

Patient Fast Fact Sheets:
An Introduction to Clinical Trial
Participation for Potential Study Patients

Cancer Disparities Research Program
MS/AL Radiation Oncology Research Partnership
NCI Disparities Summit Meeting July 17, 2007

MS/AL Radiation Oncology Research Partnership

- U56 awarded in 2003 to Singing River Hospital System to:
 - Accrue underserved to RT trials
 - Integrate patient navigator program
 - Develop community outreach to underserved
- Partner/mentor institutions:
 - UAB, UMMC
- SRHS:
 - county owned 2 hospital system on MS Gulf Coast with 375 new cancer cases/year
- Underserved include black, elderly, uninsured, underinsured

MS/AL Radiation Oncology Research Partnership

- Restructure in Sept 2005
 - New PI followed by Katrina.....
 - New organizational model, dedicated CRT staff
 - Activated 29+ trials with NCI cooperative groups + pharma
- Accruals
 - 1st accrual in April 2006 with total of 4 accruals and 8 transfers in FY06
 - Sept 06 – June 07: 25 accruals (almost 8%)

Medical Advisory Group

- **Composition**

- RadOnc, MedOncs, Surgeons, GYN Oncologist, GYN, GI, Family Practice, Pulmonology

- **Purpose**

- Review open study listings for local activation
- Grant progress reports, revisions of strategic plan
- Partner with community awareness of grant & CRT

- **Collaborative activities**

- Weekly Tumor Conferences focus on CRT cases
- CME's on CRT cases
- Monthly updates on active study listing in surgical staff lounges, medical staff conference areas (in house + external sites)
- Patient navigator expansion into private offices for assistance with at-risk cases

Casefinding and Accrual Process Overview

- **CRA reviews *all new Consults* into SRHS prior to 1st scheduled visit**
 - Includes both Radiation Oncology and Hematology/Medical Oncology clinics
- **Blue Sheet attached to record for any patient potentially eligible for an open CRT**
 - Communication form for medical staff re eligibility
- **Green Patient Fast Fact Sheet (PFFS) attached to record for distribution and review with patient by MD if CRT is reasonable option for patient**
- **MD notifies OCR for further eligibility review if PFFS given to patient**

Casefinding and Accrual Process Overview

- **CRA/CRN collaborate on continued eligibility verification with MD**
- **Informed Consent Process initiated with eligible patients**
 - **IRB-approved ICD reviewed with patient for final signature**
- **All casefinding information, accrual status, reasons for non-accrual and final trx plan are recorded in *Patient Screening Database***

Patient Fast Fact Sheet

- Designed as an **introduction** to a **specific CRT** for a patient during the treatment planning consultation
 - usually given out at 1st visit
 - CRT is presented as one of treatment options available
- **PFFS** plus SRHS pamphlet on Clinical Trials given to patient
- Deliberately avoids discussion of treatment toxicities
- Emphasizes **potential** eligibility – frequently not enough detail to determine without additional workup
 - ICD is signed prior to any non-standard workup for CRT eligibility
- Provides basic information on treatment(s) offered on study
- All study specific **PFFS** are approved by the IRB at the time of study activation

RTOG 0126 Patient Fast Fact Sheet

PATIENT INFORMATION

We would like to provide you with some very basic information about a cancer clinical trial that your physician has begun to discuss with you as a treatment option.

Cancer clinical trials, also called cancer treatment or research studies, test new interventions or treatments in people. The goal of this research is to find better ways to prevent or treat cancer or the side effects from treatment.

As one of your treatment choices for **your prostate cancer**, you are being asked to consider participating in this clinical trial. At this time, we believe that you may meet the eligibility requirements for this study.

The National Cancer Institute, through its **Radiation Therapy Oncology Group (RTOG)**, is conducting this trial in many locations. The Singing River Hospital System Regional Cancer Center is conducting the study locally. It is expected that about **1520** people will join this study.

WHY IS THIS RESEARCH STUDY BEING DONE?

One of the standard treatment options for your stage and type of prostate cancer is external beam radiation therapy. Modern radiation therapy planning methods with 3-dimensional therapy or Intensity Modulated Radiation Therapy (IMRT) allow safer delivery of higher than conventional doses of radiation. The purpose of this study is to compare the effects on you and your cancer of the standard dose of radiation therapy (39 treatments) with a higher dose of radiation (44 treatments) to see which treatment is better.

WHAT ARE THE TREATMENT POSSIBILITIES?

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer will determine which group you are assigned to. You will have approximately an equal chance (50/50) of being placed in one of the following groups:

Treatment 1

If you are randomized to this treatment, you will receive the standard dose of 3D or IMRT radiation. You will receive radiation therapy once daily, five days a week, Monday through Friday, for a total of 39 treatments.

Treatment 2

If you are randomized to this treatment, you will receive a higher dose of 3D or IMRT radiation. You will receive radiation therapy once daily, five days a week, Monday through Friday, for a total of 44 treatments.

WHAT TESTS ARE INVOLVED?

Should you receive your treatment in the study the tests you will have done are:

Physical exams before and throughout your treatment

Blood tests to monitor for side effects and tumor response

X-rays or other body scans to monitor for response to the treatment

HOW LONG ARE PARTICIPANTS IN THE STUDY?

We will be monitoring your health status **for as long as the next 13 years.**

WHAT'S NEXT?

Your doctor will discuss your treatment options with you again, including the opportunity to participate in this study. If you are interested, and you and your doctor agree that this study would be of potential benefit to you in treating your cancer, the Cancer Center Research Nurse will do further evaluation of your records to make sure you are fully eligible to join the study. If you qualify to join the study, you will be given additional information about this study and as much time as needed to ask questions and make an informed decision. In addition to your doctor, we have a Research Nurse available to help answer your questions.

WHERE CAN YOU GET MORE INFORMATION?

If you are interested in learning more about the opportunity to participate in this research study, please let your doctor know. You may call the Singing River Regional Cancer Center Research Nurse at 228-809-5639.

You can also call the Cancer Information Service at 1-800-4-CANCER or visit the National Cancer Institute's Cancer Trials Web Site at

<http://www.cancer.gov/clinicaltrials> for information on clinical trials or

<http://www.cancer.gov/cancerinformation> for information on cancer.

Evaluation of the Usefulness of the PFFS as a Recruitment Tool for Cancer Clinical Trial Accrual

- Evaluation by cancer care team and patient using Questionnaires
 - Cancer care team: global approach
 - Patient: individual case
- Concepts/variables to explore:
 - Helpfulness in introducing study as a treatment option
 - Information provided was enough to understand the treatment(s) offered on the study
 - Information provided was enough to understand why the study was being done
 - For patients who were interested and subsequently received the ICD for review, was the PFFS helpful as the initial introduction to the study

Evaluation of the Usefulness of the PFFS as a Recruitment Tool for Cancer Clinical Trial Accrual

- Methodology for Patient Evaluation:
 - Sample 100% of patients in screening database who were identified as having a potential study available at the time of initial consult based on eligibility review
 - MD did not provide a PFFS if not potentially eligible for an open study
 - Confirm receipt of PFFS + SRHS Clinical trials pamphlet
 - MD did not offer patient the PFFS if CRT was not a reasonable option
 - Questionnaire completion within 45 days of treatment initiation (on or off - study)
 - Incorporate a 2nd questionnaire exploring reasons patient DID or DID NOT accrue to study