Incidents in Radiation Therapy
- What can be done?

**ICTP School on Medical Physics**
*March 25 – April 5, 2019*
*Miramare, Trieste*

Yakov Pipman, DSc
Many recommendations. Perhaps too many!

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<td>6</td>
</tr>
<tr>
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<td>5</td>
</tr>
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<td>117</td>
</tr>
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<td></td>
</tr>
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<td></td>
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</tr>
</tbody>
</table>
What can we do?

Education and Training

Multilayered prevention

Risk assessment – (FMEA)

Learning and Reporting Systems

Analyzing – Root Cause Analysis (RCA)

Developing a Safety Culture
PREVENTION OF ACCIDENTAL EXPOSURE IN RADIOTHERAPY

Part 5: Reporting, investigating and preventing accidental exposures

https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/AccidentPreventionRadiotherapy.htm
Multilayered prevention of accidental exposures

- The term “defence in depth” is defined in the BSS as “the application of more than one single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fail”.

- “Defence in depth” can be viewed as several layers of safety provisions, such as physical components and procedures.
Multilayered prevention includes aspects of “defence in depth” but also includes aspects such as awareness and alertness which could be termed “conceptual defence”.

For this multilayered prevention of accidental exposures to work, these layers need to be independent of each other.

An implemented Quality Assurance program might provide the layers. Part of the QA should be to verify that this is the case!
Multilayered prevention of accidental exposures

*Initiating events will happen many times in any clinic*

*If there are no layers of safety provision, these events will lead to accidental exposures*
Multilayered prevention of accidental exposures

By putting in a layer of safety-provision, many initiating events are stopped from becoming accidental exposures.

When only a single layer of safety-provision is present, failure of this layer can still lead to accidental exposures.
Multilayered prevention of accidental exposures

By having multiple independent layers of safety-provision, there is a much higher likelihood that accidental exposures are prevented.
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

Consequence: Very significant dose deviation for a patient
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

Consequence: Very significant dose deviation for a patient
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

Consequence: Very significant dose deviation for a patient

Independent check of calculation

Weekly chart-check of “reasonability”
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

- Independent check of calculation
- Weekly chart-check of “reasonability”
- In vivo dosimetry

Consequence: Very significant dose deviation for a patient
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

- Independent check of calculation
- Weekly chart-check of “reasonability”
- In vivo dosimetry
- Written procedure for calculation methods

Consequence: Very significant dose deviation for a patient
Multilayered prevention of accidental exposures

Initiating event: Mistakenly inverting SSD-correction in MU-calculation

- Independent check of calculation
- Weekly chart-check of “reasonability”
- In vivo dosimetry
- Written procedure for calculation methods

Consequence: Very significant dose deviation for a patient

Awareness! Shorter SSD means shorter treatment time for same dose
Multilayered prevention of accidental exposures

Initiating event: ?

Consequence: ?

TRY IT AS AN EXERCISE!

Examples of initiating events:
- Calibration of beam made in penumbra
- Pancake chamber used upside down
- Use of wedge factor twice in calculation of treatment time
- Misunderstanding of verbal prescription
To Create Barriers we use Process Maps

PLANNING

Diagnosis

Planning CT

Reference Imaging (eg. MRI, PET-CT etc) → Fuse Data → Target Volume Delineation → Dose planning

TREATMENT DELIVERY

Delivery of treatment fraction → Correct for setup errors → Evaluate validity of matching → Match with reference images → In room Imaging → Acquire treatment images/info

Repeat as required

Review

On treatment review → Evaluate appropriateness of plan and its delivery → COMPLETE PLANNED TREATMENT

Assess for adaptive planning → Need for change in plan
10 Plan preparation

- Enter demographics
- Specify treatment course
- Delivery protocols
- Prepare DRR and other images
- Define localization imaging
- Annotate localization anatomy
- Order fields
- Prepare paper chart
- Prepare electronic chart
  - Check version of plan and patient ID
- Automatic data entry and plan modification
- Transfer patient data to treatment delivery
- Manual data entry and plan modification
- Scheduling
Failure Modes and Effects Analysis-FMEA

• Assess potential risks of each step
  – Determine the failure modes – what can go wrong?
  – What can cause each failure?

• Estimate the likelihood of each failure
  O = “Occurrence” rating
  • 1 is unlikely, 10 is inevitable

• Estimate the consequences of each failure
  S = “Severity” rating
  • 1 is mere bother, 10 is catastrophe

• Estimate likelihood that failure will NOT be detected
  D = “Detectability” rating
  • 1 is obvious, 10 is almost impossible to detect

• RPN=Risk Priority Number=O×S×D
  • 1 is minimal risk, 1000 is huge risk

From Helen Yorke- TG100
What is Safety?

- The absence of an unacceptable risk of harm.

- What is harm in RT?
  - excess morbidity
  - sub-optimal tumour control.
Quality in Radiotherapy

The degree to which radiation therapy is consistent with current professional knowledge:

- The prescription is appropriate, i.e. evidence based
- The prescription is delivered within tolerances determined by consensus in the profession
\[ \sim 99.7\% = \pm 3\sigma \]
\[ \sim 95.4\% = \pm 2\sigma \]
\[ \sim 68.3\% = \pm 1\sigma \]

\[ \mu = \bar{N} \]
Is Safety an issue in Radiotherapy?

<table>
<thead>
<tr>
<th></th>
<th>“Serious” Incidents per course</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York State</td>
<td>0.012%</td>
</tr>
<tr>
<td>Varian</td>
<td>0.002%</td>
</tr>
<tr>
<td>UK</td>
<td>0.003%</td>
</tr>
</tbody>
</table>

The chance of dying or being injured on a U.S. domestic flight is about 0.00001%

(Ford and Terezakis, IJROBP 2010)
How many patients fall into the “Quality Trap”?

There are about 750,000 patients receiving RT per year in the U.S.

At 0.01% that would be 75 serious accidents per year in the US alone!

If we ignore retreats, that is approximately 750,000 courses per year.

2.6% of 750,000 is about 20,000
TREATMENT VARIANCE REPORT

Department of Radiation Oncology

Reported on: __/__/200__  Reported by: __________  Occurrence date(s): __/__/200__

Patient ID: __________  Attending MD: __________  Radiologist: __________

Details: __________

Calculation / Plan / System / Equipment / Machine / Identification / Machine function / Identification

Description of Variance (reporting staff):

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

Summary of Variance analysis (Physics) (report attached):

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

 EFFECT CATEGORY  ✓  REPORTING CLASS  ❌

 Presented  Minor

 Corrected  Reinstallable

 Uncorrectable  Miscellaneous

 DEPARTMENTAL REVIEW: Date: __/__/200__

 Comments:

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

 Corrective action:

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________
Variance?

• A difference between what is expected and what actually occurs.

• An event that departs from the normal, the routine or from what we expected.
What information did we collect?

Department of Radiation Oncology
TREATMENT VARIANCE REPORT
Reported on __/__/200_   Reported by:____________   Occurrence date(s): __/__/200_, _____
Patient ID:___________   Attending M.D.:____________   Assigned Physicist:____________
Details:   Blocks / MLC / MU / Wedges / Geometry / Energy / Mode / Setup / Machine____/
          Calculation / Plan / # of Fx’s __ / Machine function / Identification
          Other____________________________________________________________
          Therapist(s): ____________________________________ _____
Description of Variance (reporting staff):
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
THE ABOVE SECTION TO BE COMPLETED BY REPORTER
What did we do with it?

- Bring to the attention of the attending Physician since s/he is ultimately responsible for the patient’s treatment.
- As the case may be, bring to the immediate attention of a supervisor or Physics.
- “Treatment Variance” forms are collected by Sherin.
What did we do with it?

- Analyzed the specifics of the variance
  - What is the effect on the patient
  - Is there a lesson to learn and/or changes to be made
  - What reporting category does the variance fall into.
Each case would be evaluated by the QA team, and the analysis reported

Summary of Variance analysis (Physics) (report attached[ ])

<table>
<thead>
<tr>
<th>EFFECT CATEGORY</th>
<th>√</th>
<th>REPORTING CLASS</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevented</td>
<td></td>
<td>Minor</td>
<td></td>
</tr>
<tr>
<td>Corrected</td>
<td></td>
<td>Recordable</td>
<td></td>
</tr>
<tr>
<td>Uncorrectable</td>
<td></td>
<td>Misadministration</td>
<td></td>
</tr>
</tbody>
</table>

THE ABOVE SECTION TO BE COMPLETED BY PHYSICS
Significant error?

• When evaluating the significance of an error, its effect was evaluated on the assumption that the patient’s treatment would be solely determined by that particular error.
A measure, or action, is truly redundant if it can perform the same function of a different measure, in its absence.
Proposed Corrective Action and Discussion

- Let’s change “xyhp”
- We should replace “yzz” with “rstuv”
- The last one to “zxtt” will do “abcd”
- We will now use “dkfgh”!
OVERALL ANALYSIS:
Number of cases reviewed: _____ fields _____ ESTV’s
Number of cases identified: _____

<table>
<thead>
<tr>
<th>Effect Category</th>
<th>#</th>
<th>Reporting Class</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevented</td>
<td></td>
<td>Minor</td>
<td></td>
</tr>
<tr>
<td>Corrected</td>
<td></td>
<td>Recordable</td>
<td></td>
</tr>
<tr>
<td>Uncorrectable</td>
<td></td>
<td>Misadministration</td>
<td></td>
</tr>
</tbody>
</table>

SPECIFIC CONCLUSION:

ACTION:
Newer incident reporting systems

Safer use of radiation in radiotherapy through learning and reporting

SAFRON aims to enable global shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy.

Featured Incident Reports

HDR vaginal cylinder brachytherapy treatment delivered to incorrect location
Patient received first of three intended deliveries of HDR vaginal

Featured Documents & Links

Report No. 167- Guidelines by the AAPM and GEC-ESTRO on the use of innovative brachytherapy devices
Although a multicenter, Phase III, prospective, randomized trial is
Information and Instructions for Registering with NUCLEUS

Prior to registering with Safety Reporting and Learning System for Radiotherapy (SAFRON), the registrant must register with NUCLEUS, the Agency’s information resource catalogue. The link to NUCLEUS is: http://nucleus.iaea.org/Home/index.html

Instructions for Registering with SAFRON

SAFRON is an integrated voluntary reporting registry of radiation oncology incidents and near misses. Its success is dependent on facilities registering and sharing incidents that occur in their institutions. The registration form includes details on the equipment, staff and environment in your centre. This information indicates the complexity of the processes within departments. It will be used to carry out trend analyses of incidents in relation to complexity of practice, working environment and educational background of professional staff in a range of clinic types. The information will not be seen by other users of SAFRON.
All process step for: External beam radiotherapy

1.2.4.5. Other

2. Pre-treatment phase
   2.1. Assessment of patient
      2.1.1. Identification of patient
      2.1.2. Verification of diagnosis/extent/stage
      2.1.3. Other
   2.2. Decision to treat
      2.2.1. Completion of required information
      2.2.2. Recording of patient ID
      2.2.3. Recording of previous treatment details
      2.2.4. Recording of patient's specific requirements
      2.2.5. Recording of non-standard information/protocol variations
      2.2.6. Other
   2.3. Prescribing treatment protocol
      2.3.1. Choice of dose
      2.3.2. Choice of modality
      2.3.3. Choice of energav

2.9. Other

3. Treatment phase
   3.1. Treatment setup
      3.1.1. Patient setup
         3.1.1.1. Patient ID process
         3.1.1.2. Patient data ID process
         3.1.1.3. Explanation/instructions to patient
         3.1.1.4. Patient positioning
         3.1.1.5. Use of reference marks
         3.1.1.6. Other
      3.1.2. Treatment unit setup
         3.1.2.1. Setting of treatment machine parameters
         3.1.2.2. Setting of collimator angle
         3.1.2.3. Setting of jaw position
         3.1.2.4. Setting of asymmetry
         3.1.2.5. Setting of couch position/angle
         3.1.2.6. Setting of energav
### Submit Incident Report

**Provide incident report details.**

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment modality:</td>
<td>External beam radiotherapy</td>
</tr>
<tr>
<td>Date of discovery (YYYY-MM-DD):</td>
<td></td>
</tr>
<tr>
<td>Who discovered the incident?</td>
<td></td>
</tr>
<tr>
<td>How was the incident discovered?</td>
<td></td>
</tr>
<tr>
<td>What phase in the process is the incident associated with?</td>
<td></td>
</tr>
<tr>
<td>Where in the process was the incident discovered?</td>
<td></td>
</tr>
<tr>
<td>Was anyone affected by the incident?</td>
<td>Yes, more than 1 patient</td>
</tr>
<tr>
<td>Was any part of the prescribed treatment delivered incorrectly?</td>
<td>No, all fractions could have been, potential incident</td>
</tr>
<tr>
<td>If relevant, please indicate the proportion of fractions delivered incorrectly.</td>
<td></td>
</tr>
<tr>
<td>If relevant, please estimate the dose deviation from the prescribed dose per fraction:</td>
<td></td>
</tr>
<tr>
<td>Clinical incident severity:</td>
<td></td>
</tr>
<tr>
<td>Summarize the incident in a single sentence headline:</td>
<td></td>
</tr>
<tr>
<td>If the incident is related to equipment (hardware or software), please specify the make, model and version number.</td>
<td></td>
</tr>
<tr>
<td>Describe the incident in detail:</td>
<td></td>
</tr>
<tr>
<td>Describe the causes of the incident (Select one)</td>
<td></td>
</tr>
</tbody>
</table>
### Wrong dose normalization in 1-fraction-radiosurgery

<table>
<thead>
<tr>
<th>Treatment modality:</th>
<th>External beam radiotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment used:</td>
<td>Linear Accelerator</td>
</tr>
<tr>
<td>Treatment method:</td>
<td>Stereotactic radiosurgery (cranial or body)</td>
</tr>
<tr>
<td>Date of discovery:</td>
<td>2019-01-25</td>
</tr>
<tr>
<td>Who discovered the incident?</td>
<td>Medical physicist</td>
</tr>
<tr>
<td>How was the incident discovered?</td>
<td>Found at the time of first patient treatment during regular checks</td>
</tr>
<tr>
<td>What phase in the process is the incident associated with?</td>
<td>2.6.7. Recording of definitive treatment prescription</td>
</tr>
<tr>
<td>Where in the process was incident discovered?</td>
<td>2.6.6. Authorization of plan</td>
</tr>
<tr>
<td>Was anyone affected by the incident?</td>
<td>No, but someone could have been; potential incident</td>
</tr>
<tr>
<td>Was any part of the prescribed treatment delivered incorrectly?</td>
<td>No, but patient could have been affected</td>
</tr>
<tr>
<td>First day of treatment:</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Incident Reports

**Wrong electron dose calculation from 600 cgy to 400 cgy x fraction dose deviate from 1200 cgy to 800 cgy**

<table>
<thead>
<tr>
<th>Describe the incident in detail:</th>
<th>Doctor prescribed electron for keloid case 600 cgy x 2 fraction but Physicist calculate 400 cgy x 2 fraction the incident caused by no recheck (timeout) by second physicist, the incident meet by the completed chart check by the physicist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the causes of the incident:</td>
<td></td>
</tr>
<tr>
<td>Did the incident reach the patient?</td>
<td>Yes</td>
</tr>
<tr>
<td>What safety barrier failed to identify the incident?</td>
<td></td>
</tr>
<tr>
<td>What safety barrier identified the incident?</td>
<td>Independent confirmation of dose</td>
</tr>
<tr>
<td></td>
<td>Regular independent chart checks</td>
</tr>
<tr>
<td>What safety barrier might have identified the incident?</td>
<td>Post treatment evaluations (evaluation of clinical and process)</td>
</tr>
<tr>
<td>Describe contributing factors to the incident:</td>
<td>no timeout or recheck dose calculation by the second physicist before treatment</td>
</tr>
<tr>
<td>Suggest preventive action(s):</td>
<td>Dose calculation recheck by second medical physicist must be completed before patient treatment delivery</td>
</tr>
</tbody>
</table>

**If relevant, please estimate the dose deviation from the prescribed dose per fraction:**

- >50%

**Clinical incident severity:**

- No information provided
Incidents by clinical incident severity

Distribution of clinical incident severities, with which the incident is associated
<table>
<thead>
<tr>
<th>Number of staff:</th>
<th>Radiation oncologists (physicians):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical physicists:</td>
</tr>
<tr>
<td></td>
<td>Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at treatment units treating patients:</td>
</tr>
<tr>
<td></td>
<td>Radiation Therapy Technologists (RTT) / Radiation Therapists / Staff at simulator and/or in-house CT:</td>
</tr>
<tr>
<td></td>
<td>Staff doing dosimetry i.e. treatment planning etc:</td>
</tr>
<tr>
<td></td>
<td>Staff doing technical maintenance on radiotherapy equipment:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How is most of your equipment maintenance performed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Safety infrastructure in place at the clinic: (Select all that apply to your clinic)</td>
</tr>
<tr>
<td>□ There are documented policies and procedures for most of the clinical processes</td>
</tr>
<tr>
<td>□ There are written policies and procedures for equipment quality control (including software)</td>
</tr>
<tr>
<td>□ There are appropriate education and training for staff</td>
</tr>
<tr>
<td>□ There is a committee with responsibility for on-going quality and safety improvement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety barriers in place at the clinic: (Select all that apply to your clinic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Verification of patient ID</td>
</tr>
<tr>
<td>□ Verification that pretreatment condition have been taken into account</td>
</tr>
<tr>
<td>□ Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)</td>
</tr>
<tr>
<td>□ Verification reference points</td>
</tr>
<tr>
<td>□ Physician peer review</td>
</tr>
<tr>
<td>□ Review of treatment plan</td>
</tr>
<tr>
<td>□ Independent confirmation of dose</td>
</tr>
<tr>
<td>□ Time out</td>
</tr>
<tr>
<td>□ Use of record and verifying system</td>
</tr>
<tr>
<td>□ Verification of treatment accessories</td>
</tr>
<tr>
<td>□ Image based position verification</td>
</tr>
<tr>
<td>□ In vivo dosimetry</td>
</tr>
</tbody>
</table>

https://rpop.iaea.org/SAFRON/ClinicRegistration/ClinicRegistrationEdit.aspx
ASTRO and the AAPM (2014) - medical specialty society sponsored radiation oncology PSO. Goal: Educate the radiation oncology community on how to improve safety and patient care.
What to Report or Track

- Explicit events – frequent events
- Random events
- Actual errors
- Potential errors (near misses)
- Corrective measures
Incident Reporting Depends on Factors

- Culture
- Reporting system and guidelines
- Competence to interpret reported data
- Willingness to implement
  - Changes based on collected data and analyses
- Ability to share data and provide feedback
  - Power distance index
## Organizational Culture

<table>
<thead>
<tr>
<th>Pathological Culture</th>
<th>Bureaucratic Culture</th>
<th>Generative Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not want to know</td>
<td>May not find out</td>
<td>Actively seek it</td>
</tr>
<tr>
<td>Messengers (whistle blowers) are “shot”</td>
<td>Messengers are listened to if they arrive</td>
<td>Messengers are trained and rewarded</td>
</tr>
<tr>
<td>Responsibility is shirked</td>
<td>Responsibility is compartmentalized</td>
<td>Responsibility is shared</td>
</tr>
<tr>
<td>Failure is punished or concealed</td>
<td>Failures lead to local repairs</td>
<td>Failures lead to far reaching reforms</td>
</tr>
<tr>
<td>New ideas are actively discouraged</td>
<td>New ideas often present problems</td>
<td>New ideas are welcomed</td>
</tr>
</tbody>
</table>

Reason, J., Managing the risks of organizational accidents. Different organizational cultures
Final Disposition

- Resolution and corrective action
- Responsible person
- Implementation plan
- Evaluation plan
- Follow up plan
Root Cause Analysis - when

1. Any single obviously serious event
2. Systematic events
3. High frequency sporadic events

Root Cause Analysis - how

1. Collect information – WHAT happened
2. Identify causes – WHY, WHY, WHY, WHY, WHY
3. Recommendations for remediation
4. Implement and Monitor
 Incident Reporting and Learning systems must be:

- Friendly for reporting
- Responsive
- Dynamic

Safety culture - free of fear
MANY TOOLS!!

Safety culture - free of fear

Incident Learning systems - Friendly for reporting, responsive and dynamic

Root cause analysis methods

Check lists

Standard procedures and handoffs
The art of learning from our mistakes
Resources

- IAEA → http://www.iaea.org/
- AAPM → http://www.aapm.org/
- ASTRO → https://www.astro.org/
- TreatSafely → http://www.treatsafely.org/index.php
- AHRQ (Agency for Healthcare Research and Quality)
References

ASTRO report 2012
Safety is No Accident: A Framework for Quality Radiation Oncology and Care. Zeitman A, Palta J, Steinberg M. ASTRO; 2012
Updated edition, March 2019:
https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/Safety_is_No_Accident.pdf

AAPM white-paper 2012

ASTRO safety white-papers

ASRT safety white-paper
Thank you!

ypipman@gmail.com