

Conflicts

None: Richardson, Showalter
Speaker for Elekta: Ouhb

Medical errors: definition, documentation, and reporting

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AAPM 2017

Outline

- Be familiar with current and future definition of medical event
- Understand the importance of information gathering during and after the event
- Be familiar with both in-house (yours) and regulatory guidelines when reporting an event

Do your homework in advance!

- Be familiar with the current definition of medical event (NRC and Agreement states*)
- Avoid surprises or simply misunderstanding: there is no free pass!
- When in doubts call you regulators and protect yourself and your institution
- Who should be making the call and when?(Time, administration informed etc.)
- Important to educate the brachy team about the meaning of ME and not wait for an event to inform them
- Explain and train them in data collection when needed
- Who is responsible to inform and educate staff about old and new definition? RSO/QMP
- Current proposals still not fully approved yet by the commission

Definition of ME

- From NRC and agreement states
- From institution

From NRC and agreement states

- Existing definition (Dose based).
- Proposed definition (Not approved yet): for permanent implant Source strength based.

Medical event in brachytherapy

A Brachytherapy radiation dose:

- Involving the wrong individual, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;
- Involving a sealed source that is leaking (*know what to do when faced with a leaking seed within a package*);
- When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or
- When the calculated administered dose differs from ***the prescribed dose by more than 20 percent from the prescribed dose.***

Survey slide!

- Few months ago we had March Madness
- March was also known for what?

Not a SAMs question!

March is also known for having "Patient Safety Week":

3/12---3/17/2017

Use it as a reminder to review your patient safety program!

Why should you report ME

- For punishment? Humiliation? I hope **not**!
- For the majority it is a *perception* and for some it probably was a *reality*. *Survey*
- For patient safety improvement and a regulatory requirement
- Good news: changes are in the way with the culture of safety, AAPM TG 288
- Underreported and preventable errors can and will probably cause serious patients injuries
- Opportunity for improvements after good data collection, analysis, and more important making that information available to everyone
- We owe it to our patients: solidify the trust and the institution transparency

AAPM TG 288

- **Charge:** "Develop a consensus format structure for use in a radiation-oncology incident reporting system to guide initial reporters through recording relevant narrative information about incidents clearly and more uniformly than simple free text".

Survey slide

- % medical errors: XX.X %
- near miss: XX.X %
- % would have no second thoughts in reporting their errors to regulatory agencies?
- % would rather not talk about it

Documentation of ME

- Who should participate in the documentation?
- Document what and how?
- Are there any guidelines?
- What is the purpose of the documentation?

Who should participate in the documentation?

- Everyone involved and present during the event (transparency)
- Every detail is useful
- Help identify all possible sources and remedies if enough information is collected for the evaluation team

Document what and how?

When witnessing an event:

- Priority is to maintain patient safety first
- keep track of time, items occurred, system messages, sequence of events, etc.
- Time for collective effort
- If event occurred in the past: constructive approach, team approach, no finger pointing or punitive approach, transparent, open.

None of this!!



Document what and how?

- Documentation should start as soon as it is known
- Gather specifics from start to finish.
- What took place and what happened. Not for punishment but for a better understanding

What is the purpose of documentation

- Regulatory agency: requirement
- Hospital risk management and attorney: requirement
- Help understand what happened and how to prevent it and help others to avoid it

Reporting requirements (RSO, Authorized User or Medical Physicist)

- Notify the department (regulatory) by telephone no later than the next calendar day after the discovery of the misadministration.
- Notify the referring physician of the affected individual and the individual or a responsible relative or guardian.
- These notifications shall be made within 24 hours after the licensee or registrant discovers the misadministration.

State regulator (next calendar day)

- Will take all information on the case
- Date of discovery of error (details)
- Error description (details)
- Authorized user and individual's names reporting the error
- Go over requirements: notifications, possible site visit etc.

Reporting process

- Check your institution guidelines
- NRC or agreement states: within 24 hrs.
- Notify your institution before the regulation
- You do not need a full report for this.
- Be prepared to give some facts
- If in doubts about an event, report it and let the regulators decide if a ME occurred
- Document your conversation: statements, person, date and time, any other requests.

Then what?

Based on the regulator feedback two options:

- Non-ME and no further information to be submitted. There is still work to be done internally to improve a possible near-miss.
- ME: instructions are provided to you (available in your guide) in what is expected from the institution.

Next step: written report

Within 15 days after the event a written report is to be submitted to the regulators and should include the following:

- The licensee's or registrant's name
- The prescribing physician's name
- The referring physician's name
- A brief description of the event
- Why the event occurred
- The effect on the individual
- The action taken to prevent recurrence;
- Whether the licensee or registrant informed the individual or the individual's responsible relative or guardian and what information was provided to the individual and if not, a written medical justification.
- The report shall not include the individual's name or other information that could lead to identification of the individual.

Example of a good report

On Tuesday, June 8, 2004 at 2:25 p.m., a patient was scheduled for an I-131 thyroid uptake with an oral dose between 5 and 20 microcuries. Instead, the patient was administered 9.15 microcuries (94 MBq), which resulted in an absorbed dose of 2675 rad to the thyroid (assuming a 55% radioactive iodine uptake) and 81 rad effective dose equivalent.

Each Month the Radiopharmacy prepares an oral solution of sodium iodide I-131 for uptake doses which are pipetted into individual patient dose vials. The sodium iodide I-131 uptake solution for June contained 12 microcuries per milliliter (mCi) in a total volume of 300 mL. The Radiopharmacy technologist prepared the uptake dose by pipetting one mL of solution into the patient vial, which should have yielded a dose of approximately 12 microcuries. The pipette that the Radiopharmacy technologist used to prepare this dose had been used earlier in the day to prepare therapeutic doses of I-131, and was labeled as the therapy pipette. The Radiopharmacy technologist did not realize that she had picked up the pipette labeled for therapy and assumed it was the pipette used for preparing the uptake doses. Usually the uptake pipette is stored in a shielded vial in the far right corner of the fume hood, but in this case, the therapy pipette was located in the far right corner. The Radiopharmacy technologist assayed the dose in the dose calibrator and noted that the reading was too high for an uptake dose. This caused the staff to question which pipette was used, and they confirmed that the therapy pipette was used. The Radiopharmacy staff discarded the dose in accordance with radioactive waste procedures, and proceeded to draw another uptake dose with the pipette labeled for uptake. One milliliter was drawn and assayed in the dose calibrator and read 0.915 mCi/mL. The Radiopharmacy technologist accepted the dose thinking that it was really 9.15 microcuries instead of 0.915 millicuries. The computer program is set up to accept I-131 uptake doses on the basis of correct volume and since the volume was within the acceptable range of 1 mL, the computer printed a label for the dose and it was dispensed. The nuclear medicine technologist followed the procedure for confirming the dose prior to administration by checking the patient name, ID number, the I-131 uptake procedure and checking the dose. She looked at the dose printed on the label and thought that the dose was 9.15 uCi instead of the what was printed on the label (0.915 mCi), and administered the dose to the patient.

The Radiopharmacy technologist became concerned about using the wrong pipette and contacted the Radiopharmacist, who then discovered the error. The therapy pipette contained residual millicurie amounts of therapeutic I-131 solution which contaminated the I-131 uptake dose.

B. Why the Event Occurred

The root cause was determined to be the lack of an adequate double check of the I-131 uptake dose prior to administration. A pipette contaminated with 2 millicurie I-131 was inadvertently used to prepare the uptake dose. The Radiopharmacy computer was programmed to detect volume errors, but not activity errors, so it accepted the dose and printed the label. The Radiopharmacy technologist did not detect the error when she assayed the dose for this second redraw, because she assumed that the activity displayed 9.15 uCi, rather than the actual activity displayed, which was 0.915 mCi. The nuclear medicine technologist who double checked the dose mistook the 0.9 mCi for 9 uCi on the dose label and administered the dose. She had been working in an imaging room, but was needed to cover the thyroid uptake room near the end of the work shift. This may have contributed to the error made when confirming the dose.

C. The Effect on the Patient

The absorbed dose to the thyroid was 2675 rad (assuming a 55% radioactive iodine uptake) and the effective dose equivalent was 81 rad. The patient is expected to return to xxxxx Hospital tomorrow (6/9/04) for treatment with I-131 for hyperthyroidism. The additional dose given for the uptake is a fraction of the dose that will be administered for therapy. The patient is not expected to have any adverse effects.

D. What improvements are Needed to Prevent Recurrence

A complete investigation was conducted to determine the root cause of the medical event. A new pipette will be used for each I-131 uptake patient dose, which will prevent the cross contamination. The computer will be re-programmed to accept uptake dose activity (i.e., 5 - 20 microcurie) rather than volume. The computer will not print a label for the uptake dose unless the activity is within the predefined range. The radiopharmacy staff have been trained not to over-ride the failsafe mechanisms of the computer. The nuclear medicine technologist will be retrained in the dose verification process prior to a dose administration. Both the Radiopharmacy technologist and the nuclear medicine technologist will review the dose units (i.e., microcurie, millicurie, MBq) and pass a test.

E. Actions Taken to Prevent Recurrence

1. A new pipette will be used for each I-131 uptake patient dose, which will prevent the cross contamination.
2. The computer will be re-programmed to accept uptake dose activity (i.e., 5 - 20 microcurie) rather than volume. The computer will not print a label for the uptake dose unless the activity is within the predefined range.
3. The nuclear medicine technologist will be retrained in the dose verification process prior to a dose administration.
4. Both the Radiopharmacy technologist and the nuclear medicine technologist will review the dose units (i.e., microcurie, millicurie, MBq) and pass a test.

Conclusion

- Medical events will always be here: some will be replaced by others
- Be up to date with current definitions and regulations: it is your responsibility
- Be prepared how to handle an event, do not get caught by surprise
- Be prepared on who to report to, what to report, how to report, and how to avoid similar events
- Educate everyone in your institution about this topic

The physics predicament of efficiency vs efficacy *and other ramblings....*

SUSAN RICHARDSON, PH.D., FAAPM

What *should* you do?

➤ Efficiency:

the state or quality of being efficient, or able to accomplish something with the least waste of time and effort; competency in performance

➤ Efficacy:

capacity for producing a desired result or effect; effectiveness



Hiker killed by falling boulder near Index



Woman plunges to her death while hiking in North Cascades



Hiker dies on Mount Rainier near rockfall area



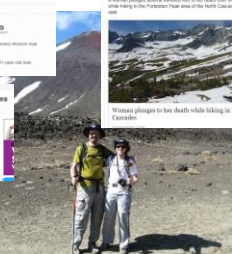
WWU student dies in Methow Valley climbing accident



Body of man who fell from cliff at Palouse Falls State Park located in river



Seattle man dies after plunging into crevasse on Mount Rainier



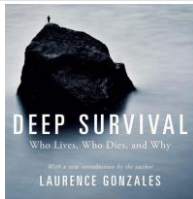
Empathy

The basis of both empathy and of learning is humility.

When we are willing to learn something, that means we were humble enough to recognize that we were deficient in that area. When we ask for instruction, we are acknowledging that the teacher knows something we do not. When we realize that we could just as easily have made the same mistake as that guy, we can start to see the complexities of what happened and why. This is the gateway to a more complete understanding of how to stay safe in the wilderness. ~~clinic.~~

<http://outontheborder.com/hiking-empathy/>

Survival – for you, and the patients



“Gradually I developed the idea that to survive, you must first be annealed in the fires of peril.”



Wilderness or Brachytherapy?

- Don't be proud that you have survived; be thankful.
- Don't condemn others for failing; learn from them.
- Don't be afraid to get out there, but do be aware of the risks and prepare accordingly.



Daily QA

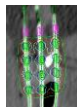
1. Electrical interlocks at entrance to room
2. Source exposure indicator lights on the after loader, control console, and in the facility
3. Viewing and intercom systems
4. Emergency response equipment
5. Radiation monitors to indicate source position
6. Timer accuracy
7. Clock (date and time) in unit's computer
8. Decayed source activity in unit's computer

6. Timer accuracy – part 1

- Measure the accuracy of delivery within +/- 1 second
- How important is this? Typical T&O delivery is ~8-10 minutes.
- Assuming 3 cycles, $3 \times 0.1667 = 0.5$ dose error (assuming linearity)
- We get +/- 20% for fractionated cases!
- The good news, this is a relatively easy test, and you can combine it with other ones (hey, you can be efficient! E.g. measured timer error at the same time you do positional accuracy).

6. Timer accuracy – part 2

- Measure the accuracy of delivery within +/- 1 second
- Let's assume, that each DWELL position has a 1 second error. (the rules don't say *how* this test is done, just to DO it).
- Each dwell is 1.3 seconds. If we are off 1 second on each dwell, we are at 176% of the dose!

[illegible]

5. Radiation monitors to indicate source position

- Every day, we measure the source position ± 1 mm.
- I will point out the obvious: this is not in a patient.
 - So what does that mean in terms of efficacy?



5. Radiation monitors to indicate source position

- Measuring where the radiation source is in a fixed phantom geometry is EASY.
- Measuring where the radiation source is in a patient is HARD.
 - Source in the afterloader on a wire – uncertainty in motor mechanics
 - Source goes into a TGT – uncertainty in TGT measurement
 - TGT goes into an applicator – uncertainty in connection/length
 - Applicator goes into a patient – where is my patient?

Slides borrowed from Jay Reiff:
<http://amos3.aapm.org/abstracts/pdf/68-19948-234349-87415.pdf>

Commonly reported Scenarios

- Multi-catheter APBI devices
- Length was incorrectly measured due to a faulty measuring device (kinked wire)
- Length was incorrectly measured due to a blockage in the catheter/applicator system
- Error range: 2 – 10 cm

More on positioning

pro

- 11 times: measuring the applicator length incorrectly or entering the length into the treatment planning system incorrectly.
- Most commonly in APBI applicators
- 5 reported events involved the catheter length being wrong and subsequent irradiation to the wrong part of the patient's breast.
- There 3 instances in the 2-3 cm range.
- There were 2 instances where the distances were off by 10 cm

Original Report

A 2-year review of recent Nuclear Regulatory Commission events: What errors occur in the modern brachytherapy era?
Susan Richardson PhD*



Hey, that person should have just measured their applicator length!

- This was the first time the institution had used that particular applicator
- The physicist DID measure the length, but was thought to have not pushed hard enough to get through the bends in the device
- The treatment was attended by a representative of the company who said the length "sounded right."
- All other daily QA tests were performed to satisfaction/regulation!



Let's return to this

And ask ourselves, what are we really proving?



3. Viewing and intercom systems

Seeing and listening to your patient – very important

- Can interrupt your treatment if patient has a problem
- Can stop treatment if your patient jumps off the table
- What does your patient look like??

Do you have the right patient on the table??

- Some/Most HDR systems do not have an active R/V system with automatic time out
- Who does the time out in your clinic?



Wrapping up

- We aren't learning from our mistakes because
- we get more and more confident every day we don't have one and b) we believe these things could never happen to us.
- But they happen to someone, so it could be us.



What do survivors do?

- Perceive and Believe
- Stay Calm
- Think, plan, and analyze
- Take decisive action
- Celebrate success



An Interactive Session for New
Brachytherapy Practitioners




Physician Perspective on Improving Safety by Learning from Mistakes

August 1, 2017
Timothy N. Showalter, MD, MPH
Associate Professor



Department of Radiation Oncology

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Overview of Content

- Culture of safety
 - Mitigating “Second Victim” effect
- Learn locally
 - But think globally
 - Examples:
 - Learning from local events
 - Anticipating local events (group thought studies)
 - Learning from registry events

[illegible]

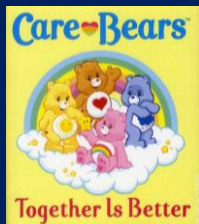
Avoid Blame at All Costs

- Radiation oncology departments are multidisciplinary, but with power imbalances
- Focus should be on process and policy
 - Not relying on individual's decisions
- Identify and ameliorate pressure points that expose patients and staff to risk
 - Recognize that having system that allows errors is unfair to both patients and staff

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Warning:
Warm and Fuzzy Moment Coming



The "Second Victim" Phenomenon

- Described by Albert Wu in 2000
 - Story: resident failed to recognize EKG signs of pericardial tamponade during overnight shift
- Error leads provider to question competence
- Lack of support
- Diverts attention from systematic improvements to decrease errors
- Providers need to provide sympathy and to discuss their own errors

Wu BMJ 2000

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Medical error, incident investigation and the second victim: doing better but feeling worse?

- 2012 update in contemporary safety era
- Increased attention to communicating with patients and families
- Less progress in supporting frontline clinicians
- Healthcare budget pressures to do more with less
- Institutional environment must be supportive— even better if formalized
 - “This must be very difficult for you. How are you doing?”

Wu BMJ Qual Saf 2012

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Remember the Second Victims

- Rad onc = multidisciplinary → hands-on personnel often not the top dog
 - Often, the top dog makes the policy and sets expectations
 - Policy & procedures should protect against errors
- Promote blame-free environment
- Morale and supportive environment essential ingredients for safety

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Learning Locally: Brachytherapy Events

- Small size of brachytherapy team is conducive to “culture of safety”
 - Co-location of personnel
 - Workflow often creates time windows for brief meetings for safety/QI discussions
- Recognition of unique challenges of brachytherapy may weaken “second victim” effect

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Learning Locally: Sources of Material

- Events and near-misses within the institution
 - Encourage reporting in existing systems
 - Focus on processes to avoid future errors
 - Creating error free systems
- Using events reported in national systems to stimulate group discussion with local context
 - e.g., NRC reports
- Anticipatory program-specific quality control processes
 - e.g., failure modes and effects analysis

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Learning from a Local Event

Example Local Events: Contamination

- ? of clogged lumen of multichannel balloon on CT
- Proceeded with treatment
 - Measurements okay
- Post-treatment investigation confirmed blood within that channel
- Entire HDR program shut down for sterilization and source exchange



Figure 1. Treatment planning CT image of multilumen balloon brachytherapy applicator. Note transition from clear to obstructed catheter lumen (marked by arrows). In retrospect, this was the first clinical finding to suggest contamination of the applicator with biological material.

2016 ABS Brachyblast

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UVA Brachy Team Safety Discussion: Changes Implemented

- Stop, investigate and contain any suspected contamination
 - Visual inspection of device
 - Placement irregularities
 - Evaluate imaging
 - Check distal end of device with wire (may limit contamination)
 - Use wire to measure length
- Avoid treatment via channel of concern
- For balloon brachy, we now remove the packaged obturator from channel 5 before insertion

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Example Local Near-Miss: Contamination

- For GYN interstitial case, 1 of 11 flexineedles noted to have friction during catheter and transfer tube length measurement
- Wire confirmed biological material in channel
- Channel not used for treatment
- Sterilization: transfer tube and race track
 - HDR program **NOT** shutdown

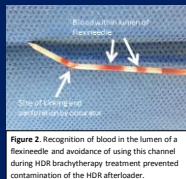


Figure 2. Recognition of blood in the lumen of a flexineedle and avoidance of using this channel during HDR brachytherapy treatment prevented contamination of the HDR afterloader.

2016 ABS BrachyBlast

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UVA Brachy Team Safety Discussion

- As a result of policy, the impact of the contamination was mitigated by early action and containment
- Additional policy changes:
 - confirm that obturators fully inserted to avoid kinking
 - Vigilance for biomaterial or abnormal friction during measurements

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Think ahead locally, too.

Quality Control Processes for Brachytherapy: A valuable safety tool



Brachytherapy 14 (2015) 366–479

BRACHYTHERAPY

A failure modes and effects analysis study for gynecologic high-dose-rate brachytherapy

Jyoti Mayadev^{1,2,*}, Sonja Dieterich¹, Rick Harse¹, Susan Lantz¹, Mathew Mathai¹,
Sanita Boddia¹, Marianne Kern¹, Jean Courquin¹, Robin L. Stern¹

¹Department of Radiation Oncology, University of California Davis Medical Center, Sacramento, CA
²Department of Radiation Oncology, Scott and White Memorial Hospital, Temple, TX

FMEA: failure modes and effects analysis

- Process broken down into individual steps
 - Each step analyzed
- All potential modes of failure identified
 - With possible causes
- Each failure mode ranked 1-10 in 3 categories:
 - Probability of occurrence
 - Severity of possible consequences
 - Ability to detect failure
- 3 scores multiplied for risk priority number (RPN)
 - Target highest RPN scenarios and processes for process improvement

Mayadev et al. Brachytherapy 2015

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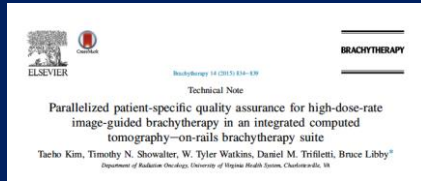
- ## FMEA for GYN HDR Brachy: Lessons

- Highest RPN failure modes included:
 - Missing error during physics check of plan
 - Applicator/patient movement after insertion
 - Inadvertent dwell change after MD review before plan export
- This knowledge influence change practice/policy:
 - Prioritizing time for physics check
 - External fixation equipment
 - Checklists

- ## Patient Safety in Dedicated IGBT Facility

- Fully integrated facilities can enhance workflow, but compresses time for safety checks
 - Preserving pauses for safety becomes a unique challenge
- Important to codify institutional policies on quality and safety within context of rapid workflow
 - e.g., dealing with interfering tasks (i.e., my clinic)

QA in Integrated IGBT Suite



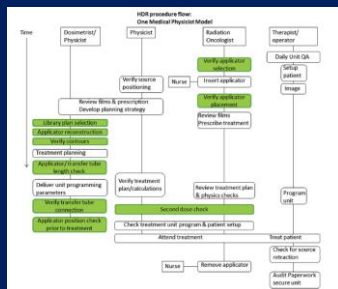
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UVA Parallel QA Procedure

- Follows ABS guidelines for gynecological brachytherapy
- Adaptation of TG-59 specified tasks for QA
- Considers which tasks can be performed in parallel vs step-wise fashion
 - Prioritize efficiency
 - Maintain/improve patient safety

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UVA's IGBT QA Workflow

- Applies local context to existing national guidelines
- Physicist led, with input from others:
 - Dosimetry/therapist
 - Other physicists
 - Physician
 - Supported by MDs and nursing

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Looking Globally for Local Lessons

Learning from Others' Events

- 33 HDR brachytherapy events in NRC system 2009-2010
 - Wrong site: 20
 - Wrong dose: 9
 - Unintended exposure: 3
 - Other: 1
- "Human error" the most frequently cited cause

Richardson PRO 2012

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Review of NRC Events

- Most common error was measuring applicator length or entering length into TPS incorrectly
 - Most common in APBI applicators
- “Each event provides a unique learning opportunity where new quality-assurance processes can be directly created and implemented in response to an event.”
- Multiple people measuring length recommended
- Verification of length in TPS

Richardson PRO 2012

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Specific Example: Wrong Site for Vaginal Cuff Brachytherapy

- Recent NRC report of wrong site error during vaginal cuff brachytherapy
 - Cylinder was erroneously inserted into rectum
 - Also reported in 1993 and 2013 at other centers
- UVA team asked:
 - Could this happen here? (YES)
 - How can we avoid this?

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Specific Example: Wrong Site for Vaginal Cuff Brachytherapy

- Applicator insertion with posterior boundary
 - Best practice is for RO to place a digit on the perineal body at the posterior border of vagina during insertion
- Insertion until cylinder stops at the vaginal cuff
 - Tactile feedback to ensure contact with cuff
- Imaging confirmation when available
 - (we use clear acrylic at UVA)
- Time out procedure with tailored checklist
 - Cylinder size, vaginal length/insertion depth

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Lesson Implemented: Vaginal Cuff Brachytherapy

- Wrong site error *almost* happened at UVA while I was away
- Team member awareness, alertness to issue identified the problem

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Learning from Mistakes: A Model for Safety

- Mistakes and near misses = opportunity to improve patient safety
 - Lessons/changes vary among centers
 - Culture and forum needed for open discussion
- Need written policies and checklists to enact change
 - But, also need ongoing vigilance and buy-in
- Level of formality of safety meetings may vary among centers
 - At UVA, was formal at first, now built-in to work

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Summary: Learning from Medical Events to Improve Safety

- Events and near misses are both focus for prevention & learning opportunities (“lemonade”)
- Brachytherapy teams can use events and near misses as learning material within “culture of safety”
 - Recognize and ameliorate “second victim” effect
- Learning material available locally, globally and via simulation (e.g., FMEA)
 - Implications viewed from local context/team to prevent errors

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