Risks and Benefits of Automation in Radiation Therapy

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Disclosures

- Research funding from ViewRay, Inc.
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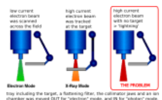
Automation: Using technology to perform tasks with minimal human effort.

Gross Injurious Machine Malfunction

- Between 1985-1987, 6 people killed by massive overdoses from Therac-25 therapy linacs

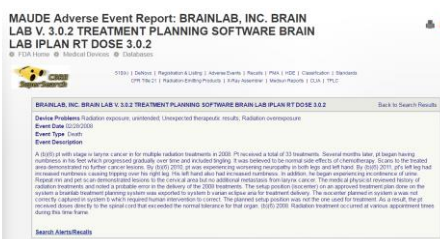
- Contributing causes:
  - Bad design and poor testing procedures by the manufacturer
  - Inadequate reporting system.

Nancy Leveson, University of Washington



http://radonc.wdfiles.com/local--files/radiation-accident-therac25/Therac25.png

Data transfer between systems



MAUDE Adverse Event Report: BRAINLAB, INC. BRAIN LAB V. 3.0.2 TREATMENT PLANNING SOFTWARE BRAIN LAB IPLAN RT DOSE 3.0.2

FDA Home · Medical Devices · Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

BRAINLAB, INC. BRAIN LAB V. 3.0.2 TREATMENT PLANNING SOFTWARE BRAIN LAB IPLAN RT DOSE 3.0.2 — Back to Search Results

Device Problems Radiation exposure, unintended; Unexpected therapeutic results; Radiation overexposure
Event Date 02/28/2008
Event Type Death
Event Description

A (b)(6) pt with stage iv larynx cancer in for multiple radiation treatments in 2008. Pt received a total of 33 treatments. Several months later, pt began having numbness in his feet which progressed gradually over time and included tingling. It was believed to be normal side effects of chemotherapy. Scans to the treated area demonstrated no further cancer lesions. By (b)(6) 2010, pt was experiencing worsening neuropathy in both legs and left hand. By (b)(6) 2011, pt's left leg had increased numbness causing tripping over his right leg. His left hand also had increased numbness. In addition, he began experiencing incontinence of urine. Repeat mri and pet scan demonstrated lesions to the cervical area but no additional metastasis from larynx cancer. The medical physicist reviewed history of radiation treatments and noted a probable error in the delivery of the 2008 treatments. The setup position (isocenter) on an approved treatment plan done on the system a brainlab treatment planning system was exported to system b varian eclipse aria for treatment delivery. The isocenter planned in system a was not correctly captured in system b which required human intervention to correct. The planned setup position was not the one used for treatment. As a result, the pt received doses directly to the spinal cord that exceeded the normal tolerance for that organ. (b)(6) 2008. Radiation treatment occurred at various appointment times during this time frame.

Search Alerts/Recalls

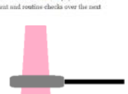
Incorrect procedures / inappropriate training

Radiation Errors Reported in [redacted]

By WALT BOGDANICH and REBECCA R. RUIZ FEB. 24, 2010

A hospital in [redacted] said Wednesday that it had overradiated 76 patients, the vast majority with brain cancer, during a five year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

The hospital [redacted] said half of all patients undergoing a particular type of treatment — stereotactic radiation therapy — were overdosed by about 50 percent after an unidentified medical physicist at the hospital miscalibrated the new equipment and routine checks over the next five years failed to catch the error.



Badly sized small field detector

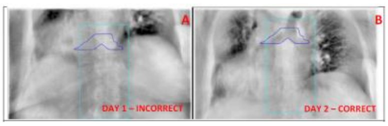
Better sized small field detector (not to scale)

Conventional Fumbles

Radiation Treatment Performed on Wrong Side of Patient's Brain

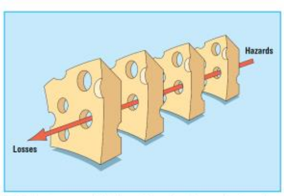
DETROIT -- A patient undergoing treatment at the Karmanos Cancer Institute in Detroit received a dose of radiation on the wrong side of the brain, according to a report filed with the United States Nuclear Regulatory Commission. According to the report, a crucial piece of information was misread prior to treatment with a gamma knife, which delivers a targeted form of radiation therapy that zeros in on specific locations in the brain.

The patient went through a routine MRI (magnetic resonance imaging) scan of the brain just before the procedure, but went into the scanner "feet first," rather than the standard practice of head first, the document said. "The gamma knife-authorized medical physicist failed to recognize the scanning error when importing the MRI images into the Gamma Knife treatment planning computer, and subsequently registered them as head first," the report said. "This r



UCLA 2011

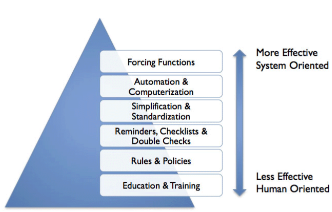
Reason's Swiss Cheese Model



The Swiss cheese model of how defences, barriers, and safeguards may be penetrated by an accident trajectory

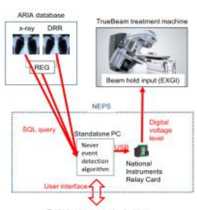
Reason, "Human Error: Models and Management, BMJ 2000; 320:768-70

Hierarchy of effectiveness

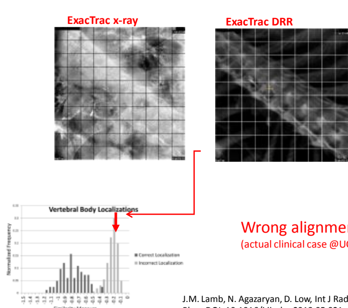


http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

Virtual therapist image review (VTIR)



- We are developing an algorithm to automatically detect patient ID and serious patient positioning errors by analyzing image similarity of setup images with planning CTs.
- We will use our algorithm to make an on-line never-event prevention system (NEPS) that will interlock the treatment machine until the right patient is in the right treatment position.



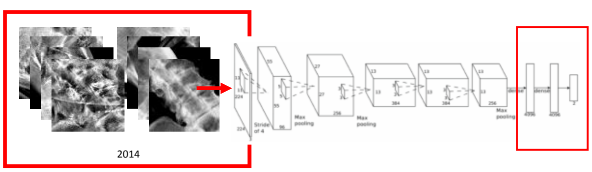
Wrong alignment
(actual clinical case @UCLA)

J.M. Lamb, N. Agazaryan, D. Low, Int J Radiat Biol Phys, DOI: 10.1016/j.ijrobp.2013.05.021

AHRQ R01 Project

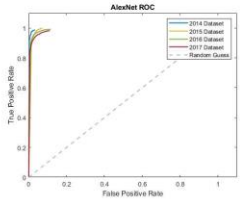
- **Specific Aim 1:** We will develop a robust never-event detection algorithm for planar x-ray setup imaging.
- **Specific Aim 2:** We will employ our never-event detection algorithms to measure the clinical never-event rate [in UCLA and VA image databases], testing the hypothesis that it has been significantly underreported.
- **Specific Aim 3:** We will implement our never-event detection algorithms in an on-line, real-time never-event prevention system (NEPS) at UCLA to test its feasibility in a clinical environment.

Preliminary Results (Aim 1)



Preliminary Results (Aim 1)

Performance Metrics		
Training Time	424 min	
Overall Accuracy	97.40%	
	2014	2015-2017
Sensitivity	97.27%	97.10%
Specificity	97.53%	94.17%



Automation in Clinical Radiotherapy Workflow

Segmentation
Planning
Plan Evaluation
Weekly chart checks
Machine QA
…

UCLA Experience With Clinical Automated Planning

- Clinically validated a publically available RapidPlan prostate model, including physician determination that results were clinically acceptable.
- 1 dosimetrists likes to use it, 2 dosimetrists tried it and don't want to use it, 4 dosimetrists didn't want to try it.
- Currently implementing RapidPlan model trained on UCLA data

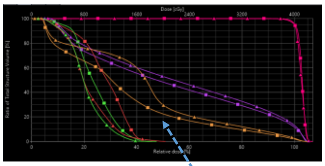
UCLA-Specific RapidPlan Prostate SBRT Model

- Trained on 50 cases from one physician, planned by one dosimetrist
- 17 model iterations to optimize DVH matching to 10 validation cases.
- 10 test cases used for "Auto-Planning Turing Test"

Physician Scores	
Clinical	Our RapidPlan
4/5	4/5
4/5	4/5
4/5	5
4/5	4/5
5	4/5
4/5	4/5
4/5	5
4/5	5
4/5	4/5
4/5	5

Patient	Plan Pair	
1	5,13	Can't tell between the two
2	15,16	Can't tell between the two
3	1,18	Can't tell between the two
4	11,20	Can't tell between the two
5	2,17	Can't tell between the two
6	**6,8**	**8 is better than 6 in a clinically significant way (**
7	12,19	Can't tell between the two
8	7,10	Can't tell between the two
9	**4,9**	**4 is better than 9 in a clinically insignificant way**
10	3,14	Can't tell between the two

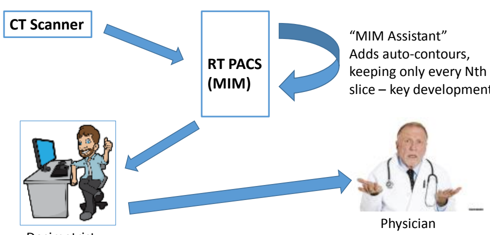
UCLA-Specific RapidPlan Prostate SBRT Model

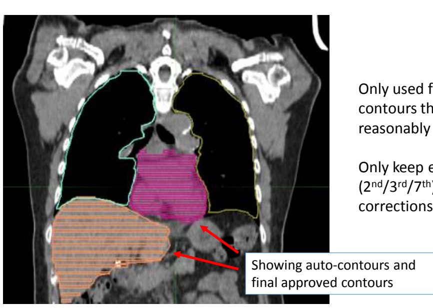


When applied to outliers in historical record, improves on clinical plan.

RapidPlan significantly lower on rectum

UCLA Experience with Clinical Contouring Automation





Only used for a subset of contours that work reasonably ok.

Only keep every Nth ($2^{nd}/3^{rd}/7^{th}$) slice to make corrections easier.

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Inability to ascertain whether it helps/hurts time
- Perfectionism
- Sensitivity to criticism / power difference
- Fear of liability
- Fear of losing skills
- Fear of losing intellectual work product

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Perfectionism
- Sensitivity to criticism / power difference
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Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Perfectionism
  "Yes I know 1-2 mm doesn't matter because all the organs are going to be a bit different at treatment time. But I'm supposed to make my part as precise as possible."
- Sensitivity to criticism / power difference
- Fear of liability
- Fear of losing skills
- Fear of losing intellectual work product

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Perfectionism
- **Sensitivity to criticism / power difference**

  "If the contours don't look right, even if it doesn't matter, the doctor will think I don't know how to do my job."
- Fear of liability
- Fear of losing skills
- Fear of losing intellectual work product

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Perfectionism
- Sensitivity to criticism / power difference
- **Fear of liability**

"What's it going to look like in court if my contours are all jaggedy?"

- Fear of losing skills
- Fear of losing intellectual work product

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

- Perfectionism
- Sensitivity to criticism / power difference
- Fear of liability
- **Fear of losing skills**

"EZFluence works really well for simple breast cases, but I worry that if I get used to it, I'll get out of practice, and it will make it harder to do complicated breast cases."

- Fear of losing intellectual work product

Human factors barriers to RT planning automation

An interview with UCLA medical dosimetrists

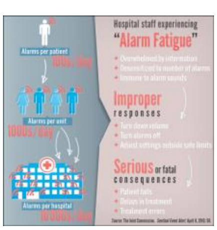
- Perfectionism
- Sensitivity to criticism / power difference
- Fear of liability
- Fear of losing skills
- Fear of losing intellectual work product

"If I could imagine working in a place where everybody just pressed a button to optimize plans, I would hate working in that place."

Although intended to reduce errors, automation can also induce errors.

- Alert fatigue
- Over-reliance on technology
  Elimination of error checks performed by humans

Alert fatigue



Joint Commission Sentinel Event Alert

- Classic examples:
  1. Beeping physiological monitors
  2. Drug-drug interaction alerts in CPOE systems

Also implicated in R&V overrides

'Alarm fatigue' linked to patient's death

US agency says monitors at MGH unheeded

By Liz Kowalczyk
Globe Staff / April 3, 2010

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Federal investigators concluded that "alarm fatigue" experienced by nurses working among constantly beeping monitors contributed to the death of a heart patient at Massachusetts General Hospital in January.

Over-reliance errors

Tesla's Self-Driving System Cleared in Deadly Crash

By NEAL E. BOUDETTE JAN. 19, 2017

"Tesla had said its camera failed to recognize the white truck against a bright sky. But the agency essentially found that **Mr. Brown was not paying attention to the road**. It determined he … should have had at least 7 seconds to notice the truck before crashing into it." - NYTimes

Image: NTSB

TRANSPORTATION \ UBER \ RIDE SHARING

Safety driver of fatal self-driving Uber crash was reportedly watching Hulu at time of accident

Police report deems accident 'entirely avoidable'

By Chaim Gartenberg | @cgartenberg | Jun 22, 2018, 9:54am EDT

Over-reliance errors in RT

FACILITATION OF RADIOTHERAPEUTIC ERROR BY COMPUTERIZED RECORD AND VERIFY SYSTEMS

Gregory A. Patton, M.D., M.S., M.S., M.B.A.,* David K. Gaffney, M.D., Ph.D.,† and John H. Moeller, M.S.†

"The common denominator among these R&V-related errors was excessive reliance upon the computer system by therapists."

"R&V cannot substitute for thinking on the part of radiation therapy team members."

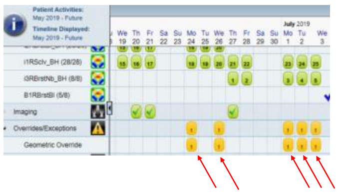
Over-Reliance Errors in RT

Plan Quality Report
Pelvis - Prostate SBRT

Patient: [redacted]
MRN: [redacted]
Course - Plan: 2019_06_TBStx - I1Prst
Dose Rx: 800.0 cGy x 5 fractions = 4000.0 cGy
Report Creation Date: 6/19/2019

Structure	Contour	Constraint	Ideal Goal	Acceptable Goal	Achieved	Result
P_Prst	PTV40	V100 %	>=95%	None	95.00 %	PASSED
Body	Body	R50%	<=4--	None	3.34 --	PASSED
Rectum	O_Rctm	V20 Gy	<=50%	None	27.20 %	PASSED
Rectum	O_Rctm	V32 Gy	<=20%	None	8.51 %	PASSED
Rectum	O_Rctm	V36 Gy	<=10%	None	5.43 %	PASSED
Rectum	O_Rctm	V40 Gy	<=5%	None	2.11 %	PASSED
Bladder	O_Bldr	V20 Gy	<=40%	None	39.63 %	PASSED
Bladder	O_Bldr	V40 Gy	<=10%	None	7.76 %	PASSED
Femur	O_Femr_Lt	V16 Gy	<=5%	None	0.00 %	PASSED
Femur	O_Femr_Rt	V16 Gy	<=5%	None	0.11 %	PASSED

Alert Fatigue in RT



Final thoughts

- Essential to consider human factors when implementing automation in the clinic.
- Introducing automation will prevent some errors, cause others
- In the long run, automation will be a force for good

How do we learn about errors?

Radiation Offers New Cures, and Ways to Do Harm

The Times found that on 133 occasions, devices used to shape or modulate radiation beams — contributing factors in the injuries to Mr. Jerome-Parks and Ms. Jn-Charles — were left out, wrongly positioned or otherwise missed.

On 284 occasions, radiation missed all or part of its intended target or treated the wrong body part entirely. In one case, radioactive seeds intended for a man's cancerous prostate were instead implanted in the base of his penis. Another patient with stomach cancer was treated for prostate cancer. Fifty patients received radiation intended for someone else, including one brain cancer patient who received radiation intended for breast cancer.

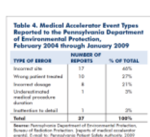


Table 4. Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, February 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

- Academic studies of reported error rates of 1-4% per patient including errors with little/no clinical impact
- Per-patient reported error rates in the range of 0.1% for errors resulting in under/over-dose by 5% or more [1,2].
- It is likely that errors are under-reported [3-5]
- In-vivo dosimetry studies have shown ~0.5% per patient rate of unreported and otherwise undetected “serious” errors [6]

1. Huang, et al, *Error in the delivery of radiation therapy: Results of a quality assurance review.* International Journal of Radiation Oncology*Biology*Physics, 2005. **61**(5): p. 1590-1595.
2. Yeung, T.K., et al, *Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period.* Radiotherapy and Oncology, 2005. **74**(3): p. 283-291.
4. Williams, M.V., *Improving patient safety in radiotherapy by learning from near misses, incidents and errors.* British Journal of Radiology, 2007. **80**(953): p. 297-301.
4. Mutic, S. et al , *Event (error and near-miss) reporting and learning system for process improvement in radiation oncology.* Medical Physics, 2010. **37**(9): p. 5027-5036.
5. Rahn Iii, D.A., et al., *A Real-Time Safety and Quality Reporting System: Assessment of Clinical Data and Staff Participation.* International Journal of Radiation Oncology*Biology*Physics, 2014. **90**(5): p. 1202-1207.
6. Mans, A., et al. "Catching errors with in vivo EPID dosimetry." *Medical physics* 37.6 (2010): 2638-2644.

AHRQ R01

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Another actual incident report

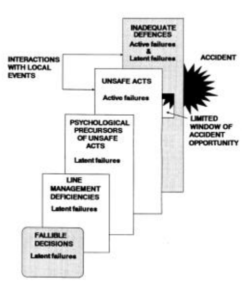
1. I brought patient John Doe into the room with the vacloc setup and covered with the sheet. Frank and I setup the patient and we went outside the room.
2. Frank is driving and doing the MVCT on the Tomotherapy machine, and I was doing the encounter, timeout and charting.
3. Once images were done and matched, and saved, the images were sent over. I was importing the MVCT image document and noticed the vertical shift was over 10mm tolerance (14mm) approx., and told my coworker to stop the treatment machine.

Independent, automated, failsafe backups of human decision making, while still leaving the human in control of the workflow.

- Construction management systems
- Ground proximity warning systems for avoiding "controlled flight into terrain"
- Air traffic control conflict detection systems
- Physician decision support, e.g. detecting harmful drug-drug interactions and missed allergies using computerized order entry.

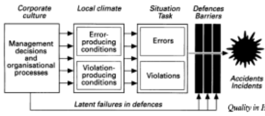
An actual incident report

1. Exactrac automatic fusion resulted in a 20 – 25 mm longitudinal misalignment that was not caught by the treating therapists. The misregistration performed by automatic alignment may have been caused by the initial vertical offset. **The therapists did not think the large shift was cause for concern and shifted the patient based on the 25 mm misregistration.** During followup verification imaging they then concentrated on aligning the two wrong vertebral bodies. When they couldn't get a good alignment they proceeded to image and align with CBCT.
2. When CBCT was performed the patient was already misaligned by 1 vertebral body. The therapists did not observe the large discrepancy during CBCT image registration and again concentrated on a limited field of view as they attempted to fuse the two mismatched vertebral bodies.
3. An therapists unfamiliar with Exactrac imaging was filling in on the machine during the treatment. Thus, only the therapist driving the Exactrac IGRT was familiar with the process. **The fill-in therapist was not certain of the alignment but defaulted to the judgment of the Exactrac therapist.** Thus, there was only limited "second check" of alignment at the machine.



Phil. Trans. R. Soc. Lond. B. **327**, 475–484 (1990)

Reason's psychology of errors



Quality in Health Care 1995;4:80–89

Fig 3 Stages of development of organisational accident

Some of Reason's Recommendations (Reason 1995):

- "Human rather than technical factors represent the greatest threat to complex and potentially hazardous systems."
- "Effective risk management depends on a confidential and preferably anonymous incident reporting system."
- "Automation and increasingly advanced equipment do not cure human factors problems."

Reason's psychology of errors

Quality in Health Care 1995;4:80–89

Understanding adverse events: human factors

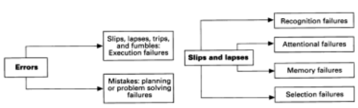


Fig 1 Distinguishing slips, lapses, and mistakes

Fig 2 Varieties of slips and lapses

Errors (as defined above)
vs.
Violations (known deviations from safe practices, procedures, standards or rules)