Roles of Medical Physicists in Radiation Therapy Trials

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Disclosures

- Receive research grants from NIH and Varian Medical Systems
- Invited Speakers by Varian medical Systems and BrainLab

Outlines

Credentialing is one of the key processes for an institution to participate a clinical trial, which is to ensure the institution has the infrastructure, resources, and mechanism/culture to successfully conduct the designed clinical trials.

This presentation will discuss how a medical physicist can

- find credentialing information
- perform credentialing processes: initial credentialing, maintenance and ongoing credentialing
- identify challenges in the processes of credentialing

Resources for Credentialing and QAs

https://clinicaltrials.gov/ct2/home

Medical Physics Section in NRG

- Review protocol draft versions and recommend changes
- Establish relationship with PIs for goals and technical consensus
- Become a resource to answer technical questions from institutions
- Participate in reviewing credentialing for the protocol
- Present progress reports of the protocol
- Participate, as needed, data review and case review
- Participate in manuscript preparation
- Recommend secondary analysis studies for the protocol

Credentialing Consideration

- IROC in US is NCI-sponsored and cooperative groups for dosimetric and physics credentialing

http://rpc.mdanderson.org/RPC/home.htm

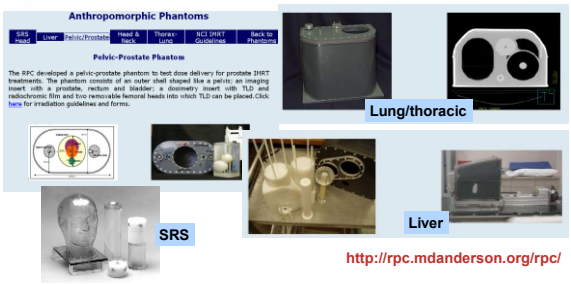
Essentials for Conducting Clinical Trails

- A team approach:
  - Physicians (both radiation oncology and other specialists)
  - Physicists
  - Statisticians
- Set commons standard
- Establish common criteria
- Perform credentials
- Maintain QA programs
- Maintain and monitor data collection
- Outcomes studies

Credentialing Consideration

- Protocol specific
- Treatment unit requirements
- Imaging and motion management specifications
- Planning system requirements
- Delivery technique specifications
- Immobilization requirements
- Simulation requirements
- Verification requirements
- Data management requirements

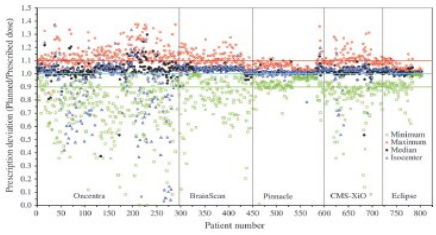
Credential through Phantom Study



Technical Challenges between Centers

- Treatment machines
  - Different machines and calibration methods
  - Irradiate provided TLD or other dosimeters for QA control
- Treatment techniques
  - Different planning systems, calculation algorithms, margins, and prescription methods for 3D-CRT, IMRT
  - Pass specified IMRT phantom planning and QA test
- Treatment accuracy
  - Different verification methods, IGRT, portal images
- New technologies are rapidly being implemented

Planned vs. Prescription Dose



Das et. al. JNCI, 2008

Physics Challenges for Credentialing Clinical Trial

- Staffing and resources
  - Staffing shortage
  - Staff training
  - Resources: equipment, device, data management
- Quality assurance
  - Equipment
  - Consistency

How to Meet QA Requirements

- Establish a well-defined QA program
- Follow the recommendations and guidelines of government and professional organization
- Develop QA protocols for each procedure
- Assign responsibility to individuals/group
- Document QA materials for audit
- ……

Quality Assurance (QA)

- Facility-specific QA
- Equipment-specific QA
- Patient specific QA
- Process specific QA

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Facility-Specific QA: General

- Facility infrastructure
- Equipment
- IT and data management
- Staffing
- ……

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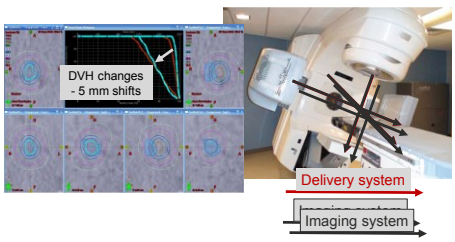
Equipment-Specific QA: General

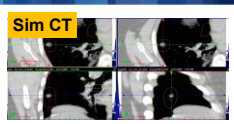
- System and devices
  - Delivery system
  - Imaging system
  - Planning system
  - Immobilization system
  - Measurement devices
  - Motion management devices
  - ……
- Protocols – AAPM TGs

Device-Specific QA: Isocenter Concurrence

Consistency of Imaging and Delivery



Patient-Specific QA: Positioning Accuracy



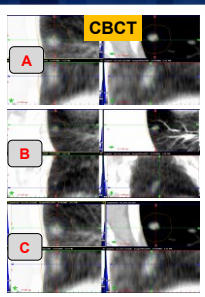
Three-step verification:

A - Prior to correction

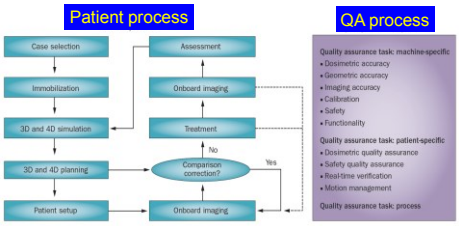
B - After correction before treatment

C - After treatment

RTOG0631, Yin et al TCRT 2008



Process-Specific QA: General



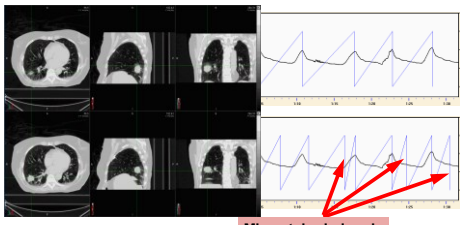
Salama, Kirkpatrick, and Yin
Nature Reviews|Clinical Oncology 2012

Process-Specific QA: Details

Issues related to operational tasks:

- **The protocol development process – appropriate approval process**
- **SOPs to execute the protocols**
- **SOPs to document and report the data and results**
- **Staffing level is appropriate**
- **Staff training and continuous training are available and appropriate**
- **Proper follow-up actions are taken for any actual and/or potential ("near miss") treatment incidents**

Procedure-Specific QA: 4DCT Artifact



Summary

- A unified standard needs to be developed and adopted for credentialing of clinical trials
- Adequate staffing and resources are required
- A mechanism for monitoring credentials should exist
- Multi-dimensional QAs, including IGRT QA are essential and challenging but should be considered

Thank you for your attention