Enhancing Our Safety Culture by Understanding Recent Mishaps (Part 2): Brachytherapy

Bruce Libby, PhD
Associate Professor and Chief of Clinical Brachytherapy Physics
University of Virginia Health System

Conflicts of Interest

• Royalties from UpToDate.com

Learning Objectives

• To review and understand the root causes of brachytherapy medical events
• To review and understand corrective actions that should be in place
• To review and understand the established recommendations for safe delivery of brachytherapy and to foster a culture of safety
• To discuss communication among users, seed vendors, and TPS makers on use of identical terminology to reduce possible sources of errors
Recent Work

Strategies to Prevent Errors in Brachytherapy: Learning from our Mistakes
R. Lee, MD
World Congress of Brachytherapy
Barcelona, May 2012
A 2 Year review of recent NRC events: What errors occur in the modern brachytherapy era
Susan Richardson
Practical Radiation Oncology
Volume 2, Issue 3 (2012)
“Those who cannot remember the past are condemned to repeat it.” - George Santayana

“Everything old is new again”

Peter Allen, All That Jazz

Britney Spears

OOPS I DID IT AGAIN
“Lessons Learned From Investigations of Therapy Misadministration Events”
Lee Ostrum, et al
IJROBP 34:227-234 (1996)

7 Events categorized (5 brachytherapy)
• Event 1- HDR- wrong data card was used to treat the patient
• Event 3- Manual LDR- wrong sources were used in a Henschke applicator
• Event 5- Manual LDR- source ribbons came out and nurse taped them to the patient’s abdomen
• Event 6- Manual LDR- sources were 0.79 mgRaeq, physicist recorded 0.79 mCi
• Event 7- HDR- source broke off inside patient, radiation monitors ignored (Indiana PA event)

Direct Causes of Medical Events
• Organizational policies and procedures
• Lack of training and experience
• Lack of supervision
• Decision errors
• Hardware failures (only event 7 was due to hardware failure)
Conclusions

- Many medical events occur primarily due to an absence of procedures
- Changes in routine (exacerbated by lack of policies and procedures)
- Hardware failures seldom occur but they can lead to severe consequences!

Event 6

- Ir-192 seeds were ordered in mg-Raeq, plan was performed in mCi (pre 1996)
- TG-43 introduces the concept of Air Kerma Strength (U) to replaces activity, mg-Raeq (1995, with updates in 2004, 2007)

| Physics Resident 1 | 1.76 | 7.24 |
| Physics Resident 2 | 1.79 | 7.21 |
| Junior Physicist   | 1.79 | 7.23 |
| Senior Physicist*  | 1.79 | 7.21 |

* asked the mfr for the conversion factors that the mfr used
From the Manufacturer’s Web site (July 9, 2012)

“We are the first and only provider of Iridium 192 in nylon ribbons in a wide range of activities from 0.10 to 10 mg Raeq per seed or 0.3 to 30 mg Raeq per centimeter.”

Event 7

- NUREG 1480 “Loss of an Ir-192 source and therapy misadministration at IRCC, Indiana, PA on November 16, 1992”
- Machine error made worse by human error

Executive summary

- An area radiation monitor in the treatment area was observed in an alarm condition when the source should have been retracted
- Three technologists and the MD were aware of the alarm condition, a room and patient survey was not conducted
- The treatment console reported that the source was “safe”
- The staff claimed to have had experienced difficulties with the area radiation monitor (Primalert) but errors could not be reproduced
Hardware Malfunction

- Source broke off inside the patient
- Manufacturer's emergency procedures were to manually retract a stuck source wire
- Breakage was not considered possible by the manufacturer

Policies and Procedures Malfunction

- No systematic radiation safety training to the staff
- Manufacturer's emergency procedures did not include radiation safety
- Expectation that the medical director or medical physicist would provide safety training (which was not done)

Policies and Procedures Malfunction (cont’d)

- Staff failed to respond to the radiation alarm
- Technologist reset the radiation monitor by unplugging it
- No radiation survey with a survey meter was performed
- Patient wound up received a dose of 16000 Gy (prescribed dose was 18 Gy)
“The safety culture at IRCC contributed significantly to the event. Technologists routinely ignored the Prim-Alert 10 alarm. Its problems were worked around and not fixed. Technologists did not survey patients, the afterloader, or the treatment room following HDR treatments. No one was sure who was responsible for radiation safety training or the radiation safety program. The authorized user failed to wear a film badge on both occasions when the source was encountered.”

Hooray for physicists

• A second source wire broke on Dec. 7, 1992 in Pittsburgh (same consulting group as Indiana, PA incident)
• The physicist was aware of the previous issue and recognized the problem, with proper intervention

Analysis of Treatment Delivery Errors in Brachytherapy Using Formal Risk Analysis

B. Thomadsen, et al
Process Trees and Fault Trees were developed (TG100)

Majority of LDR errors
- Wrong sources loaded
- Sources not loaded properly
- Wrong units entered in the treatment planning system
- Sources not fixed in applicator (or applicator in patient)
- 75% of treatment errors were during treatment delivery

HDR errors
- Most common error was a failure to enter the correct treatment distance (default distance was used)
- Other errors included incorrect connection between applicator and treatment channel, incorrect source strength, applicator shift in patient, source drive mechanism
BrachyVision Applicator Properties

Default is 130 cm (usually longer than needed)

“Interfering Tasks”

- Important in HDR as compared to LDR, because more actions are compressed into a very short duration, and distractions can divert attention long enough to cause a problem
- As IGBT becomes more common, this could be an increased problem

Image Guided Brachytherapy Suite at the University of Virginia

Siemens Somatom CT-on-rails
Trumpf OR couch (w/ carbon fiber insert)
Siemens Somatom CT-on-rails
Anesthesia
Words of Wisdom

“Your job is stay off the front page of the newspaper”
NY Times Article

- Most of the seeds, 40 in all, landed in the patient's healthy bladder, not the prostate.
- MD rewrote his surgical plan to match the number of seeds in the prostate
- That was the correct procedure! (10CFR 35- "After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose)."

NY Times Article (cont'd)

- Botched 92 of 116 cancer treatments over a span of more than six years
- The team continued implants for a year even though the equipment that measured whether patients received the proper radiation dose was broken
TG 137 recommendation

Postimplant dosimetry at the nominal optimal dosimetry time for respective radionuclides. Because of the existing dose-response data, the postimplant dosimetry for 125I implants should be performed at 1 month (±1 week) after the procedure. For 123I and 125I seeds, postimplant dosimetry should be performed at their respective nominal optimal times, 10 ± 4 and 10 ± 2 days, respectively.

Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection
Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania and Other VA Medical Centers

http://www.va.gov/oig/54/reports/VAOIG-09-02815-143.pdf
Released May 3, 2010

VA OIG Report Conclusions

- Wrong seed activity for one case due to pre-printed order form
- No evidence of record falsification
- QMP program deficient
- No post-implant dosimetry for 12 months
- “Clinical Outcomes” within the norm
- Two other VA hospitals were not performing post implant dosimetry
- Criteria for medical event is controversial
What is a medical event in permanent brachytherapy?

10CFR35
- Wrong Patient
- Wrong Site
- Wrong Isotope
- Wrong Dose

ASTRO Working Group
Problems in using dose
- Timing of post implant dosimetry
- Imaging modality differences
- Observer variability
- Planning margins may vary
- Planning system uncertainties
- Seed Migration (administration vs. result)
ASTRO Recommendation

- Source strength based criterion (>20% of source strength implanted outside PTV) is more appropriate for defining ME in permanent brachytherapy.

Definition of Medical Event in Permanent Implant Brachytherapy
NRC-April 24, 2012

W. Robert Lee, MD, MS, MEd
On behalf of the American Brachytherapy Society (ABS)
Process Trees/TG100

- Brachytherapy is well suited to the creation of process trees because we are used to working with checklists.

### Daily QA Check List

- [QML1] Quality Management Policy
- [QML2] Quality Management Plan
- [QML4] Quality System
- [QML5] Training Program
- [QML6] Equipment Maintenance
- [QML7] Radiation Safety
- [QML8] Quality Control
- [QML9] Environmental Management
- [QML10] Safety

### Eye Plaque Process

- Skilled is referred for consult as Radiation Oncology, corresponding referral to and of the date of the consult.
- [QML11] Articulation office issues event result to Oncology Imaging, including tumor diagram.
- [QML12] Daily QA Check List
- [QML13] Eye Plaque Process
- [QML14] Patient is referred for consult with Radiation Oncology, nursing and resident notifies BL of the date of the consult.
- [QML15] Ophthalmologist office faxes exam result to Radiation Oncology, including tumor diagram.
- [QML16] After consult, Physics is given diagram of eye with tumor location and size.
- [QML17] Questions about tumor location and use of notched plaque answered.
- [QML18] Physics develops plan and consults with Oncology office of proposed dates of implant. Plan is done using COMS dose calculation software, with 70% confidence level.
- [QML19] Prior to implant, the dose calculation must be the COMS button is showing (not USC).
- [QML20] Note: Preplans cannot be finalized without QA dates due to seed activity.
- [QML21] Preplans are checked for finalization by resident and consultant, and are reviewed by the Radiation Oncologist.
- [QML22] Seeds are ordered and the order is checked.
- [QML23] Seeds are received and assayed. Assay is checked.
- [QML24] Plaque is prepared.
- [QML25] Assayed value entered into preplan. Tentative on and off times communicated to Ophthalmology.
- [QML26] Plan second check performed.
- [QML27] OR-plaque is placed, plaque on time entered into preplan.
- [QML28] Source assay and on time, off time is calculated and communicated to Ophthalmology.
- [QML29] Final plan is printed. Preplan, written directive, and final plan are scanned into MOSAIC.
- [QML30] Source assay, on time, off time, final entered into physics consult for Radiation Oncologist to sign, copy is sent to Ophthalmology.
Other Issues

Seed Ordering

Is there a way for physicists, seed vendors, and TPS vendors to speak a common language?
Seed Registry

VariSeed Software

Labels for Type A Package

(Courtesy Lory Bradley Oncura)
BrachyVision Source Properties

Issues with Physicists

- Seed ordering
- Seed returning
Seed Ordering Errors

- Incorrect patient name or name does not match order and plan
- Incorrect source model number on plan
- Incorrect quantity of seeds on order form or needle loading plan
- Seed quantities not broken down correctly (preloaded linked vs. preloaded loose)
- Incorrect address
- Incorrect PO #
- Customer marks I-125 and Pd-103 on order forms or enters info in both locations

(courtesy Kurt Maffei, Bard)

Even more errors (returns)

- No package return authorization number or FedEx tracking number
- No hospital name, contact number, city or state
- No sales order number
- No Hazardous Goods Declaration or improperly filled out Declaration

(courtesy Kurt Maffei, Bard)

Still More Errors (Seed Returns)
Mick Cartridges Returned

Bad Needle Return

Bad Linked Seed Return

(courtesy Kurt Maffei, Bard)
Where do we go from here?

For Agreement states are there central repositories of medical events? (what can manufacturers do to assist in reporting?)

Technical Service Bulletins

Conclusions
• “Greed is good” - Gordon Gekko
• “Fear is good” - Bruce Libby

Walt Bogdanich wants to talk to you about your brachytherapy program

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