Advancing Safety in Brachytherapy

L. B. McLemore, M.S.

Acknowledgements

- Keith Furutani, Ph.D.
- Adil Akhtar, M.S.
- Kelly Classic, CMHP
- Division of Physics at Mayo Clinic

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…

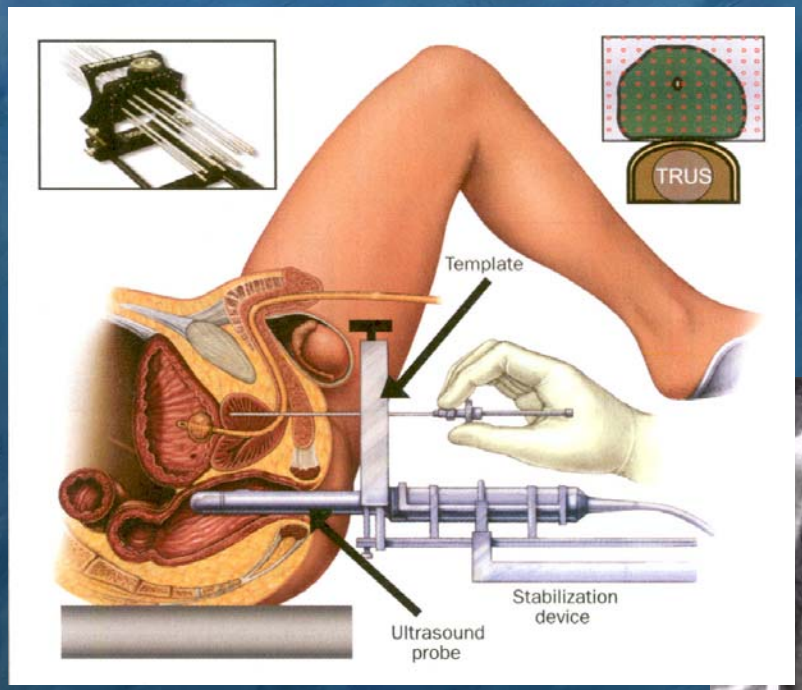
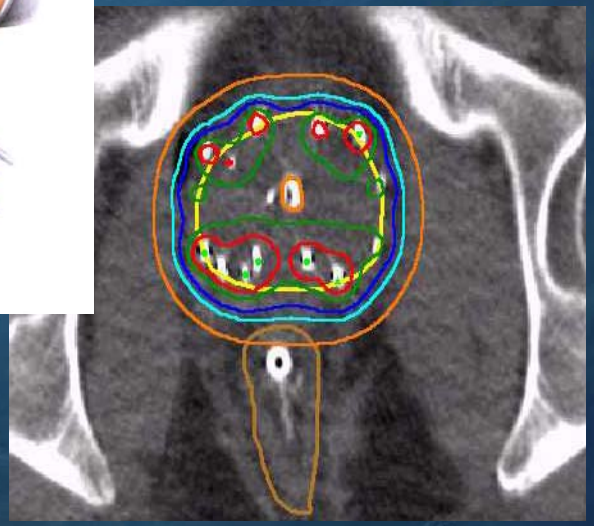


Figure taken from *Mayo Clinic Proceedings*: December 2008;83(12):1364-1372



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

An intraoperative real-time sleeved seed technique for permanent prostate brachytherapy

Navesh K. Sharma[1], Randi J. Cohen[1], Thomas N. Eade[2], Mark K. Buyyounouski[1], Robert G. Uzzo[4], Jinsheng Li[1], Kevin Crawford[1], David Y.T. Chen[4], Shawn McNeeley[3], Eric M. Horwitz[1,*]

AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137

Ravinder Nath[a)]
Department of Therapeutic Radiology, Yale University School of Medicine, New Haven, Connecticut 06510

Robotically assisted prostate brachytherapy with transrectal ultrasound guidance—Phantom experiments•

Gabor Fichtinger[1,*], Everette C. Burdette[2], Attila Tanacs[1], Alexandru Patriciu[1,3], Dumitru Mazilu[4], Louis L. Whitcomb[1,3], Dan Stoianovici[1,4]

Recommendations for permanent prostate brachytherapy with ^{131}Cs: A consensus report from the Cesium Advisory Group

William S. Bice[1,2,*], Bradley R. Prestidge[2,3], Steven M. Kurtzman[4], Sushil Beriwal[5], Brian J. Moran[6], Rakesh R. Patel[7], Mark J. Rivard[8]

Effect of edema, relative biological effectiveness, and dose heterogeneity on prostate brachytherapy[a)]

Jian Z. Wang,[b)] Nina A. Mayr, Subir Nag, Joseph Montebello, Nilendu Gupta, Nina Samsami, and Christos Kanellitsas
Department of Radiation Medicine, The Ohio State University, Columbus, Ohio 43210

Introduction

- Sobering Times

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

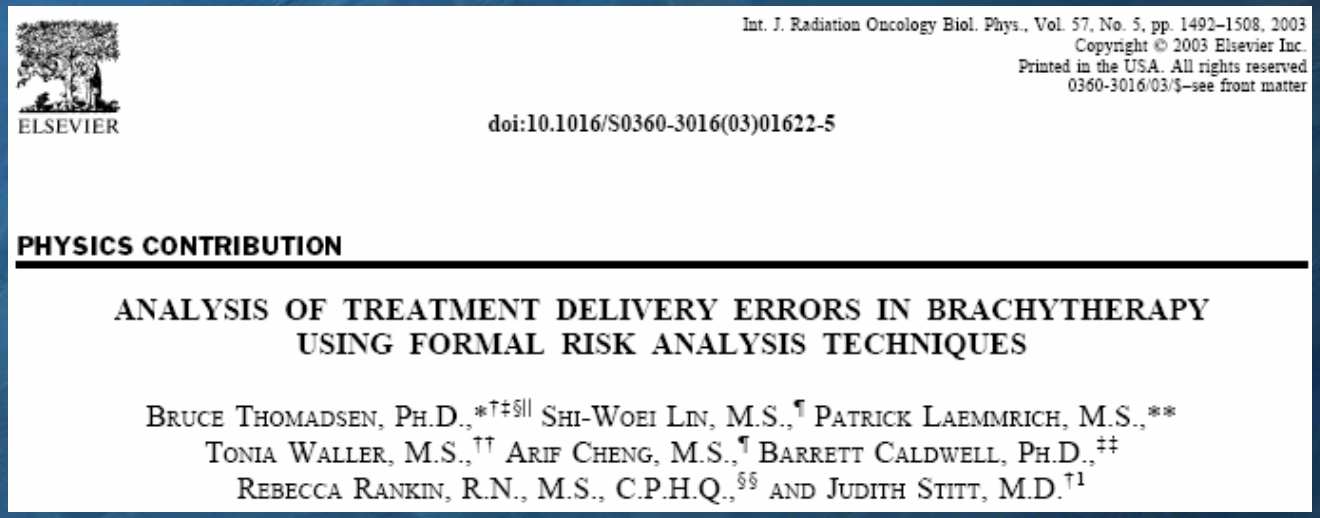
- Physicists thrive on improving quality
  - → often leads to mechanical/system complexity
    - → leads to increased opportunities to make an error.

- Mechanical
- Human
- Process

LDR Brachy

Errors & Mistakes

- Take a look…



Int. J. Radiation Oncology Biol. Phys., Vol. 57, No. 5, pp. 1492–1508, 2003

0360-3016/03/$–see front matter

ELSEVIER

doi:10.1016/S0360-3016(03)01622-5

PHYSICS CONTRIBUTION

ANALYSIS OF TREATMENT DELIVERY ERRORS IN BRACHYTHERAPY USING FORMAL RISK ANALYSIS TECHNIQUES

Bruce Thomadsen, Ph.D.,*†‡§‖ Shi-Woei Lin, M.S.,¶ Patrick Laemmrich, M.S.,** Tonia Waller, M.S.,†† Arif Cheng, M.S.,¶ Barrett Caldwell, Ph.D.,‡‡ Rebecca Rankin, R.N., M.S., C.P.H.Q.,§§ and Judith Stitt, M.D.†‖

- 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.

Safety Culture

The New York Times

Health

WORLD | U.S. | N.Y. / REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH

finding problems.

Over all, the implant program lacked a "safety culture," the nuclear commission found. Dr. Kao and other members of his team, the commission said, were

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

- 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.”

NUREG/BR-0117, No. 09-04: NRC Licensee Newsletter, (Winter 2009).

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."

von Thaden, T.L. and Gibbons, A.M.: The safety culture indicator scale measurement system (SCISMS). Technical Report HFD-08-03/FAA-08-2. (2008)

Safety Culture: Promoting/Strengthening

Key Practical Issues in Strengthening Safety Culture, INSAG-15, IAEA, Vienna (2002).

- 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."

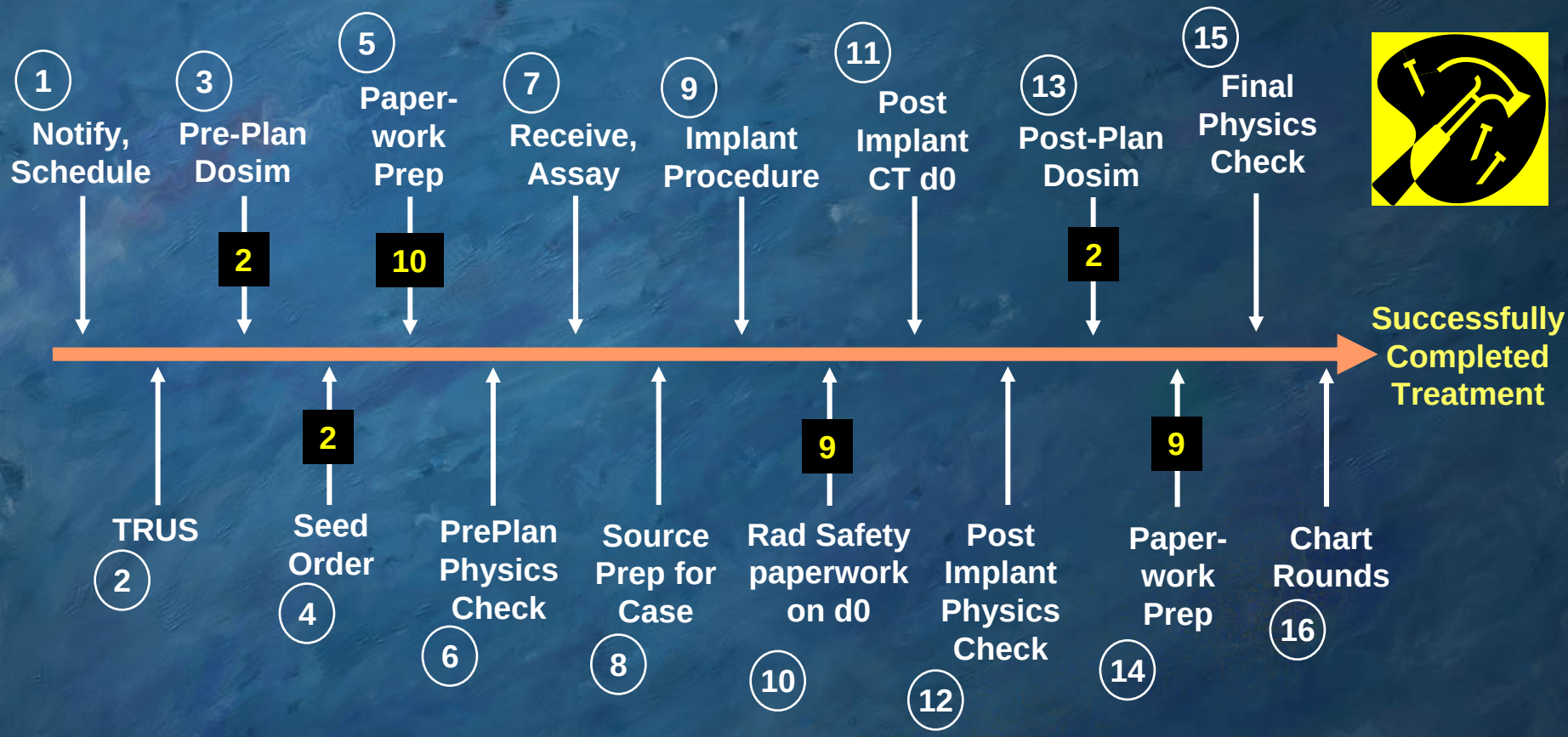
Safety Culture in Action

- **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

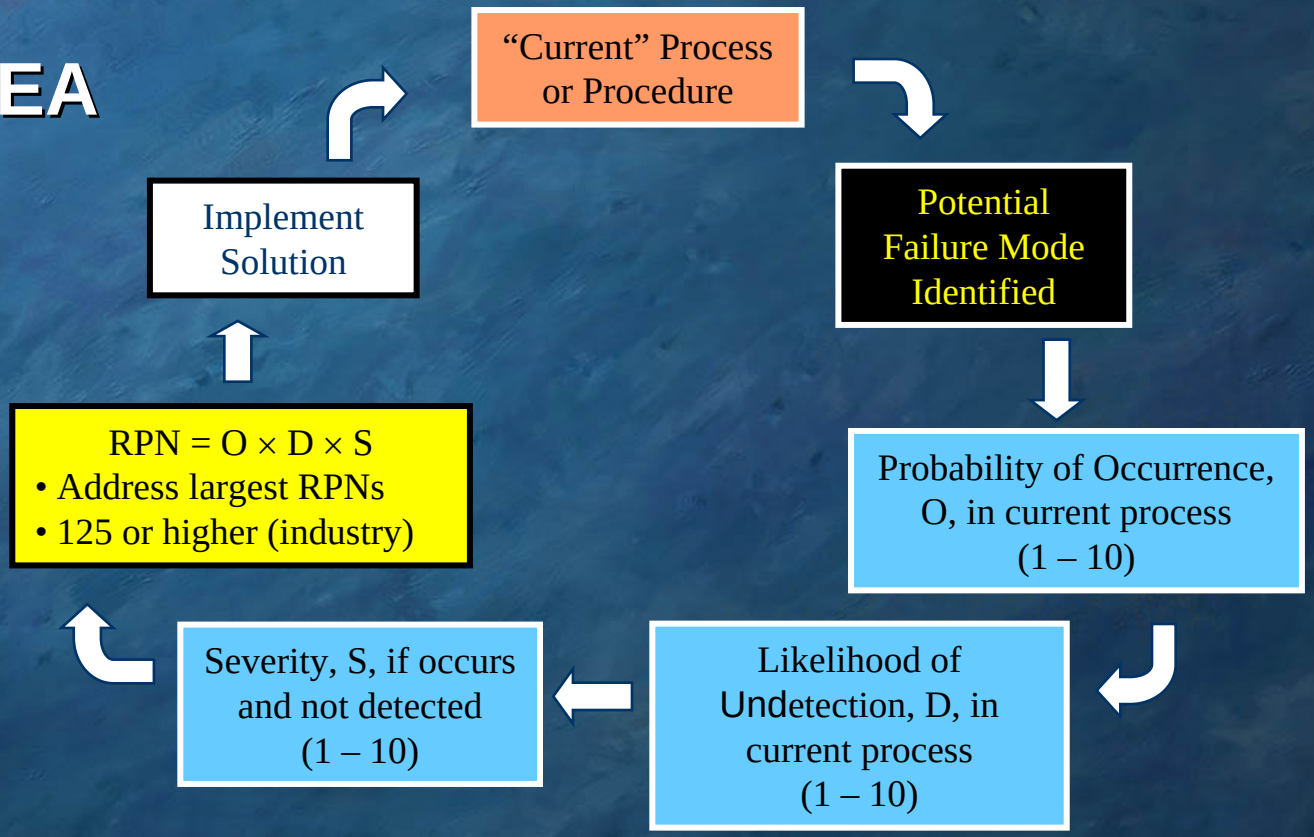


- Global view
- Which branches are breaking.
- Identify and implement solution(s).
- Observe for effectiveness.

- 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

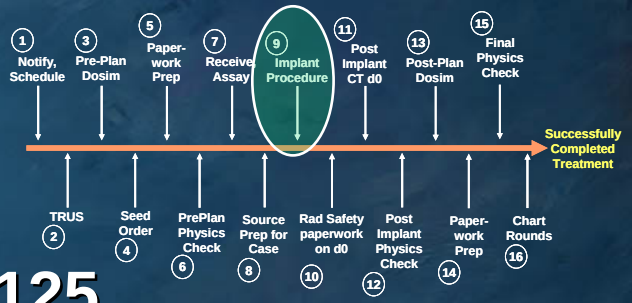
- **FMEA**



Frank Rath, Tools for Developing a Quality Management Program: Proactive tools (Process Mapping, Value Stream Mapping, Fault Tree Analysis, and Failure Mode and Effects Analysis). *IJROBP*, 71(1),Supplement:S187-S190 (2008).

http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis

Safety Culture in Action: Risk Analysis



- FMEA (example)
  - (Branch 9) FM_{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
    - Non-Detection, D: 6
    - Severity, S: 7

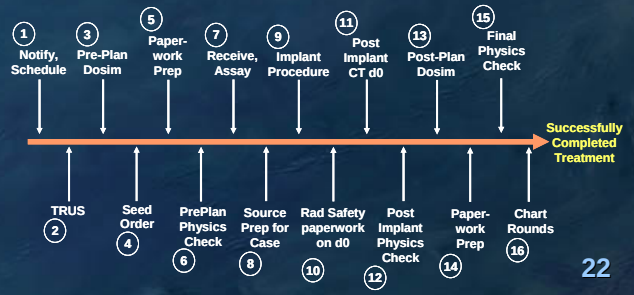
O: 3	Low likelihood of occurring
D: 6	Less likely to be detected if it does occur
S: 7	Potentially severe outcome if occurs and not detected

- RPN = O × D × S = 3 × 6 × 7 = **126**

Safety Culture in Action: Risk Analysis

- **FMEA**

	O	D	S	RPN
FM_{Pot} 1	3	2	4	24
FM_{Pot} 2	2	5	8	80
FM_{Pot} 3	4	4	6	96
FM_{Pot} 4	2	3	6	36
FM_{Pot} 5	3	6	7	126
FM_{Pot} 6	2	2	9	36
FM_{Pot} 7	2	1	6	12
FM_{Pot} 8	4	5	3	60



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**

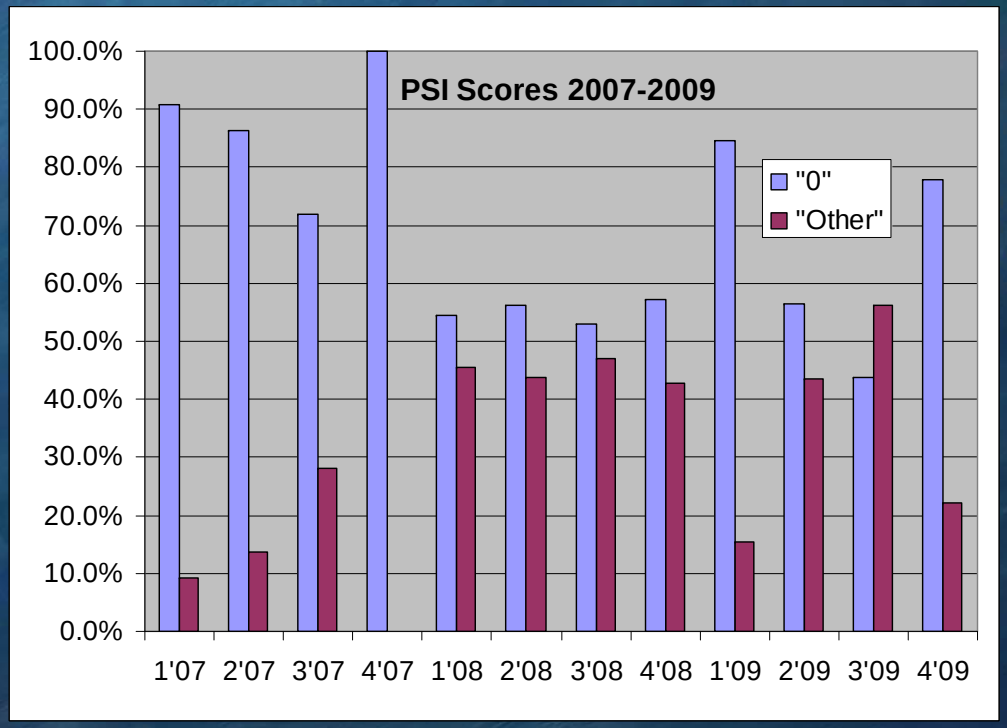
      S. Mutic, et. al. Experience with Error Reporting and Tracking Database Tool for Process Improvement in Radiation Oncology. *Med. Phys*. Volume 36, Issue 6, pp. 2807-2808 (June 2009)
  - **Princess Margaret Hospital**
    - **QA review of incident reports (external beam)**

      Grace Huang, et al., Error in the delivery of radiation therapy: Results of a quality assurance review. *IJROBP*. Volume 61, Issue 5, pp. 1590-1595 (April 2005)
  - **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

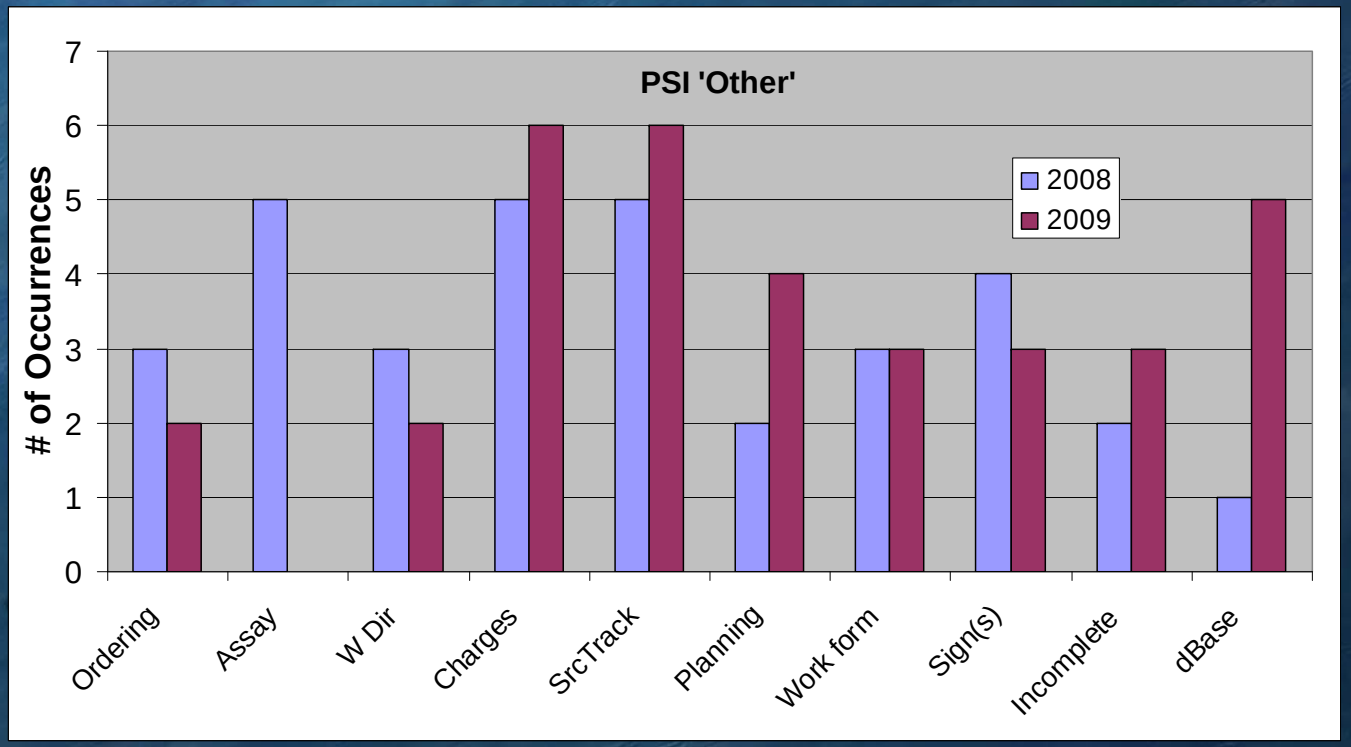
"0"	no deviations and/or dose within 5% of that prescribed
"other"	unintended deviation from prescribed dose > 5% or any noted deviation from procedures or missing documentation.
"1"	unintended deviation from prescribed dose > 10% and/or no written directive.
"2"	unintended deviation from prescribed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



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

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.
"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: 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/

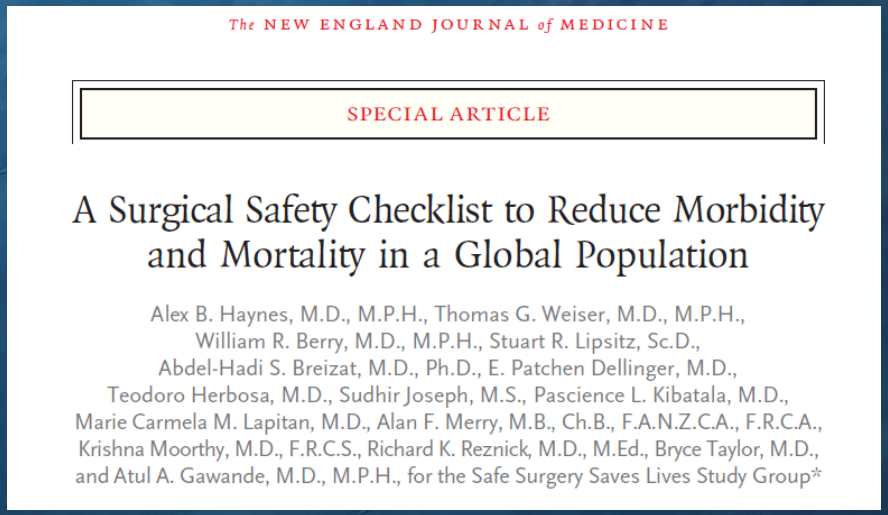
Safety Culture in Action: Solutions: Checklists

- **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.**



The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H., William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D., Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D., Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatala, M.D., Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A., Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D., and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group*

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

The Checklist Manifesto: How to Get Things Right.

- 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
Atul Gawande, The Checklist Manifesto: How to Get Things Right. Metropolitan Books, Henry Holt and Company, LLC. First Edition (2010).

Safety Culture in Action: Solutions: Checklists

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

Atul Gawande, The Checklist Manifesto: How to Get Things Right. First Edition (2010).

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

Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56

Ravinder Nath
Department of Therapeutic Radiology, Yale University School of Medicine, New Haven, Connecticut 06510

CLINICAL INVESTIGATION **Prostate**

AMERICAN BRACHYTHERAPY SOCIETY (ABS) RECOMMENDATIONS FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER

SUBIR NAG, M.D.,*† DAVID BEYER, M.D.,*‡ JAY FRIEDLAND, M.D.,*§ PETER GRIMM, D.O.,*‖ AND RAVINDER NATH, PH.D.*¶

AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137

Ravinder Nath[a)]
Department of Therapeutic Radiology, Yale University School of Medicine, New Haven, Connecticut 06510

Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40

Gerald J. Kutcher
Department of Medical Physics, Memorial Sloan-Kettering Cancer Center, New York, New York 10021

Permanent prostate seed implant brachytherapy: Report of the American Association of Physicists in Medicine Task Group No. 64[a)]

Yan Yu[b)]
Department of Radiation Oncology, University of Rochester, Rochester, New York 14642

American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: Quality assurance for clinical radiotherapy treatment planning

Benedick Fraass[a)]
University of Michigan Medical Center, Ann Arbor, Michigan

AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems

Douglas Pfeiffer[a)]
Imaging Department, Boulder Community Foothills Hospital, Boulder, Colorado 80301

Third-party brachytherapy source calibrations and physicist responsibilities: Report of the AAPM Low Energy Brachytherapy Source Calibration Working Group

Wayne M. Butler
LEBSC; Schiffler Cancer Center, Wheeling Hospital and Jesuit University, Wheeling, West Virginia 26003

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

M. Saiful Huq et. al., A Method for Evaluating Quality Assurance Needs in Radiation Therapy. *IJROBP.* 71(1), Supplement 1:S170-S173. (2008).

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

- Atul Gawande, The Checklist Manifesto: How to Get Things Right. Metropolitan Books, Henry Holt and Company, LLC. First Edition (2010).
- Frank Rath, Tools for Developing a Quality Management Program: Proactive tools (Process Mapping, Value Stream Mapping, Fault Tree Analysis, and Failure Mode and Effects Analysis). *IJROBP*, 71(1),Supplement:S187-S190 (2008).
- Bruce Thomadsen et al., Analysis of Treatment Delivery Errors in Brachytherapy Using Formal Risk Analysis Techniques. *IJROBP*, 57(5):1492-1508 (2003).
- Ravinder Nath et al., Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56. *Med. Phys.* 24(10):1557-1598 (1997).
- International Nuclear Safety Advisory Group, Key Practical Issues in Strengthening Safety Culture, INSAG-15, IAEA, Vienna (2002).
- von Thaden, T.L. and Gibbons, A.M.: The safety culture indicator scale measurement system (SCISMS). Technical Report HFD-08-03/FAA-08-2. (2008).
- James Reason, Human Error. Cambridge University Press (1990).
- James Reason, Managing the Risks of Organizational Accidents. Ashgate Publishing Limited. (1997).

References and Recommended

- M. Saiful Huq et al., A Method for Evaluating Quality Assurance Needs in Radiation Therapy. *IJROBP*. 71(1),Supplement 1:S170-S173 (2008).
- Ravinder Nath et al., AAPM Recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137. *Med. Phys.* 36(11):5310-5322 (2009).
- Yan Yu et al., Permanent prostate seed implant brachytherapy: Report of the AAPM Task Group No. 64. *Med. Phys.* 26(10):2054-2076 (1999).
- Andrew Hopkins, Safety Culture, Mindfulness and Safe Behavior: Converging ideas? Working Paper 7. National Research Centre for OHS regulation (2002).
- A. Hopkins, What are we to make of safe behaviour programs?. Safety Science 44(7):583-597 (2006).
- http://gawande.com/the-checklist-manifesto
- http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis
- http://en.wikipedia.org/wiki/Root_cause_analysis
- http://en.wikipedia.org/wiki/Fault_tree_analysis