### Making Hi Tech Radiotherapy Safe



Connecticut Chapter AAPM March 25, 2010

Howard Amols Memorial Sloan Kettering Cancer Center New York, NY

#### We are gathered here today because .....

#### The New York Times

FRONT PAGE

#### THE RADIATION BOOM Radiation Offers New Cures, and Ways to Do Harm

#### **BY WALT BOGDANICH**

JANUARY 24, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final



Scott Jerome-Parks, with his wife, Carmen, was 43 when he died in 2007 from a radiation overdose.

# Until recently, serious radiation therapy accidents were almost unheard of

### BUT

unheard of  $\neq$  unknown unheard of  $\neq$  rare

### **3 Myths We Wish to Dispell**

- 1. You need new high technology to have an accident
- 2. Radiation therapy accidents are rare
- 3. Most accidents happened long ago in third world countries

There has been a focus on high-technology as the source of most radiation therapy accidents.

This is only partially true.

New technology may contribute to errors, but almost every RT disaster involving new technology required significant help from humans in order to happen.

Really big errors are usually a team effort!

"Those who don't know history are destined to repeat it."

Edmund Burke

Emphasis will be on how:

systematic errors, and/or individual acts of stupidity coupled with:

deficient QA/QC program, bad communications, and carelessness

results in major errors.

There is something fundamentally wrong with the historical method by which the medical profession has approached QA/QC:

- 1. Medical staff do not normally make mistakes
- 2. When mistakes are made it's because one individual screwed up, and we must find and punish the offender
- 3. Preferably someone relatively low in the pecking order

It has been pointed out many times that if commercial airlines had the same error rates as hospitals there would be a major airline crash EVERY DAY.

`And that's the truth!' Lily Tomlin

(Their prices may be ridiculous, you may not get there on time, and your baggage may end up in a different city, but airlines usually get you where you want to go in one piece)

### Making Hi Tech Radiotherapy Safe

Part 1: Learn how to mess up

### Making Hi Tech Radiotherapy Safe

- Part 1: Learn how to mess up
- Part 2: Don't do that!

# **7 STEP RT DISASTER RECIPE**

- **1.** Overwork your staff
- 2. Buy new equipment that you don't know how to use
- 3. Give your staff unreasonable deadlines
- 4. Never hire outside auditors or ask for help
- Ignore `suspicious' or unusual clinical outcomes (they're anomalies or overly kvetchy patients).
- Always trust the manufacturer. They would never cover up problems about equipment safety (the Toyota response)

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- 6. Always trust the manufacturer. They would never cover up problems about equipment safety (the Toyota response)
- 7. Hire inadequately trained staff (not required if you follow steps 1-6).

1. The grand daddy of radiotherapy accidents: The Ohio Cobalt-60 disaster

2. The daddy of radiotherapy accidents: The Therac disaster

3. Son of radiotherapy accidents: The New York IMRT accident

4. Grandchildren, nieces, and nephews: Moffit, Cox, and others

### THE GRAND DADDY OF RADIATION DISASTERS:

#### Riverside Methodist Hospital, Columbus, OH 1972



(at least 10 deaths + 78 serious injuries)

### THE GRAND DADDY OF RADIATION DISASTERS

By his own statement, Callendine is a perfectionist, who often insisted on checking two separate calibration systems against each other when monitoring the output of a cobalt

radiation source. "I recognize that anyone can make a medical mistake," he recalls, "so we wanted to minimize this.... When George signs his name, I want to be sure. It's a personal thing,"

Notwithstanding Callendine's reputation and long service, Mansfield and others in Riverside's administration had concluded by 1972 that changes had to be made. Because Because both Callendine and his equipment were gone when he arrived, Axt was forced to reconstruct Riverside's radiation physics program almost from scratch. His clinical experience had been limited to a 14-month stint at the University of California Medical Center at San Francisco not enough to qualify for American Board of Radiology certification. Part of his training there involved working with cobalt-60.

often a cobalt-60 source should be calibrated to check its output, but an average recommendation might be once every two or three months. Yet in the 27 months between his arrival and the discovery of the radia tion overdoses in January, 1976, Axt apparently calibrated the source only twice—and not at all after May, 1974

Why did Axt stop making cobalt-60 calibrations? Mainly, he told attorneys who interviewed him at length in June, 1977, he stopped because his time was fully occupied by other, higher-priority projects. Very soon after his arrival at Riverside, Axt was given considerable responsibility for the acquisition, installation and testing of a new linear accelerator—one of the most advanced and complex high-energy nuclear therapy machines available.

 Decay was determined from straightline plot on semi-log graph paper with calendar ordinate



 When edge of graph paper was reached, physicist continued plot on linear paper



To compensate for the assumed lower output, technicians dialed in cobalt-60 exposure times that were, increasingly, too long. By March of 1975, the resulting radiation overdoses were averaging 10 per cent. And by January, 1976, when the problem was finally discovered, the overdoses were ashigh as 40 per cent.

As far as anyone knows, neither Fahey nor anyone else at Riverside ever checked Axt's calibrations or instructed him to make a calibration during 1974 or 1975. So two simple mistakes went undetected for nearly two years, while the overdoses climbed. At first, because the overdoses were marginal and because therapeutic radiation in *any* dosage almost always produces some unwanted side effects, the overdoses went unnoticed. But by late 1975, the number and intensity of complaints from Riverside's cancer patients and their doctors were increasing,

One patient, Ohio Bell telecommunications specialist Jim Baily, says his cobalt treatments left him "weak as a kitten" and produced "incapacitating diarrhea." After receiving two sets of treatments, estimated later at 26 per cent and 40 per cent overdoses, Baily recalls, "I told Dr. Fahey about these effects and his reply was that they were normal. Dr. Steven Andresen, a radiation therapist who joined the Riverside staff under Pahey in September, 1975, later told NRC investigators he almost immediately noted more significant patient reactions than he had seen elsewhere. Because the number of such reactions seemed to be increasing. Andresen says, he asked Axt in late January, 1976, when he last "put a meter under" the cobalt-60 teletherapy device to check its output.

When Axt could not give him a specific date for the last calibration, Andresen became concerned and directed him to make one immedi-



Merv and Sam are about to have a brief encounter of the 3<sup>rd</sup> kind

#### MIL WITHINGED WELC MELOVELEU.

Under close questioning, Axt admitted the attempted cover-up. He had faked the reports, he later told attorneys, simply because he was afraid of losing his job. On May 6, Mansfield suspended Axt and notified the NRC of the new development. NRC investigators returned to Columbus, where Axt told them he had never viewed calibration of the cobalt teletherapy device as a high-priority duty, and in his mind the device's

### **RIVERSIDE ANALYSIS**

Was this Axt's fault? Of course it was. But he had a lot of help!

# He had a lot of help!

- 1. Administration didn't hire enough staff
- 2. External audits weren't part of the QC program
- 3. Everyone was in a rush to get their new Linac running
- 4. MD's ignored `suspicious' clinical reactions
- 5. Therapists ignored unusually long treatment times

**Therac 25 Disaster** 

(screwing up, 80's style)

An Investigation of the [Therac-20 &] Therac-25 Accidents

Nancy Leveson, University of Washington Clark S. Turner, University of California, Irvine

IEEE Computer, Vol. 26, No. 7, July 1993, pp. 18-41.

June 1985-January 1987: 6 accidents involved massive overdoses by the Therac-25 with resultant deaths and serious injuries. They have been described as the worst series of radiation accidents in the 35-year history of medical accelerators.

### A. Machine Calibration / Malfunctions -6

Place: U.S. & Canada

Time: 1985-87

Cause: Therac-25 Linac malfunction

Impact: 16,000 to 18,000 cGy to 6 patients

In-depth Analysis of Therac-25 incidents

Therac 25 incidents

- 1. Kennestone Center, Marietta, GA
- 2. Hamilton Cancer Center, Ontario
- 3. Yakima Valley, Washington
- 4. East Texas Cancer Center, Tyler, Texas

### Chronology of Therac-25 incidents 1985-87

June 3<sup>rd</sup>: Marietta, GA incident 1985 July 26th: Hamilton, Ontario incident Oct.: Georgia patient files a lawsuit Dec.: Yakima incident Jan. 31<sup>st</sup>: Yakima letter to AECL 1986 Feb. 24<sup>th</sup>: AECL letter to Yakima March 21st: Tyler, TX overdose April 11th: Tyler, TX 2nd incident April 15th: AECL files incident report to FDA Jan.17<sup>th</sup>: Yakima, 2<sup>nd</sup> incident 1987 Feb. 10<sup>th</sup>: FDA asks AECL to pull the plug

1<sup>st</sup> accident: Kennestone Regional Oncology Center, June 1985, Marietta, Georgia.

The Therac-25 had been operating for about 6 mo; other Therac-25s had been operating, without incident, since 1983.

June 3, 1985, patient set up for 10-MeV (scanning) electron treatment to clavicle area. When the machine turned on, she felt a "tremendous force of heat . . . red-hot sensation." Patient said, "You burned me." The technician replied that was not possible. No marks on patient at the time, but treatment area felt "warm to the touch." AECL contacted and asked if Therac could operate in electron mode without scanning.

Three days later AECL said it was not possible.

Clinical explanation was sought for reddening of the skin.

The oncologist attributed it to her disease or to normal treatment reaction.

The physicist later estimated that she received 1-2 doses in the 150- 200 Gy range.

Health-care professionals and institutions were not required to report incidents to manufacturers.

Other Therac-25 users were unaware of what had occurred until after subsequent accidents.

Even then, most information came through personal communication among themselves.

2<sup>nd</sup> accident: Hilton Cancer Foundation, Ontario, July 1985 (7 weeks later).

Therac shut down after 5 seconds with "H-tilt" error. Therac's display read "no dose" and indicated "treatment pause."

2<sup>nd</sup> attempt to treat by pressing `proceed key' (standard operating procedure). Operators accustomed to frequent malfunctions that had no untoward consequences for the patient.

Again, the machine shut down in the same manner. Repeated process 4 more times.

Engineer was called who found nothing wrong. Also not unusual for Therac-25. On July 30 AECL sent a service engineer to investigate. The FDA, CRPB, and the users were informed that there was a problem, although users claim they were never informed that a patient injury had occurred.

AECL could not reproduce the malfunction, but suspected a transient failure in the microswitch used to determine turntable position.

AECL also altered the software so that computer checked for "in transit" status of the switches when the turntable was moving.

That a more serious software error was the real problem was not yet realized

3<sup>rd</sup> accident: Yakima Valley Memorial Hospital, WA, December 1985.

On February 24, 1986, AECL sent a written response to Yakima: "After careful consideration, we are of the opinion that this damage could not have been produced by any malfunction of the Therac-25 or by any operator error." And "there have been no other instances of similar damage to this or other patients."

At that time, Yakima did not believe that the patient was overdosed because the manufacturer had installed additional hardware and software safety devices to the accelerator. They were not aware of any other incidents, 4<sup>th</sup> Hospital, March-April, 1986. Tyler Texas

After 2<sup>nd</sup> accident the ETCC physicist immediately took the machine out of service and called AECL to alert the company to this apparent overdose.

The Tyler physicist then began his own careful investigation. He worked with the therapist, who remembered exactly what she had done on this occasion. After a great deal of effort, they were eventually able to elicit the Malfunction 54 message. What was the real problem:

- **1.** If an electron treatment followed an x-ray treatment, and
- 2. The Therapist typed a certain command sequence very quickly, then....
- 3. Electron current in accelerator guide remained at x-ray values
- 4. X-ray targeted would be retracted
- **5.** Electron scanning would not be activated

### **THERAC ANALYSIS**

Was this AECL's fault? Of course it was. But like Axt, they had some help!

### They had a lot of help!

- 1. There were no regulations for error reporting
- 2. No communication between institutions
- 3. Three institutions saw really suspicious linac behavior, but none investigated
- 4. Suspicious clinical results ignored

#### Accidents are seldom simple

1. usually involve complex web of interacting events with multiple contributing technical, human, and organizational factors

2. tendency to believe that the cause of an accident had been determined (e.g., microswitch failure) without adequate evidence to come to this conclusion

3. assuming that fixing a particular error (microswitch and software bug) would prevent future accidents. There is always another software bug.

Patient reactions were the only real indications of the seriousness of the problems with the Therac-25.

The Therac-25 software "lied" to the operators. The machine could not detect the massive overdose because ion chambers saturated at the high dose rate of the unscanned electron beam.

A common mistake in engineering is to put too much confidence in software. Software design errors are harder to find and eliminate.

Hardware failure modes are generally more limited and building protection against them is easier.

A lesson to be learned from the Therac-25 accidents is not to remove standard hardware interlocks when adding computer control. Déjà vu all over again

(screwing up, modern style)

**IMRT** accident

New York, 2005

### Background

- March 2005, New York City (`the city')
  - A patient is due to be treated with IMRT for head and neck cancer (oropharynx)



- March 4 7: An IMRT plan is prepared: "10ropharyn". Verification plan created by TPS. EPID dosimetry confirms correctness.
- March 8: patient treated correctly with "1 Oropharyn".
- March 9-11: Fractions #2, 3 and 4 also correct. Verification images for the kV imaging system are created and added to the plan, now called "1AOropharyn".

 March 11: Physician wants modified dose distribution (reducing dose to teeth) "1AOropharyn" is copied and saved to the DB as "1BOropharyn"

• March 14: Re-optimization for "1B Oropharyn".

- New optimal fluences saved to DB.
- MLC motion control points for IMRT generated. Normal completion.

#### • March 14

- "Save all" is started. All new and modified data should be saved to the DB.
- In this process, data is sent to a holding area on the server, and not saved permanently until ALL data elements have been received.
- Data to be saved included: (1) fluence data, (2) DRRs and (3) MLC control points

- March 14, 11 a.m.
- fluence data is saved normally.
  - Next in line is the DRR. The "Save all" process continues but is not completed.
  - Saving of MLC control point data would be after the DRR, but will not start because of the above.

#### • March 14, 11 a.m.

- An error message is displayed.
- The user presses "Yes", which begins a second, separate, save transaction.
- MLC control point data is moved to the holding area.

8	Please note the following messages and inform your System Administrator: Failed to access volume cache file <c:\program files\varian\rv71\cache\504.mimagedrf<br="">Possible reasons are: - Directory not existing or write-protected - Disk full</c:\program>									
	Do you want to save your changes before application aborts?									
	<u>Yes</u> <u>N</u> o									

Error message displayed. It's purpose is so that you can click `yes' or `ok' or `proceed'

#### • March 14, 11.a.m.

- The DRR is, however, still locked into the faulty first attempt to save.
- This means the second save won't be able to complete.
- The software would have appeared to be frozen.



The frozen state of the second "Save All" progress indication

- March 14, 11.a.m.
  - Within 12 s, another workstation is used to open the patients plan to load into VARIS and to treat.

- March 14, 11 a.m.
  - No verification plan, no pre-treatment dosimetry, no review by 2<sup>nd</sup> physicist
  - Several computer crashes ignored and over-ridden.
  - Plan approved by physician

### What they didn't notice:



### • What they should have seen:

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Coll Rtn (Deg)	90.0	90.0	90.0	90.0	90.0		
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K1 [cm]	+1.5	+1.5	+1.5	+1.5	+1.4		2.24
X2 [cm]	+9.5	+9.8	+9.8	+9.8	+9.5	CODE CONTRACTOR	20.0
Field Y [cm]	14.3	15.0	15.0	15.0	15.D		100
Y1 [cm]	+7.0	18:0	+9.0	+6.9	+6.0	H. West Man	
Y2 [cm]	+7.3	+6.5	+6.0	+8.6	+9.0		
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### • March 14, 2005, 1 p.m.

#### • Expected display:

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#### • March 14, 2005, 1 p.m.

• What they also didn't notice:



### **Discovery of accident**

#### March 14-16, 2005

- The patient is treated without MLCs for 3 fractions
- On March 16, a verification plan is created and run on the treatment machine. The operator notices the absence of MLCs.
- A second verification plan is created and run with the same result.
- The patient plan is loaded and run, with the same result.

### Impact of accident

• The patient received 13 Gy per fraction for three fractions, i.e. 39 Gy in 3 fractions

### Was there a bug in the Varian software:

Of course, but the software had a lot of help:

- 1. Error messages ignored and not investigated
- 2. Treatment plan QA not performed
- 3. No 2<sup>nd</sup> physics check
- 4. MD rushed the plan modification
- 5. Therapists weren't watching MLC display

### And The Beat Goes On.... grandchildren, nieces, and nephews of radiation therapy accidents

Moffitt Cancer Center, Tampa, Fla., 2004-5., 77 SRS patients overdosed >50% because PDD factor not used in TG-51 calibration. Uncovered after 1 year during RPC inspection for participation in RTOG.

CoxHealth, Springfield, Mo., 2004-09. 76 SRS patients overdosed >50 percent. Used too large a dosimeter to calibrate SRS fields. No independent check, no mandated state or federal reporting reguirement, no requirement for physicists or therapists to be certified. UK, 1982-90: incorrect SSD correction (did not know how TPS worked). 1045 patients, 30% underdose, >492 RT failures

Bend, Oregon, 1980's: incorrect TPC. 13% overdose Spain, 1990: Linac `repair' led to 36MeV e- beam no matter what was programmed. No dosimetry check. 27 patients, 15 deaths

France, 2004: incorrect MU for dynamic wedge. 23 patients overdosed 20%, 4 deaths

Glasgow,2006: incorrect calculation of MU. Planner thought TPS calculated MU/Gy and not MU/fraction. It didn't! 67% overdose results in death

France, 2006-7: large ion chamber used for SRS. 145 overdoses.

#### How to make high tech radiation therapy safe:

Step 1: Make low tech radiation therapy safe!

Arguably, high tech radiotherapy isn't safe because it's being given by the same idiots who still haven't figured out how to make low tech radio-therapy safe!



(pssst – is he talking about us?)

### **Radiation Accidents: Common Threads**

#### new equipment + new software + new physicist = systematic error

understaffing, overworking, undertraining

no internal redundancy, no external audits

no common sense, no time outs

no communication, no central reporting

manufacturer and institutional denial

unusual clinical results ignored

### **Radiation Accidents: Common Threads**

unusual clinical results not followed up

sometimes the only independent backup dosimeter for detecting systematic dosimetry or calculational errors are the patients!

#### **Use of High Tech In Surgery**



e.g.; robotics, lasers, laproscopic

#### Use of Hi-Tech in RT: inverted training/culpability Pyramid



e.g.; Linac, MLC, IGRT, R/V, treatment planning

#### **Special Dangers of Hi-Tech**

**1. Systematic errors harder to detect** 

2. Humans get complacent. Don't really check computers

- 3. Many treatment components too complex for humans to check (e.g., DMLC files, MU for IMRT)
- 4. Many treatment aids/devices are invisible
- 5. Errors made on day 1 can propagate
- 6. Programmers don't understand what we do
- 7. We don't understanding what programmers do
- 7. Too easy to `over ride'
- 8. Manufacturers training programs often inadequate

Nothing is foolproof for the sufficiently talented fool

R/V systems, computer controlled Linacs, image guided patient positioning systems, etc. reduce but do no prevent errors. They enable humans to make different kinds of mistakes faster and more efficiently.

#### Types of Human Errors (most → least likely)

- 1. Staff follows policy, but makes human error (e.g.; policy says treatment plan to be checked before first treatment, but second checker fails to detect error)
- 2. Staff does not follow policy (e.g.; treatment plan not checked)
- 3. Policy deficient (e.g.; there was no policy to check plan). Most common for new technology
- 4. Zebra errors: bizarre sequence of events, almost impossible to foresee or prevent

### **ROSIS – first 200 reports**

Who discovered the reported event?

• Mainly Radiation Therapists on the treatment units



### **ROSIS – first 200 reports**

At what "check-station" did the discovery happen?

Mainly at chart check. However, most discoveries through "vigilance" at time of treatment.



### The End

