Introduction to Quality and Safety

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Tom Baker Cancer Centre
Disclosure

Peter Dunscombe is a Founding Partner of TreatSafely, LLC
Introduction to Quality and Safety

Session Objectives

• To consider how safe radiotherapy actually is based on selected published statistics.

• To suggest that sub-optimal quality in radiotherapy could be a major issue.
Outline

1. Is Safety an Issue in Radiotherapy?
2. Discussion Point.
3. Is Quality an Issue in Radiotherapy?
4. Discussion Point.
5. Three SAMs questions.
Outline

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Is Safety an Issue in Radiotherapy?

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Is Safety an Issue in Radiotherapy?

What is Safety?
Safety is the absence of an unacceptable risk of harm. In our context harm is excess morbidity or sub-optimal tumour control.

Note: the definition of safety is controversial and depends on the context. We can take this as a working definition for our purposes.
The New York State experience

- Serious* Incident Rate: 0.01% per course
- In other words about 1 in every 10,000 courses
*where serious means needed follow up care
The Varian estimate

• Serious* Incident Rate: 0.0001% per treatment
• In other words 1 in every 1,000,000 treatments
• With 20 treatments per course this would be about 1 in every 50,000 courses

* where serious means “involve an incident that puts a patient at risk of harm”
The UK experience

- Serious* Incident Rate: 0.003% per course
- In other words about 3 in every 100,000 courses

*where serious means clinically adverse events per course
Outline

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Discussion Point

Is Safety an issue in Radiotherapy?

<table>
<thead>
<tr>
<th>Source</th>
<th>“Serious” Incidents per course</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York State</td>
<td>1 in 10,000</td>
</tr>
<tr>
<td>Varian</td>
<td>2 in 100,000</td>
</tr>
<tr>
<td>Towards Safer Radiotherapy</td>
<td>3 in 100,000</td>
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</tbody>
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How do you answer this question?
Discussion Point

Is Safety an issue in Radiotherapy?

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The chance of dying or being injured on a U.S. domestic flight is 1 in 10,000,000.

(Ford and Terezakis)
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Is Quality an Issue in Radiotherapy?

What is Quality?
Is Quality an Issue in Radiotherapy?

**Quality:** 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 consensus determined tolerances.
Is Quality an Issue in Radiotherapy?

To explore Quality, and its relationship to Safety, in Radiotherapy let’s just look at the technical aspects of radiation therapy:

Is the prescription delivered within consensus determined tolerances?
Is Quality an Issue in Radiotherapy?

Is this distribution realistic: most patients receive acceptable treatments with a minority being harmed?
Is Quality an Issue in Radiotherapy?

Or is this more realistic: there’s a continuous distribution from acceptable treatments to harmful treatments?

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If you believe this distribution there must be patients who, due to departures from quality, receive treatments that do not result in obvious injuries but for whom the probability of the desired outcome is compromised.
We will now attempt to estimate the number of patients that fall into the “Quality Trap”

The means of estimating the number of patients relies on some highly suspect maneuvers.

**Viewer discretion is advised**
What is the error rate?

Let’s say the error rate is 0.001% per year.

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<tr>
<td>New York State</td>
<td>0.01%</td>
</tr>
<tr>
<td>Varian</td>
<td>0.002%</td>
</tr>
<tr>
<td>UK</td>
<td>0.003%</td>
</tr>
</tbody>
</table>
What is the threshold for harm?

Of course there is no one threshold. Even if the concept of a threshold were valid it would depend on many factors. The Nuclear Regulatory Commission says you have to report events with dose deviations of >20%.

Let’s call 20% the threshold for harm.

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What is the $\sigma$ of this distribution?

IF: the distribution of deviations can be represented by a Gaussian

IF: the “event rate” is $10^{-5}$

IF: the threshold for harm is 20%
What is the $\sigma$ of this distribution?

$\sigma = 4.5\%$

IF: the distribution of deviations can be represented by a Gaussian

IF: the “event rate” is $10^{-5}$

IF: the threshold for harm is 20%
So how many patients fall into the “Quality Trap”?

- It depends on the boundaries.
- If we define the Quality Trap to be deviations greater than 10% then, with $\sigma = 4.5\%$, approximately 2.6% of courses are sub-optimal.
So how many patients fall into the “Quality Trap”?

- U.S. population
  = $3 \times 10^8$
- Annual cancer incidence rate = $5 \times 10^{-3}$
- It is estimated that about 50% of cancer patients would benefit from radiotherapy
So how many patients fall into the “Quality Trap”? 

So there should be about 750,000 patients receiving RT per year in the U.S.

If we ignore retreats then there are approximately 750,000 courses per year.

2.6% of 750,000 is about 20,000
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~20,000 patients per year in the US have their outcome compromised by sub-optimal radiotherapy?
Discussion Point

20,000 patients per year in the US have their outcome compromised by sub-optimal radiotherapy?

Table 1. Institution passing rates with the Radiological Physics Center phantoms

<table>
<thead>
<tr>
<th>Phantom</th>
<th>Head and neck</th>
<th>Prostate</th>
<th>Thorax</th>
<th>Liver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irradiations</td>
<td>250</td>
<td>64</td>
<td>24</td>
<td>4</td>
</tr>
<tr>
<td>Pass</td>
<td>179</td>
<td>55</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>Fail</td>
<td>71</td>
<td>9</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Year introduced</td>
<td>2001</td>
<td>2004</td>
<td>2004</td>
<td>2005</td>
</tr>
</tbody>
</table>

Ibbott et al. IJROBP 71 (2008) S71 – S75

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Discussion Point

20,000 patients per year in the US have their outcome compromised by sub-optimal radiotherapy?

“These QA data stemming from prospective clinical trials show undisputedly that non adherence to protocol specified RT requirements is associated with reduced survival, local control and potentially increased toxicity.”

QA makes a clinical trial stronger: Evidence-based medicine in radiation therapy
Damien C. Weber a,e,* , Milan Tomsej b , Christos Melidis c , Coen W. Hurkmans d,e

R & O 105 (2012) 4-8

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Time for a SAMs Question.

The safety of a course of radiotherapy compared with a flight on a US domestic airplane is:

- **20%** Much safer (RT is ~100 times safer than flying)
- **20%** Somewhat safer (a factor of ~10)
- **20%** Similarly safe.
- **20%** Somewhat less safe (by a factor of ~10)
- **20%** Considerably less safe (by a factor of >100)
The safety of a course of radiotherapy compared with a flight on a US domestic airplane is:

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And another SAMs Question.

The evidence suggests that what percentage of cancer patients (excluding skin) would benefit from radiotherapy:

- 20% ~ 10%
- 20% ~ 25%
- 20% ~ 50%
- 20% ~ 75%
- 20% ~ 100%
And another SAMs Question.

The evidence suggests that what percentage of cancer patients (excluding skin) would benefit from radiotherapy:

And just one more SAMs Question.

The RPC experience, reported in 2008, is that the percentage pass rate at the 1\textsuperscript{st} attempt at IMRT validation with a Head and Neck phantom was:

- 20\% \sim 20\%
- 20\% \sim 45\%
- 20\% \sim 70\%
- 20\% \sim 95\%
- 20\% \sim 100\%
And just one more SAMs Question.

The RPC experience, reported in 2008, is that the percentage pass rate at the 1\textsuperscript{st} attempt at IMRT validation with a Head and Neck phantom was:

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<table>
<thead>
<tr>
<th>Percentage</th>
<th>Approx. Value</th>
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<tbody>
<tr>
<td>20%</td>
<td>~ 20%</td>
</tr>
<tr>
<td>20%</td>
<td>~ 45%</td>
</tr>
<tr>
<td>20%</td>
<td>~ 70%</td>
</tr>
<tr>
<td>20%</td>
<td>~ 95%</td>
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What’s the Summer School all about?

Target Dose

Benefit

Harm

Underdose

Target Dose

Overdose

Harm