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

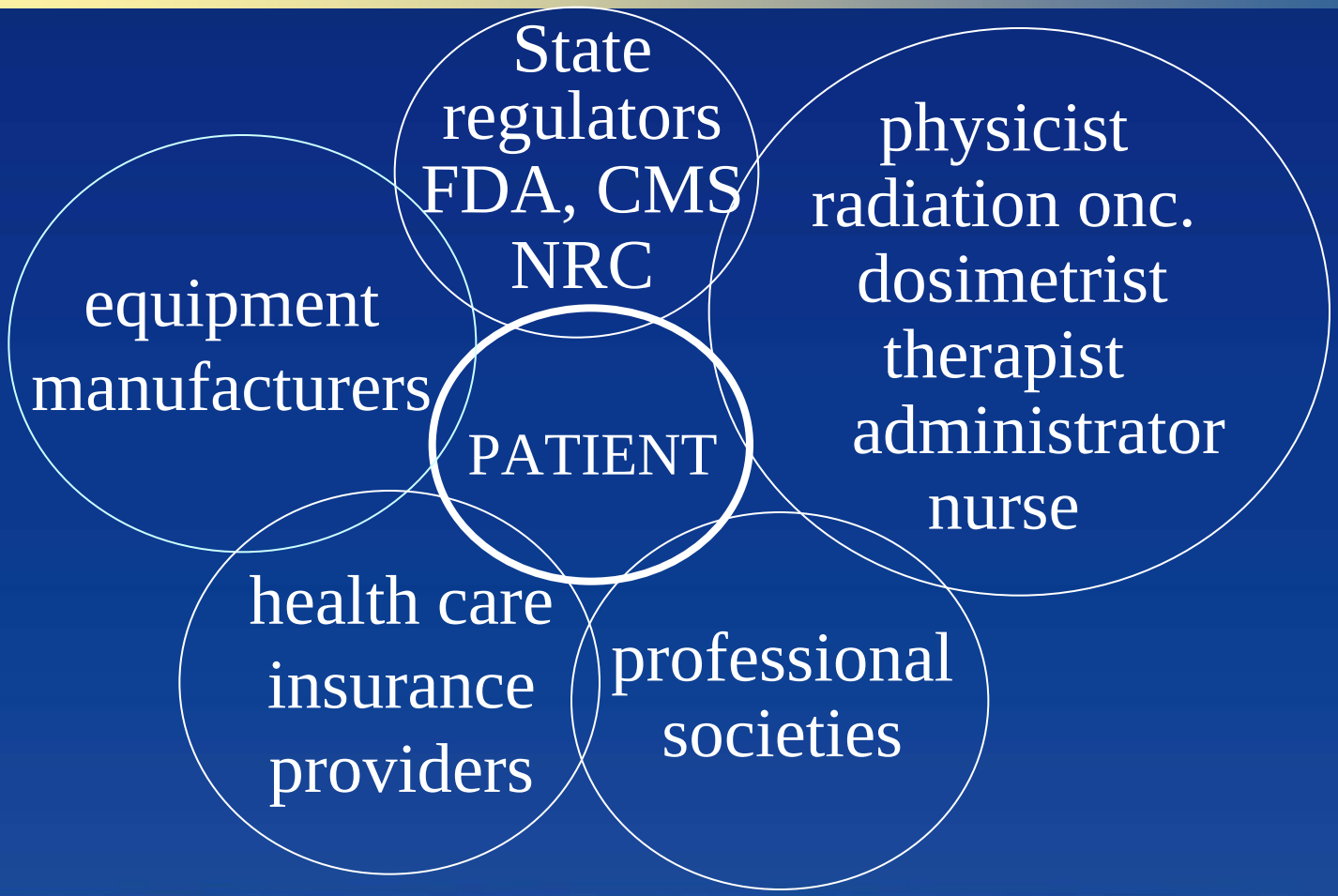
Working together is key

- 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?



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 comes 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

- Implementing IMRT in Clinical Practice: A Joint Document of the American Society for Therapeutic Radiology and Oncology and the American Association of Physicists in Medicine. J. M. Galvin, G. A. Ezzell *et al* J Rad Onc Biol Phys 2004
- 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

Some statements are clearer than others

ACR/ASTRO Practice-Guideline for Intensity Modulated Radiation Therapy

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!