Radiation Therapy Safety

Daniel Low, Ph.D.

Thanks to Jeff Williamson, Mike Steinberg, James Purdy
Radiation Therapy

♦ 1.6M new cancer cases this year in US

♦ Approximately 60% of cancer patients receive radiation therapy during the course of their disease

♦ Half of them are for curative intent
Goals

- Deliver radiation prescription dose to within absolute 5% & 5mm

Diagram showing the process:
- CT Simulation
- Treatment Plan
- Position Patient
- Treat Patient
Why is the Present More Challenging than the Past?

• **2D RT:** 1950-1985
  – 2D x-rays for planning RT

• **3D CRT:** 1985-2000
  – Image-based planning on 3D anatomical model

• **IMRT:** 2000-present
  – Intensity modulation
  – Inverse planning
Table 1. Institution passing rates for ATC/RPC Phantom test.

<table>
<thead>
<tr>
<th>Phantom</th>
<th>Head and neck</th>
<th>Neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irradiations</td>
<td>250</td>
<td></td>
</tr>
<tr>
<td>Pass</td>
<td>179</td>
<td></td>
</tr>
<tr>
<td>Fail</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>Year introduced</td>
<td>2001</td>
<td></td>
</tr>
</tbody>
</table>

“...roughly 30% of institutions failed to deliver a dose distribution to the head-and-neck IMRT phantom that agrees with their own treatment plan to within 7% or 4 mm.”

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with the back of his hand and throat, nauseated and thirsted, and his right arm paralyzed — could be studied and talked about so that others might live his nightmare.

In New Jersey, 30 cancer patients at a veterans hospital in East Orange were overdosed — and 20 more received substandard treatment — by a medical team that lacked experience in using a machine that generated high-powered beams of radiation. The mistakes, which have not been publicly reported, continued for months because the hospital had no system in place to catch the errors.

In Louisiana, Landreaux A. Donaldson received 38 straight overdoses of radiation, each nearly twice the prescribed amount, while undergoing treatment for prostate cancer. He was treated by a machine so new that the hospital made a mistake even with training instructors still on site.

In Texas, George Garst now wears two external devices for urine and one for fecal matter because of radiation injuries he suffered after a medical procedure.

A hospital in Missouri said Wednesday that it had overdosed 76 patients, the vast majority with brain cancer, during a five-year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

The hospital, CoxHealth in Springfield, said half of all patients undergoing a particular type of treatment — stereotactic radiation therapy — were overdosed by about 50 percent after an unidentified...
Device versus Process Errors

♦ Large catastrophic errors
  ♦ Majority are human or process related errors although poor device design often contributes

♦ 97 of 116 implants were medical events, many were wrong site

♦ Failures of process rather than devices

♦ QA is a team effort: focus on key physician as well as technical steps
Current QA Paradigm Focus

- Approach developed in the 2D RT era
  - Most extant guidance is limited to 2D RT

- Tends to focus on **devices**
  - planning systems, LINACs, imaging systems
  - Acceptance testing, commissioning, periodic QA
  - Process QA: limited to quantitative verification of device outputs, e.g., plan review and chart checks
QA Formulation

- Current QA Protocol formulation methodology
  - Consensus opinion of small group of experts
  - Periodically check all device functions/outputs that could compromise overall delivery accuracy
  - Fixed test frequencies **not** driven by actual device reliability or risk estimates
  - “One size fits all” menu of tests

- Tolerance levels:
  - Limit dose delivery uncertainty to 5% & 5 mm
  - Errors in anatomic modeling, dose computation, dose delivery, and calibration add quadratically
  - Assume variations about target values are well behaved random variables with **no catastrophic outliers**
Process-Based QA

- AAPM TG-100 proposal (S. Huq, Chair)
- Failure modes and effects analysis (FMEA)
- Fault-tree Analysis (FTA)

“Method for Evaluating QA Needs in Radiation Therapy”
Breast Brachytherapy Process Map

Successful treatment
Consultation and decision to treat
Imaging and diagnosis
MD plan approval
Subsequent treatments
Chart filing
Decision of treatment technique
Technical planning of procedure room, intraoperative imaging equipment, personnel, post-procedure imaging
Assemble, sterilize applicator kit and accessories
Identify patient
Position patient on procedure table

Pre-Implantation Preparation
Paraboloid, marker insertion

Intraoperative documentation
Volume of fluid
Fill balloon with contrast/saline mixture
Insert deflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Intraoperative documentation
Diameter of balloon
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Boolean operations
Protocol for CTV margin
CTV construction
Delineate ROIs and planning structures
Protocol for delineation of targets
MD: delineate GTV
Import images into planning computer

Evaluation
Enter prescription
Optimization/Dose calculation
Optimization settings
Manual reoptimization
Dwell position construction
Catheter localization/labeling
Segmentation
Import imported images into planning computer
Identify and communicate planning process between dosimetrists, physicists, physician

Documentation
Compare treatment record with plan
Run treatment
Communication equipment (intercom, display monitor) on Check balloon rotation
Connect transfer tubes to applicator
Program treatment unit
Import patient file
Check balloon leakage and visibility
Fluoroscope or Ultrasound positioned
Verify contrast concentration if needed
Patient positioned in room
Identify patient

Scheduling
Identify patient
Check balloon for leakage
Program treatment unit
Verify program
Connect transfer tubes to applicator
Check balloon rotation
Communication equipment on
Run treatment
Documentation

Physical plan review
Check that dose distribution satisfies prescription
Check that previous treatments were accounted for
Check normal tissue are within tolerances
Check plan for quantitative consistency

Successful treatment
Consultation and decision to treat
Imaging and diagnosis
MD plan approval
Subsequent treatments
Chart filing
Decision of treatment technique
Technical planning of procedure room, intraoperative imaging equipment, personnel, post-procedure imaging
Assemble, sterilize applicator kit and accessories
Identify patient
Position patient on procedure table

Pre-Implantation Preparation
Paraboloid, marker insertion

Intraoperative documentation
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Intraoperative documentation
Diameter of balloon
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Boolean operations
Protocol for CTV margin
CTV construction
Delineate ROIs and planning structures
Protocol for delineation of targets
MD: delineate GTV
Import images into planning computer

Evaluation
Enter prescription
Optimization/Dose calculation
Optimization settings
Manual reoptimization
Dwell position construction
Catheter localization/labeling
Segmentation
Import imported images into planning computer
Identify and communicate planning process between dosimetrists, physicists, physician

Documentation
Compare treatment record with plan
Run treatment
Communication equipment (intercom, display monitor) on Check balloon rotation
Connect transfer tubes to applicator
Program treatment unit
Import patient file
Check balloon leakage and visibility
Fluoroscope or Ultrasound positioned
Verify contrast concentration if needed
Patient positioned in room
Identify patient

Scheduling
Identify patient
Check balloon for leakage
Program treatment unit
Verify program
Connect transfer tubes to applicator
Check balloon rotation
Communication equipment on
Run treatment
Documentation

Physical plan review
Check that dose distribution satisfies prescription
Check that previous treatments were accounted for
Check normal tissue are within tolerances
Check plan for quantitative consistency

Successful treatment
Consultation and decision to treat
Imaging and diagnosis
MD plan approval
Subsequent treatments
Chart filing
Decision of treatment technique
Technical planning of procedure room, intraoperative imaging equipment, personnel, post-procedure imaging
Assemble, sterilize applicator kit and accessories
Identify patient
Position patient on procedure table

Pre-Implantation Preparation
Paraboloid, marker insertion

Intraoperative documentation
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Intraoperative documentation
Diameter of balloon
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Boolean operations
Protocol for CTV margin
CTV construction
Delineate ROIs and planning structures
Protocol for delineation of targets
MD: delineate GTV
Import images into planning computer

Evaluation
Enter prescription
Optimization/Dose calculation
Optimization settings
Manual reoptimization
Dwell position construction
Catheter localization/labeling
Segmentation
Import imported images into planning computer
Identify and communicate planning process between dosimetrists, physicists, physician

Documentation
Compare treatment record with plan
Run treatment
Communication equipment (intercom, display monitor) on Check balloon rotation
Connect transfer tubes to applicator
Program treatment unit
Import patient file
Check balloon leakage and visibility
Fluoroscope or Ultrasound positioned
Verify contrast concentration if needed
Patient positioned in room
Identify patient

Scheduling
Identify patient
Check balloon for leakage
Program treatment unit
Verify program
Connect transfer tubes to applicator
Check balloon rotation
Communication equipment on
Run treatment
Documentation

Physical plan review
Check that dose distribution satisfies prescription
Check that previous treatments were accounted for
Check normal tissue are within tolerances
Check plan for quantitative consistency

Successful treatment
Consultation and decision to treat
Imaging and diagnosis
MD plan approval
Subsequent treatments
Chart filing
Decision of treatment technique
Technical planning of procedure room, intraoperative imaging equipment, personnel, post-procedure imaging
Assemble, sterilize applicator kit and accessories
Identify patient
Position patient on procedure table

Pre-Implantation Preparation
Paraboloid, marker insertion

Intraoperative documentation
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Intraoperative documentation
Diameter of balloon
Volume of fluid
Fill balloon with contrast/saline mixture
Insert inflated balloon in center of cavity
Create access incision
Identify and localize treatment site
Identify patient

Boolean operations
Protocol for CTV margin
CTV construction
Delineate ROIs and planning structures
Protocol for delineation of targets
MD: delineate GTV
Import images into planning computer

Evaluation
Enter prescription
Optimization/Dose calculation
Optimization settings
Manual reoptimization
Dwell position construction
Catheter localization/labeling
Segmentation
Import imported images into planning computer
Identify and communicate planning process between dosimetrists, physicists, physician

Documentation
Compare treatment record with plan
Run treatment
Communication equipment (intercom, display monitor) on Check balloon rotation
Connect transfer tubes to applicator
Program treatment unit
Import patient file
Check balloon leakage and visibility
Fluoroscope or Ultrasound positioned
Verify contrast concentration if needed
Patient positioned in room
Identify patient

Scheduling
Identify patient
Check balloon for leakage
Program treatment unit
Verify program
Connect transfer tubes to applicator
Check balloon rotation
Communication equipment on
Run treatment
Documentation

Physical plan review
Check that dose distribution satisfies prescription
Check that previous treatments were accounted for
Check normal tissue are within tolerances
Check plan for quantitative consistency

Successful treatment
Consultation and decision to treat
What to Do?

- FMEA/FTA is doable (UCSD and Brachytherapy)
  - What about multiple small clinics without full time physics, what do they do?
- FMEA/FTA does not consider process interactions
- STAMP?
- How do we translate work from academic/large centers to everyone and make the processes safer?
  - Answer: Standardize!
Standardize?

- “Thus, first-time users of this technology should ascertain which of these aims are desirable for their own clinics and tailor their commissioning and QA programs accordingly.”

- “Clinics should have the option to customize these standards to their own specifications, or to select from various national/international guidelines.”
Standardize

Imagine: AA, UA, Delta, SWA started standardizing...
Standardization

Instead of chaos: Everyone is expected to conform!
Standardize and Rationalize

- Standardized procedures
  - Allows the development of FMEA, FTA, STAMP to be developed by national organizations
- Standardized QC/QA
- Risk-based QA
- Treatment Directives
WE’VE DEVELOPED A BLAME CULTURE AROUND HERE AND I WANT TO KNOW WHO’S RESPONSIBLE!!