RT Patient Safety: The same old paradigm

James M. Galvin, DSc
Thomas Jefferson University Hospital
Department of Radiation Oncology
and
Radiation Therapy Oncology Group
Headquarters QA
RT Patient Safety Depends on a Large Number of Factors

- Fail Safe equipment design
- Complete and effective QA procedures in place prior to equipment release
- Clearly documented user manuals
- Qualified user trainers
- Well trained personnel
- Timely and detailed reporting of events
- Appropriate governmental regulations
Point #1

- Catastrophic errors are different
Catastrophic errors are not simply a type of plan quality errors

- Errors relating to the quality of a patient’s treatment plan and catastrophic treatment failures are different
  - Errors relating to plan quality are associated with factors like not strictly adhering to the written prescription or inaccurate contouring
  - Catastrophic failures and malfunctions relate to equipment/software failures and/or human error
Catastrophic errors must be handled differently

- We now recognize that the two types of problems identified in the previous slide require different solutions
  - The RTOG, working with the RPC and ITC, offers a good model for handling errors related to quality of the final delivered dose for clinical trials
  - Catastrophic failures and treatment unit malfunctions require some additional QA steps not included in the RTOG model
Point #2

• We are all in this together
Working together is key

- All stakeholders must work together to solve the problem of catastrophic errors
- No single group can do it alone
- Physicists are in a unique position to make this happen
Medical physicists play a key role in guaranteeing safety for the patient

- Medical physicists are active in many professional societies (AAPM, ASTRO, ACR)
- Medical physicists know the equipment
- Medical physicists know the QA procedures
- Medical physicists know the clinical applications
- Medical physicists know the patient
Who are the stakeholders?

- Patient
- Physicist
- Radiation oncologist
- Dosimetrist
- Therapist
- Administrator
- Nurse
- State regulators (FDA, CMS, NRC)
- Equipment manufacturers
- Health care insurance providers
- Professional societies
- Physicist
- Radiation oncologist
- Dosimetrist
- Therapist
- Administrator
- Nurse
Point #3

• We need to get past the myths
Myth - Billing has nothing to do with patient safety

- Initially, billing for IMRT was tied to appropriate QA procedures
- It is possible that the connection is now dated (i.e., a new definition of both procedures and reimbursement is needed)
- Third party carriers also care about patient safety
- If you are not paid for it, you still have to do it!
Myth - Our relationship with regulators must be adversarial

- Regulators care about patient safety
- Physicists live in constant fear of being too prescriptive in defining QA procedures
- TG 40 was a revolutionary document
  - Recommendations were copied into many regulatory documents
  - We are still arguing about the appropriateness of this use of TG 40
Myth - The FDA can directly assure patient safety

- The FDA review process assures that a device is designed to perform as indicated without causing injury or harm to a patient.
- Procedure does not necessarily include review of the QA processes for avoiding catastrophic errors.
- Virtually all approvals for start of marketing for x-ray equipment come through substantial equivalence to a predicate device – 510(K).
Myth - The FDA can directly assure patient safety

• If the manufacturer has not thought of a particular way a device can fail, it is unlikely that the FDA will identify the problem during their review process

• Avoiding catastrophic errors can best be accomplished through a collaborative effort involving manufacturers and relevant professional societies
Myth - Existing reports and literature provide a way forward

• TG 142 gives very clear tolerances and frequencies for tests that are not defined in any AAPM literature
  — What exactly is the imaging and treatment coordinate coincidence test?

• Our message on the use of patient-specific QA measurements could be even clearer
  — This test is not discussed in TG 142
Point #4

• At any point in time, we need to have a single clear message
Clarity of our message for IMRT

- Describes in detail the plan-on-phantom patient-specific QA measurement process for IMRT
- Points out that this QA method is recommended by the ASTRO/ACR Joint Economics Committee
- Backup MU calculations are also recommended
Dose Delivery Verification by Physical Measurement - The medical physicist should assure verification of actual radiation doses being received during treatment delivery. Prior to the start of treatment, accuracy of dose delivery should be documented by irradiating a phantom containing a calibrated dosimetry system to verify that the dose delivered is the dose planned.
Message for IGRT

ACR Technical Standard for Medical Physics Performance Monitoring of Imaging-Guided External Beam Radiation Therapy IGRT

Mechanical Integrity Section - whether room-mounted and rigid or gantry-mounted and moving, imaging equipment must be able to maintain a known relationship to the treatment coordinate system

Specifics for Winston/Lutz testing procedure are given
Point #5

• We need an effective error reporting system
General comments

- An error reporting system will only work when key information about what occurred is made available as quickly as possible after the event.
- Better still, before it occurs!
- A cooperative effort that engages both industry and professional organizations is also need here.
Point #6

• We must proceed with care
Steering this ship is easy

Until we have to turn!
Point #7

- We need a solution for catastrophic errors that works now.
General comments

• In the short term, stay on message relative to recommended QA
• Proceed with care in changing procedures
  — All stakeholders must be involved in decisions relating to change
• Introduce new QA ideas with clear plan for implementing a transition
Specific recommendations for IMRT

- Patient-specific QA measurement is the most robust tool currently available for guarding against catastrophic errors for IMRT and other advanced technologies that are IMRT “like”
- 85% of institutions currently perform this type of test prior to the first treatment
Specific recommendations for IGRT

• As stated in TG 142, a modified Winston/Lutz test should be performed the morning of any SRS, SRT or SBRT treatment
Conclusion

• RT catastrophic failures need a different QA approach
• The patient-specific QA measurement is our best defense for IMRT
• Winston/Lutz test is critical for IGRT
• Change is always welcomed, but proceed with care!