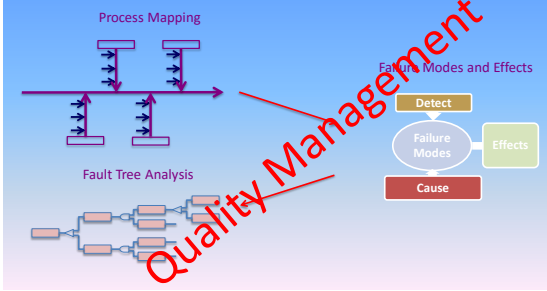
Risk-based QM for "Incorrect Isocenter at Day 1 Setup"

Ellen Yorke
Memorial Sloan Kettering Cancer Center

TG 100 risk based QM development



Risk-based QA/QM for "Incorrect isocenter" at Day 1 setup

This FM describes the isocenter being positioned in the wrong place, due to a device failure. Other causes of this error include a more subtle error (rank 142, step 182), a human failure (inadequate training or inattention, rank 77, step 183). This FM can be a crucial one, especially if the mispositioning happens for multiple fractions or in hypofractionated treatments. One of the best QC steps available is the daily use of IGRT setup techniques and this is one of the major benefits of the IGRT concept. Careful IGRT is an effective technique but it should be accompanied by a departmental protocol limiting the shifts that can be made without a special investigation e.g., physician inspection and approval. If IGRT is not available, then careful use of the patient setup documentation during the setup procedure is crucial. Imaging to confirm the correct location as often as possible will minimize the opportunity for this error to continue through multiple fractions. Other QC can involve using or carefully understanding differences in table coordinates that demonstrate problems with the patient setup – especially if the immobilization device used for the patient can be registered to the table. In such cases, review of table coordinates used for treatment at the weekly physics or therapist chart check can also warn the user of problems to be investigated.

Day 1 Treatment: position patient for treatment

FTA for "Incorrect Treatment Isocenter on Day 1"

- Hardware failure (device failure)
- Human failure (Inattention)
- Human failure (Inadequate training)
  - I would add 'inadequate or incorrect documentation'

"The TG-100 FMEA was also performed with the assumption that there were no specific QA/QC measures in place. The rationale for this concept may be difficult to grasp at first as there are established QM measures associated with most of the analyzed steps and it is tempting to estimate likelihood of failure based on an existing QM program. However, assuming the absence of these QA/QC measures when performing the FMEA allows for a systematic, ground-up redesign of a QM program without possible confusion arising from the presence of existing measures, which may be misplaced or ineffective. Therefore, all risk probability estimates in this report were performed assuming that there were no specific QA/QC measures in place"

- The high risk of the "Device Failure" shows that sometimes the TG100 approach is in functional agreement with judicious regular physics "QA" as recommended by several other TGs

Device Failure: Lasers

- Standard Physics QA can reduce O, D to ≤ 4
- Old-fashioned laser QA
  - Lasers widely used for non-IGRT patients and to approximately localize patient for IGRT
  - The TG142 recommendations are in line with the philosophy of tailoring QA to clinical use
    - Daily & Monthly: 2 mm - non IMRT, 1.5 mm - IMRT, 1 mm - SRS/SBRT
- Beyond lasers

TG100: One of the best QC steps available is the daily use of IGRT setup techniques and this is one of the major benefits of the IGRT concept. Careful IGRT is an effective technique **but it should be accompanied by a departmental protocol limiting the shifts that can be made without a special investigation e.g., physician inspection and approval**.

Device Failure: IGRT

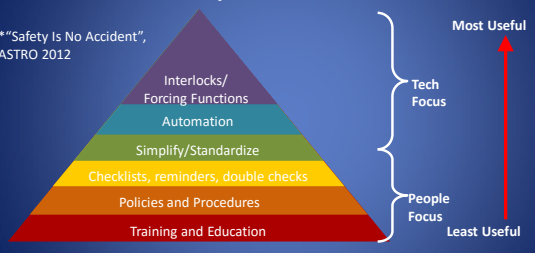
- Linac-based IGRT
  - Requires near-coincidence of 2 or 3 isocenters
    - Treatment beam, MV imaging, kV imaging
  - CBCT also should have good image quality
- QM for IGRT device failure guided by TG100 methods is in line with recommendations of TG142, 179
  - TG 142: Monthly QA
    - 2 mm for non srs/sbrt, 1 mm for srs/sbrt)
  - TG 179: Suggests procedures as well as tolerance/frequency
    - Daily for imaging/treatment isocenter coincidence (2 mm)
    - Monthly: geometric calibration, image quality
      - TG179 *"Where noted, users can modify test frequency and tolerance according to clinical usage and machine capability…."*

Device Failure- Other

- TG 100 (Appendices A1-3) identified: "Incompatibility between treatment machine and R&V system" and added
  - "Should be found during acceptance testing"
  - Risk if the TPS, linac and R&V system use different coordinate systems
- If Day 1 isocenter is correctly placed, and corresponding couch coordinates are recorded, subsequent errors can be quickly identified by noting large couch couch shifts
  - Software could be designed to flag these
  - Particularly valuable if immobilization locked to couch

Hierarchy of Effectiveness*

*"Safety Is No Accident", ASTRO 2012



AAPM 2013, B. Miller, et al

Some policies and procedures, though low on the pyramid, can keep D low regardless of cause

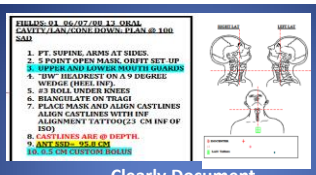
- Policy and procedures
  - Imaging prior to 1st treatment
    - port films, orthogonal images, cbct
  - Films reviewed and approved by an attending physician ASAP
    - **Preferably prior to actual treatment**
  - Chart Rounds reviews 1st day images within a week
    - New eyes, usually during first week of treatment
    - May prevent 'wrong isocenter' from propagating through treatment
    - Each patient should get a review BUT
      - How much time/patient?
      - What about extreme hypofractionation?

Encourage a Safety Culture

- All personnel: **question** unclear instructions
- All personnel: **ask** about what you don't know or understand
- All personnel: **question** odd occurrences
- All personnel: **respond** in a timely and collegial fashion
  - Provide **contact information** for all procedures

Mitigating Inadequate Training

- Clear, standardized presentation of setup information from simulation
  - immobilization directions, tattoo locations, shifts
- Competency exams for new simulator and treatment machine therapists
  - How to preparing and interpret setup instructions
- Physicist plan checker performs virtual check of setup instructions
  - Do they make sense with respect to the plan?


FIELDS: 01, 06/07/00 13 ORAL CAVITY, LAN/CONE DOWN, PLAN @ 100 SAD

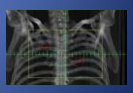
1. PT. SUPINE, ARMS AT SIDES.
2. 5 POINT OPEN MASK, ORFIT SET-UP
3. UPPER AND LOWER MOUTH GUARDS
4. "BW" HEADREST ON A 9 DEGREE WEDGE (HEEL INF).
5. #3 ROLL UNDER KNEES
6. BIANGULATE ON TRAGI
7. PLACE MASK AND ALIGN CASTLINES ALIGN CASTLINES WITH INF ALIGNMENT TATTOO(23 CM INF OF ISO)
8. CASTLINES ARE @ DEPTH.
9. ANT SSD= 95.8 EM
10. 0.5 CM CUSTOM BOLUS

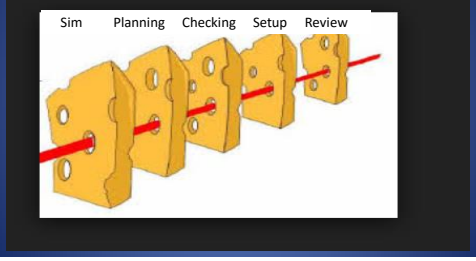
Clearly Document

- Tattoos from previous treatment
- Anatomical reference points (e.g. tragi)
- Planners' shifts from simulation tattoos
- Anatomical structures to register on-treatment imaging with DRRs or planning CT
- Setup photos

Inattention- Anyone can do it!

- Incomplete or incorrect simulator instructions
- Planner implements shifts but does not mention them in instructions
- Physics checker does not notice inconsistencies
- Treatment therapists do not follow instructions or
- Treatment therapists do not notice inconsistent instructions
- MD incorrectly reviews films
  - The T-spine is pretty featureless territory
  - We add a carina outline to help
- Chart rounds flies by too quickly to notice



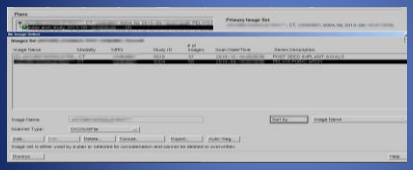


FOLLOWING 3 SLIDES ARE FROM ERIC FORD

Wrong Isocenter

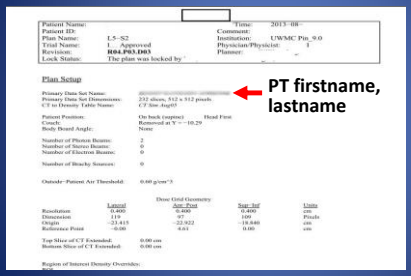
- Patient presents for R neck Tx. Previous RT.
- CT sim, isocenter marked.
- Dosimetrist picks prior CT instead of current CT.
- On first Tx: IGRT indicates 2 cm shift.
- RTT discusses with dosimetrist. Standard fractionation. MD not present.
- Elect to treat.
- Dosimetrist discusses with colleague and finds the error.
- Correction made for next treatment.

Select Correct CT Scan



Multiple CT scans

Check for Correct CT Scan

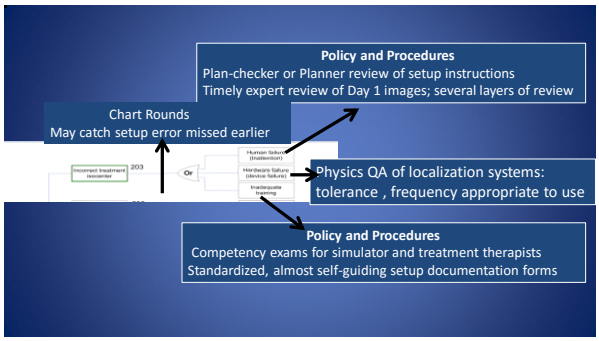


PT firstname, lastname

Wrong Isocenter

Possible Solutions

- Include date in the name of the scan
- Greater awareness during physics checks
- Introduce error checks into software
- Vendors: please help!


Policy and Procedures
Plan-checker or Planner review of setup instructions
Timely expert review of Day 1 images; several layers of review
Chart Rounds
May catch setup error missed earlier
Physics QA of localization systems:
tolerance , frequency appropriate to use
Policy and Procedures
Competency exams for simulator and treatment therapists
Standardized, almost self-guiding setup documentation forms