Prospective risk analysis for radiotherapy using Failure Modes and Effects Analysis (FMEA)

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Introduction

• Radiotherapy is highly complex
• Potential safety risks not always obvious
• Management of risk through:
  • Systematic quality control
  • Incident learning
• Prospective risk analysis is recommended
Prospective risk analysis

- Assessment of risks before incidents develop
- Systematic analysis of process
- Failure Modes and Effects Analysis (FMEA) is the most commonly recommended approach in radiotherapy [1]
- Not widely conducted in NZ radiotherapy yet

Image source: The Virtual Leader
Aims

• Conduct the first FMEA in CCDHB Radiation Oncology
• Follow guidelines in AAPM TG100 report [1]
• Focus on stereotactic radiotherapy for the treatment of brain metastases
• Make recommendations for any new safety inventions that should be introduced
Stereotactic radiotherapy for brain metastases

- Used to treat 1-3 brain metastases where the lesions are not amenable to surgery
- Lesion is between 1.6cm and 3cm diameter
- High radiation dose delivered in 1 to 5 treatments
- A number of critical structures can be nearby e.g. brainstem, optic chiasm or cochlea
Stereotactic radiotherapy for brain metastases

Treatment delivered using 1 or 2 continuously shaped arcs of radiation focussed on the target
Method

(1) Multidisciplinary team formed
(2) Team education
(3) Draw up process map
(4) Identify failure modes
(5) Score failure modes: severity, occurrence, detectability
(6) Review scoring
(7) Identify safety interventions
Results: Process map

- Stereotactic brain metastases treatment has 22 steps, each with up to 23 sub steps
- 140 sub-steps in total
Results: Identify failure modes

- 225 possible failure modes identified
- Example:
  - There is missing information on the referral form, in particular information about previous radiotherapy treatment
  - Effect is that patient is treated without consideration of previous radiation dose to treatment area and too much radiation dose is delivered
Results: Scoring

Risk Priority Number (RPN) = Occurrence x Severity x Detectability

<table>
<thead>
<tr>
<th>Score</th>
<th>Occurrence (O)</th>
<th>Severity (S)</th>
<th>Detectability (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Qualitative measure</td>
<td>Frequency</td>
<td>Qualitative measure</td>
</tr>
<tr>
<td>1</td>
<td>Failure Unlikely</td>
<td>0.01%</td>
<td>No effect</td>
</tr>
<tr>
<td>2</td>
<td>Occurrence Likely</td>
<td>0.02%</td>
<td>Inconvenience</td>
</tr>
<tr>
<td>3</td>
<td>Relatively few failures</td>
<td>0.05%</td>
<td>Minor dosimetric error</td>
</tr>
<tr>
<td>4</td>
<td>Occasional failures</td>
<td>0.1%</td>
<td>Limited toxicity or tumour under dose</td>
</tr>
<tr>
<td>5</td>
<td>&lt;0.2%</td>
<td>Limited toxicity or tumour under dose</td>
<td>Wrong dose, dose distribution, location, or volume</td>
</tr>
<tr>
<td>6</td>
<td>Occasional failures</td>
<td>&lt;0.5%</td>
<td>Potentially serious toxicity or tumour under dose</td>
</tr>
<tr>
<td>7</td>
<td>&lt;1%</td>
<td>Potentially serious toxicity or tumour under dose</td>
<td>Very wrong dose, dose distribution, location, or volume</td>
</tr>
<tr>
<td>8</td>
<td>&lt;2%</td>
<td>Potentially serious toxicity or tumour under dose</td>
<td>Very wrong dose, dose distribution, location, or volume</td>
</tr>
<tr>
<td>9</td>
<td>&lt;5%</td>
<td>Possible very serious toxicity or tumour under dose</td>
<td>Very wrong dose, dose distribution, location, or volume</td>
</tr>
<tr>
<td>10</td>
<td>Failures Inevitable</td>
<td>&gt;5%</td>
<td>Catastrophic</td>
</tr>
</tbody>
</table>

Failure mode example:
Occurrence 4/10
Severity 8/10
Difficulty in detectability 4/10

RPN = 128
Precise delineation of the target area for treatment on the scan.
Results: Safety intervention recommendations

- Safety interventions designed for 7 top scoring failure modes
- Balance of resource implications against risk
- In general, the interventions were extra/improved checks
- Recommendations approved by department quality group and will be implemented
Conclusions

• 6 meetings over 3 months
• Challenging to identify all failure modes
• Scoring is subjective
• Identifies high risk steps
• Allows more effective focussing of quality control
• Changes to process are being implemented
• Developing a department policy, guidelines and toolkit
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- Kerryn Waight

References