Overview

WHAT are radiation treatment overdoses?

SO WHAT: What are the impacts?

NOW WHAT do we do to reduce patient safety risk?
WHAT are radiation therapy overdoses?

More than half of all cancer patients receive radiation therapy.

Death or serious disability associated with:
- Use or function of a device in patient care in which the device is used or functions other than intended
- Burns

are both a “never event” (National Quality Forum)

Impacts of radiation therapy overdoses

It is estimated 1 in 20 patients will suffer injuries. Some are normal complications from radiation.

New York State data from 2001 to 2008 found 621 mistakes (133 modulation errors, 284 missed correct body part, 50 were given radiation for someone else)

In 2013, 3 French physicians were convicted of manslaughter & lost their licenses for overdoses
NOW WHAT do we do to reduce patient risk?

- Review radiation therapy administration process
- Causes of radiation therapy errors
- Case studies

Radiation Therapy Process

- Radiation therapy program developed
- Treatment plan entered into computer
- Radiation administered to patient

Physician  Medical Physicist  Medical Physicist  Therapist
Preventing Radiation Treatment Overdoses:
Cause Mapping Case Studies

More Detailed Process

1) Therapy machine set up, calibrated
2) Radiation therapy plan developed
3) Treatment plan entered into computer
4) Patient positioned in machine
5) Radiation administered to patient

What Can Go Wrong

1) Therapy machine set up, calibrated
2) Radiation therapy plan developed
3) Treatment plan entered into computer
4) Patient positioned in machine
5) Radiation administered to patient

- Calibration, set up incorrect
- Entry errors
- Wrong treatment
- Wrong patient
- Patient positioned incorrectly
Preventing Radiation Treatment Overdoses: Cause Mapping Case Studies

![Radiation Therapy Errors – Error Type](image1)

![Radiation Therapy Errors – Error Causes](image2)
Case Study 1: Programming Overdose

Entry errors

1) Therapy machine set up, calibrated
2) Radiation therapy plan developed
3) Treatment plan entered into computer
4) Patient positioned in machine
5) Radiation administered to patient

Case study 1: Programming Overdose

Step 1. Outline

<table>
<thead>
<tr>
<th>What</th>
<th>Problem(s)</th>
<th>Fatal radiation overdose</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Date</td>
<td>March 14, 2005</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>(Over 3 days)</td>
</tr>
<tr>
<td>Where</td>
<td>Different, unusual, unique</td>
<td>Computer crash, staff shortage</td>
</tr>
<tr>
<td></td>
<td>Facility, site</td>
<td>Manhattan, NY</td>
</tr>
<tr>
<td></td>
<td>Unit, area, equipment</td>
<td>Intensity Modulated Radiation Therapy</td>
</tr>
<tr>
<td></td>
<td>Task being performed</td>
<td>Treatment for tongue cancer</td>
</tr>
</tbody>
</table>

Impact to the Goals

<table>
<thead>
<tr>
<th>Patient Safety</th>
<th>Patient death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee</td>
<td>Unable to properly program equipment</td>
</tr>
<tr>
<td>Compliance</td>
<td>Fined by city</td>
</tr>
<tr>
<td>Patient Services</td>
<td>Patient received overdose on 3 occasions</td>
</tr>
<tr>
<td>Labor/Time</td>
<td>Investigation</td>
</tr>
</tbody>
</table>

Frequency

First time hospital has had issue like this
Preventing Radiation Treatment Overdoses:
Cause Mapping Case Studies

**Programming Overdose**
**Step 2. Cause Map**

- **Patient Safety Goal Impacted**: Patient death
- **Patient received 7x overdose on 3 occasions**
- **Radiation ineffectively modulated**
- **Collimator wide open**

**Solution:** Increased training

**Programming Overdose**
**Step 2. Cause Map**

- **Collimator wide open**
- **Collimator incorrectly programmed**
- **Changes to programming lost**
- **Computer crash**

**Solution:** Increased training

- Did not realize programming was lost
Preventing Radiation Treatment Overdoses:
Cause Mapping Case Studies

Programming Overdose
Steps 2. Cause Map and 3. Solutions

Patient Safety Goal Impacted -> Patient death
Patient received 7x overdose on 3 occasions
Radiation ineffectively modulated
Error not noticed for 3 days
AND
Testing performed 3 days later
Solution: Fail safe
Collimator wide open
Solution: Test each programming
Testing performed 3 days later
Solution: 2 therapists
Therapist watching patient not screen

Case Study 2: Machine Set-up Error, Overdose

1) Therapy machine set up, calibrated
2) Radiation therapy plan developed
3) Treatment plan entered into computer
4) Patient positioned in machine
5) Radiation administered to patient

Calibration, set up incorrect
Case study 2: Miscalibration Overdoses

Step 1. Outline

<table>
<thead>
<tr>
<th>What Problem(s)</th>
<th>Patient death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Over 27 days starting April 6, 2005</td>
</tr>
<tr>
<td>Where Facility, site, Unit, area, equipment Task being performed</td>
<td>Missing filter, 3.5x amount of radiation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Impact to the Goals</th>
<th>Patient Safety</th>
<th>Compliance</th>
<th>Patient Services</th>
<th>Organization</th>
<th>Property, Equipment</th>
<th>Labor, Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal Impacted</td>
<td>Patient death</td>
<td>Fine from city</td>
<td>Patient received 3.5x overdose from treatment on 27 occasions</td>
<td>Fine from city</td>
<td>Follow-up exams, testing</td>
<td>Support, treatment</td>
</tr>
</tbody>
</table>

Miscalibration Overdoses

Step 2. Cause Map
Preventing Radiation Treatment Overdoses:
Cause Mapping Case Studies

### Miscalibration Overdoses

#### Step 2. Cause Map & 3. Solutions

- **Patient receiving radiation therapy**
- **Treating aggressive form of breast cancer**
  - **Patient received 3.5x overdose on 27 occasions**
  - **3.5x desired dose delivered to patient**
  - **Radiation not filtered**
  - **Wedge left out of linear accelerator**
    - **Error missed by therapists, during weekly check**
    - **Error not noticed for 27 days**
    - **Ineffective safeguards/checks**
      - **Solution: Improve safeguards/checks**
      - **Solution: Add wedge in check**
      - **Solution: Add command to insert wedge**

#### What’s Being Done

- **FDA initiative**
  - Justification for use of radiation-related procedures
  - Optimization of dose during procedures
  - Safeguards to alert with higher than expected dose
- **FDA/CMS partnership**
  - Quality assurance methods for accreditation
NOW WHAT

- Identify possible improvements to process
  - Minimize distractions
  - Add a double check
  - Alerts/ guides for high risk

- Remember the 5 Rights of medication safety:
  - Right medication
  - Right dose
  - Right time
  - Right route
  - Right patient

Case Study 3: Wrong Patient Overdose

1) Therapy machine set up, calibrated
2) Radiation therapy plan developed
3) Treatment plan entered into computer
4) Patient positioned in machine
5) Radiation administered to patient

Wrong patient
Case study 3: Wrong Patient Overdoses

Step 1. Outline

<table>
<thead>
<tr>
<th>What</th>
<th>Problem(s)</th>
<th>Patient receives radiation for another patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Date</td>
<td>March 1, 2006</td>
</tr>
<tr>
<td></td>
<td>Different, unusual, unique</td>
<td>Second therapist took over treatment</td>
</tr>
<tr>
<td>Where</td>
<td>Facility, site</td>
<td>?</td>
</tr>
<tr>
<td>Task being performed</td>
<td>Radiation therapy</td>
<td></td>
</tr>
</tbody>
</table>

Impact to the Goals

| Patient Safety | Risk for injury |
| Compliance     | Reportable error |
| Patient Services | Patient received unnecessary radiation |

Step 2. Cause Map and 3. Solutions

- Solution: Escort patient from room
- Solution: Chart control
- Solution: Turnover process
- Patient B's chart indicated need for radiation
- Lack of communication between therapists
- Solution: Verify patient identity
- Ineffective verification of patient identity
Examples


More Resources