CaPSURE™ Chronicles
Cancer of the Prostate Strategic Urologic Research Endeavor
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Department of Defense Prostate Cancer Research Program Transformative Impact Award

SAN FRANCISCO, CA – UC San Francisco (UCSF) Department of Urology has been awarded a federal grant of $9.45 million to "transform and revolutionize" the treatment of prostate cancer, which is the second most common form of cancer among American men. Dr. Peter R. Carroll, MD, MPH will be the principal investigator for this 3-year study. UCSF was selected from among 52 research groups nationally who applied for this grant funded by the Department of Defense (DoD) Prostate Cancer Research Program Transformative Impact Award.

"Through early detection and treatment of prostate cancers, death rates from this disease have fallen 40 percent over the past 20 years, but the price of this success has been that many thousands of men with low-risk prostate cancer have undergone unnecessary surgery, radiation, and other treatments – all of which carry risks of potentially serious side effects," said Peter R. Carroll, MD, MPH, professor and chair of the UCSF Department of Urology.

This award "was envisioned to transform and revolutionize the clinical management of prostate cancer," said Colonel Wanda Salzer, MD, director of the Congressionally Directed Medical Research Programs. "Dr. Carroll's multi-institutional project epitomizes the integration of new technologies in medicine and communications to help patients understand their disease risk and select optimal treatment options."

PURPOSE OF THE STUDY

The study will explore how the addition of new genetic tests will help to predict which low-risk prostate cancer tumors will be aggressive and require treatment versus those tumors that will not progress and can be monitored over time by the patient's urologist. The researchers defined "low-risk" prostate cancer as having a prostate specific antigen (PSA) level of 10 or lower, a Gleason grade of 6 or lower on biopsy, and prostate cancer that is confined within the prostate gland.

Imprecise information about if the prostate cancer tumor will spread creates a gap in our knowledge about the best way to approach treatment. This uncertainty can be a source of anxiety for men with prostate cancer and can lead to over-treatment. The researchers hope to close this knowledge gap by the addition of these new genetic tests. Additionally, decision support to interpret the results of the genetic tests and the potential for the prostate cancer to spread outside the gland, will be provided to both the man and his urologist.

STUDY AIMS

The study has two aims: First, to develop and validate an integrated risk prediction model. This model will include clinical information (i.e., such as prostate-specific antigen, Gleason tumor grade, and tumor stage); diet and lifestyle (e.g., tobacco use and body size); plus tumor genetics. Tumor tissue donated from biopsy and radical prostatectomy specimens will be used for genetic analyses to provide better information to men diagnosed with low-risk prostate cancer. The hope is that by adding tumor genetics it will result in better information about the true risk of cancer progression.

Tissue samples collected from 945 men diagnosed and treated at UCSF will be used to create the first integrated risk prediction model. Additional tissue from 800 men, already enrolled in CaPSURE, will be used to validate the model. Combining all of the clinical, lifestyle, and biologic (genetic) information from these 1,745 men, the integrated risk prediction model will be created.

This integrated risk prediction model will then be included into a decision support tool that can be used by the man and his urologist when deciding upon the best approach to choose treatment or opt for surveillance using information that is tailor-made to his own unique biology.

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UCSF
University of California
San Francisco

In year 2, the second aim is to develop and pilot a web-based software tool that incorporates a decision support intervention that can be used by any man who is newly diagnosed with low-grade prostate cancer, to interpret their risk of disease progression and treatment needs. For this aim, the team will leverage the expertise of co-investigator Dr. Jeff Belkora, who has successfully developed and launched decision support tools for women with breast cancer, both at UCSF as well as in diverse national community settings. The decision support team also includes a genetic counselor and coaches for men. Men will be able to use the web-based patient portal along with a live telephone-based coach to help them understand their risk for aggressive cancer and their treatment options.

The development of the web-based patient portal will be done in collaboration with prostate cancer advocates, the community-based experts from the CaPSURE sites (doctors and nurses), and the UCSF research team which includes:

- **Industry Partners**
  - GenomeDx (see http://genomedx.com/)
  - Genomic Health (see http://www.genomichealth.com/)
- **Urology**
  - Imelda Tenggara-Hunter
  - Matthew R. Cooperberg MD, MPH
  - Stacey Kenfield, ScD
  - Jeanette M. Broering, RN, PhD, MPH
- **Urology and Epidemiology & Biostatistics**
  - June M. Chan, ScD
  - John Witte, PhD
- **Pathology and Urology**
  - Jeff Simko, MD, PhD
- **Epidemiology & Biostatistics**
  - John Neuhaus PhD,
  - Erin Van Blarigan ScD
- **Surgery & the Phillip R. Lee Institute for Health Policy Studies**
  - Jeffrey Belkora, PhD
- **Psycho-Oncology**
  - Laura Dunn, MD

WHAT DOES THIS MEAN for CaPSURE?

Active CaPSURE™ participants who were diagnosed with low-risk disease will be contacted by US postal service mailed letter or by phone asking for their permission to allow the researchers at UCSF to have access to their original prostate biopsy and the blocks from their radical prostatectomy specimen. These slides will be examined for a number of genetic markers that may increase or decrease a man's risk for aggressive disease. If you are contacted and are interested in allowing the researcher access to your tissue, you will be asked to sign consent and HIPAA forms along with a brief diet and lifestyle questionnaire. You can mail these forms back to us at UCSF. We will take care of requesting your blocks. Genetic information from your tissue will be combined with the clinical information provided by your doctor and your questionnaires in order to create the integrated risk prediction tool.

During the third year of the project, five CaPSURE sites will be asked to participate in a randomized clinical trial (RCT) that tests the effectiveness of the web-and-phone based decision support tools compared to the usual approach to treatment decision making for prostate cancer treatment. The RCT will be open to men newly diagnosed with prostate cancer.

"The unique strength of this project is that it embraces the full translational research pathway, and aims to not only create a novel personalized medicine intervention, but follows through to develop and evaluate the impact of this intervention in the community setting", said Dr. June M. Chan, ScD and co-investigator.

ABOUT CaPSURE™ at UCSF

The Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE™) is a prostate cancer registry that began in May of 1995. Since that time, over 14,700 men have participated in CaPSURE™. To date, 165 scientific papers have been published on a wide variety of topics such as patient-reported quality of life after treatment, clinical outcomes after treatment, and the economics of prostate cancer care. Information about the published studies from CaPSURE can be found online at: http://urology.ucsf.edu/research/cancer/capsure.

ABOUT UCSF

UC San Francisco is a leading university dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care. For more information see http://www.ucsf.edu/.

Thank you all
for your contributions to
CaPSURE™
Best wishes to you for a healthy and happy 2014!

	January 2014	*February 2014*	*March 2014*	*April 2014*	*May 2014*	*June 2014*
Doctor/ Healthcare worker visits (# of visits, Type of doctor)						
Tests/Imaging (Type of test, # of tests)						
Medications ***changes only*** (Names, dates/dosage)						
Injections (Names, dates/dosage)						
Hospital/ER Visits (Name of hospital, # of days)						
Outpatient Surgeries/ Procedures (Name of procedure)						

******This sheet is strictly to help you fill out our next questionnaire. Please keep for your records.******

	July 2014	*August 2014*	*September 2014*	*October 2014*	*November 2014*	*December 2014*
Doctor/ Healthcare worker visits (# of visits, Type of doctor)						
Tests/Imaging (Type of test, # of tests)						
Medications ***changes only*** (Names, dates/dosage)						
Injections (Names, dates/dosage)						
Hospital/ER Visits (Name of hospital, # of days)						
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