# The Value of Rapid Reviews

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## Purpose:

Describe the value of rapid (pre-treatment) reviews within the clinical trial environment.

## Methods and Materials:

The Radiological Physics Center (RPC) performs rapid reviews for several different study groups and for a variety of disease sites including colon, breast, endometrial and cervix. Rapid reviews have been performed for high dose rate brachytherapy studies, 3D CRT and IMRT studies. The purpose of rapid reviews is to verify that the radiation oncologist is capable of treating a patient per protocol specifications prior to treatment commencing with the goal of reducing the number of deviations.

The rapid review process requires that the institution electronically submit the protocol patient treatment plan prior to the commencement of treatment for a dosimetric and clinical review. Dependent on the protocol, the first patient or every patient submitted by a physician might require a rapid review. Rapid reviews enable the RPC to provide feedback to the physician to rectify errors prior to the start of treatment. Deviations are assessed according to defined criteria within the specific protocol.

When submitting the electronic data the institution is informed that the rapid review process can take up to 3 business days if all of the information that is requested is submitted to the Image Guided Therapy (ITC) QA Center located in St. Louis. The following must be submitted for each electronic case:

1. Digital Treatment Planning Data are to be submitted via secure FTP. Each user has it's own password protected account into the sFTP.
2. The Digital Data Submission Information (DDSI) Form.

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*******            Image Guided Therapy QA Center              *******
* ATC *        DIGITAL DATA SUBMISSION INFORMATION FORM         * ATC *
*******          for ATC-supported clinical trials              *******

Protocol ID:    GOG 0258                    Case Number: 076-0258-018
Subm. Category: RAPID REVIEW / Initial Case
Subm. Type:     Initial                     Pt. Initials: HL

Institution Name:       RPC
            RTOG #:                         RTF #:  1111
            NSABP #:                        NCI #:
            GOG #:    0258

CONTACT PERSONNEL FOR DATA SUBMISSION

Physician:                                          Ph:
    Email:                                          Fx:

Physicist:                                          Ph:
    Email:                                          Fx:

Dosimetrist:                                        Ph:
    Email:                                          Fx:

Res Assoc:                                          Ph:
    Email:                                          Fx:

SUBMISSION INFORMATION

Dose Prescription:    48Gy : 1.8Gy in 25 fractions
Dose Delivery:        IMRT
Dose Calculation:     Heterogeneity Corrected
Submission Method:    SFTP
SFTP Login:           rtog-
Data Directory:       LH2
TPS Mfr / Name:       Varian Medical Syste / Eclipse
TPS SW Version:       11.0
Dose calc algorithm:  AAA

First Treatment (Implant) Date:    Jun 24, 2013
ITC Digital Data Submission Date:  Jun 14, 2013
Date of CT Series:                 Jun  4, 2013

Form completed by:                                  Date: Jun 19, 2013
Wed Jun 19 12:50:49 CDT 2013                        Form rev: 11101201
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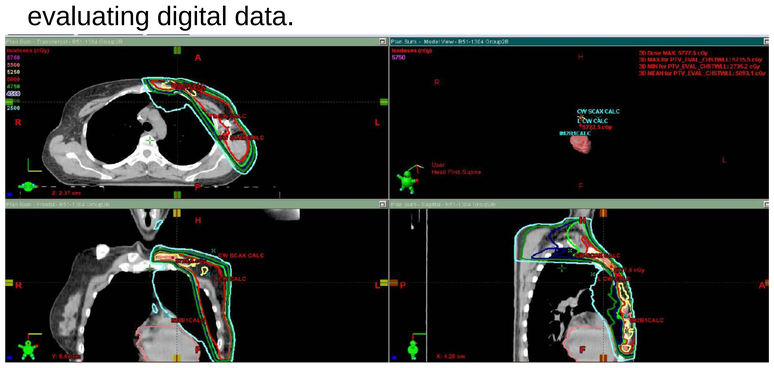
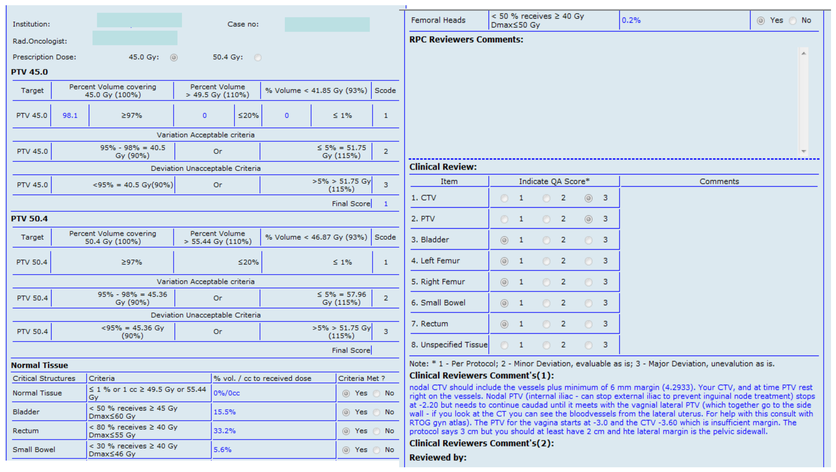
3. Color isodose images which are used as a check in evaluating digital data.



4. Email to itc@wustl.edu to alert the staff the you have submitted your data.

Once the data has been reviewed by ITC, the data along with the DDSI form is then provided to the RPC to perform a dosimetric evaluation (see below). This evaluation is then provided to the Radiation Oncologist to perform the clinical review online.



Institution: Case no:
Rad.Oncologist:
Prescription Dose: 45.0 Gy: 50.4 Gy:

**PTV 45.0**

| Target | Percent Volume covering 45.0 Gy (100%) | Percent Volume > 49.5 Gy (110%) | % Volume < 41.85 Gy (93%) | Scode |
|---|---|---|---|---|
| PTV 45.0 | 98.1 | 0 | ≤20% 0 | ≤ 1% 1 |
| Variation Acceptable criteria | | | | |
| PTV 45.0 | 95% - 98% = 40.5 Gy (90%) | Or | ≤ 5% = 51.75 Gy (115%) | 2 |
| Deviation Unacceptable Criteria | | | | |
| PTV 45.0 | <95% = 40.5 Gy(90%) | Or | >5% > 51.75 Gy (115%) | 3 |
| | | | Final Score | 1 |

**PTV 50.4**

| Target | Percent Volume covering 50.4 Gy (100%) | Percent Volume > 55.44 Gy (110%) | % Volume < 46.87 Gy (93%) | Scode |
|---|---|---|---|---|
| PTV 50.4 | ≥97% | ≤20% | ≤ 1% | 1 |
| Variation Acceptable criteria | | | | |
| PTV 50.4 | 95% - 98% = 45.36 Gy (90%) | Or | ≤ 5% = 57.96 Gy (115%) | 2 |
| Deviation Unacceptable Criteria | | | | |
| PTV 50.4 | <95% = 45.36 Gy (90%) | Or | >5% > 51.75 Gy (115%) | 3 |
| | | | Final Score | |

**Normal Tissue**

| Critical Structures | Criteria | % vol. / cc to received dose | Criteria Met ? |
|---|---|---|---|
| Normal Tissue | ≤ 1 % or 1 cc ≥ 49.5 Gy or 55.44 Gy | 0%/0cc | Yes No |
| Bladder | < 50 % receives ≥ 45 Gy Dmax≤60 Gy | 15.5% | Yes No |
| Rectum | < 80 % receives ≥ 40 Gy Dmax≤55 Gy | 33.2% | Yes No |
| Small Bowel | < 30 % receives ≥ 40 Gy Dmax≤46 Gy | 5.6% | Yes No |
| Femoral Heads | < 50 % receives ≥ 40 Gy Dmax≤50 Gy | 0.2% | Yes No |

**RPC Reviewers Comments:**

**Clinical Review:**

| Item | Indicate QA Score* | Comments |
|---|---|---|
| 1. CTV | 1 2 3 | |
| 2. PTV | 1 2 3 | |
| 3. Bladder | 1 2 3 | |
| 4. Left Femur | 1 2 3 | |
| 5. Right Femur | 1 2 3 | |
| 6. Small Bowel | 1 2 3 | |
| 7. Rectum | 1 2 3 | |
| 8. Unspecified Tissue | 1 2 3 | |

Note: * 1 - Per Protocol; 2 - Minor Deviation, evaluable as is; 3 - Major Deviation, unevalution as is.

**Clinical Reviewers Comment's(1):**
nodal CTV should include the vessels plus minimum of 6 mm margin (4.2933). Your CTV, and at time PTV rest right on the vessels. Nodal PTV (internal iliac - can stop external iliac to prevent inguinal node treatment) stops at -2.20 but needs to continue caudad until it meets with the vagnial lateral PTV (which together go to the side wall - if you look at the CT you can see the bloodvessels from the lateral uterus. For help with this consult with RTOG gyn atlas). The PTV for the vagina starts at -3.0 and the CTV -3.60 which is insufficient margin. The protocol says 3 cm but you should at least have 2 cm and hte lateral margin is the pelvic sidewall.

**Clinical Reviewers Comment's(2):**

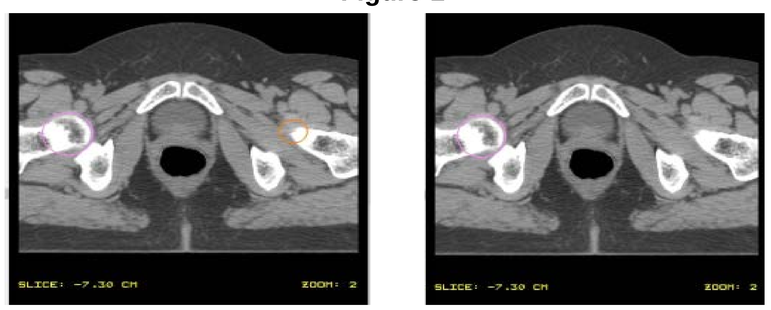
**Reviewed by:**

## Results:

For three protocols, where rapid reviews were required for the first patient placed on protocol, 24%, 48% and 53% required a revision and resubmission for a re-review due to a significant protocol deviation. Of these three protocols there were 29 Radiation Oncologists who submitted patient cases and participated in the rapid review process for two or more of the protocols. Of the 29 Radiation Oncologist, 14% of them had to perform a resubmission on a minimum of two protocols. For one protocol, where rapid reviews were required for all patients, 81% of the submitted patient cases required a revision and resubmission for a re-review. Radiation Oncologists who completed the rapid review process received no major deviations on subsequent patient's placed on protocol.

Figures 1 - 3 are examples of some of the Rapid Review submissions which had to go through the resubmission process along with the comments from the clinical reviewer.

**Figure 1**

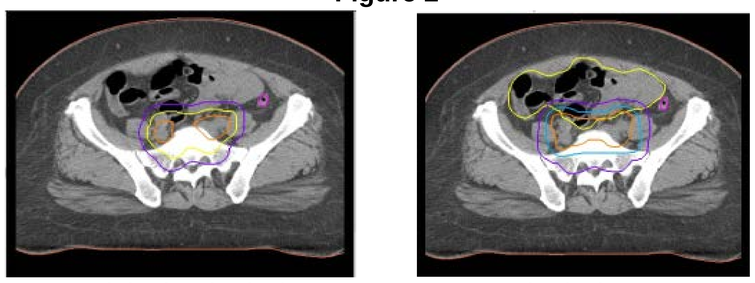



Original Submission reSubmission

Clinical Comments: Femurs: slices -7.3 and -7.55 have bone contours outside the bone

## Results (cont'd):

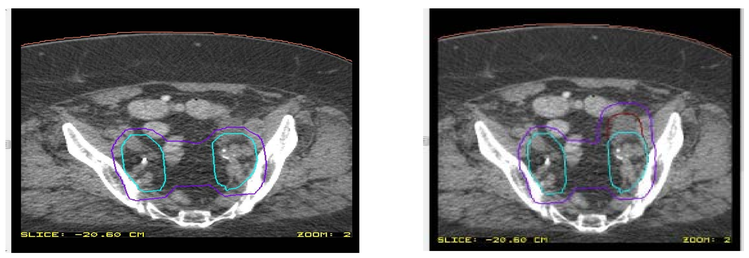
**Figure 2**



Original Submission reSubmission

Clinical Comments: For the lymph node volume the CTV needs at least a 6mm margin on the vessel. It appears that the attempt was to draw around the vessels, then add a vessel PTV to serve as the CTV but there are areas where the vessel contouring cuts directly thru a vessel and the PTV no longer gives margin on the vessel. In addition the vagina/CTV was not contoured according to atlas (4.2931) there for the anterior and posterior margin are too large (some margin into the bladder and rectum is acceptable if no ITV but these contours include virtually the entire rectum and bladder) and the lateral margins are too small

**Figure 3**




Original Submission reSubmission

Clinical Comments: The left external iliac nodal CTV should come more anterior, it does not cover the seroma that is present. Specifically on slices 20.6-22.4 the seroma is NOT covered and on slice 22.7 it is just covered by the PTV. Slices 19.7-20.3 have the very top of the seroma and only are included in the PTV not the CTV

## Conclusions:

Rapid reviews serve the purpose of reducing the number of protocol deviations by providing feedback to Radiation Oncologists on how to better comply with the requirements of the protocol prior to commencing treatment of a patient on the study.

## Support:

Work supported by PHS grants CA10953 and CA081647 awarded by NCI, DHHS