Developing a QA Program in Support of Cooperative Group Clinical Trials

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and RPC Staff

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QA Infrastructure for Clinical Trials

Cooperative Group

Participating Institutions

Funding Agency

QA Office

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Radiological Physics Center

- Formed when AAPM received funding from NCI and announced competition
- Founded in 1968 to monitor institution participation in clinical trials
- Funded continuously by NCI as structure of cooperative group programs have changed
- Now 40 years of experience of monitoring institutions and reporting findings to study groups and community
The mission of the Radiological Physics Center is to assure NCI and the Cooperative Groups that institutions participating in clinical trials deliver prescribed radiation doses that are clinically comparable and consistent. We do this by assessing the institution’s radiotherapy programs, helping the institutions implement remedial actions, assisting the study groups in developing protocols and QA procedures, and summarizing our findings for the radiation therapy community.
Components of a QA Program

- Remote audits of machine output
  - 1,674 institutions, 14,188 beams measured with TLD (2008)

- Treatment record reviews
  - Review for GOG, NSABP, NCCTG, RTOG (brachy)

- Independent recalculation of patient dose
  - Continue to find errors

- On-site dosimetry reviews
  - 50 institutions visited (~150 accelerators measured)

- Credentialing
  - Phantoms, benchmarks, questionnaires, rapid reviews
RPC TLD Network

1,674 RT facilities in 27 countries throughout the world, including 52 EORTC members
TLD Irradiation

Institutions receive acrylic block containing dosimeters
Institutions with One or More Unacceptable TLD Measurements
Why are TLDs out of criteria?

- Inexperience
- Variations in training
- Mistakes at commissioning
- New technologies pull resources from basic QA procedures
Benefits of the TLD Program

- Helps institutions stay vigilant
- Problems contribute to priorities for visits
- May satisfy state/local requirements for independent review
- Identifies problems that have direct impact on every patient treated
- It is a model for other remote programs
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Purpose of Patient Dose Review

- Maintain low uncertainty in doses delivered to protocol patients by discovering and correcting errors
- Provide study groups with accurate dose data

Improve Clinical Trials
RPC Patient Dose Review

- Independent calculation of tumor dose
- Agree within 5% (15% for implants)
- Verify dose, time, fractionation per protocol
- Notify institution if major deviation seen during review to prevent further deviations
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Visit Priority

- Chart Problem
- TLD Problem
- Other

Patients Treated
On-Site Dosimetry Review Visit

The **only** completely independent comprehensive radiotherapy quality audit in the USA and Canada

- Identify errors in dosimetry and QA and suggest improvements.
- Collect and verify dosimetry data for chart review.
- Improve quality of patient care.
### On-Site Dosimetry Review

Selected discrepancies discovered 2004 – 2008

<table>
<thead>
<tr>
<th>Errors Regarding</th>
<th>Number of Institutions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review QA Program</td>
<td>127 (77%)</td>
</tr>
<tr>
<td>*Wedge Transmission</td>
<td>53 (32%)</td>
</tr>
<tr>
<td>*Photon FSD (small fields)</td>
<td>46 (28%)</td>
</tr>
<tr>
<td>Off-Axis, Beam Symmetry</td>
<td>42 (25%)</td>
</tr>
<tr>
<td>*Photon Depth Dose</td>
<td>34 (21%)</td>
</tr>
<tr>
<td>*Electron Calibration</td>
<td>25 (15%)</td>
</tr>
<tr>
<td>*Photon Calibration</td>
<td>22 (13%)</td>
</tr>
<tr>
<td>*Electron Depth Dose</td>
<td>19 (12%)</td>
</tr>
</tbody>
</table>

*70% of institutions received at least one of the significant dosimetry recommendations.*
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Credentialing

Why?

- Education
- Evaluate ability to deliver dose
- Improve understanding of protocol

Reduce deviation rate
General Credentialing Process

- Previous patients treated with technique
- Facility Questionnaire
- Knowledge Assessment Questionnaire
- Benchmark case or phantom
- Electronic data submission
- RPC QA & dosimetry review
- Clinical review by radiation oncologist

Feedback to Institution
Treatment Planning Benchmark

* Demonstrates ability of planner to generate a dose distribution that complies with protocol
RPC Phantoms

Pelvis (14)

Thorax (15)

H&N (30)

Liver (2)

SRS Head (4)
Number of Phantoms Mailed per Year

- SRS head
- Liver
- Prostate
- Lung
- H&N

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Treat phantom as if it were a patient
Deliver treatment
RPC Compares Treated Distribution with Plan
Phantom Results

Comparison between institution’s plan and delivered dose.

Criteria for agreement: 7% or 4 mm DTA (5%/5mm for lung)

<table>
<thead>
<tr>
<th>Site</th>
<th>Institutions</th>
<th>Irradiations</th>
<th>Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td>H&amp;N</td>
<td>472</td>
<td>631</td>
<td>75%</td>
</tr>
<tr>
<td>Pelvis</td>
<td>108</td>
<td>130</td>
<td>82%</td>
</tr>
<tr>
<td>Lung</td>
<td>67</td>
<td>77</td>
<td>71%</td>
</tr>
<tr>
<td>Liver</td>
<td>15</td>
<td>18</td>
<td>50%</td>
</tr>
</tbody>
</table>
# Explanations for Failures

<table>
<thead>
<tr>
<th>Explanation</th>
<th>Minimum # of occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>incorrect output factors in TPS</td>
<td>1</td>
</tr>
<tr>
<td>incorrect PDD in TPS</td>
<td>1</td>
</tr>
<tr>
<td><strong>IMRT Technique</strong></td>
<td>3</td>
</tr>
<tr>
<td>Software error</td>
<td>1</td>
</tr>
<tr>
<td>inadequacies in beam modeling at leaf ends (Cadman, et al; PMB 2002)</td>
<td>14</td>
</tr>
<tr>
<td>QA procedures</td>
<td>3</td>
</tr>
<tr>
<td><strong>errors in couch indexing with Peacock system</strong></td>
<td>3</td>
</tr>
<tr>
<td>equipment performance</td>
<td>2</td>
</tr>
<tr>
<td><strong>setup errors</strong></td>
<td>7</td>
</tr>
</tbody>
</table>
Value of QA

- Meets goal of improving compliance with protocol
- Reduces deviations
- Detected significant errors, misunderstandings, equipment failures, QA issues