CAUSAL ANALYSIS

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LEARNING OBJECTIVES

• At the conclusion of this session attendees will...

1. Learn how to initiate a causal analysis and gather data for the investigation process

2. Understand the challenges of collecting and managing the data and contributing factors that you discover

3. Learn how to avoid future incidents by developing appropriate recommendations to address causal factors
WHY CAUSAL ANALYSIS?

CAUSAL ANALYSIS
PROFESSIONAL SYMPOSIUM – SAM
SU-B-CELESTIN-0

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DISCLOSURES
I HAVE NO RELEVANT FINANCIAL DISCLOSURES

Vice Chair of AAPM Work Group on the Implementation of TG-100

Vice Chair of AAPM TG-314: Guidance for Fault Recovery in Radiation Therapy

Section Lead of AAPM Medical Physics Practice Guideline 15.a: Peer Review in Clinical Physics (TG-358)

Member of the AAPM Working Group on Prevention of Errors

Member of ASTRO Multidisciplinary QA Subcommittee

Quality and Safety Champion at MCA, Leader of our SA-ILS team, Point person for all RCAs
WE’RE THINKING RETROSPECTIVE, NOT PROSPECTIVE

Prospective approaches to risk mitigation are essential to good clinical operations.

Since 2016, our field has focused on TG-100 principles:

- Process Mapping
- Failure Modes and Effects Analysis
- Fault Tree Analysis

All within a multi-disciplinary group framework

Creating thoughtful, risk-informed processes, which involve stakeholders from all clinical areas will allow us to plug gaps and keep our patients and our staff safe.

But we are all human, and all humans eventually make mistakes -- sometimes in really inventive and unexpected ways.
A MOMENT ABOUT LANGUAGE (WORD CHOICE)

Language is important in the investigative process (as is tone, attitude, real or perceived interest, real or perceived bias…)

Difference between “event” and “incident” and “error”

This is a stressful (at best) time for the staff involved
Anything we can do to diffuse the situation, to allow for full disclosure and thorough analysis, will be to our benefit
Using language that produces an emotional response will not set us off on the right foot
The methodology is important, and can have lasting consequences on what is discovered, what is changed, and if future events are prevented.

It will result in the identification and implementation of sustainable systems-based improvements that make patient care safer in settings across the continuum of care.

Safety is a moving target, especially in tech heavy fields like ours, but with the right tools we’ve got a lot of positive momentum.

When working on the investigation, after an event has taken place, you’re going to need tools.

RETROSPECTIVE ANALYSIS
ROOT CAUSE ANALYSIS

RCA is applied to methodically identify and correct the root causes of events, rather than to simply address the symptomatic result.

Based on the premise that problems are best solved by attempting to address, correct, or eliminate root causes as opposed to addressing just the obvious symptoms or superficial causes.

Focusing correction on root causes has the goal of entirely preventing problem recurrence.
WHAT DO WE DO ONCE AN EVENT HAS OCCURRED?

Two main choices:

WHO IS TO BLAME? or WHERE DID THE ERROR OCCUR?
This approach mandates that the staff will always be perfect

After an event the focus is on blame, discipline, retraining and adherence to policies and procedures

But what to do when the same event happens again?

FIND THE RIGHT QUESTION FROM THE BEGINNING
Acknowledge that staff are human and will make mistakes, despite being well-trained and thoughtful professionals

What is the basis for this problem

Why did the systems/processes allow this to happen in the first place

After an event the focus is on changing the process: training, changes to the culture, staffing
LET’S GET THIS STARTED ON A GOOD NOTE

• Who will be involved?
  • Absolutely a multidisciplinary effort
  • All staff members who had a hand in the evolution of this event need an opportunity to contribute to the narrative, and to the suggestions for improvement
  • Experienced investigators from within or outside of the department who can steer the conversations in a productive direction
  • Frequently Team Leads, Managers, and Supervisors want to be involved
    • This makes sense, if there are recommendations to be made, they need to know about them
    • However, this can be very tricky…they may have an agenda besides the fact-finding and suggestion-making
    • This is not a punitive or blame-casting event
    • They also might dominate the conversation, prevent frank discussion, and bring canned solutions to the session
    • And they can bring the group to an unmanageable size—being nimble is valuable
There’s no viable path forward without talking to those involved in what happened

• The investigator (this is hopefully you!) needs to engage with the stakeholders to begin to understand what took place

• The stakeholders may offer their own ideas as to why, but what you’re really after at this moment is the “what”

• Once you gather the stories of the event, relevant policies and documentation, supporting evidence from the EMR or R&V, and other related information like screen captures or photos you’re ready

• If you can get everyone in a room together, that’s terrific
  • But it is not the only way
  • Some of our fellow physicists do thorough individual interviews and only a small group meeting
  • Some (like MCA) get everyone together via Zoom to work through the details

• Time is not on your side, better recollections lead to better reconstructions and improved mitigations
  • We lose nuance and detail as days pass, work quickly
GIVING GENTLE DIRECTION

Participants need to be able to speak freely and candidly

But once it comes time to think about remedies, gentle guidance can be hugely beneficial

LET TG-100 HELP YOU

Some teams may immediately jump to the idea that “more policies and procedures” will fix their issue. In a large report from New York shared in Safety Is No Accident, in only 16% of incidents was not having a policy or procedure found to be a contributing factor.
NEXT STEPS
HOW DO WE PUT THE “A” IN RCA?

Grace is going to discuss Analysis Tools next

We won’t be giving a quiz later (although there are SAM questions!) but the hands-on activity will need you to recollect these ideas and suggestions.
CASE 2

SRS COMMISSIONING ERROR

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CASE 2 IS MORE COMPLEX
MORE COMPLEX CASES SIMULATE REAL LIFE EXPERIENCES

• A qualified medical physicist commissioned a replacement intracranial stereotactic radiosurgery (SRS) program that included new hardware and software. The immobilization system for this new SRS program included a substantial base plate and accessories, and so the physicist decided to contour them, so they were included in the dose calculations.

• The physicist assumed that heterogeneity corrections were applied in the new SRS planning software because it had been in their previous SRS TPS from a different vendor. The vendor manual for the new software specifically stated that heterogeneity corrections are not used and not to include the baseplate and accessories in the contours.

• However, this information was unknown to the commissioning physicist.
CASE 2 IS MORE COMPLEX
MORE COMPLEX CASES SIMULATE REAL LIFE EXPERIENCES

• Plan information was displayed in a different system which indicated that doses are calculated according to the standard algorithm. Multiple staff members assumed this meant heterogeneity corrections were included since the standard algorithm for this system is to include heterogeneity corrections.

• The result was a long physical pathlength but relatively short effective pathlength used in the dose calculations. An independent monitor unit check program from a different vendor failed to identify this error.

• This software had the characteristic of assigning water density to any contour outside of the designated patient surface and therefore reproduced the original error. While this feature of the second check software is listed in the manual, it was not understood by some staff.
CASE 2 IS MORE COMPLEX
MORE COMPLEX CASES SIMULATE REAL LIFE EXPERIENCES

• Independent end-to-end testing was performed using a phantom (i.e., without the baseplate and accessories) and so it did not identify the dose calculation error.

• A different physicist, aware that the independent monitor unit check software treats material outside the designated patient surface as bolus material, specifically removed the baseplate and accessories contours when performing a second check.

• This led to the discovery of the dose calculation error.

• An independent audit was initiated, and the heterogeneity calculation error was identified. The incorrect assumption regarding heterogeneity correction resulted in a ~10% difference in the delivered dose as compared to the planned dose for patients treated before the miscalculation was discovered.
Wrong Dose to SRS Target(s)
Wrong dose to SRS site(s)

- The commissioning physicist assumed that heterogeneity corrections were applied.
- Multiple other staff members assumed heterogeneity corrections were included.
- Independent monitor unit check program failed to identify the error.
- Independent end-to-end testing was performed without the baseplate and accessories.
- There was no commissioning partner or independent checker.

1. a. i. 3 Inadequate training support
2. a. i. ii Lack of review of preexisting reports
1. c. iv Lack of continuing education
6. d. ii Inappropriate assumptions
1. b. i Relevant policy nonexistent
2. a. iii Lack of review of preexisting reports

- Commissioning physicist did not recognize and follow information in the vendor’s manual.
- The practice did not receive any vendor training.
- Independent monitor unit check software by default assigned water density along the path length, mimicking the error.
- Independent MU software characteristics not well known to staff.
- Could not identify the issue as all pieces of equipment were not in use.
- Commissioning physicist did not recognize and follow information in the vendor’s manual.
- Leadership transition coincided with commissioning process.
- Commissioning happened during a busy time for the practice and additional staff resources were not available.
- Commissioning physicist was senior-level with years of SRS leadership experience.

1. f. vi Inadequate supervision
1. f. vii Outdated practices
1. a. i. 1 Staffing not consistent with professional clinical recommendations
1. d. i Poor, incomplete, unclear or missing documentation
1. d. ii Inappropriate assumptions
6. d. ii Inappropriate assumptions

TPS provides general information only
Expected display software to function like previous TPS versions
1. f. viii Lack of peer review

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CASE 2 IS MORE COMPLEX
MORE COMPLEX CASES SIMULATE REAL LIFE EXPERIENCES

- Causal Taxonomy
  - 2. Technical a. Proper acceptance testing and commissioning of new equipment iii. Lack of review of preexisting reports x2
  - 1. Organizational management a. Planning for program maintenance or expansion ii. Inadequate capital resources 3. Inadequate training support
  - 1. Organizational management d. Communication i. Poor, incomplete, unclear or missing documentation
  - 6. Procedural issues d. Failure to develop an effective plan ii. Inappropriate assumptions x2
  - 1. Organizational management c. Training; acquiring, and transmitting knowledge and skills iv. Lack of continuing education
  - 1. Organizational management b. Policies, procedures, regulations i. Relevant policy nonexistent
  - 1. Organizational management f. Leadership and external issues v. Inadequate supervision
  - 1. Organizational management f. Leadership and external issues vii. Inadequate supervision
  - 1. Organizational management f. Leadership and external issues vii. Inadequate supervision
  - 1. Organizational management a. Planning for program maintenance or expansion i. Inadequate human resources 1. Staffing not consistent with professional clinical recommendations
  - 1. Organizational management f. Leadership and external issues vi. Lack of peer review
CASE 2 IS MORE COMPLEX
MORE COMPLEX CASES SIMULATE REAL LIFE EXPERIENCES

• As you can see, and likely determined for yourself there are numerous failures that have conspired to cause the final, adverse, outcome
  • There are human failures
  • There are systemic failures
  • There are active causes
  • There are latent causes
  • Some barriers were in place but did not work, while others did

• Taken together, a complex event can illustrate how the entry-level technique of using the “5 Whys” can be insufficient to get the full picture and an accurate analysis
LIMITATIONS OF THE 5 WHYS

• In principle, using the 5 Whys should be fine

• But in practice it can cause some undesirable situations and outcomes
  • It can yield results that are unrepeateable
  • It can inadvertently focus on just one of a small number of causes instead of the large spectrum of contributing factors and causes
  • Some folks might take the “5” literally and stop too soon
  • It can cause us to drift from objective to subjective analysis

• So use the spirit of the 5 Whys technique, but don’t let yourself or your team stop short of seeing the kaleidoscope of root causes, contributing factors, and latent conditions that set this event in motion
OTHER IMPEDIMENTS

• Bruce is going to talk now about other things that can interfere with productive and complete analysis
LOOKING BACK, LESSONS LEARNED

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RETROSPECTIVE ANALYSIS

If you have a local repository, this can be a gold mine for incidents related to vulnerabilities in your clinic or group’s policies and procedures.

There are treatment deviations and near-misses at clinics across the world every day.

We’re fortunate that a small portion of these are shared with us and available for community learning.

If you’re starting from scratch, the RO-ILS quarterly reports can yield valuable information, albeit not specific to your practice patterns.
WHAT CAN RO-ILS OFFER US?

Every case study has a section at the end with lessons learned.

The case we looked at during my example had two sections:

- Lessons for community
- Lessons for vendors

Are there common themes among highlighted incidents?
Practices should cultivate a high-quality safety culture. Safety culture underlies a practice’s ability to make improvements because it affects what and how staff learn and how practices adapt. Safety culture is hard to achieve and easy to lose, so constant vigilance is required.

Regardless of experience, anyone can make an error. A valuable indicator of a practice’s safety culture is the comfort level of staff to speak up and be listened to. We all hope to work in an environment with a low power distance index, meaning that feedback is accepted between members of differing power levels within the practice.

It is crucial that practices conduct thorough investigations upon discovery of an error, and that they are not satisfied with finding one root cause, or “the” problem…but that they understand there are multiple causes, both proximal and progenitor. In doing this well, the practice can dramatically reduce search satisfying bias.
TIME LEFT FOR DISCUSSION

Thank You For Your Interest In These Topics!

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