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

Rebecca Day, Nalini Latta, Rob Louwe, Nichola Naidoo, Kerryn Waight.

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

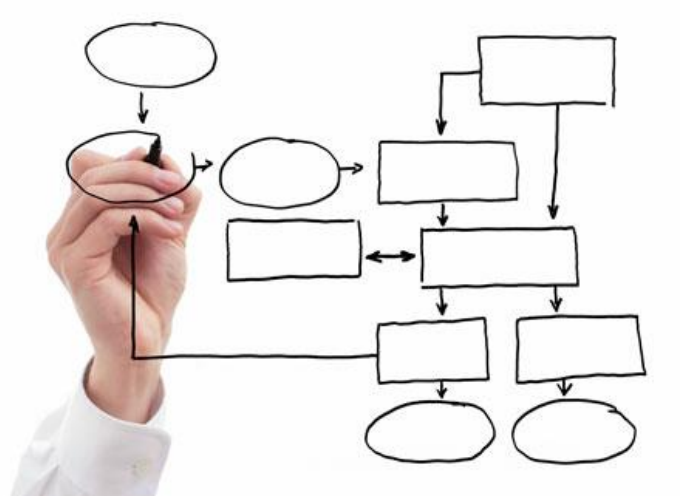


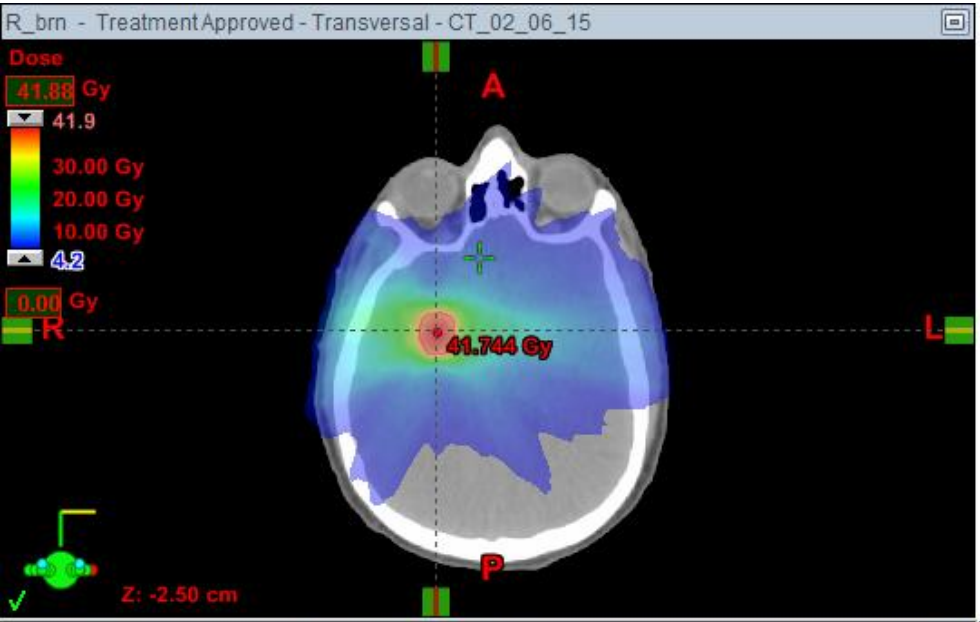
Image source: The Virtual Leader

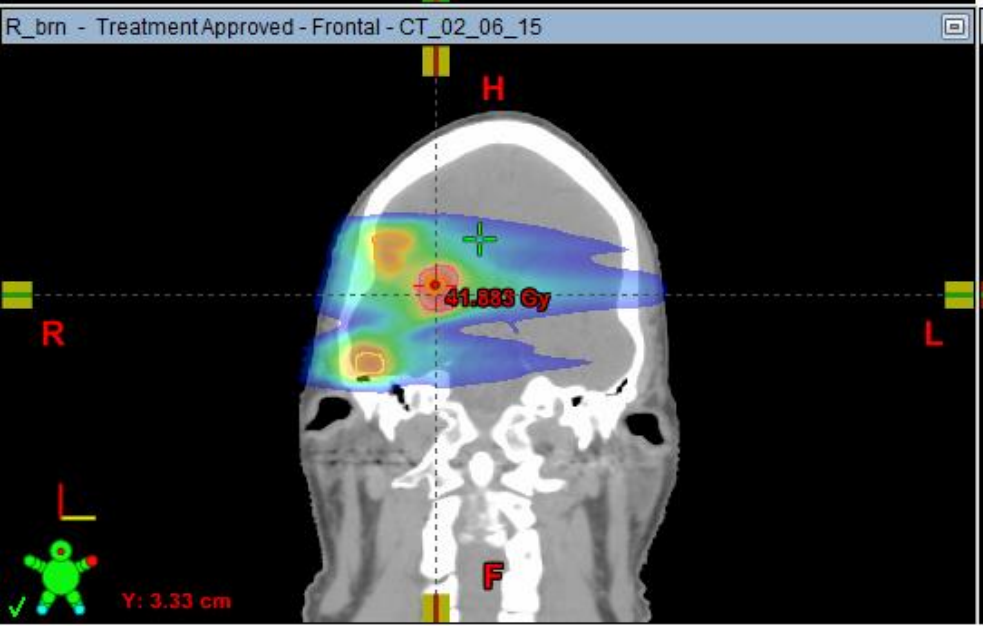
Aims

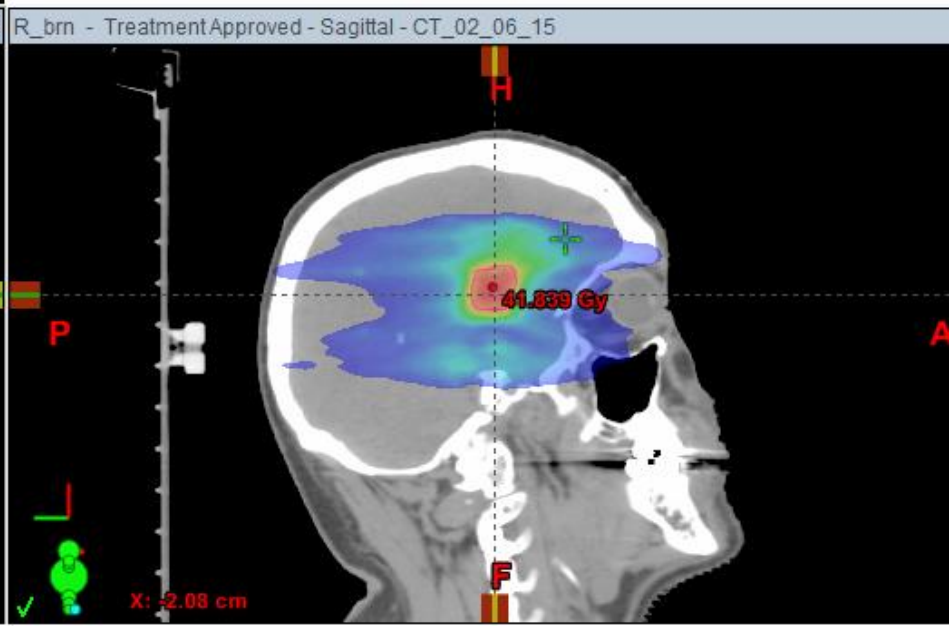
- Conduct the first FMEA in CCDHB Radiation Oncology
- Follow guidelines in AAPM TG100 report [1]
- Focus on stereotactic radiotherapy for the treatment of brain metastases
- Make recommendations for any new safety inventions that should be introduced

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







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

Image source: Brooks Group

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

Score	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative measure	Frequency	Qualitative measure	Categorization	Estimated probability of failure going undetected
1	Failure Unlikely	0.01%	No effect		0.01%
2		0.02%	Inconvenience	Inconvenience	0.2%
3		0.05%			0.5%
4	Relatively few failures	0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0%
5		<0.2%	Limited toxicity or tumour under dose	Wrong dose, dose distribution, location, or volume	2.0%
6	Occasional Failures	<0.5%			5.0%
7		<1%	Potentially serious toxicity or tumour under dose		10%
8	Repeated Failures	<2%			15%
9		<5%	Possible very serious toxicity or tumour under dose	Very wrong dose, dose distribution, location, or volume	20%
10	Failures Inevitable	>5%	Catastrophic		>20%

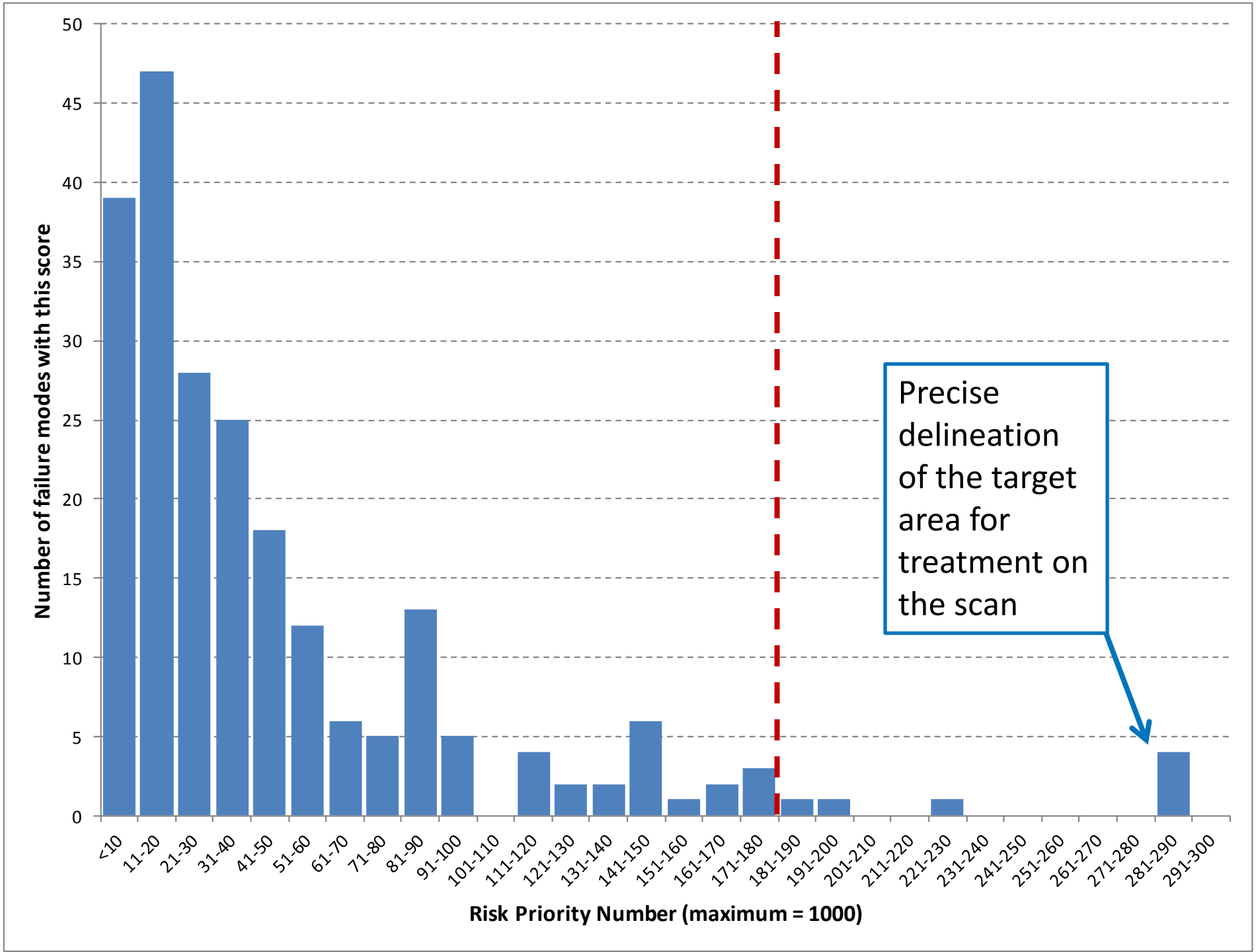
Failure mode example:

Occurrence 4/10

Severity 8/10

Difficulty in detectability 4/10

RPN = 128


Number of failure modes with this score
50
45
40
35
30
25
20
15
10
5
0
<10
11-20
21-30
31-40
41-50
51-60
61-70
71-80
81-90
91-100
101-110
111-120
121-130
131-140
141-150
151-160
161-170
171-180
181-190
191-200
201-210
211-220
221-230
231-240
241-250
251-260
261-270
271-280
281-290
291-300
Risk Priority Number (maximum = 1000)
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

Image source: Kwirkly

rebecca.day@ccdhb.org.nz

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- Nichola Naidoo
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References

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2. Preventing Accidental Exposures from New External Beam Therapy Technologies, International Commission on Radiological Protection Publication 112, Annuals of the ICRP, 2009.
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