The Credentialing Process for the NSABP B-39 / RTOG 0413 Partial Breast Irradiation Trial

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Purpose:

Develop a credentialing process for the NSABP B-39 / RTOG 0413 Partial Breast Irradiation (PBI) trial.

Methods and Materials:

NSABP B-39 / RTOG 0413, is a Phase III trial comparing whole breast irradiation versus Partial Breast Irradiation (PBI) delivered with 3D conformal radiation therapy (3D-CRT), MammoSite or multi-Catheter brachytherapy. For each PBI technique,an institution, radiation oncologist and physicist team must be credentialed. The credentialing verifies that all personnel involved with treatment planning have read the protocol prior to enrolling patients to limit the number of deviations. Credentialing also allows feedback to the team prior to patient treatment to correct any mistakes. Each institution must complete online the knowledge assessment and facility questionnaires and download a CT benchmarks case and plan it using PBI techniques.

PBI Credentialing Requirements:

Each Radiation Oncologist and Physicist team **must complete** the credentialing process before a patient can be placed on the protocol (See Section 5.1 of the protocol). Once the team has met the minimum requirements for credentialing, a letter will be sent to the Radiation Oncologist from NSABP informing them that they have successfully completed the credentialing process and can begin placing patients on the study.

Each Radiation Oncologist and Physicist team at an institution must complete the PBI QA Knowledge Assessment and Facility Questionnaires and complete the benchmark case for each PBI technique for which the institution wants to be credentialed. (Note: If a Radiation Oncologist at the same institution has been credentialed previously, then all subsequent Radiation Oncologists need **ONLY** to complete the PBI QA Knowledge Assessment Questionnaire and Sections I and II of the PBI Facility Questionnaire.)

- **Questionnaires:**
  - PBI QA Knowledge Assessment Questionnaire
  - PBI Facility Questionnaire
- **Benchmark Cases**: For each PBI technique (3D CRT, MammoSite or Multi-Catheter) for which an institution would like to be credentialed, the specific benchmark case must be planned per protocol and submitted electronically to the ITC (see below on How to Submit Digital Data). A completed PBI treatment dosimetry summary form (either 3D CRT or MammoSite/Multi-Catheter) must be completed and a hard copy of the plan, including isodose lines and BEVs, must also be mailed to the RPC at: 7515 S Main Street, Suite 300, Houston, TX 77030

➢ An institution will choose one of the treatment planning systems listed below to download the proper CT image set. Some of these image files have been compressed (i.e. zipped) and must be decompressed using decompression software such as winzip. If the files cannot be downloaded, it's highly probable that your institution's firewall is preventing the transfer. This can be resolved by calling your IT department or downloading the images from outside the institution's firewall such as your home pc.

- o Philips Pinnacle
- o CMS XiO
- o Nucletron Plato
- o All other treatment planning systems

Methods and Materials continued:

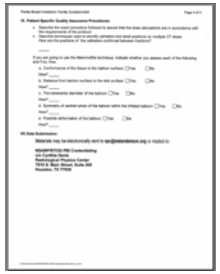
How to Submit Digital Data:

Digital data for PBI credentialing (benchmark cases) as well as ALL PBI protocol cases are to be submitted to the Image-guided Therapy QA Center (ITC) using either DICOM or RTOG Data Exchange format. The ITC will process these data and make them available for review by study chairs (or designates), the RPC, and the RTOG HQ Dosimetry Group. For further information and for instruction an institution can contact the ITC (314-747-5415 or itc@castor.wustl.edu).

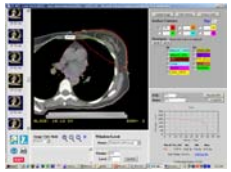
Checklist for Digital Data Submission to the ITC
Digital Data Submission Procedures
Digital Data Submission Information Form
ATC Compliant Treatment Planning Systems

The following are the Knowledge Assessment and Facility Questionnaires

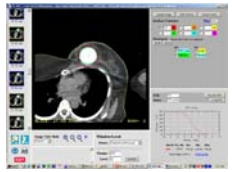
Methods and Materials continued:



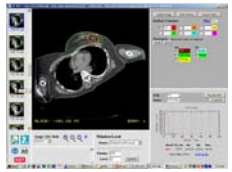
Benchmark Cases



3D conformal benchmark



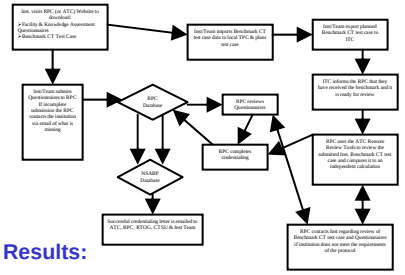
MammoSite benchmark



Multi-catheter benchmark

Methods and Materials continued:

NSABP B-39/RTOG 0413 Credentialing Process
for each PBI Modality



Results:

As of mid-July, teams at 533 distinct institutions have submitted applications for credentialing for at least one PBI technique. 884 radiation oncologists for 3D-CRT credentialing, 588 radiation oncologists for MammoSite and 169 radiation oncologists for multi-catheter brachytherapy. Of those applications, 82% became credentialed for 3D-CRT, 76% for MammoSite, and 71% for multi-catheter.

Overall # of distinct institutions credentialed	435
	# of distinct Rad. Onc. Credentialed	# of distinct Rad. Onc. in process
3D	604	139
MammoSite	408	126
Multi-Catheter	98	51
	# of distinct institutions applied for credentialing	# of distinct institutions credentialed
3D	408	333
MammoSite	306	224
Multi-Catheter	71	43

Reasons for which a radiation oncology team failed to become credentialed included; incomplete application, incorrect answers on knowledge assessment, the treatment planning system could not submit data electronically, and the CT benchmark was not planned per protocol.

The first patient enrolled by each institution received a rapid review prior to patient treatment. The next 4 cases received a timely review. These reviews included a dosimetric and clinical review. At the present time this protocol has accrued 1571 patients; 578 treated with 3D-CRT, 162 treated with MammoSite, and 53 treated with multi-catheter brachytherapy. **Of the 793 patients patients treated to date on the PBI arm there have been no dosimetric deviations.**

Conclusions:

The purpose of credentialing is to verify that the radiation oncologist and other personnel involved are familiar with the protocol and can plan a case per protocol prior to placing a patient on protocol. This process enables us to give a "team" feedback prior to treating a patient on the trial potentially enabling us to reduce the number of deviation incurred on the trial. The PBI credentialing process has been successful in educating participating facilities and helping to minimize dosimetry errors.

Support:

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