Risk Assessment Guidance for QM in Brachytherapy

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Conflicts

The presenter has no conflicts relevant to this presentation.

Learning Objectives

- To understand how risk assessment can guide the development of Quality Management

Example Procedure

- Let's use a brachytherapy procedure for which physicists currently may be developing QM: Intracavitary breast brachytherapy using a balloon catheter.
- These would be
  - MammoSite
  - Contura

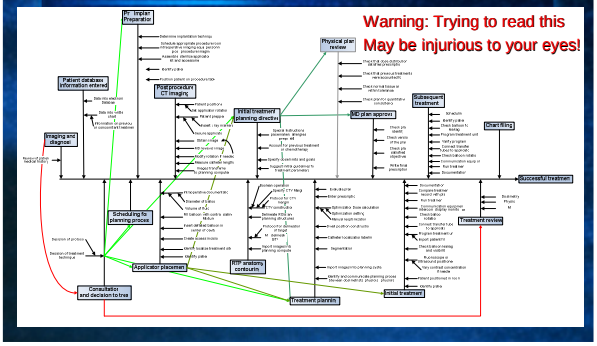
Possible Levels of QM

- Acceptance Testing
- Commissioning
- Periodic Testing
  - Daily
  - Source change
- Per patient

First Step - Process Mapping

- We made a process map for the procedure.
- The purpose of the map is to understand the process and the interrelationships of the steps.
- There are many way to come to this understanding, process mapping is but one.

Breast Brachytherapy Process



Second Step - FMEA

- As described in the TG 100 overview, go through the process and at each step ask how could this fail.
- At each step there are probably several ways it could fail.
- If in doubt, include any failure (low risk failures will sort out latter).

Third Step - Rank failures

Our intracavitary breast brachytherapy FMEA had:

- 89 possible failures.
- A range of RPN from 1 to 648.
- The top 20% of the failures had RPN numbers greater than 320,
- Giving 20 failures to address off the bat.
  - More than 20% because several steps at the end have the same value.

Third Step - Rank failures

Our intracavitary breast brachytherapy FMEA also had:

- 34 possible failures with Severity rankings of 8 or above.
- 6 of these are redundant with the list for the top 20% RPN values.
- That gives a total of 48 potential failures to consider as the first cut – a little more than half.

Interesting…

It is interesting to note how few of the very severe potential failures made the high RPN list.

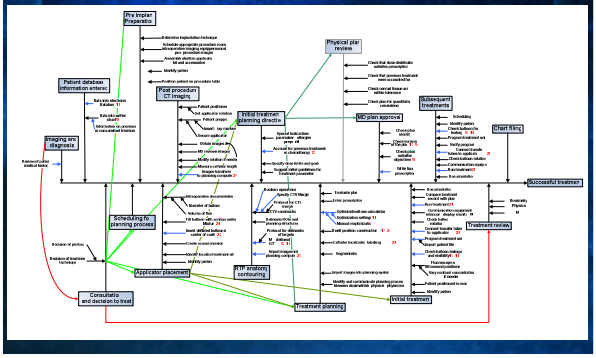
Eliminate Some Steps

- 10 of the steps had S≤3.
- 7 more with 4 ≤ S<8 have O ≤4 and RPN < 90, values of little concern
- Those could be dealt with later if they prove to be a problem.
- That eliminates 17 steps of the 89, leaving 72.
- The remaining 24 (72-48) still have to be addressed in the QM plan, but the top give an idea of the greatest hazards.

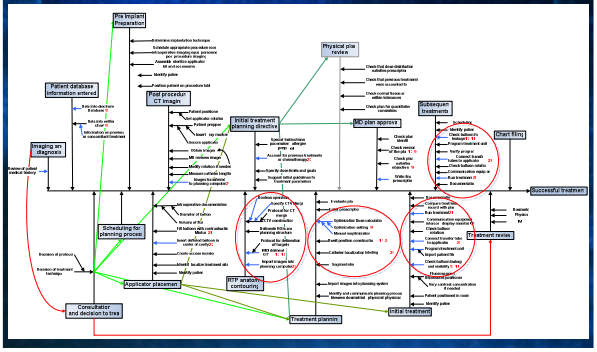
Fourth Step - Mark Process Map

- Shows if potential failures are uniformly distributed through the process or clustered.
- If clustered, should consider the major step as a hazard.

Marked Process Map



Highlighted Process Map



Top 6 RPN

	Major Processes	Step	Potential Failure Modes	Potential Causes of Failure
1	Initial treatment	Run treatment	Source fails to enter catheters, catheter not connected or not connected tightly enough	Inattention
2	Initial treatment	Run treatment	Source fails to enter transfer tube, locking ring not locked	Inattention
3	Treatment Planning	Re-optimize plan	Reoptimization causes unintended hot or cold spots or inadvertently inflates or deflates dose distribution	Inadequately trained, poor inter-disciplinary communication, lack of attention
4	Initial treatment	Run treatment: multicatheter	Incorrect balloon rotation	Failure to check rotation, poor documentation
5	Treatment planning	Catheter localization/ labeling: multicatheter	Catheter trajectory inaccurately localized	Wrong catheter slice images, inadequately trained personnel, poor inter-disciplinary communication, inattention
6	Treatment planning	Catheter localization/ labeling: multicatheter	Incorrect catheter number assigned	Inadequately trained personnel, inattention, poor labeling on photograph, poor inter-disciplinary communication

S=10

	Major Processes	Step	Potential Failure Modes	Potential Causes of Failure
1	Patient database information	Entry of patient data in chart (e or written)	Incorrect patient ID data	Documentation error
2	Transfer images and other DICOM Data	Incorrect handling objects (other than images) between scanner and tps	Incorrect transfer of images	Incompatible DICOM formats, limitations of treatment planning systems or scanners, failure of commissioning
3	Transfer images and other DICOM Data	Transfer CT image data set	Data incompatibility	Incompatible DICOM formats, failure of commissioning
4	Initial treatment	Run treatment	Treatment device failure (source fails to progress)	Equipment failure
5	Imaging and diagnosis	Review of patient medical history	Incorrect patient file reviewed	Documentation error, human error
6	Initial treatment	Run treatment	Treatment device failure (device fails to retract source)	Equipment failure

S=10 Failure Modes

- 2 are failures of the source movement.
- 4 of the 6 result from failures to be working with the right patient or the right patient files.
- These are the same as with external-beam, the worst you can do is mix up patients.
- 2 of these 4 should be eliminated on commissioning

Caveat

Remember, we assumed that there was no QM for this first pass, so we considered what could happen without:

For example, the source cable could pass through the transfer tube and push the catheter out of the connector and just flap in the breeze if not inserted properly and there was no interlock.

More on the First Potential

- In fact, there is an interlock to help prevent this failure.
- This failure requires two failures:
  - The operator fails to connect the catheter well, and
  - The interlock fails.
- The interlock failure can be either:
  - Failure of the blocking ball bearings to close, or
  - Failure of the stepper to detect the increased friction.

QM Design

- Thus, it is seen to be very important to check that the catheter connect interlock works!
- Since for a Nucletron, the interlock is just two ball bearings on springs and a resistance sensor, any of these could stop functioning as they wear.

QM for the First Potential

- Quality Assurance
  - Check that the unit detects a blockage by sending the source out with no catheter – part of daily operation check.
  - Check that transfer tube ball bearings work – for frequency see below.
- Quality Control – each time a catheter is inserted into a transfer tube, give it a tug.

Training

- Of the top 20, 11 had “Inadequate training” as a possible cause for failure.
- That was only one possible cause, but obviously, before doing the procedure, everyone needs to be adequately trained and practiced, practiced, practiced.

Attention

- Of the top 20, 8 had “Lack of attention” as one possible cause. All 8 had other possible causes in addition.
- You *cannot just have “pay more attention”* as a QM step!
- There must be some other action that catches errors due to inattention.

Commissioning

- 7 of the potential failures were systematic problems that would be caught on commissioning.
- These were mostly failures with high severity ratings.
- Examples:
  - Transferring of images
  - Source strength decay
  - Dose calculation algorithm
  - Boolean operations.

Identification

- 6 of the potential failures involved the patient's identity, either in person or as for the plan.
- Obviously, knowing on whom you are working is important.

QA of the Treatment Plan

- Several items on the short list would be caught on a check of the treatment plan
  - Optimization not appropriate
  - Plan not satisfactory
  - Prescription
- It appeared important that the physician check the physicist/planner and that the physicist check the physician.

Not Problems

- Some potential failures fall far enough down the list as to not need QM
- Examples:
  - Identifying the patient and plan for subsequent treatments after doing so on the first, if have only 1 patient under treatment.
  - Checking communication devices as morning QA: their failure becomes apparent.

Interlock Failures

- Several high severity problems have preventative interlocks on the unit, for example:
  - Source distance
  - Step size
  - Transfer tube and catheter connection
  - Source movement and retraction
- That moves the QM to checking the operation of the interlocks.

Interlock Failures 2

- Looking at history, after commissioning, none of these fail. That implies very infrequent checks are OK.
- The severity of failure is high, which implies frequent checks.
- Some (connection interlocks) require failure of interlock AND failure of operator to cause a net failure. (The interlocks are QC.)

Interlock Failures 3

- Could check the QC interlocks at source change.
- Could check the control interlocks weekly.
- Don't need to check source decay calculation after commissioning, but would be good to spot check monthly.

Redundant Systems

- Redundant systems would include the GM on the unit, the area monitor and the handheld detector.
- These do not need QA since if one or two fail, the failure would be noticed but the other(s) would serve the function adequately.

Another Caveat

- Note: These recommendations are based on risk analysis, not regulations.
- Following them may be hazardous to your license.

Conclusion

- Risk analysis gives guidance for developing a QM program.
- This short presentation did not give time to present an entire program, only some of the considerations.
- Starting by ignoring the current QM helps see what steps may be eliminated or spaced with less frequency.
- Not all potential failures require QM.
- All steps not dropping out by low values require QM.

Conclusion 2

- This approach helps see what potential failures can be addressed:
  - At commissioning, and not thereafter;
  - With source changes;
  - Daily machine (high S, high O, high PRN);
  - Per patient.