Medical errors: definition, documentation, and reporting

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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 for ME 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*). Survey
- 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 and update 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 % (10%?)
- near miss: XX.X % (47%?)
- % would have no second thoughts in reporting their errors to regulatory agencies? (98.7%?)
- % would rather not talk about it (0.3%?)

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

Are there any guidelines?

- Yes (from regulations) but perhaps not enough
- Reports lack valuable information
- Breakdown in the communication (regulators-institution)?
- Need of a standard form with mandatory items for better understanding, information sharing, analysis, education, prevention etc.

What is the purpose of documentation

- Regulatory agency: requirement
- Hospital risk management and legal (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 (or NRC) 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
- Will 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 microcurie. Instead, the patient was administered 915 microcurie (34 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 microcurie per milliliter (ml) 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 microcurie. 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 uptakes. 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 microcurie instead of 0.915 millicurie. 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 circling 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 (ie., 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: old and current ones will be replaced by new ones (like med. Phys.)
- Be up to date with current regulations: it is your responsibility!
- Be prepared in how to handle an event, avoid being caught by surprise
- Understand and prepare for: when to report, what to report, how to report, corrective actions to avoid similar events
- Educate everyone in your department about this topic