

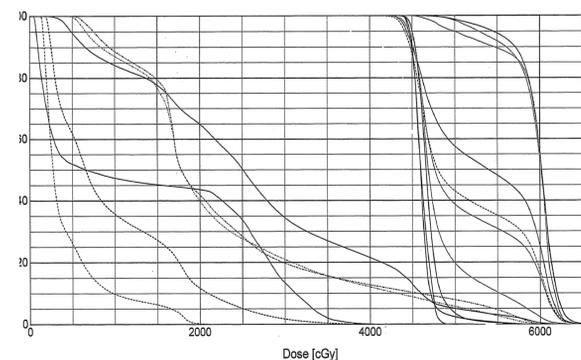
Purpose:

One of the Radiological Physics Centers (RPC) quality audits used to assure the NCI and Cooperative Trial Groups that institutions participating in clinical trials deliver and report radiation doses that are clinically comparable and consistent is a retrospective review of clinical patient treatment charts. However, there is no standard regarding what patient and dosimetry data to include within a submitted trial patient's chart depending on treatment modality (brachytherapy vs. external beam) and protocol specific requirements. This work identifies the required data needed to perform a clinical trial quality audit review based on the evaluation of nearly 2000 patient charts.

Methods and materials:

Since 2005, the RPC reviewed 1997 patient charts equating to over 13,000 points of calculation. In order to perform these dose recalculations, a minimal amount of data is needed for the external beam and brachytherapy treatments. A review of these charts has identified the required patient specific and machine specific data required. In addition the data needs to be submitted in a useable format (CT images submitted in DICOM format, isodose lines and DVHs in color).

X In black and white the DVH is too difficult to read

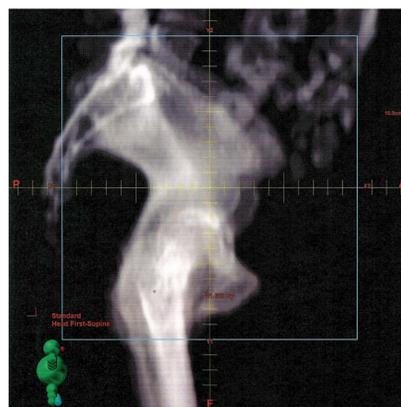


✓ In color the lines are easy to read and determine dose

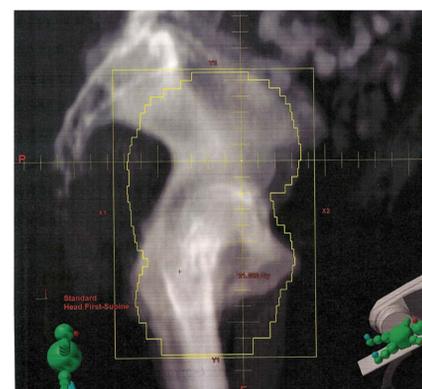


Methods and materials continued:

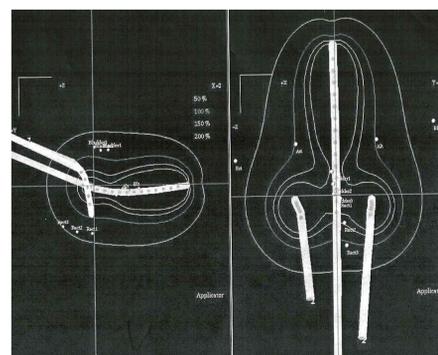
X Does not show block placement



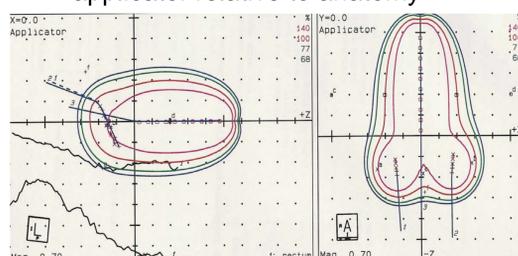
✓ Can see blocking, therefore able to determine the effective field size



X Black and white isodose lines make it difficult to read

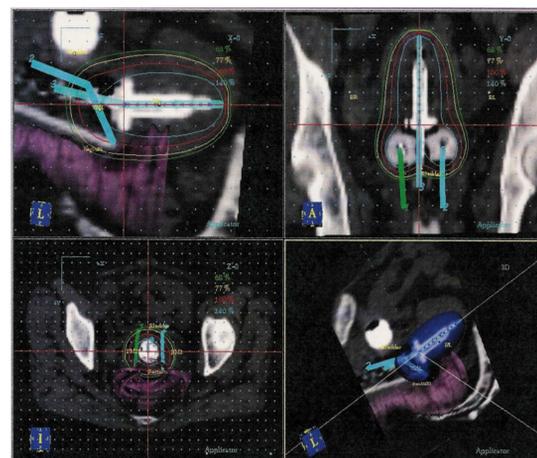


X Can not determine position of applicator relative to anatomy



Methods and materials continued:

✓ In color with placement against anatomy



X The daily treatment record only shows monitor units delivered per day

| COMMENTS | WT. | DAILY DOSE | TOTAL DOSE | DAILY DOSE |
|----------------|-------|------------|------------|------------|
| Micro Vx Iq. 2 | 136.2 | 180 | 180 | |
| VF PK LT | | 180 | 360 | |
| | | 180 | 540 | |
| | | 180 | 720 | |
| micr | | 180 | 900 | |
| | 139 | 180 | 1080 | |
| | | 180 | 1260 | |
| AP/R+VF | | 180 | 1440 | |
| | | 180 | 1620 | |
| | | 180 | 1800 | |
| | 137 | 180 | 1980 | |
| | | 180 | 2160 | |
| No tx 6/24 | | 180 | 2340 | |
| no tx 6/25 | 135 | 180 | 2520 | |
| | | 180 | 2700 | |

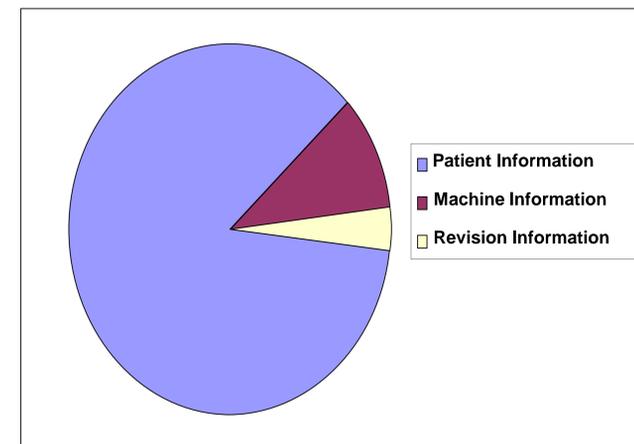
✓ The daily treatment record shows monitor units delivered per field per day

| DAYS/FRACT | Date | PA | LT | RT | RT | | | |
|------------|------|-------|-------|-------|----|----|--|-----|
| 0/1 | 8/15 | 1X18X | V 16K | 1X18X | 1B | GF | | 180 |
| | | | 67 | 67 | 67 | | | 180 |
| 1/2 | 8/26 | 1X18X | V 16K | 1X18X | 1B | GF | | 180 |
| | | | 67 | 67 | 67 | | | 360 |
| 2/3 | 8/27 | 1X18X | V 16K | 1X18X | 1B | GF | | 180 |
| | | | 67 | 67 | 67 | | | 540 |
| 3/4 | 8/30 | 1X18X | V 16K | 1X18X | 1B | GF | | 180 |
| | | | 67 | 67 | 67 | | | 720 |
| 4/5 | 8/31 | 1X18X | V 16K | 1X18X | 1B | GF | | 180 |
| | | | 67 | 67 | 67 | | | 900 |

Results:

Comprehensive data requirements for external beam and brachytherapy are presented. Since 2005, the RPC sent out 1021 letters requesting data or clarifications regarding the treatment. 86% of these request were for patient specific information. The most common information omitted from a brachytherapy chart were the HDR dwell times and location, and for external beam charts it was the daily treatment records indicating the monitor units delivered per field.

Figure 1: The general categories of information missing which the RPC requests more data of the institution



Over the last six years, 1021 letters requesting information were sent to institutions. Of the 1021 letters: 85% (868 letters) were sent for patient information, 10% (103 letters) were sent for additional machine information and 4% (38 letters) were sent for revision of information. The percentages do not add up to 100% due to the same institution receiving a request in more than one category.

Conclusions:

For the RPC to state that trial patient doses are clinically comparable and consistent, the necessary patient and dosimetry data must be submitted in a timely manner. Development of a required data submission checklist to be included with each protocol will minimize trial data submission deficiencies and increase the efficiency of the RPC's quality audits.

Support:

The investigation was supported by PHS grant CA10953 awarded by the NCI, DHHS.