MAYO CLINIC

CAUSAL ANALYSIS

B THOMADSEN, G KIM, C BUCKEY
UNIVERSITY OF WISCONSIN, MADISON, WI
UNIVERSITY OF CALIFORNIA, SAN DIEGO, LA JOLLA, CA
MAYO CLINIC ARIZONA, PHOENIX, AZ

2022 AAPM Spring Clinical Meeting
New Orleans, LA

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

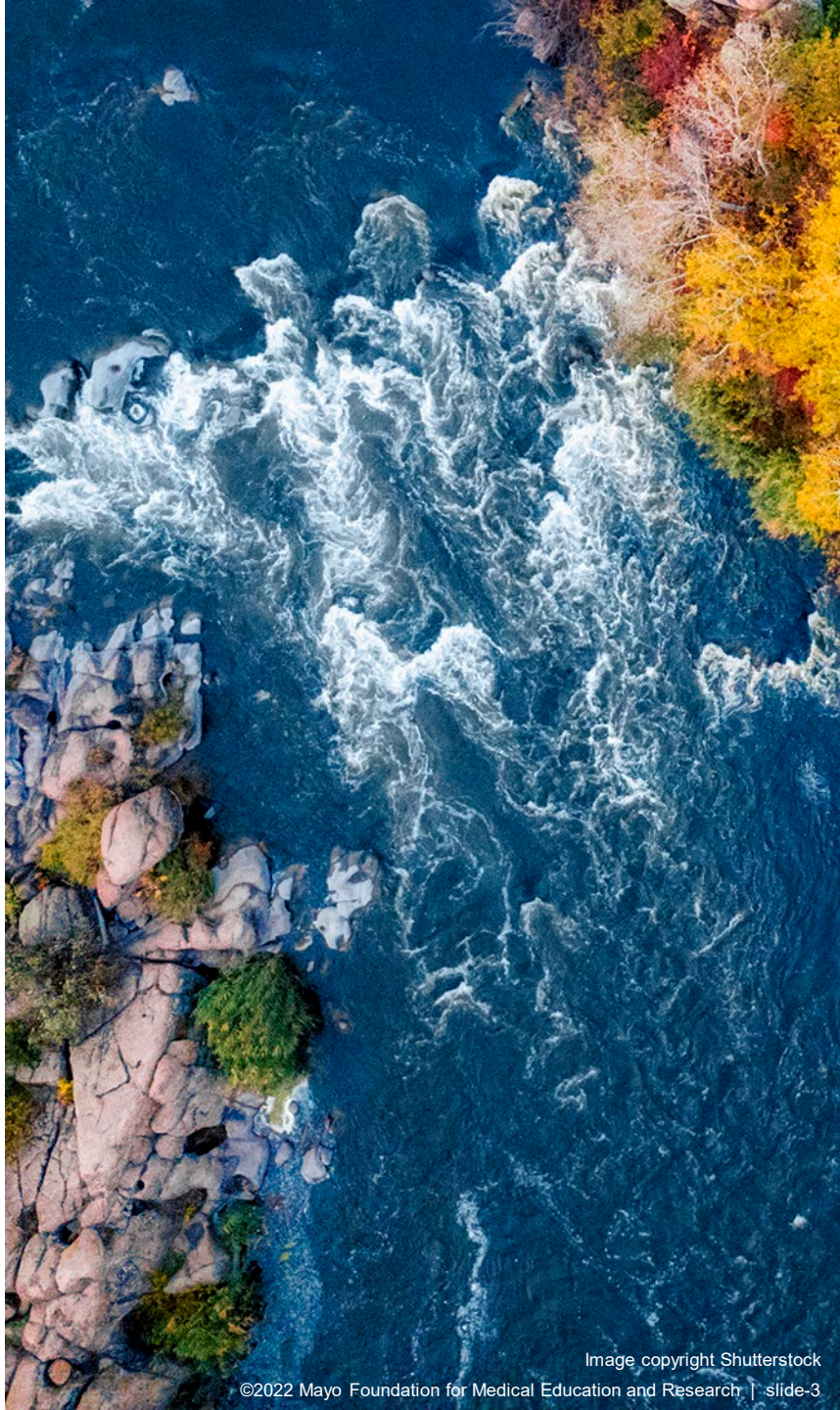
MAYO CLINIC

WHY CAUSAL ANALYSIS?

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

Courtney R Buckey, PhD, DABR
Mayo Clinic Arizona

2022 AAPM Spring Clinical Meeting
New Orleans, LA



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

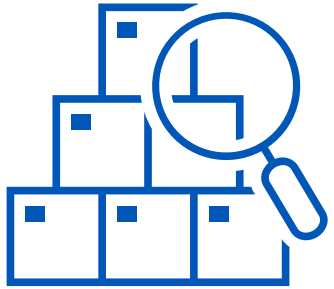
Quality and Safety Champion at MCA, Leader of our SA-ILS team, Point person for all RCAs

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 form 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

RETROSPECTIVE ANALYSIS

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

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

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

GET TALKING

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 <u>not</u> 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

TABLE III. Ranking of QM tools based on the effectiveness with examples, in part following the suggestions of ISMP (Ref. 67). The lower numbers are the most effective.

1. Forcing functions and constraints
   - Interlock
   - Barriers
   - Computerized order entry with feedback

2. Automation and computerization
   - Bar codes
   - Automated monitoring
   - Computerized verification
   - Computerized order entry

3. Protocols, standards, and information
   - Check-off forms
   - Establishing protocol/clarify protocol
   - Alarms
   - Labels
   - Signs
   - Reduce similarity

4. Independent double check systems and other redundancies
   - Redundant measurement
   - Independent review
   - Operational checks
   - Comparison with standards
   - Increase monitoring
   - Add status check
   - Acceptance test

5. Rules and policies
   - Priority
   - Establishing/clarify communication line
   - Staffing
   - Better scheduling
   - Mandatory pauses
   - Repair
   - PMI (preventive maintenance inspection)
   - Establish and perform QC and QA (hardware and software)

6. Education and information
   - Training
   - Experience
   - Instruction

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.

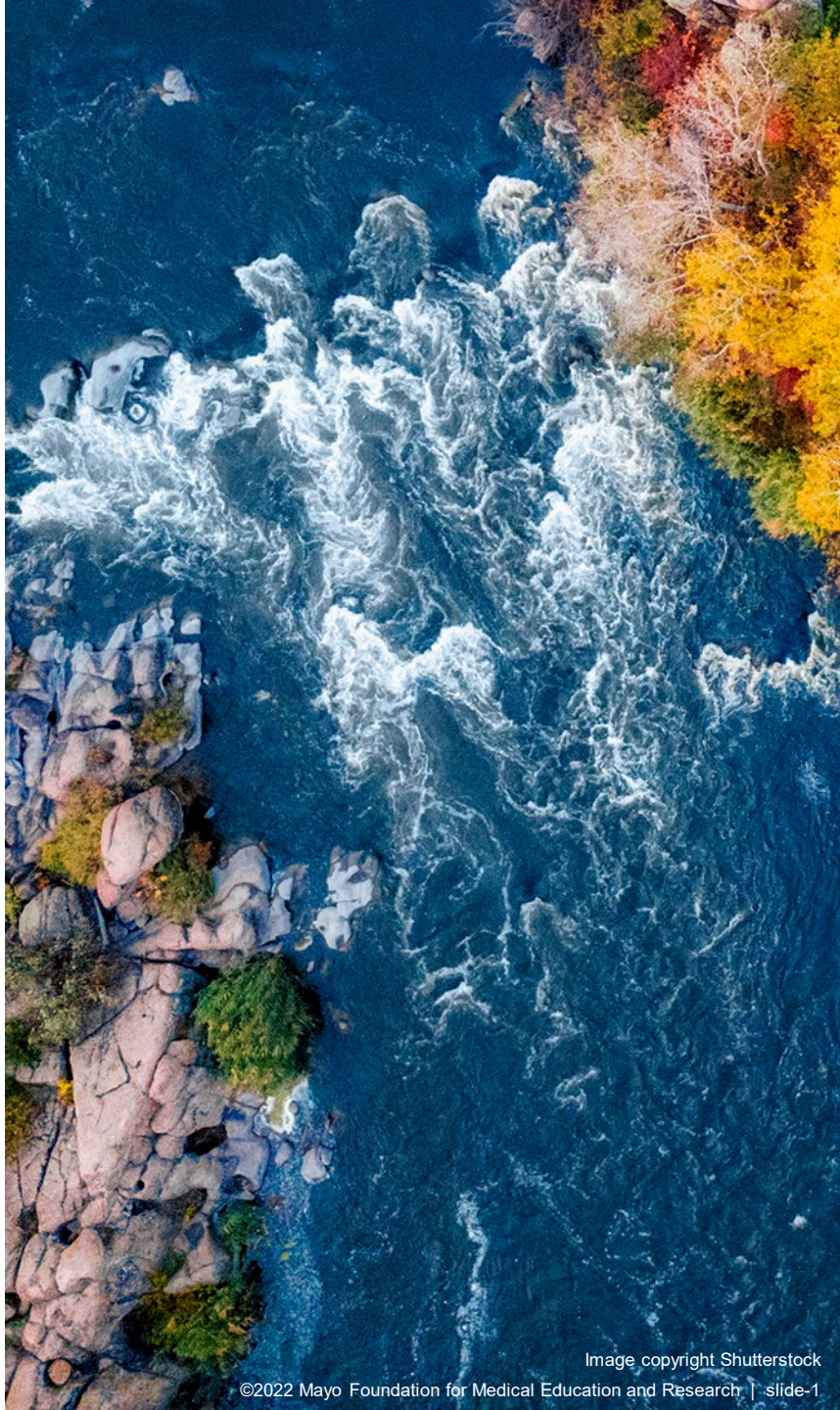
MAYO CLINIC

CASE 2

SRS COMMISSIONING ERROR

Courtney R Buckey, PhD, DABR
Mayo Clinic Arizona

2022 AAPM Spring Clinical Meeting
New Orleans, LA



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.

DIAGRAM OF CASE 2

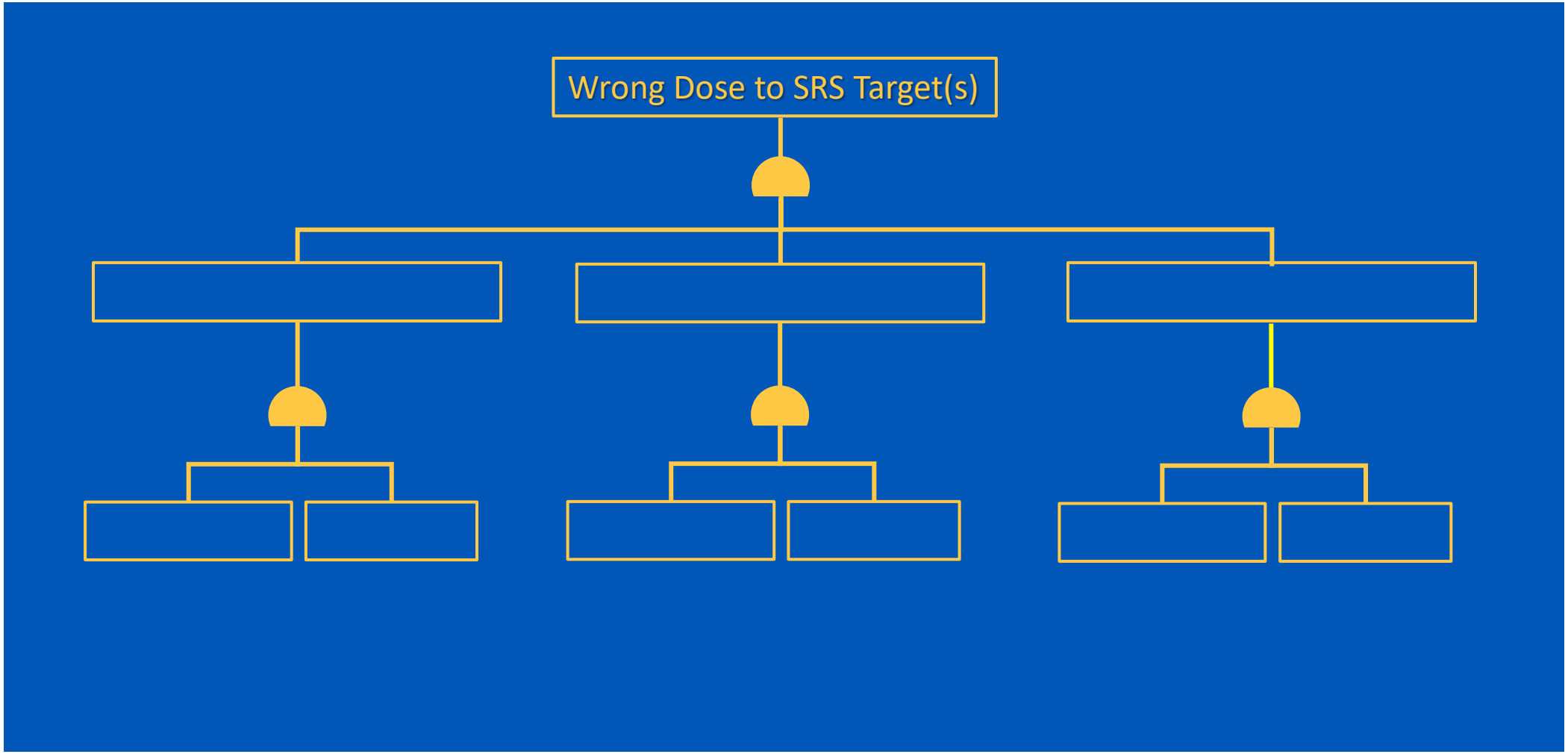
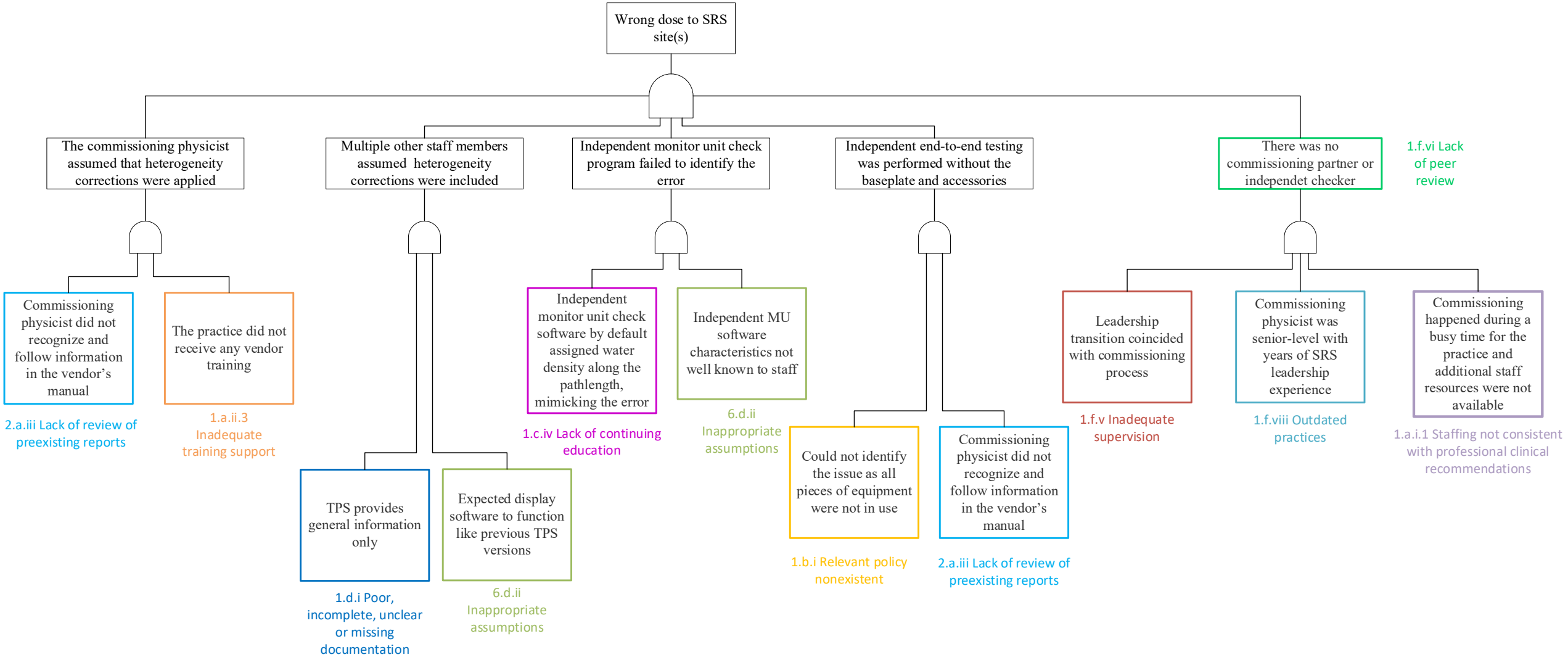


DIAGRAM OF CASE 2



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 viii. Outdated practices
  - 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

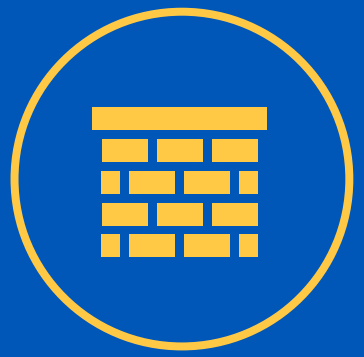
- As you can see, and likely determined for yourself there are numerous failures that have conspired to cause the final, adverse, outcome
  - There are human failures
  - There are systemic failures
  - There are active causes
  - There are latent causes
  - Some barriers were in place but did not work,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



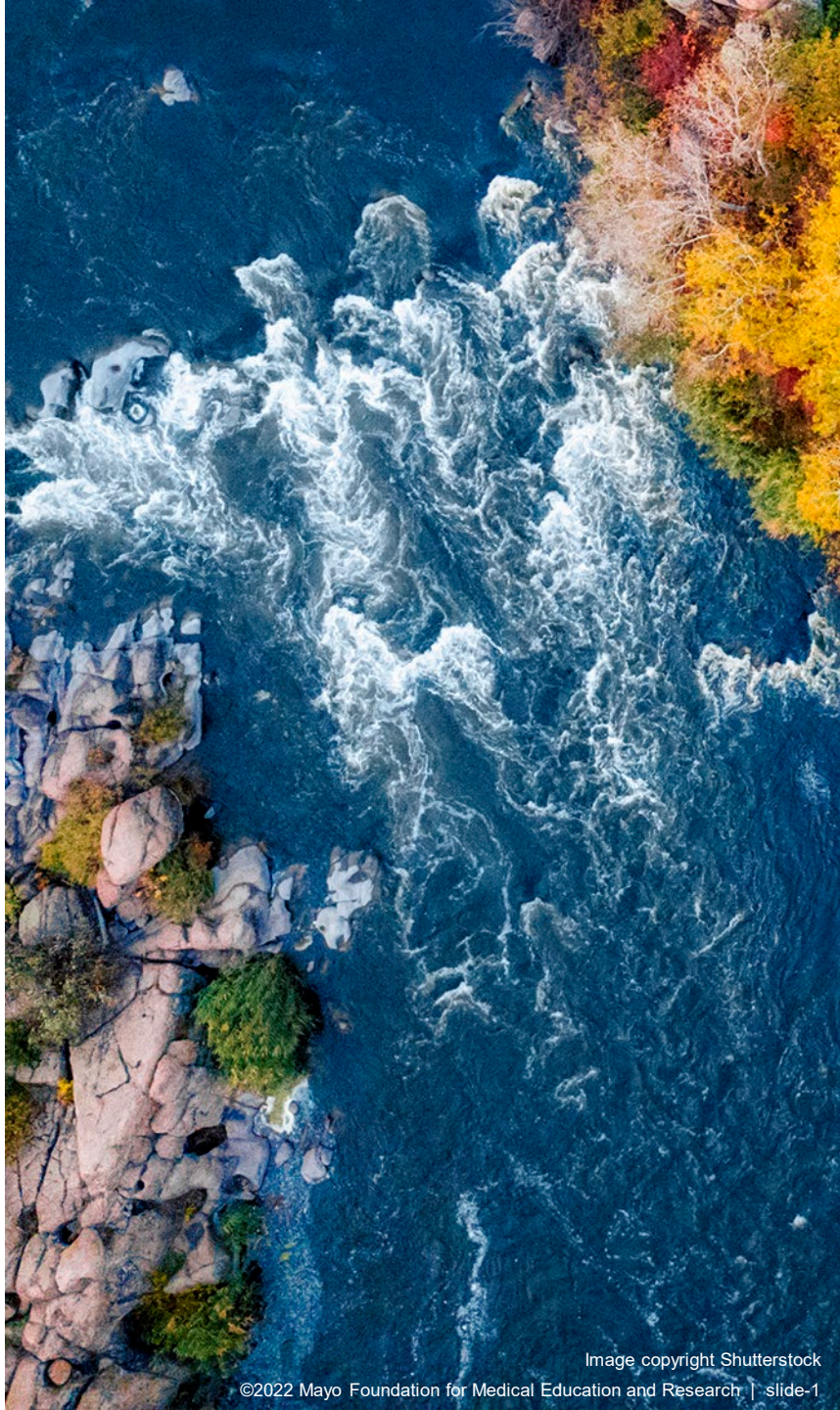
MAYO CLINIC

LOOKING BACK, LESSONS LEARNED

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

Courtney R Buckey, PhD, DABR
Mayo Clinic Arizona

2022 AAPM Spring Clinical Meeting
New Orleans, LA



RETROSPECTIVE ANALYSIS

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

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?

RO•ILS
RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

RO-ILS CASE STUDY 04:
SRS HETEROGENEITY CORRECTION AND COMMISSIONING

The RO-HAC discussed this event with the RO-ILS practice and appreciates their time and willingness to share more information in a confidential and protected environment. This excerpted and non-identifiable account of the event is being shared with the practice's permission in order to educate the radiation oncology community.

CASE EXAMPLE

Overview:

A qualified medical physicist commissioned a replacement intracranial stereotactic radiosurgery (SRS) program that included new hardware and software. The practice assumed that heterogeneity corrections were accounted for in the new treatment planning system (TPS) and included the base plate and accessories when contouring to account for their density in calculations. The result was a long physical pathlength but relatively short effective pathlength used in the dose calculations. However, the new planning software does not apply heterogeneity corrections, as indicated in the vendor supplied software manual. This 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. While the treatments were within acceptable national SRS guidelines, this difference was more than intended.

LESSONS LEARNED FOR THE RADIATION ONCOLOGY COMMUNITY AT LARGE

Commissioning of treatment planning software is standard work for all radiation oncology programs. Errors during the commissioning process result in systematic errors that affect many patients, and the clinical consequences can be severe.

- **Acceptance and Commissioning:**
  - All practices should review existing guidance on commissioning and acceptance testing, including 2019 Safety is No Accident, AAPM Task Group (TG) 106 on Accelerator Beam Data Commissioning and AAPM-RSS Medical Physics Practice Guideline (MPPG) 9.a. for SRS-SBRT.
    - Within the MPPG 9.a., it explicitly references tissue heterogeneities for SRS systems. A responsibility of the medical physicist is to "[p]erform acceptance testing and commissioning of the SRS-SBRT system, including validation of the treatment planning system accuracy with small fields and tissue heterogeneities (if relevant to the scope of SRS-SBRT services offered), [and] accuracy of targeting through end-to-end (E2E) testing…"
  - Adequate resources (time and staff) should be provided when commissioning.
- **Independent Verification Procedures:**
  - Peer review processes should include an independent verification (e.g., a second physicist should verify values from commissioning data to detect errors). AAPM TG-106 states: "…Check on the report and collected data. Have a qualified medical physicist perform an independent audit of the collected data and subsequent report."
  - External, independent end-to-end testing should be performed with standardized procedures and all equipment.
- **New Equipment:**
  - Whenever new equipment and/or processes are implemented, the entire team's focus on error pathways should be heightened. Extra caution should be taken, and staff should spend time in the planning stages examining how all the various components and stakeholders of the process will interact, particularly when different equipment and systems are integrated. Testing various scenarios may be helpful.

- **Training:**
  - Administrators should provide financial means and clinic coverage to support attendance at vendor supplied training.
  - New staff should also be eligible to receive specialized training (e.g., vendor provided training) to ensure that normalization of deviance is not transmitted between staff.
  - Staff competency should be assessed regularly and include knowledge of the use, functionalities and potential weaknesses of equipment.
- **Learning and Safety Culture:**
  - Practices should cultivate a high-quality safety culture, as demonstrated by this practice. Safety culture underlies a practice's ability to make improvements because it affects what and how staff learn and how practices adapt.
  - Regardless of experience, anyone can make an error. Additionally, a valuable indicator of a practice's safety culture is the comfort level of staff to speak up and be listened to. In this case, a junior physicist identified an error of more senior staff. This demonstrates the presence of a low power distance index in this practice, which is highly desirable. Low power distance index means that feedback is accepted between members of differing power levels within the practice.
  - Search satisfying bias, which is the tendency to stop looking once one explanation for an error is found, was not present in this case. This practice should be commended because they did not stop their investigation of this event until all sources of error were examined. It is crucial that practices conduct thorough investigations upon discovery of an error, as this practice has done.

LESSONS LEARNED FOR THE VENDORS

Heterogeneity corrections are now standardly accounted for in radiation dose calculations for many clinical systems. If a vendor software does not include heterogeneity corrections, this information should be prominently disclosed to the user. This may be done through mandatory attendance of a vendor training course or on-site vendor presence during the commissioning process. When designing and selling equipment, vendors must think extensively about how software and equipment would be utilized in the clinic and potential pitfalls during implementation. In this instance, it is not surprising that the practice wanted to account for the additional structure of the baseplate and accessories given its thickness. Extra instructions regarding heterogeneity in this instance from the vendor would seem prudent.

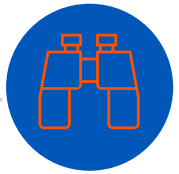
Optimal software design is also very important. Vendors have the unique opportunity to elevate practitioners' strengths and diminish their weaknesses by supporting them with equipment and software that is designed to act as a complementary safeguard. This may include functionalities such as:

- An alert that appears on screen during plan review indicating heterogeneity corrections information.
- Rather than stating that the practice defaults were being utilized, the software could state explicitly what setting is being utilized (e.g., heterogeneity off OR heterogeneity on).
- It would be helpful for software from the same vendor to contain consistent features. For example, employing the same alert indicating atypical heterogeneity corrections for the practice could be shown in various software.

LESSONS LEARNED

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**

MAYO CLINIC

TIME LEFT FOR DISCUSSION

Thank You For Your Interest In These Topics!

gweyakim@health.ucsd.edu
brthomad@wisc.edu
Buckey.Courtney@mayo.edu

