Advancing Safety in Brachytherapy

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Acknowledgements

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Educational Objectives

• Errors: where and what (in general).
• Become familiar with the “Safety culture” concept and some key issues identified for strengthening it.
• Become familiar with a few practical process improvement strategies.
Introduction

• For those who may be unfamiliar...

• Implant radioactive sources into prostate
  • I-125, Pd-103, Cs-131
• Monotherapy or combined with ExtB
• Template guided
• Transperineal approach
• TRUS: primary imaging modality in OR
Introduction

• Exciting Times
  • Introduction of new isotope
    • Cs-131
  • Further standardization recommendations on dose Rx and reporting methods
  • Intraoperative planning continues to develop
  • Innovative implant techniques
    • Robot-assisted
  • Studies on the effects of edema, RBE, and dose heterogeneity
  • …and more


Introduction

• **Sobering Times**

• **The New York Times articles:**
  • At V.A. Hospital, a Rogue Cancer Unit (June 20, 2009)
  • Radiation Offers new Cures, and Ways to Do Harm (Jan. 24, 2010)
  • They Check the Medical Equipment, but Who Is Checking Up on Them? (Jan. 27, 2010)
  • As Technology Surges, Radiation Safeguards Lag (Jan. 27, 2010)
  • At Hearing on Radiation, Calls for Better Oversight (Feb. 27, 2010)
Introduction

“Each of us has a responsibility to increase patient safety and improve the quality of care.”

Michael Herman, Ph.D. (AAPM President); AAPM Newsletter Mar/Apr 2010.
Errors & Mistakes

• Physicists thrive on improving quality
  → often leads to mechanical/system complexity
  → leads to increased opportunities to make an error.

• Mechanical
• Human
• Process

LDR Brachy
Errors & Mistakes

• Take a look…


• Where? (LDR): source prep, loading, unit conversions, applicator placement

• What caused? (LDR): failure to detect, procedures, resources/conditions
What now?

• What are we to do?
  • Try harder?...get more training?
  • Maintain...and wait to find out?

• Revise our processes?
• Increase QC and/or add more QA tests?

• This is NOT a new problem.
“Over all, the implant program lacked a “safety culture,” the nuclear commission found.”

The New York Times

At V.A. Hospital, a Rogue Cancer Unit. June 20, 2009
Safety Culture

• There is a wealth of information out there.
  • Aviation and Nuclear Industry
  • IAEA
  • NRC
  • Wikipedia

• Did you know?
  • Safety Science Journal
    “...an international medium for research in the science and technology of human safety.”

http://www.elsevier.com/wps/find/journaldescription.cws_home/505657/description#description
Safety Culture: Definitions

• Aviation Industry (good working definition)

• Safety Culture: “…refers to the extent to which **individuals and groups** will **commit** to personal responsibility for safety; **act** to preserve, **enhance** and **communicate** safety information; strive to **actively learn**, **adapt** and **modify** (both individual and organizational) behavior based on lessons **learned from mistakes**; and be held **accountable** or strive to be **honored** in association with these values.”

Safety Culture: Definitions

• NRC
  • “Characteristics of a strong safety culture include:
    • valuing safety over production,
    • adhering to procedures,
    • supporting conservative decision-making,
    • maintaining a questioning attitude, and
    • conducting problem identification and resolution.”

Safety Culture:
Promoting/Strengthening

International Nuclear Safety Advisory Group,
Key Practical Issues in Strengthening Safety Culture,

- Commit to safety
- Use procedures
- Conservative decision making
- Reporting Culture
- Challenge Unsafe Acts / Conditions
- The Learning Organization
- Underpinnings: Communication, Clear Priorities, and Organization
Safety Culture: Promoting/Strengthening

- **Conservative decision making**
  - Stop and review safety before beginning to carry out a procedure.
  - S.T.A.R. (Stop, Think, Act, Review)
  - S.L.A.M. (not in INSAG-15)
    - Stop, Look, Assess, Manage

- **Reporting Culture**
  - “Failures and ‘near misses’…”
  - “Near misses…present a greater variety and volume of information for learning.”
  - “A good reporting culture will be regarded by staff as ‘just’ and will be built on an atmosphere of trust.”

Safety Culture in Action

- **Risk Analysis** and Reporting
  - Fosters: Learning
  - Fosters: Reporting Culture
  - Fosters: Communication, Clear Priorities, and Organization
Safety Culture in Action: Risk Analysis

• **Tools**
  • Root cause analysis
    • What? and Why?...Retrospective
  • Process tree
    • What and Where did...? Retrospective (generally), but can be Prospective
  • FMEA (Failure Mode and Effects Analysis)
    • What, How and Where could...? – prospective, and prioritize by risk
  • Fault trees
    • Complements FMEA – OR vs AND (detailed look at PFM)
Process Tree: Prostate Seed Implant

1. Notify, Schedule
2. Pre-Plan Dosim
3. Pre-Plan Prep
4. TRUS  
5. Paper-work Prep
6. Seed Order
7. Receive, Assay
8. PrePlan Physics Check
9. Source Prep for Case
10. Rad Safety paper work on d0
11. Post Implant Physics Check
12. Post Implant CT d0
13. Post-Plan Dosim
14. Paper-prep
15. Final Physics Check
16. Chart Rounds

• Global view
• Which branches are breaking.
• Identify and implement solution(s).
• Observe for effectiveness.

• Threshold: # of breaks?, severity?
• Could be used for near-miss
  • Requires good reporting
• Retrospective…but could be Prospective with practice
### Safety Culture in Action: Risk Analysis

**FMEA**

- **Implement Solution**
- **Potential Failure Mode Identified**
- **“Current” Process or Procedure**
- **Probability of Occurrence, O, in current process (1 – 10)**
- **Likelihood of Undetection, D, in current process (1 – 10)**
- **Severity, S, if occurs and not detected (1 – 10)**
- **RPN = O \times D \times S**
  - Address largest RPNs
  - 125 or higher (industry)

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[http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis](http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis)
**Safety Culture in Action: Risk Analysis**

- **FMEA (example)**
  - *(Branch 9) $F_{pot}$: Use of wrong I-125 sources for implant.*
    - **Potential Causes**
      - Human: Mislabeled storage container
      - Human: Two patients with similar names (inattention in selection)
      - Process: Verification Failure
    - **Occurrence, $O$: 3**
      - Low likelihood of occurring
    - **Non-Detection, $D$: 6**
      - Less likely to be detected if it does occur
    - **Severity, $S$: 7**
      - Potentially severe outcome if occurs and not detected
    - **RPN = $O \times D \times S = 3 \times 6 \times 7 = 126$**
Safety Culture in Action: Risk Analysis

- FMEA
  - For more information:

Safety Culture in Action

- **Risk Analysis and Reporting**
  - Fosters: Learning
  - Fosters: Reporting Culture
  - Fosters: Communication, Clear Priorities, and Organization
Safety Culture in Action: Reporting Errors

- **Error Reporting**
  - **Washington Univ. in St. Louis**
    - Web-based Error Reporting
  
  - **Princess Margaret Hospital**
    - QA review of incident reports (external beam)

- **Mayo Clinic**
  - Plan Check Scoring system (0, Other, 1, 2)
Safety Culture in Action: Reporting Errors

- **2008-2009**
- **More than 41% are “other”**
- **Includes pre- and post-implant evaluation**

- No dose deviations to patient.
- All Others were
  - Documentation
  - and... Near misses

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<table>
<thead>
<tr>
<th>Year</th>
<th>&quot;0&quot;</th>
<th>&quot;Other&quot;</th>
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<tr>
<td>2007</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>2008</td>
<td>95</td>
<td>4</td>
</tr>
<tr>
<td>2009</td>
<td>90</td>
<td>5</td>
</tr>
</tbody>
</table>

*PSI Scores 2007-2009*

- "0": no deviations and/or dose within 5% of that prescribed
- "other": unintended deviation from prescribed dose > 5% or any noted deviation from procedures or missing documentation.
- "1": unintended deviation from prescribed dose > 10% and/or no written directive.
- "2": unintended deviation from prescribed dose ≥ 20% and/or wrong patient, wrong isotope, wrong treatment site, or leaking source.
Safety Culture in Action: Reporting Errors

“0” no deviations and/or dose within 5% of that prescribed
“other” unintended deviation from prescribed dose > 5% or any noted deviation from procedures or missing documentation.
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![Graph showing PSI 'Other' reporting errors from 2008 to 2009](chart.png)
Safety Culture in Action: Solutions

• Solutions: often combination of...
  • Can you take the switch away?
    • Example: sources available for use in TPS
  • Correct the obvious...
    • Training Deficiencies or gaps
    • Conditions/Resources
• Standardize procedures
• Implement QC/QA
Safety Culture in Action: Solutions

• What if I told you there is a way that you could reduce your errors/mistakes by as much as 30%...
  • AND it will not require $$ to accomplish...

• Would you be interested?
Safety Culture in Action: Solutions: Checklists

• What if I told you that the way to do this is by using checklists?

• Still interested?
Safety Culture in Action: Solutions: Checklists

• World Health Organization (WHO)
  • Convened in 2007 in response to increasing volume of surgeries and the care associated being unsafe – a public danger.
    • 234 million major operations worldwide annually
    • 7 million suffer complications, half of which are likely to be preventable

http://www.who.int/patientsafety/safesurgery/en/
Safety Culture in Action: Solutions: Checklists

• **World Health Organization (WHO)**
  • The directing and coordinating authority for health within the United Nations system.
  • Responsible for:
    • providing leadership on global health matters
    • shaping the health research agenda
    • Setting norms and standards
    • Articulating evidence-based policy options
    • Providing tech support for countries
    • Monitoring and assessing health trends

http://www.who.int/en/
Safety Culture in Action: Solutions: Checklists

- WHO Safe Surgery Saves Lives Program
  - Hypothesized that a program to implement a checklist would reduce complications and deaths associated with surgery.

Alex B. Haynes et. al., A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. 

http://www.who.int/patientsafety/safesurgery/en/
Safety Culture in Action: Solutions: Checklists

• WHO Safe Surgery Checklist
  • Eight pilot hospitals where the overall complication rates in surgery ranged from 6%-21%.
    • 4 in high income countries and among the leading hospitals in the world
    • 4 in low or middle income countries
  • In two-thirds of the patients, on average, 1 of 6 specific safety steps was being missed during surgery.

Safety Culture in Action: Solutions: Checklists

- WHO Safe Surgery Checklist project
  - Spring 2008 began implementing checklist
  - October 2008 (after checklist implemented):
    - Rate of major complications fell by 36%
    - Deaths fell by 47%
    - Infections fell by almost 50%
    - Number of patients returning to OR due to bleeding or other technical problems fell by 25%

Safety Culture in Action: Solutions: Checklists

• Not untrained or incapable people, it’s inability to deliver on the volume and complexity of what we know EVERY time.

• In a complex environment, two main difficulties.
  • “the fallibility of human memory and attention,…”
  • The lull factor: “…people can lull themselves into skipping steps even when they remember them.”

• “Checklists seem to provide protection against such failures.”

Dr. Gawande: director of WHO’s Global Challenge for Safer Surgical Care
Checklists (items to consider/address)

- Define pause points (you can’t use a checklist for everything)
- DO-CONFIRM or READ-DO
- Should not be lengthy
  - 5-9 items (rule of thumb)
  - 60-90 seconds
- Simple and exact (organization is important)
- Test and refine

Gawande website: Checklist for Checklists

http://gawande.com/the-checklist-manifesto
Safety Culture in Action: Solutions: Checklists

- Most difficult: deciding on “the killer items”.
- “Just ticking boxes is not the ultimate goal here. Embracing a culture of teamwork and discipline is.”

Safety Culture in Action: Solutions: QC/QA

- Increase QC and/or QA tests...
  - Regulations
  - Current reports and guidelines
  - Future reports and guidelines
Safety Culture in Action: QC/QA

• Regulations
  • This **IS** your starting place
  • Bottom line: you **MUST** meet them
  • NRC (www.nrc.gov)
    • 10CFR35: Medical Use of By-Product Material
    • 10CFR20: Standards for Protection Against Radiation
  • Agreement State
Safety Culture in Action: QC/QA

• Current Reports and Guidelines


Safety Culture in Action: QC/QA

- **Current Reports and Guidelines**
  - Provide guidance on what processes should be in place, and things the processes should address.
  - Don’t account for each institution’s compilation of equipment, their organization of systems, and flow.

  “Because practice standards and complexity of treatment planning and design are so variable, procedure-specific QA is highly individualized not only to the institution but to each type of procedure.” TG56

- **It’s a white-knuckle ride**
  - Difficult to keep up.
  - No one can do it all: Focus on SAFETY

Safety Culture in Action: QC/QA

• Future Reports and Guidelines
  • ?
    • Safety is not going away.
  • TG100
    • Identify structured QA approach to help prioritize QM activities
      • Achievable (resources)
      • Meaningful (optimize benefit to patient)
Conclusion

• Reality check: We’ll **NEVER** reach zero errors or mistakes

• Foster Safety Culture
  • Know your process
  • Establish and follow procedures
  • Analyze and Learn
    • Use some tools (Process Tree, FMEA, etc.)
    • Develop/Strengthen a reporting culture
  • Maximize solutions (combine them)
    • Solutions don’t have to be complex: A STUPID checklist may very well be your best defense
  • QC/QA

• Communication: it is **HUGE**
Conclusion

- “The illiterate of the 21st century will not be those who cannot read and write, but those who cannot learn, unlearn, and relearn.”

Alvin Toffler: Rethinking the Future
References and Recommended


References and Recommended

- [http://gawande.com/the-checklist-manifesto](http://gawande.com/the-checklist-manifesto)
- [http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis](http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis)