Dosimetry requirements and QA in a clinical trial
(External beam and brachytherapy)
Importance of Radiotherapy QA

Ensures:

Adherence to a trial protocol

Minimises variations across recruiting sites

Trial outcomes reflect differences in randomised schedules **NOT** departures from protocol

Treatment complies with nationally accepted standards

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Peters L J et al. JCO 2010;28:2996-3001

Critical Impact of Radiotherapy Protocol Compliance and Quality in the Treatment of Advanced Head and Neck Cancer: Results From TROG 02.02
Development of UK Radiotherapy QA

1989:
QA associated with individual trials
QA funding within grant application
CHART, START, RTO1, PARSSPORT
Independent sites RMH, MVH

2006:
Coordinated approach
RMH, MVH,

2010:
Central funding granted
Secured from the NIHR
Part of the NCRN portfolio

National RTQA central funding:
2010-13
2013-16
Funding approval for a 3yr period
Negotiation on an annual basis

Local RTQA funding:
Investigator site funding
NHS support cost
Activity over and above routine activity
Claimed through CLRNs

RT QA now seen as a National concern
Multi-professional integrated community
The Clinical and Translational Radiotherapy Research Working Group
An NCRI working group set up in 2009

Aims:
• To develop a portfolio of practice-changing trials in radiotherapy and radiobiology
• To ensure coordination across research
• To actively promote translation of new discoveries into practice
NCRI Radiotherapy Trials QA (RTTQA) Group

Design and implement Quality Assurance programmes for all NIHR portfolio trials that include a radiotherapy component

National approach
QA programmes

Pre-trial
- Facility questionnaire
- Process document
- Workshops and TMG meetings

On-trial
- TRIAL QA CONTACT
- SUPPORT
- ADVICE

- TRIAL QA CONTACT
- SUPPORT
- ADVICE
- Process document
- Workshops and TMG meetings
- Dosimetry audit
- Data collection
- Case review
- Dummy Run
- Planning
- Benchmark cases
- Outlining
- Prospective
- Retrospective
- Case review
- Dummy Run
- Planning
- Benchmark cases
- Outlining
Radiotherapy Guidelines  
Facility Questionnaire & Process Document

**HYBRID**

A multicentre randomised phase II study of 
**HYpoparation of Bladder Radiotherapy with or without Image guided Adaptive planning**

**RADIOThERAPY PLANNING AND DELIVERY GUIDELINES**

Version 2  

**Chief Investigator:** Dr Robert Maguire  

**Sponsor:** The Institute of Cancer Research  

**Approval:** Cancer Research UK; Clinical Trials Awards & Advisory Committee (CTAAC)  

**Funders:** Cancer Research UK  

**Coordinating Trials Unit:** ICR Clinical Trials and Statistics Unit (ICR-CTSU)  

The Institute of Cancer Research

**Main REC Reference Number:** 13/LO/1350  

**ISRCTN:** ISRCTN188118986  

**Clinical Trials.gov Identifier:** NCT01810757  

**CRUK Reference Number:** CRUK/12/055

The HYBRID trial has been scientifically approved by Cancer Research UK's Clinical Trials Awards & Advisory Committee (CTAAC). The HYBRID trial is part of the National Institute for Health Research Clinical Research Network Trial Portfolio.

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**Facility Questionnaire**

This facility questionnaire is an integral part of the Radiotherapy QA programme for the HYBRID trial. Please complete with information specific to this trial. Note: text boxes are expandable. Additional information may be requested if necessary.

Please direct enquiries and email the completed questionnaire to:  

**Name:** Elizabeth Miles (RTQA Group Coordinator)  

**Address:** Mount Vernon Cancer Centre  

**Phone:** +44(0)1822 84 4226/34712  

**Email:** emiles@mountvernons.nhs.uk

**Centre Information**

**Centre Name:**  

**Centre Address:**  

**Contact Information**

**Completed by:**  

**Position:**  

**Email:**  

**Phone:**  

**Submission date:**

**Please provide contact details for the lead of each of the following groups:**  

**Clinical Oncologist:**  

**Email:**  

**Phone:**  

**Radiographer:**  

**Email:**  

**Phone:**  

**Any additional staff:**  

**Position:**  

**Email:**  

**Phone:**

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**Process Document**

Procedures for Planning, QA and Treatment Delivery at <HOSPITAL NAME>

1. Equipment used for PATHOS

   1.1 Please complete the table below detailing all equipment/software used for patients recruited to the PATHOS trial.

   **Equipment used for PATHOS patients**

   - CT Scanner and Model(s)
   - Linac Manufacturer
   - Linac Model
   - Number of Matching Linacs
   - MLC Model
   - Energies Used
   - Delivery Method (e.g.DynamicArc, VMAT, etc.)
   - TPS and Version
   - Dose Calc Algorithm

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This is a controlled document which should be referred to in conjunction with the HYBRID protocol and should not be copied, distributed or reproduced without the written permission of the ICR-CTSU.
Tumour & Organ at risk Outlining

Outlining Benchmark Case

Consensus outlines

Individual submissions reviewed against this standard

Feedback to centres
Treatment Planning

Planning Benchmark Case

Dose distribution

Adherance to pre-defined dose constraints

Feedback to centres

<table>
<thead>
<tr>
<th>Dose Constraints</th>
<th>Optimal</th>
<th>Mandatory</th>
<th>Achieved (VODCA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D_{99%} CTV</td>
<td>≥95% of prescribed dose</td>
<td></td>
<td>97.6%</td>
</tr>
<tr>
<td>D_{(Total Vol-1cc)} CTV</td>
<td></td>
<td></td>
<td>97.6%</td>
</tr>
<tr>
<td>Mean CTV dose</td>
<td>+/- 1% of prescribed dose</td>
<td>+/- 2% of prescribed dose</td>
<td>100%</td>
</tr>
<tr>
<td>D_{99%} PTV</td>
<td>≥90% of prescribed dose</td>
<td></td>
<td>93.2%</td>
</tr>
<tr>
<td>D_{(Total Vol-1cc)} PTV</td>
<td></td>
<td></td>
<td>89.8%</td>
</tr>
<tr>
<td>D_{95%} PTV</td>
<td>≥90% of prescribed dose</td>
<td>≥85% of prescribed dose</td>
<td>96.6%</td>
</tr>
<tr>
<td>D_{1cc} PTV</td>
<td></td>
<td>≤107% of prescribed dose</td>
<td>103.5%</td>
</tr>
</tbody>
</table>
Treatment delivery and verification

Daily delivery of a fractionated treatment

Correct positioning of patient

Assess position of target and OARs

Adaptive RT
  Anatomy recognition
  On line plan selection

Assess training and competency

Feedback to centres
Dosimetry audit

- Independent external review
- Audit of entire treatment planning and delivery process
- Plan dose applied to a phantom, calculated by TPS, infer dose to patient (assumptions made)
- TPS calculated vs delivered dose
- Detector used traceable back to primary standard
- Collaborative work
Collaboration

- NPL
- Radiation Dosimetry Group
  - Led by Rebecca Nutbrown
- NPL has funding to develop audit of advanced radiotherapy technique
- National and clinical trial implication
- External beam radiotherapy and brachytherapy

National Rotational Radiotherapy Audit
National SABR Lung dosimetry Audit
National Brachytherapy HDR/PDR Audit
National SRS Audit
UK National Rotation Radiotherapy Audit

- Collaboration
  - NPL, IPEM, RTTQA, Royal Surrey Hospital

- National Audit and Trial credentialing
  - Commercial detector array and alanine
  - PTW Octavius II phantom with PTW 729 2D Array

- Completed visits
  - 44 centres, 47 systems
  - Point dose differences (mean (+/-sd))
    - 0.1 +/- 2.6% (3DTPS test)
    - 0.2 +/- 2% (clinical plan)
  - Accurate TPS modelling and treatment delivery
National SABR Lung dosimetry Audit

- Collaboration
  - NPL, UK SABR consortium, RTTQA

- National Audit
  - Pilot audit - solid water block using alanine
  - Phantom audit - CIRS thorax phantom with alanine and gafchromic film
  - Subsequent trial credentialing

- Completed visits
  - 21 centres
  - The absolute dosimetry results show that modelling and delivery was within +/-3% accuracy for 18/21 of centres
National Brachytherapy HDR/PDR Audit

- Collaboration
  - RTTQA, NPL, IPEM
  - First full UK brachytherapy audit

- National Audit and Trial credentialing
  - Ion chamber and alanine dosimetry

- Completed visits
  - 44 centres
  - UK mean dose 2% higher than TPC calculated

Line source in phantom & typical cervix plan
National SRS audit

• Collaboration
  • NPL, Royal Surrey Hospital, RTTQA

• National Audit and Trial credentialing
  • Ion chamber and film dosimetry

• Visits
  • Planned June 2015-June 2016
  • End-to-end: Image-Plan-Deliver
Dosimetry audit

Nationwide credentialing for clinical trials
Multiple centre dose audit feasible
50 centres IMRT/VMAT dosimetry audit in last 5 years
44 centres brachytherapy audit
58 centres have received a dosimetry audit

UK dosimetry audit network
www.uk-dan.co.uk
Looking to the future

Metrology for accuracy of clinical dose delivery in hadron therapy

• Objectives: long-term multidisciplinary pan-European support for the successful and effective implementation of hadron therapy

• Addressing steps of clinical dose delivery:
  • Beam characterization and modelling
  • Dosimetry techniques for complex beam delivery
  • Verify accuracy of clinical and secondary dose delivery: end-to-end assessments of delivery accuracy
  • Design of protocols and guidelines for quality control and inter-centre comparisons: Audit procedures for inter-centre verification
Looking to the future

Global Harmonisation Group
www.rtqaharmonisation.org

- Encourage collaboration between global clinical trial QA groups
- Standardise RTQA procedures for RT clinical trials
- Promote consistency in reporting
- Develop standards for credentialing of new techniques
- Automation of RTQA processes
UK clinical trial RTQA programmes

- Facilitates initial adoption of new technology and advanced techniques
- Driver for change
- Promotes improvement in techniques
- Allows discussion of technical issues within a wide forum
- Establish within routine clinical practice

**Inherent difficulties but substantial achievements**
MRT QA??

- RTTQA timeline 1989-2010 (21 years!!)
- MRT Build on RTTQA experience
- CTAAC funded trial
- CTRad: MRT member representatives
  Recent appointment of person to review MRT research capability in the UK

What can be taken from existing RTQA processes for external beam and brachytherapy?

What are the equivalent QA processes for MRT?

What development work is needed?

Increase in the number of multicentre MRT trials?
Where does QA fit into the trial process?

RTQA is now a recognised requirement for multi-centre trials.
Where does QA fit into the trial process?

1. Trial planning & design
   - CI contact with RTTQA for a preliminary evaluation of the level of QA that may be appropriate for the trial
   - CTRad Proposals guidance meeting. Pre-submission peer input to facilitate successful funding

2. Funding proposal
   - Development of RT planning and QA guideline document alongside trial protocol

3. Funding secured
   - Finalise QA programme

4. Trial begins
   - Continuation of pre-accrual QA and implementation of on-trial QA programme

5. End of trial declaration
   - Implementation of pre-accredual QA programme