

PASS *Periodicals*

A publication of the Prostate Active Surveillance Study

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Welcome to *PASS Periodicals*!

The 1st issue of the Prostate Active Surveillance Study participant newsletter

Each issue will keep you up-to-date on what's going on with PASS and bring you summaries of developments in prostate cancer research that are relevant to early prostate cancer. We hope that you enjoy your first issue of PASS Periodicals.

Thank you for your participation in PASS!

Canary PASS: Today's Foundations will Provide Answers for Tomorrow

To start things off, here is some history of PASS. The idea for PASS came about in 2007 when the Canary Foundation, a non-profit organization dedicated to early detection of cancer, organized a team of leading prostate cancer researchers. The team designed a study to address one of the most important questions in prostate cancer research; how to distinguish cancers that appear low-risk and become aggressive from those that will remain indolent, or seemingly inactive. Men with aggressive cancers may benefit from immediate treatment, while men with indolent cancers would not benefit from radical treatment. The study design was to recruit a multi-site group of men on active surveillance who agree to donate their blood, urine, and tissue specimens over time. The goal was to discover new, and improve existing, tests that may distinguish between aggressive and indolent cancers. The Canary Foundation formed a unique partnership with the National Cancer Institute's (NCI) Early Detection Research Network (EDRN) to help provide coordination and data management for the study, and the Canary Prostate Active Surveillance Study (PASS) was born.

PASS started enrolling participants in July 2008. Men with clinically localized prostate cancer who manage their cancer using active surveillance are offered the opportunity to join the study. Since PASS started, the study has expanded from six sites to nine. The map shows the locations of each of the study sites, and contact information can be found at:

<http://clinicaltrials.gov/ct2/show/NCT00756665>



Today, over 650 men have enrolled in PASS. There are over 150 participants that enrolled during the first year of the study who are now in their third year of follow-up visits. Specimens (blood, urine, prostate tissue) have been collected at over 1,500 participant visits. This has built a large and growing biospecimen repository for biomarker assays. To date, about 90 participants have received treatment such as surgery or radiation. The majority of men who underwent treatment had progression of cancer, for example their cancer went from Gleason 6 to Gleason 7. Others had a significant increase in tumor volume (percent of positive biopsy cores) or in PSA. Many men underwent treatment even with no significant increase in grade, volume, or PSA. We are excited to have enrolled so many patients and are expanding the study so that we can address critical questions in prostate cancer.

NIH Panel Endorses Active Surveillance

The National Institutes of Health (NIH) recently convened an independent panel at a State-of-the-Science Conference to address the role of active surveillance in the management of men with localized prostate cancer. The panel considered material presented at the conference by speakers, comments of conference participants, and the results of a systematic review of the literature. The consensus of the panel was that active surveillance is a viable option and should be offered to patients with low-risk prostate cancer. However, the panel pointed out that there are still many research needs regarding active surveillance in localized prostate cancer. Some of the needs are: development and validation of molecular, genetic, and imaging markers; determination of the optimal protocols for active surveillance; creation of cohort studies that collect longitudinal data on active surveillance participants. The NIH panel stated that “all patients being considered for active surveillance should be offered participation in multicenter research studies.” Currently, PASS is the only multicenter active surveillance study in North America.

The panel’s complete draft statement, and other information about the conference, can be found at <http://consensus.nih.gov/2011/prostate.htm>

PSA Screening

PSA screening has been in the news since the U.S. Preventive Services Task Force (USPSTF) made their recommendation against screening on October 7, 2011. While the use of PSA screening is controversial, there are some things that we do know. On one hand, it is well documented that PSA screening increases prostate cancer diagnoses. Many of these cancers may never have harmed a man even if they were never diagnosed. Because most cancers are still treated with surgery or radiation, it is clear that we “overtreat” some prostate cancer. This causes unnecessary side effects of

treatment. On the other hand, PSA screening has led to more low grade, low stage cancers being detected, and there has been a clear decrease in prostate cancer deaths since PSA screening became widely used. Although screening trials do not currently show conclusive evidence of a benefit to screening, they are immature at this time. They may show a benefit to screening with longer follow-up. Therefore, we feel that PSA screening should not be stopped. However, selective or smarter screening strategies and selective intervention should be considered. Better biomarkers will aid in developing smarter screening strategies, and PASS is one large scale effort to improve biomarkers and ultimately avoid “overtreatment.”

Biomarkers in Urine Correlate with Aggressive Disease in Preliminary Studies

The first preliminary findings of biomarker research from PASS were presented at the Genitourinary Cancers Symposium on February 2, 2012 in San Francisco. We reported on the ability of two urine tests (PCA3 and TMPRSS2) to predict grade or volume of disease. Preliminarily, we have found that these markers actually do correlate to both grade and volume of cancer. These findings are based on an analysis of data collected at the first study visit from 401 men in PASS. As we collect more urine samples, we will be looking at how these markers predict cancer progression. Prostate biopsies are invasive and don’t always pick up all of the cancer. If a diagnostic test could be developed that would help predict aggressive disease or disease progression without a biopsy, this would be ideal for future use in men with low risk prostate cancer.

With two grants from the Department of Defense, and more grants underway, we’ll expand on our preliminary study of urine biomarkers, and study other biomarkers that we hope will help us identify aggressive cancers. As always, none of this would be possible without the continued support of our participants. **Therefore, thank you again for taking part in this important study!**

PASS Periodicals is produced by the PASS Coordinating Center at the Fred Hutchinson Cancer Research Center in Seattle, WA.

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