

## Welcome to the 2<sup>nd</sup> Issue of the Prostate Active Surveillance Study Participant Newsletter

In this issue, we will give you an update on the study and summarize developments in research related to early stage prostate cancer. We also want to thank you for your continuing support. We hope you enjoy reading this issue of PASS Periodicals!

### Canary PASS Today

The Canary Prostate Active Surveillance Study (PASS) continues to enroll men at nine sites in North America. Sites include:

- ❖ Beth Israel Deaconess Medical Center (Boston, MA)
- ❖ Eastern Virginia Medical School (Norfolk, VA)
- ❖ Stanford University (Stanford, CA)
- ❖ University of British Columbia (Vancouver, BC, Canada)
- ❖ University of California San Francisco (San Francisco, CA)
- ❖ University of Michigan (Ann, Arbor, MI)
- ❖ University of Texas Health Science Center San Antonio (San Antonio, TX)
- ❖ University of Washington (Seattle, WA)
- ❖ Veteran Affairs Puget Sound Health Care System (Seattle, WA).

The men who enroll were diagnosed with localized prostate cancer, like yourself. They too have chosen to use active surveillance to manage their cancer. At each study visit we are collecting clinical information and samples to continue our research on prostate cancer.

Here is a current description of the study:

- ❖ Over 1000 men have enrolled in PASS.
- ❖ The average age of men entering the study is 63.
- ❖ About 170 participants have received treatment such as surgery or radiation.
- ❖ Specimens (blood, urine, prostate tissue) have been collected at more than 3,400 study visits.
- ❖ Over 1,800 of these samples have been used for biomarker research.
- ❖ Many of the first men enrolled in PASS are still using active surveillance. This fall, the first group of men to enroll are completing 5 years of study visits.

### PASS: Long Term Follow-up

As participants finish with study visits, they may start the long-term follow-up part of PASS. This will happen when a participant has completed five years of study visits, receives treatment, or moves away from the study site.

In the long-term follow-up part of PASS, data about disease status will be collected once per year. Data will be collected by phone or by a short mailed questionnaire. Men will not need to go into the clinic or have specimens collected.

The data collected is necessary for a complete understanding of prostate cancer. Prostate cancer often changes very slowly, so it is important to monitor changes over many years. Long-term follow-up data will be important for PASS researchers to address critical questions in prostate cancer research.

### Research in PASS

A question frequently asked of the PASS study coordinators is when results from biomarker studies will be published. We greatly appreciate the enthusiasm and dedication of PASS participants!

We would like our participants to understand that for many biomarker studies we need at least three years of follow-up and at least 500 participants. The more participants and the more follow-up, the better our results will be. This means that it will take several more years to complete some of our studies.

However, there are some questions that we can start answering now. The results of the first biomarker study in PASS have been published in *Clinical Cancer Research*! In this study, two biomarkers that are found

in urine were examined for their correlation with disease characteristics at study entry. These biomarkers are pieces of RNA known as PCA3 and TMPRSS2:ERG. We found that the level of these markers in urine do correlate with biopsy Gleason grade and cancer volume. While these results are encouraging, further work is needed to determine the clinical use of these markers.

If you wish to read the paper online, see:

<http://clincancerres.aacrjournals.org/content/19/9/2442.long>

In the last newsletter, we talked about some of the controversy about PSA screening. Now we are looking at PSA data in PASS. Preliminary results from the first study were presented at the Genitourinary Cancer Symposium on February 14, 2013 in Orlando, FL. In that study, multiple PSA values were examined in 151 men on PASS. There was a decreased risk of cancer progression in men with decreasing PSA velocity, or change over time. We are in the process of confirming these initial results.

### Prostate Cancer Research in the News – PIVOT: Prostate Cancer Intervention versus Observation Trial

This past year the results of the Prostate Cancer Intervention Versus Observation Trial, or PIVOT, were published in the New England Journal of Medicine. In 1994 this trial started enrolling men diagnosed with localized prostate cancer. The trial was designed to measure survival in men who were treated with surgery compared to men whose cancer was observed. In PIVOT, the men who were observed did not use active surveillance. This means that their cancer was not monitored as closely by lab tests and prostate biopsies as the monitoring used in PASS.

In the PIVOT study, 731 men were randomly assigned to either receive surgery or observation. They were then followed for an average of 10 years. The researchers found that during the follow-up period 171 of the 364 patients (47.0 percent) who were assigned to surgery died. During the same period, 183 of the 367 patients (49.9 percent) who were assigned to observation died. The overall difference in survival was not significantly different in the two groups.

When the data was broken down further, the researchers found no difference between the two groups in mortality for men with low risk cancer or with a PSA score less than 10 ng/ml. However, in men with intermediate risk cancer or a PSA score above 10 ng/ml there appeared to be a slight benefit to receiving surgery.

One of the limitations to this study was that it lacked a large enough number of men to ensure that statistics could show all meaningful effects. Originally, the design called for enrolling 2,000 men. However, randomly assigning men to receive surgery or observation turned out to be very challenging and fewer men were enrolled. Despite this drawback the study's finding that there is no benefit of surgery for men with low-risk disease is consistent with other study results.

If you wish to read the paper about PIVOT, see:

<http://www.nejm.org/doi/full/10.1056/NEJMoa1113162>

The associated editorial, co-authored by Dr. Thompson who is Principal Investigator at the PASS site in San Antonio, is at:

<http://www.nejm.org/doi/full/10.1056/NEJMe1205012>

***To all of the PASS participants, whether you just joined the study, have been on the study for many years, have had treatment, or moved away from your study site, the members of the PASS research team can't thank you enough for taking part in this important study! Your continued participation is invaluable and we thank you for your support.***

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

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