Credentialing Requirements for NSABP B-39 / RTOG 0413

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Purpose:

NSABP B-39 / RTOG 0413 is a Phase III trial comparing Whole Breast Irradiation versus Partial Breast Irradiation (PBI). The partial breast arm consists of 3 techniques, 3D Conformal Radiation Therapy, MammoSite and Multi-catheter HDR. For each of these techniques NSABP and RTOG requires an institution, radiation oncologist and physicist "team" to be credentialed. Credentialing requires completing knowledge assessment and facility questionnaires, importing a DICOM CT image set, performing a treatment plan using the image set and exporting the images, structures and isodoses to the Image-Guided Therapy QA Center (ITC).

Methods and Materials:

An institution can obtain the knowledge assessment and facility questionnaires from the RPC's website (http://rpc.mdanderson.org). These questionnaires can be completed online, emailed, faxed or mailed directly to the RPC. An institution may be credentialed for one or more of the PBI techniques. A CT benchmark case exists for each PBI technique. The institution is required to import the appropriate CT image set into their treatment planning system. The benchmark must be planned per protocol. The benchmark must then be digitally exported to the ITC along with all required hard copy data. The RPC will review each benchmark case submitted. Once the RPC has completed its review NSABP will be informed that the institution has met the requirements for credentialing and will be allowed to enter patients on the protocol.

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 (complete online or mail/email Microsoft Word document)
  - PBI Facility Questionnaire (complete online or mail/email Microsoft Word document)
- **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

➢ Click on 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.

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

Methods and Materials continued:

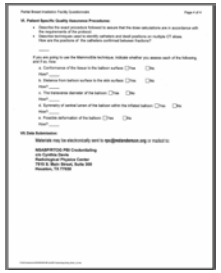
How to Submit Digital Data(click on links to download procedures):

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 to obtain an FTP account for submitting data, please contact the ITC (314-747-5415 or itc@castor.wustl.edu).

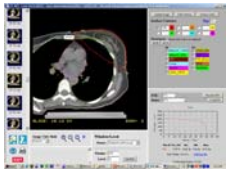
Checklist for Digital Data Submission to the ITC
Digital Data Submission Procedures
Digital Data Submission Information Form
ATC Compliant Treatment Planning Systems

The following are the Knowledge Assessment and Facility Questionnaires

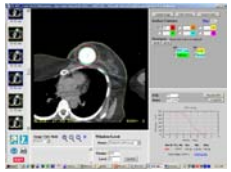
Methods and Materials continued:



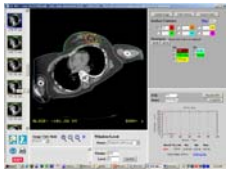
Benchmark Cases



3D conformal benchmark



MammoSite benchmark



Multi-catheter benchmark

Results:

As of mid-July, 151 Radiation Oncologists have been credentialed to participate on the PBI arm of this study using the 3D conformal therapy technique, 71 have been credentialed to use the MammoSite technique and 31 have been credentialed to use the multi-catheter technique. The RPC has had 160 institutions apply to be credentialed using 3D conformal therapy of which 77 are credentialed. The RPC has had 104 institutions apply to be credentialed using MammoSite of which 53 are credentialed. The RPC has had 33 institutions apply to be credentialed using Multi-catheter of which 13 are credentialed.

The RPC starts the credentialing process for this study once we have received the knowledge assessment, facility questionnaire and a hard copy of the benchmark case. The RPC considers this a "complete RPC package." If one of these items are missing the RPC will contact the institution and request the data which is missing. Credentialing can not be completed until the benchmark case is electronically sent to the ITC. The following table shows the average amount of time it takes an institution to complete the credentialing process once they have submitted "complete RPC package."

	Average time to be credentialed (days)	Minimum time to be credentialed (days)	Maximum time to be credentialed (days)
3D	23	1	119
MammoSite	29	1	96
Multi-Catheter	30	1	85

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.

Support:

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