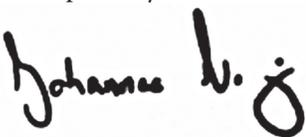
Prostate cancer is the leading cancer among Floridian men and last year was no exception with an estimated 1 man every 31 minutes being diagnosed with the disease; consequently, the incidence (number of new diagnoses) within our State continued to increase for the fourth consecutive year. These statistics, coupled with significant prostate cancer disparities between rural and urban populations and across ethnic and racial groups, are resulting in segments of the Floridian population being under-diagnosed or diagnosed at later stages, receiving dissimilar disease management and treatment modalities and, potentially, decreasing their survival expectations.

The Florida Prostate Cancer Advisory Council, the collaborative, multi-institutional, interdisciplinary and legislatively mandated advisory body is working to “bridge the gaps” in outreach, education, and awareness of prostate cancer by establishing a communication platform that will create systemic synergy between stakeholders and enhance the information required for patients, advocates, care providers, insurers, and members of the Legislature to make knowledgeable prostate cancer-related decisions. Nevertheless, after conducting a Florida focused SWOT (strengths, weaknesses, opportunities and threats) analysis, it was determined that we know very little about prostate cancer in Florida. For example, we don’t know the full human or financial burden of the disease, how variable the care is, what drives variation or the cost efficacy of the care provided. Additionally, and more importantly, we have a very limited understanding of socioeconomic and racial/ethnic disparities and we need to better pinpoint why there are so many Floridian men being diagnosed at later stages.

The lack of information, coupled with the recent screening controversy, creates an information void for Floridian men and could, potentially, increase the disparities that plague counties throughout Florida. With this stated, the initial recommendations of the Florida Prostate Cancer Advisory Council were formulated within the concept of improving the acquisition of relevant prostate cancer data, creating disease-based projects that enhance health related decisions and improve the efficacy/costs associated with variable care delivery, and disseminating the validated information throughout the State by utilizing the robust existing infrastructure of the Regional Cancer Collaboratives and associated stakeholders.

The SWOT analysis contained in the following pages will highlight the context and underscore the significance of the Council’s recommendations for enhancing the acquisition, validation, and dissemination (AVD) of prostate cancer information to Floridian men, family members, neighbors, friends and the stakeholders that we serve.

Respectfully,

A handwritten signature in black ink that reads "Johannes Vieweg". The signature is written in a cursive, flowing style.

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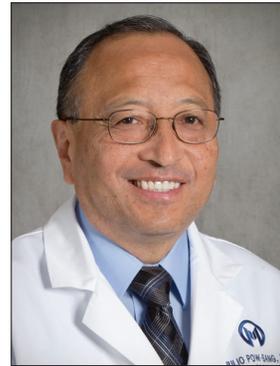
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EXECUTIVE SUMMARY AND RECOMMENDATIONS

INTRODUCTION:

The objective of this document is to highlight the need for new and robust information streams that will facilitate prostate cancer decision-making, consider the following: patients, advocates, caregivers and policy makers currently rely on estimated data or, as with other State registries, information that is two to three years old when attempting to quantify the size and the scope of the prostate cancer problem within the State of Florida. We simply do not know what we should know and the lack of detailed information may result in patient confusion, a lack of consensus on best treatment options between caregivers and, potentially, our limited number of advocacy resources being pointed in the wrong directions.

Nevertheless, the estimated data sets that are available present a growing concern with prostate cancer incidence that, coupled with our lack of knowledge about what is precipitating the frequency of late stage diagnoses, are the catalysts for the following legislative recommendations that are categorized under the acquisition, validation, and dissemination (AVD) of information themes that resulted from the Florida Prostate Cancer Advisory Council's strengths, weaknesses, opportunities, and threats (SWOT) analysis:

RECOMMENDATIONS:

ACQUISITION

- Work with the Florida Cancer Data System to determine the extent of the information currently available for prostate cancer decision-making.
- Develop the funding streams required to support prostate cancer-based projects that will enhance the information available for health and advocacy related decisions and improve the efficacy and reduce the aggregate costs associated with variable care delivery.
- Investigate the value of becoming a Surveillance, Epidemiology and End Results (SEER) reporting State.

VALIDATION

- Establish a mechanism to validate the prostate cancer information that is provided to Floridians (educational material, evidence-based treatment information, incidence, disparities, etc...).

DISSEMINATION

- Work with the Regional Cancer Control Collaboratives and the Florida Cancer Control & Research Advisory Program and request that these existing infrastructures be a conduit to disseminate validated prostate cancer information throughout the State.
- Create a web-based communication platform that is recognized as the trusted source for prostate cancer information within the State.

CONCLUSION:

The Florida Prostate Cancer Advisory Council will engage its statewide network of collaborators in an effort to fill the current information void and will disseminate the validated information with interpretive recommendations to Florida's stakeholders, including the Governor, President of the Senate, Speaker of the House, and State Surgeon General, on an annual basis, to ensure that all Floridians have the ability to make informed prostate cancer-related decisions.

FLORIDA PROSTATE CANCER TIMELINE & SWOT ANALYSIS

INTRODUCTION:

From the first bill hearing in September 2010 to the delivering of the recommendations outlined within this document, the following timeline highlights the prostate cancer work accomplished within the last six months:

- **5/2011** House Bill 137 unanimously approved by the Florida House and Senate
- **5/2011** House Bill 137 signed into statute by Governor Scott
- **6/2011** Prospective members of the Florida Prostate Cancer Advisory Council contacted
- **7/2011** Florida Cancer Control & Research Advisory Council (C-CRAB) endorses the proposed PCAC membership
- **7/2011** The Florida State Surgeon General, Dr. Farmer, endorses the proposed PCAC membership
- **8/2011** Formal letters of invitation sent to PCAC members
- **8/2011** First PCAC conference call conducted
- **9/2011** First face-to-face PCAC meeting in Orlando
- **9/2011** SWOT analysis presented
- **10/2011** SWOT analysis finalized
- **11/2011** PCAC prostate specific antigen (PSA) screening position statement approved

SWOT ANALYSIS:

A SWOT analysis is a qualitative and quantitative analytical method that is utilized to identify the strengths, weaknesses, opportunities and threats of an entity or situation. The Florida Prostate Cancer Advisory Council conducted a SWOT analysis to determine the existing resources and current obstacles to accomplishing the following legislatively designated objectives:

1. Present prostate-cancer related policy recommendations to the Florida Department of Health and other appropriate governmental agencies.
2. Assess the accuracy of prostate cancer information disseminated to the public.
3. Develop effective communication channels among all private and public entities in the State involved in prostate cancer education, research, treatment, and patient advocacy.
4. Plan, develop, and implement activities designed to heighten awareness and educate residents of the State, especially those in underserved areas, regarding the importance of prostate cancer awareness.
5. Disseminate information about recent progress in prostate cancer research and the availability of clinical trials.
6. Minimize health disparities through outreach education.
7. Communicate best practice principles to physicians involved in the care of patients with prostate cancer.
8. Establish a communication platform for patients and their advocates.

Each element of the SWOT analysis evaluates the impact on the Florida Prostate Cancer Advisory Council's ability to accomplish the listed objectives and is the catalyst for the recommendations outlined within the Executive Summary.

STRENGTHS:

INFRASTRUCTURE:

Florida possesses a robust infrastructure comprised of State resources, patient advocates, and professionals conducting outreach, educating patients and the public, and raising awareness about prostate cancer throughout the State. The resources are geographically dispersed and consist of the following:

State Resources (listed alphabetically):

Florida Cancer Control & Research Advisory Council (C-CRAB):

The Florida Cancer Control and Research Advisory Council (also known as C-CRAB) was created by the Florida Legislature in 1979 (Chapter 1004.435, Florida Statutes). The Council's mandate includes:

- Advising the Governor, the State Legislature, and State agencies on cancer control issues
- Approving the Florida Cancer Plan
- Preparing position statements on cancer-related legislation
- Aiding in the development of grants and projects to reduce the cancer burden in Florida
- Allocating funds, if available, for patient care for low-income citizens with cancer

Florida Biomedical Research Advisory Council:

The 11-member Florida Biomedical Research Advisory Council (BRAC) advises the Florida State Surgeon General on the direction and scope of the James & Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program.

Florida Cancer Data System:

The Florida Cancer Data System (FCDS) is Florida's statewide, population-based cancer registry and has been collecting incidence data since 1981, when it was contracted by the State of Florida Department of Health in 1978 to design and implement the registry. The University of Miami Miller School of Medicine has maintained the FCDS (<http://fcds.med.miami.edu>) since that time.

Florida Cancer Plan Council:

The purpose of the Florida Cancer Plan Council (FCPC) is to promote implementation of the Florida Cancer Plan 2010 by coordinating the efforts of Florida's cancer control partners. The FCPC is comprised of volunteer stakeholders, throughout the State, that coordinate cancer control efforts. The FCPC represents 24 areas across Florida and includes the chairs of the Regional Cancer Collaboratives, the American Cancer Society, the American College of Surgeons, the Florida Cancer Data System, various medical societies, cancer hospitals, universities, and cancer survivors.

Florida Center for Universal Research to Eradicate Disease (FL CURED):

The Florida Center for Universal Research to Eradicate Disease (FL CURED) was created by the 2004 Florida Legislature. The legislation followed a Senate Interim Report, commissioned by Senate President Jim King, which concluded there was a need for improved coordination, information sharing and reduced duplication within Florida's medical research enterprise.

Florida Department of Health/Comprehensive Cancer Control Program:

The mission of the Florida Department of Health is to protect and promote the health of all residents and visitors in the State through organized State and community efforts, including cooperative agreements with counties. Florida's public health and related agencies take on three main roles:

1. Health protection
2. Health promotion and disease prevention
3. Health treatment

In 2001, the Florida Comprehensive Cancer Control (CCC) Program, housed in the Bureau of Chronic Disease Prevention and Health Promotion, was created through a cooperative agreement with the Centers for Disease Control and Prevention (CDC). The main objective of the cooperative agreement is to reduce the cancer burden through a collaborative effort with public and private partners. The CDC started the National Comprehensive Cancer Control Program (NCCCCP) to help states, tribes, and territories form coalitions, also called programs, to fight cancer.

Regional Cancer Control Collaboratives (Figure 1):

These voluntary organizations include people from local health care providers, community-based organizations, advocacy groups and others interested in networking and working together to improve cancer control services for the following five geographic regions:

FIGURE 1 Regional Cancer Control Collaboratives

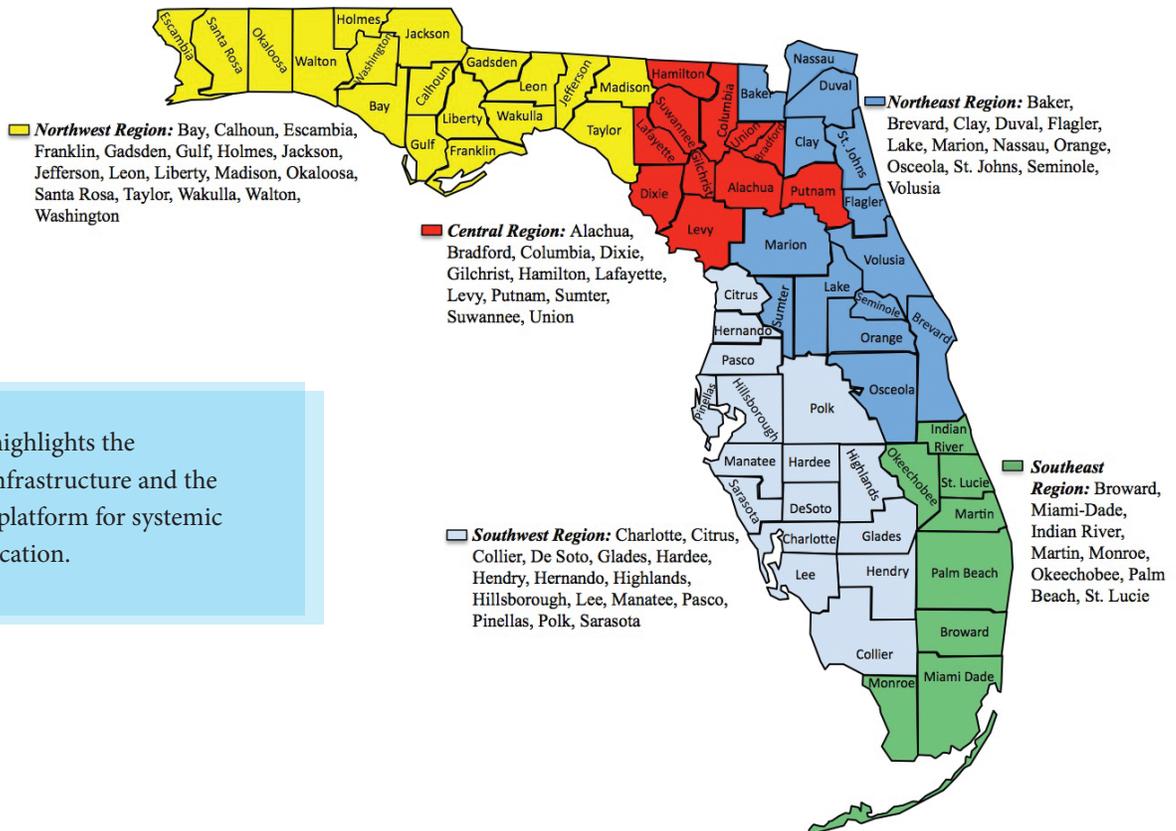


Figure 1 highlights the existing infrastructure and the potential platform for systemic communication.

Tertiary Teaching Hospital Resources with Established Residency Programs:

- Florida State University & Tallahassee Memorial HealthCare
- H. Lee Moffitt Cancer Center *(residents provided through the University of South Florida)
- Mayo Clinic
- University of Florida & Shands HealthCare
- University of Miami and UM Hospital

** Denotes the State's only National Cancer Institute (NCI) designated cancer center*

Advocates, Outreach & Awareness:

Through conducting research for the SWOT analysis it was determined that there were numerous local prostate cancer resources available in geographically disperse communities throughout the State. The following list represents the prostate cancer resources that have a systemic statewide focus:

- 100 Black Men
- Advanced Prostate Cancer Collaboration
- American Cancer Society - Man to Man
- H. Lee Moffitt Cancer Center M-Power Diversity Team
- Prostate Cancer Foundation
- Florida Prostate Cancer Advisory Council
- University of Florida Prostate Disease Center
- Us Too - Living with Prostate Cancer

Analysis:

There is an impressive infrastructure of resources being deployed throughout the State with both similar and different cancer focuses. The Florida Prostate Cancer Advisory Council will need to ensure that their mandated and adopted scope of work does not create redundancy, compete, or conflict with the work being performed by the existing committees, councils, and programs. Additionally, the existing infrastructure can be utilized as a platform for systemic communication to prostate cancer stakeholders throughout the State.

Recommendations:

1. The Florida Prostate Cancer Advisory Council will introduce their scope of work to the Regional Cancer Control Collaboratives and the Florida Cancer Control & Research Advisory Program and request that this existing infrastructure be a conduit to disseminate validated prostate cancer information throughout the State.

WEAKNESSES:

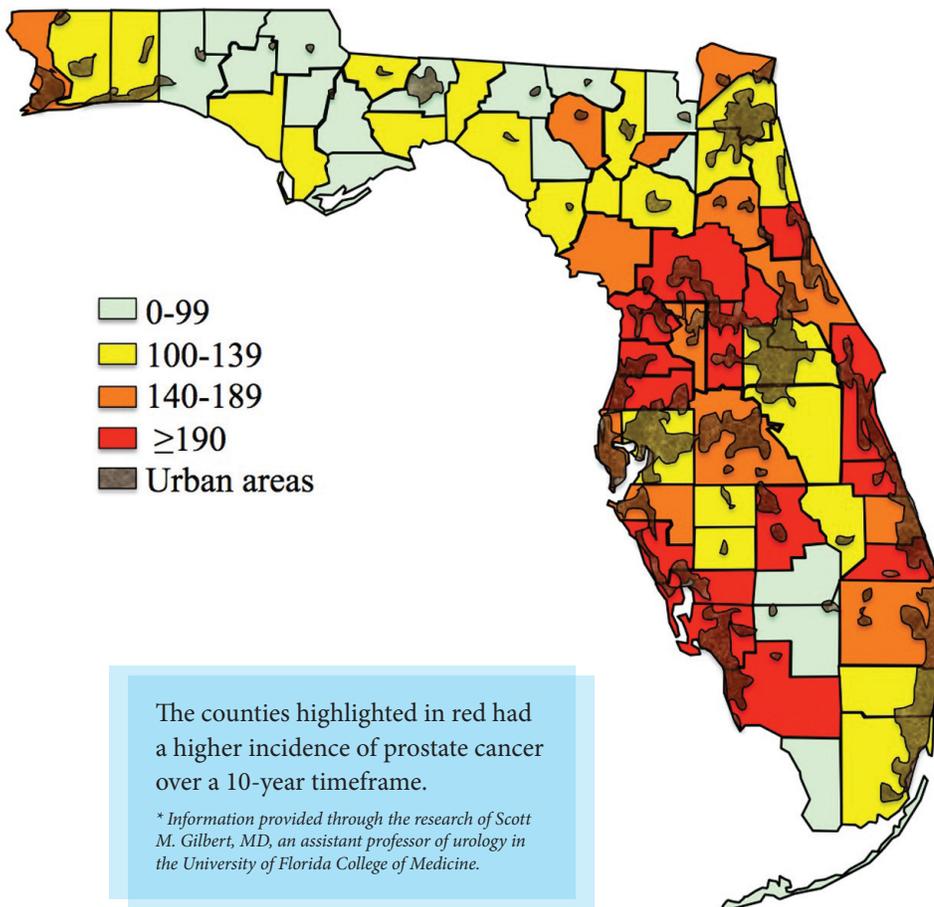
INCIDENCE:

According to the 2011 American Cancer Society Cancer Facts & Figures, prostate cancer was the leading cancer diagnosis among men in the United States, and Florida had the second highest estimated incidence of prostate cancer nationally. Through aggregating the prostate cancer incidence data for a 10-year time period, geographic areas of concern begin to emerge when plotted by county (Figure 2):

FIGURE 2

Prostate Cancer Incidence Rates

Age-Adjusted diagnosis per 100,000 males, 1998-2007



DISPARITIES:

The State adjusted prostate cancer incidence rate in 2008 was 114.9 per 100,000 for white men versus 208.49 for black men. When looking at the incidence rate by county, two counties in Florida had a fivefold higher incidence rate for black men versus white men and one county had a tenfold higher incidence rate.

Additionally, the State adjusted prostate cancer mortality rate in 2008 was 17.54 per 100,000 for white men versus 47.78 per 100,000 for black men. However, a county-by-county analysis of the aggregated rates demonstrates that there are seven counties in Florida where a black male has a fivefold higher chance to succumbing to prostate cancer than his white counterpart and two counties where the mortality risk increased to tenfold.

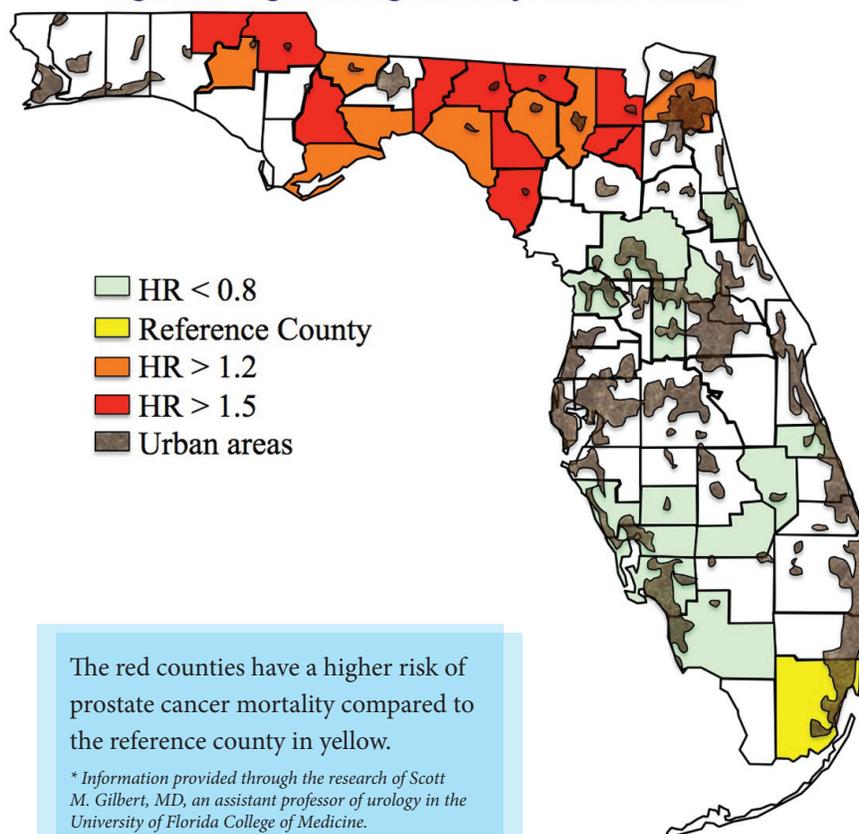
The lack of correlation between the incidence and mortality data paints an unclear picture of the prostate cancer disparities within Florida. Additionally, by bringing in the incidence and mortality disparities within the amorphous “other” category, the initial interpretation of the data available underscores that disparities are of paramount concern; however, there is an inability to focus on potential solutions due to the lack of granular data.

LATE STAGE DIAGNOSES:

In spite of the increasing incidence and the disparities, prostate cancer is often portrayed as an unimportant disease of the elderly that is fraught with over-diagnosis and over-treatment. This inaccurate portrayal of prostate cancer often conceals the growing concern over late stage diagnoses in the State of Florida. Figure 3 displays hazard ratio (HR) thresholds for men diagnosed with prostate cancer in Florida between 1998 and 2007 and could potentially explain the lack of correlation between prostate cancer incidence and mortality disparities.

Light-green-colored counties denote areas where men have lower mortality compared to the reference county, (Miami-Dade, shown in yellow, was selected as the reference county due to its uniquely diverse population, and it is the largest urban area with a good age distribution), while men from orange- and red-colored counties have a higher mortality risk. Men from non-colored counties (shown in white on the map), have a similar mortality risk compared to men from Miami Dade ($0.8 > HR < 1.2$).

FIGURE 3 Mortality (Non-Specific) Hazard Ratios
Age and Stage-at-Diagnosis Adjusted, 1998-2007



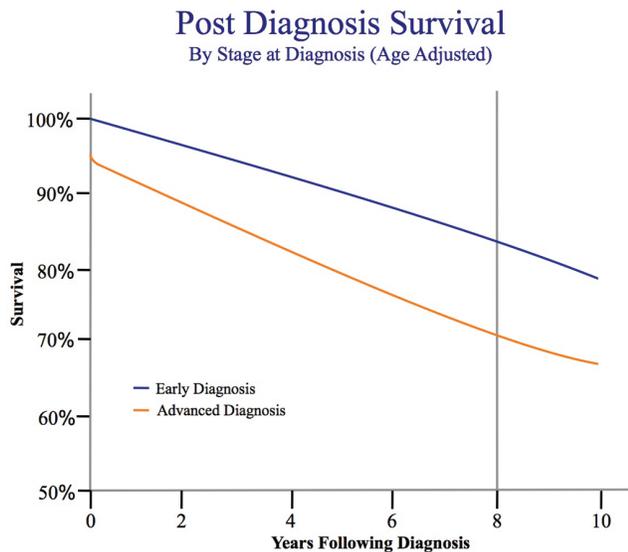
Interestingly, and potentially importantly, the Florida counties with the highest risk of death appear to cluster in North and Northwest Florida. These counties are also burdened with the lowest number of prostate cancer resources, as well as relatively high proportions of men presenting with later stage and more aggressive prostate cancers. Such widespread variation signals that where you live matters. However, we do not know why the risk of death is higher in this area of Florida.

Additionally, as demonstrated by the Post Diagnosis Survival By Stage at Diagnosis graph (Figure 4), how early your cancer is diagnosed potentially impacts life expectancy. The age-adjusted predicted survival for all men diagnosed with prostate cancer in Florida between 1998 and 2007 was stratified by disease presentation, and for the purposes of this survival plot, advanced diagnosis was defined as men whose initial presentation and diagnosis of prostate cancer was at an advanced stage (non-localized) and/or and aggressive grade (Gleason sum score 8-10). As shown, the plots are initially separated by a 5% difference in survival; however the relative separation increases over time.

FIGURE 4

Figure 4 demonstrates that the stage at diagnosis may equate to a reduced life expectancy compared to early stage diagnosis.

** Information provided through the research of Scott M. Gilbert, MD, an assistant professor of urology in the University of Florida College of Medicine.*



ANALYSIS:

Despite our initial findings, we know very little about prostate cancer in Florida. We do not know the full human or financial resource burden of prostate cancer and we do not know how variable the care is or what drives variation. Additionally, we have a very limited understanding of the socioeconomic and racial/ethnic disparities and we don't know why there are so many Floridian men being diagnosed at later stages or the efficacy of the care provided. Lastly, other than mortality, there is no data on outcomes and there is no information that currently exists to benchmark against.

RECOMMENDATIONS:

1. Collaborate with the Florida Cancer Data System to determine the extent and timeliness of the information currently available for prostate cancer decision-making.

COMMUNICATION:

A qualitative analytical exercise called a Summary of Executive Opinions was conducted by the Florida Prostate Cancer Advisory Council to determine the additional prostate cancer-specific weaknesses in Florida. The following bulleted list of items represents the outcome of the exercise and, categorically, fall under the communication nomenclature:

- Appearance of an apparent void of dialogue among practitioners, researchers, and health care administrators statewide
- No clear forum for participation by patients and family members
- Absence of a publically accessible clearing house of information for new drug and emerging treatment options
- Significant lack of public awareness relating to prostate cancer, its detection, dangers, and treatments
- Internet and publically reported misinformation
- Lack of knowledge of existing support groups
- Lack of a quality central source for prostate cancer guidance
- No coordination in data sharing
- Web-based resources are not interactive and are difficult to navigate without previous knowledge of the disease

ANALYSIS:

The communication issues are compounded by the variability and non-validated information that is available to the public.

RECOMMENDATIONS:

1. Establish a mechanism to validate the information that is provided to Floridians (educational material, evidence-based treatment information, incidence, disparities, etc...).
2. Create a web-based communication platform that is recognized as the trusted source for prostate cancer information within the State. Additionally, use the platform as a conduit and a “one-stop shopping” solution for patients and family members who are looking for information on education, support groups, outreach events, evidence-based practice guidelines, clinical trials, etc...

OPPORTUNITIES/THREATS:

The difference between a threat and an opportunity will be dependent upon what is done with the environmental information that is provided and when the tactical response is completed. Example, the U.S. Preventive Services Task Force recommendation against prostate cancer screening is, potentially, a threat to Floridian men with a strong family history of prostate cancer. In response to this recommendation, the PCAC collaborated to release a position statement (Attachment A) with the primary objective of providing clarity on the issue for men who might be confused by the mixed messages they are hearing.

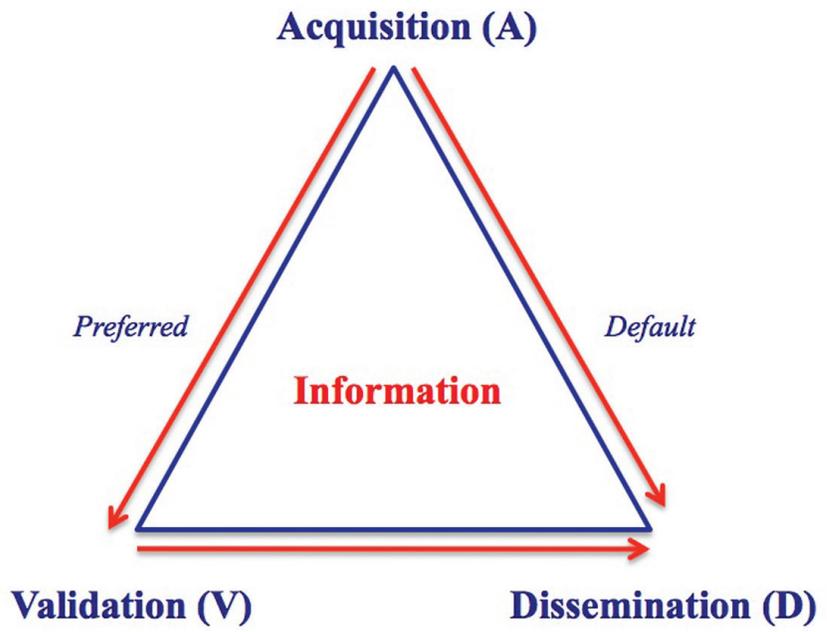
The example thematically underscores that the principle threat that emerged, and reemerged, throughout the analysis was unambiguously informational. Specifically, we do not have the information required to make informed decisions on pressing issues such as the increasing incidence of prostate cancer or the number of late stage diagnoses and there are no existing processes for validating a majority of the information that is disseminated to the public.

ANALYSIS:

With an overarching objective of turning the current and future threats (weaknesses) into opportunities and based on the outcome of the SWOT analysis, the PCAC has developed a tactical strategy of acquisition, validation and dissemination of information (Figure 5: AVD). As highlighted within this analysis, the current infrastructure for the dissemination of information is currently in place; however, the information is peripheral, does not provide an opportunity for informed decision-making, and, at times, is not validated. The effect of the current paradigm is the increased potential for confusion for patients, family members, and other stakeholders working to raise the awareness of prostate cancer.

FIGURE 5

Demonstrates that the preferred method of data dissemination to Floridians should include a process of validation



RECOMMENDATIONS:

1. The Florida Prostate Cancer Advisory Council will work to secure the necessary funding required to leverage a Statewide network of collaborators to improve the acquisition of prostate cancer data, create disease-based projects that enhance health-related decisions, improve the efficacy and reduce the aggregate costs associated with variable care delivery, and will use the existing infrastructure and the development of a new web-based conduit to disseminate validated information to the communities that we serve.
2. Investigate the value of becoming a Surveillance, Epidemiology and End Results (SEER)* reporting State.

** Through collecting information on incidence, prevalence and survival from specific geographic areas representing 28 percent of the U.S. population and by compiling reports on all of these plus cancer mortality for the entire country, SEER is the leading source of cancer statistics in the United States.*

FUTURE DIRECTION AND CONCLUSION:

During the ensuing months, the Florida Prostate Cancer Advisory Council will develop a robust web-based resource that is designed to disseminate the following validated prostate cancer information:

- Educational information for patients, family members, and care advocates
- A calendar of the events throughout the State that are designed to enhance education and awareness
- The latest developments in evidenced-based practices for the treatment of prostate cancer
- Information about recent progress in prostate cancer research and the availability of clinical trials
- Information on the existing communication networks within Florida

Through the process of acquisition and validation, the Council will disseminate the information required for sound prostate cancer-related decision-making to patients, advocates, and caregivers as soon as it is available, through the existing infrastructure and the new web-based platform, and will provide annual interpretive suggestions to the legislative governing body that represents all Floridians.

ATTACHMENT A

Response to the US Preventive Services Task Force's Draft Recommendation for PSA Screening

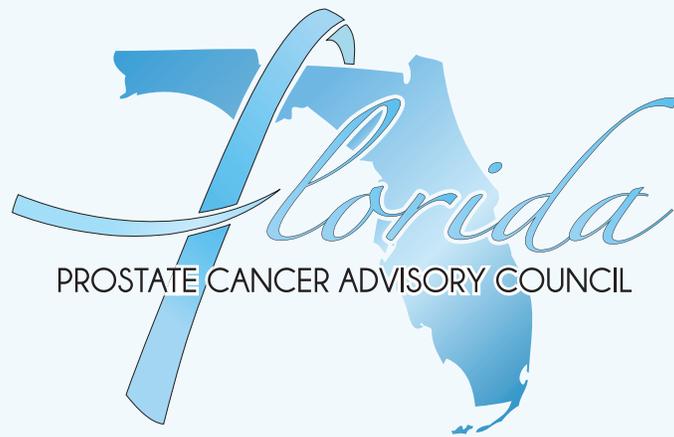
November 21, 2011

The State of Florida Prostate Cancer Advisory Council wishes to comment on the forthcoming U.S. Preventive Services Task Force recommendation that men should no longer be screened for prostate cancer. Prostate cancer is the leading cancer among Floridian men. With this stated, the Council acknowledges that PSA screening may lead to the over-treatment of non-clinically relevant prostate cancer tumors in the general population. However, when interpreted correctly, PSA testing, in combination with digital rectal examinations (DRE), provides valuable information that helps physicians assess cancer risk and predict disease progression. This information is especially relevant for high-risk populations, such as African American men and men with a family history of prostate cancer.

Most men diagnosed with prostate cancer do not require immediate, active therapy, but a large number of aggressive and eventually lethal cancers would go undetected without PSA screening. The dilemma is that no reliable tests exist to date that allows for the differentiation of aggressive from non-aggressive cancer variants; thus more research addressing this important issue should be encouraged and funded as a national priority. Based on current evidence, the Council recommends that men age 50 years and older (age 40 for men at high risk) should be informed by their health care providers annually regarding the risks and benefits of PSA screening. Men diagnosed with prostate cancer should make informed decisions, in consultation with their treating physicians, as to the need for therapeutic interventions versus an active surveillance treatment plan that consists of continued PSA testing, DREs, and biopsies.

The Council maintains that prostate cancer screening and early detection remain important components of responsible and personalized patient care in appropriately informed men and should be performed in those who request screening, and especially in men at high risk, or with no regular access to health care.

Florida Prostate Cancer Advisory Council



PROSTATE CANCER ADVISORY COUNCIL