Current Methodologies in Risk Assessment

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Disclosures

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I am the president of the non-profit Center for the Assessment of Radiological Sciences, a 501(c)(3) non-profit Patient Safety Organization listed with the Agency for Healthcare Research and Quality and dedicated to improving the safety and quality of radiotherapy.

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Learning Objectives

1. To become familiar with the current methodologies in risk assessment.
2. To learn about some current quality activities.
3. To understand Systems approach to patient quality and safety.

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Conventional Approach to Radiotherapy QA

- In general, QA addresses the equipment, to make sure it all works correctly, consistently and safely.
- The number of tests were proliferating.
  - In radiotherapy alone, the AAPM has published 78 reports as of 2015.
  - Many have recommendations for QA.
  - Not to mention other organizations and regulations.
- Time spent in QA left little time of other things (like thinking), *if* the QA could even be completed.
- The number of events were not decreasing.
- Also, could procedural differed between facilities be important?

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An Example of Paradigm Problem: Annual Calibration and QM

- The annual calibration takes several days to complete.
- If everything checks out, the effort was mostly wasted – that is it could have been spent checking things with a higher likelihood of failure.
- If some problem was found, how long had it been wrong and shouldn't t it have been found earlier?

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What is New?

- A lot has happened over the last 25 years!
- Our understanding of how events happen and how to address the problems that lead to events has deepened.
- We have learned that the obvious, simple approaches do not work well.
- While radiotherapy was early to introduce quality management (back in 1920s) we have fallen behind many other disciplines in addressing safety issues.
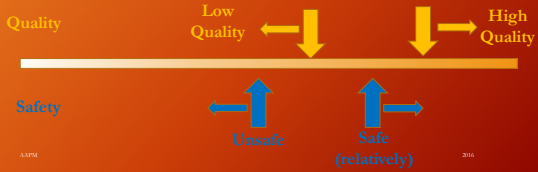
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What is New?

One thing is recognizing the quality-safety continuum

Quality

Low Quality → High Quality

Safety

Unsafe Safe (relatively)

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So, What Else is New?

Another thing is recognizing safety culture.

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Nature of Culture

- Culture start at top management and percolates through the organization.
  - Assuming a hierarchical, which is common.
  - The more hierarchical the more this is true.
  - Workers pick up on the attitudes of superiors.
  - Rewards follow the values of superiors.
- Peers reinforce the culture.
- Weak supervision allows degeneration of the culture.

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Common Traits of a Positive Safety Culture (USNRC 2012)

1. **Leadership values safety**
2. **Problems identified and resolved**
3. **All individuals take responsibility for safety**
4. **Work implemented to maintain safety**
5. **Continuous learning encouraged**
6. **Environment fosters raising concerns**
7. **Communications focus on safety**
8. **Respectful work environment**
9. **Questioning attitude**

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Necessity of the Traits

- While the traits are good, an organization need not exhibit the traits to be safe.
- For example, an organization without trust or respect can, and likely would, establish procedures with layers of redundancy, possibly automatic, to prevent errors since the leaders would have no trust that the workers would execute their jobs correctly.

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Value of the Traits

- Safety is easiest and most natural in organizations that exhibit *and inherently value* such traits.
- A positive safety culture is in the nature of an organization and cannot be forced on an organization.
- While practices can be imposed, forcing practices that *appear* as good traits likely will not have the same effect as if the organization developed them naturally.

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Forcing the Traits

- Forcing practices that *appear* as good traits can be counterproductive if it uses resources that could be devoted to actual safety practices.
- Forcing good *behavior* can be productive and *may* change practices or eventually culture.
- For example, Time-out before procedures, forced by JC, has led to the practice becoming almost routine, without thought. This may not have worked as well as trying to change the culture first.

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An Important Trait: Blame-free Culture

- After an event, the traditional approach is to find who is responsible: assign blame.
- If the event was not terrible, send the culprit for training (punishment– Blame and Train).
- If it was serious, say it after me, "YOU'RE FIRED!"
- The problem is, the blame game forces problems underground so no one knows about them and *they cannot be fixed*.
- In a blame-free culture, individuals feel free to discuss problems, even if they are the source, and the issues can be fixed.

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Who to Blame?

- Equipment can cause failure.
  - This is rare, maybe because we have put so much emphasis on preventing it.
  - But expect that sometimes, equipment does fail.
- Studying reported events, they all are human failures.
  - Humans may start the event.
  - Even for equipment failures, they evolve into events due to human failures.
  - Humans do fail – all humans. It has to be expected.
- But truly, all failures are system failures because the system was not designed to prevent the effects of failures.

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Vocabulary

Now's a good time to clarify some vocabulary.

- *Incident* – a situation or actions that could have resulted, or did result, in unnecessary harm to a patient, staff or other person.
- *Event* – an incident that affected a patient, staff or other person.
- *Near event*, *close call, good catch* – an incident that had no affect on any person. Sometimes referred to as a *near miss*.
- *Hazardous condition*, a situation with the potential to lead to an incident.

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Vocabulary 2

- *Failure* – not achieving the desired end or goal.
- *Error* – a failure to execute a planned action as intended.
- *Mistake* – a failure due to inappropriate planning.

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So, Back to Who to Blame?

- The person responsible for the system? That will go far.
- Don't worry about it.* Almost everyone is trying to do a good job.
- Just try to make things better.

*Sometimes you do need to worry about it when there is negligence as opposed to error or mistake, but that is a separate presentation.

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Approaches to improve patient quality and safety

- There are proactive approaches to treatment quality, planning for quality as procedures are designed. You will hear next about the TG-100 methodology.
- There are reactive approaches, adjusting procedures after something doesn't go as expected. "Reactive" is not a pejorative.
- Better then learning from your failures is being able to learn from everyone else's failures.
- This comes from national and international incident reporting systems.

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Advantages of the New Approaches

- All of the approaches will improve quality.
- A systems approach attempts to adapt the system to flow organically and be robust to errors and mistakes.
- Particularly the proactive approach can help use resources effectively, efficiently and rationally.

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Reporting-Gathering

- Several regulatory agencies collect data on events, such as the NRC, States, FDA. Their utility for YOU is limited for many reasons.
- The IAEA runs a voluntary radiotherapy event data base.
- Many facilities hesitate to report to a voluntary database fearing the effects should information about their events leak or are subpoenaed.
- But there is something new (relatively)…

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Patient Safety Organization (PSO)

- Patient Safety and Quality Improvement Act, 2005 established PSO listed by Agency for Healthcare Research and Quality.
- PSOs have to have extensive data security.
- Any information given to or received from a PSO is protected from discovery.*

*Okay, a lot of legal language goes here about what information is shielded and how the information must be handled, that it does not cover information in the facility's records etc., etc.,

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PSOs

AHRQ expects that PSOs:

1. Gather data about events using common taxonomies and keep them in a data base.
2. Analyze the data and extract lessons that can improve quality and distribute that information widely to the community.
3. Work with the clients who report events and help them remediate problems uncovered in the analysis of their events to improve their processes.

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Radiotherapy PSOs

There are two PSOs that work with radiotherapy:

- The Center for the Assessment of Radiological Sciences (CARS) which went live September 2013.
- Clarity, which runs RO-ILS

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Effects of Quality Initiatives

- Taking on any of the quality improvement activities, proactive, reactive or incident reporting, should involve much of the staff.
- As the staff in a facilty sees action going on, and hopefully quality improvements, the culture of the facility tends to improve.
- Be warned, however, if staff reports problems and nothing changes, the culture can deteriorate.

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Summary

- Quality and safety science and engineering have come a long way over the last few decades with a lot of applications in healthcare, and just coming into radiotherapy.
- There are several approaches and activities that can improve safety at a facility.
- Any of the activities, if followed through, will likely improve quality.
- All the approaches work best TOGETHER!
- Activities performed consistently and diligently over time improves the safety culture at a facility.

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