The Value of Credentialing

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Purpose:

The Radiological Physics Center (RPC) has performed credentialing of institutions to participate in a number of protocol studies. The purpose of credentialing is to verify that the radiation oncologist and other personnel involved are familiar with the protocol prior to enrolling patients with the goal of reducing the number of major and minor deviations. Credentialing has been performed for high and low dose rate brachytherapy studies, stereotactic studies and IMRT studies. Credentialing has also been done for several different study groups and for a variety of disease sites including eye, lung, esophagus, brain, breast, prostate, head & neck and cervix.

Methods and Materials:

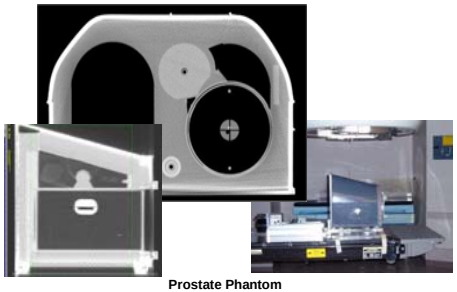
Over the years, the RPC's credentialing procedures have required one or more of the following: review of the institution's physics and QA procedures, submission of knowledge assessment and facility questionnaires, calculation of geometric benchmark cases, importing and planning on a predetermined CT image set, irradiating an anthropomorphic phantom, and submitting the first 2 patients for review. The credentialing process not only evaluates the quality of the specific clinical procedure at the institution, but also assures that the institution and participating radiation oncologist have experience in the procedure. The credentialing process enables us to offer feedback to the institution to correct mistakes that may occur with a protocol patient. A retrospective review of radiotherapy of patients entered on the studies is performed. All patients submitted to the study are subjected to a retrospective review of the radiotherapy treatment. The retrospective review involves a recalculation of patient dose, a review of the treatment records, and verification films. Deviations from protocol guidelines were assessed according to predefined criteria and are reported to the protocol PI.

Knowledge Assessment

Methods and Materials continued:

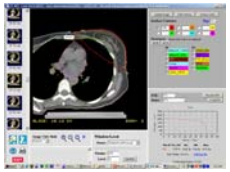
IMRT Head and Neck Phantom

Lung Phantom

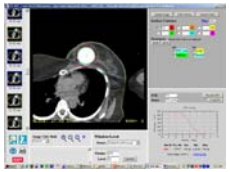


Prostate Phantom

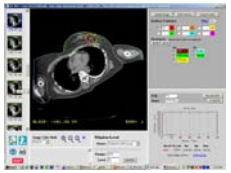
Benchmark Cases



3D conformal benchmark



MammoSite benchmark



Multi-catheter benchmark

Results:

A gynecological protocol allowed LDR or HDR brachytherapy to be used as a treatment modality. If an institution wished to use HDR brachytherapy, then the radiation oncologist needed to go through the credentialing process. Credentialing required that the institution submit a patient treated in similar fashion as the protocol to the RPC for a dosimetry and clinical review. If the institution wished to use LDR brachytherapy no credentialing was required.

Total Percent Deviations for Credentialed and Non-Credentialed Institutions (337 patients)

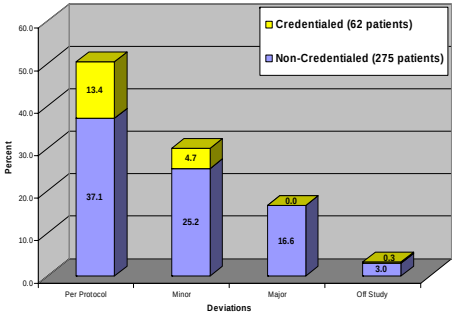


Figure 1: Of those patients that were treated on protocol, 50% were treated per protocol, whether or not the institution was credentialed for HDR. Minor deviations were due to field placement, time, dose and/or boost. Major deviations were due to field placement, time, dose or brachytherapy procedure. Institutions that were credentialed to treat with HDR did not commit any major deviations. Those patients classified as off study were due to either patient ineligibility, incomplete RT and/or disease progression.

Two gynecological protocols allowed LDR and HDR brachytherapy to be used as treatment modalities. The protocol required that each radiation oncologist be credentialed for both modalities. The credentialing consisted of a rapid review of the first two patients placed on study for each modality.

Total Percent Deviations for two cervix protocols

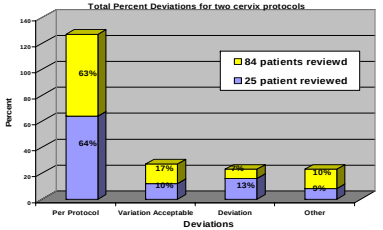
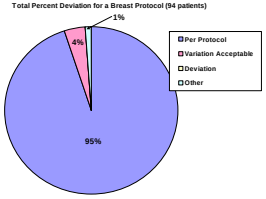


Figure 2: Minor and major deviations were due to time, and dose. Those patients classified as other were due to either patient ineligibility, incomplete RT and/or disease progression.

A breast protocol required that all institutions be credentialed for LDR and HDR brachytherapy. Each institution was required to create a plan using an idealized benchmark case.

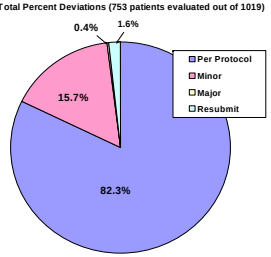
Total Percent Deviation for a Breast Protocol (94 patients)



Results:

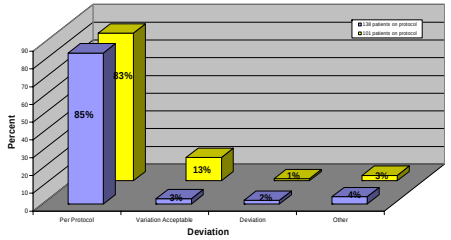
A partial breast irradiation protocol required all radiation oncologists to be credentialed for a minimum of one of the PBI techniques (MammoSite, Multi-catheter brachytherapy and/or 3D conformal radiation therapy). The radiation oncologist needed to plan a pre-determined CT data set and submit the data electronically for a dosimetric review.

Total Percent Deviations (753 patients evaluated out of 1019)



Two prostate protocols required that all radiation oncologists to be credentialed in order to participate on these protocols. Credentialing consisted of submission of two benchmark cases and a patient case which had been treated in similar fashion to the protocol.

Percent Deviation for 2 Prostate Protocols



Four protocols for which credentialing was required of all participants had rates of deviation on the order of 0% to 4% and two protocols that had limited credentialing requirements had rates of deviation on the order of 7% to 16%. In another study some institutions were credentialed for one technique but not for another. Those institutions that were credentialed received no deviations on the protocol, whether they utilized the technique for which they were credentialed or not, while those institutions not credentialed had a deviation rate of 16%.

Conclusions:

It appears that institutions that go through a credentialing process are better prepared to comply with the requirements of the protocol. This may be because the credentialing process provides feedback on how to better comply with the treatment protocol prior to submitting a patient onto the study. Therefore, the frequency of deviations can be reduced for institutions that go through the credentialing process.

Summary:

QA is an important component of clinical trials. A credentialing procedure can be a valuable component of clinical trial QA to reduce deviations.

Support:

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