First, do no harm:
Towards Risk Analysis and Risk Management in Radiation Therapy

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Outline

1. The Issues
2. Towards Quantifying Risk in Radiation Therapy: Risk Analysis
4. Conclusions
The Issues

Patients are entitled to hold the expectation that they will not be harmed during an encounter with a health care system.

The Issues

Health care providers have an obligation to minimize the risk of harm to patients (and to be seen to be doing so).

The Issues

The US Institute of Medicine estimates that between 44,000 and 98,000 deaths per year in the US are attributable to medical errors.

To Err is Human: Building a Safer Health System. 1999. IoM, National Academy Press, Washington, DC

The Issues

In Canadian hospitals, the overall incidence rate of adverse events was estimated to be 7.5%. 37% of these were preventable and 20% resulted in death.

Journal of the Canadian Medical Association. 2004, 170, 1678-1686
Issues

Premise

We can meet patients’ expectations and providers’ obligations by
• maximizing benefit to patients
• minimizing harm to patients
while, at the same time,
• staying within resource constraints
• acknowledging other stakeholders
if
• we quantitatively understand the characteristics of the systems within which patients and providers interact.

Issues

Benefit and Harm

Harm results from an unacceptable deviation from a “quality treatment”

Deviation from optimum dose

Issues

Benefit and Harm

An acceptable treatment can be accepted without further improvement.
A tolerable treatment is not ideal but can reasonably be tolerated.
An unacceptable treatment is one that would not be acceptable on any reasonable basis.
(adapted from ICRP 60)

• As Close As Reasonably Achievable to the Optimum: quality management
• Avoidance of Harm: risk management

Issues

Risk Descriptors 1

Incident: an unwanted or unexpected change from normal system behaviour that causes, or has the potential to cause, an adverse event
Adverse Event: an incident that occurs during the process of providing health care and results in sub-optimal treatment, unintended injury or complication leading to disability, death or prolonged hospital stay for the patient
**Risk Descriptors 2**

**Error:** failure to complete a planned action as it was intended or a situation in which incorrect methods and/or data are used in an attempt to achieve a given aim (relates to rules and skills)

**Mistake:** selection of inappropriate plans and decisions (relates to knowledge)

**Misadministration:** deviation from a prescription that exceeds a defined value

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**Risk Defined**

\[ r = f(p,c) \]

where:

- \( r \) is the risk
- \( p \) is the probability of the event
- \( c \) is the consequence of the event per patient

The number of patients involved might also be a factor in assessing risk.

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**Current Approaches: Comparison of Alternatives**

<table>
<thead>
<tr>
<th>Method</th>
<th>System analysis</th>
<th>HTA</th>
<th>RCA</th>
<th>FMEA</th>
<th>RCM</th>
<th>4.6.2</th>
<th>4.6.3</th>
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<tbody>
<tr>
<td>PRA Microsystems</td>
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<td>+</td>
<td>+</td>
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<td>+</td>
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<tr>
<td>FMEA</td>
<td>+---------------</td>
<td>+</td>
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<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
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<tr>
<td>HTA</td>
<td>+---------------</td>
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<td>+</td>
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<td>+</td>
</tr>
<tr>
<td>RCA</td>
<td>+---------------</td>
<td></td>
<td></td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

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**Risk Analysis**

To quantify risk to a patient effectively we need to know two things about modes of system failure.

We need to know:

- the probability of a particular event occurring, \( p \)
- and the consequence if that event does occur, \( c \)

\[ r = f(p,c) \]

- The number of patients actually or potentially affected is likely to influence risk management strategies.
Fault Tree

- If we can develop a fault tree we should be able to work out \( p = f(p, c) \)
- Development of a fault tree will be facilitated by a taxonomy
- Development of a taxonomy will be facilitated by a process map

Thomsen et al. 2003 IJORB 57, 1492-1508
Chang et al. 2005 IJQHC 17, 95-105

Process Map

Taxonomy: Domains

The Process Map suggests that there are five domains within which Incidents may occur:

1. Assessment
2. Prescription
3. Treatment Preparation
4. Treatment Delivery
5. Follow-up

Taxonomy: Prescription Elements

Should an Incident occur it will have consequences for one or more Prescription Elements
In radiation therapy, these Prescription Elements can conveniently be classified as:

- Dose
- Volume
both are 4D concepts
and can be applied to targets and organs at risk
Risk Analysis

Taxonomy: Source

We consider that Incidents may arise from two general sources:

- **Infrastructure** – calibrated equipment such as linacs; software; hard and soft copy beam data; protocols; etc.
- **Processes** – performing the required tasks in the environment created by the **infrastructure** provided

Taxonomy: Occurrence

We consider that Incidents may occur in two general ways:

- **Sporadic** – will occur unpredictably
- **Systematic** – will occur predictably under similar circumstances

A Digression

**A Digression: Uncertainties in Radiation Therapy**

What about random errors?

We consider what are frequently called random errors, for example in connection with patient set-up, to be uncertainties in the sense that they are associated with the limitations of measurement techniques and the ability of humans to repeat a process in exactly the same way.

Lee et al. *Medical Decision Making*, to be published
A Digression

Simulation results for RT treatment technique prescription

<table>
<thead>
<tr>
<th>Required treatment</th>
<th>Prescribed treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>100.0</td>
</tr>
<tr>
<td>2-field</td>
<td>0.0</td>
</tr>
<tr>
<td>4-field</td>
<td>0.0</td>
</tr>
<tr>
<td>Palliative</td>
<td>0.0</td>
</tr>
</tbody>
</table>

NOTE: Percentages are mean percentages.

A Digression

Risk Analysis

Taxonomy

Prescription

Preparation

Delivery

Follow up

Dose

Volume

Assessment

Infrastructure

Process

Infrastructure

Sporadic

Systematic

A Digression

Analysis of existing databases

As a first step towards a fault tree for radiation therapy we have taken the incidents reported in:

1. NRC database
2. IAEA “Lessons learned from accidental exposures in radiotherapy” 2000
3. ROSIS database

And categorized them according to the taxonomy
So what do we know?

There is some, but not a high, degree of consistency between the relative incident rates between the different databases.

As the databases were established for different purposes this is not too surprising.

However, the lessons to be learnt from conflicting information are unclear.

Consequence Metrics

With every error will be associated a consequence denoted by c

\[ r = f(p, c) \]

Metrics that have been used include:
- Death
- Disability
- Unexpected hospitalization
- Life years lost
- Quality adjusted life years lost

In radiation therapy, prescription elements have two components: dose and volume; both are 4D concepts.

Is there a way of combining these two elements into one metric which can be used to quantify the consequence?

The Equivalent Uniform Dose consolidates 3 dimensional dose and volume information into one number.

A biological EUD can also be calculated – 4D consequence metric

Niemierko 1997 Med Phys, 24, 103-110

EUD as a consequence metric, c

Standard two field tangential breast treatment

<table>
<thead>
<tr>
<th>Treatment Configuration</th>
<th>EUD Breast</th>
<th>EUD Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed Treatment</td>
<td>51.0</td>
<td>12.8</td>
</tr>
<tr>
<td>15MV instead of 6MV – whole course</td>
<td>55.7</td>
<td>14.8</td>
</tr>
<tr>
<td>SAD + 10cm – whole course</td>
<td>42.3</td>
<td>10.7</td>
</tr>
<tr>
<td>12MV – one fraction</td>
<td>50.6</td>
<td>12.7</td>
</tr>
<tr>
<td>Missing wedge – whole course</td>
<td>52.1</td>
<td>12.9</td>
</tr>
<tr>
<td>Missing wedge – one fraction</td>
<td>52.1</td>
<td>12.9</td>
</tr>
<tr>
<td>Coll. Rotation 10 – whole course</td>
<td>50.6</td>
<td>12.7</td>
</tr>
<tr>
<td>Coll. Rotation 10 – one fraction</td>
<td>51.0</td>
<td>12.7</td>
</tr>
</tbody>
</table>

With thanks to Sandy Iftody C.M.D. and Nicolas Ploquin M.Sc.
**EUD as a consequence metric, c**

The Equivalent Uniform Dose may be an appropriate measure of the consequence of an incident in radiation therapy. The EUD allows us to compare both dose and volume effects using a metric that should be indicative of outcome.

**Integrating Operations with Risk Analysis: Risk Management**

There are three components of operations that could readily be coordinated with risk analysis:

1. Assignment of responsibilities
2. Quality control
3. Incident learning

**Integrating Operations with Risk Analysis: Responsibilities**

<table>
<thead>
<tr>
<th>Role</th>
<th>Radiation Oncologist</th>
<th>Delivery Therapist</th>
<th>Physicist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Therapy</td>
<td>Follow-up</td>
<td>Delivery</td>
<td>Veriﬁcation</td>
</tr>
<tr>
<td>Simulation</td>
<td>Simulation</td>
<td>Physicist</td>
<td>Treatment Planning</td>
</tr>
<tr>
<td>Dosimetry</td>
<td>Dosimetry</td>
<td>Physicist</td>
<td>Treatment Aids</td>
</tr>
<tr>
<td>Moultries</td>
<td>Moultries</td>
<td>Physicist</td>
<td>Dose and Volume Prescription</td>
</tr>
<tr>
<td>Pathology</td>
<td>Pathology</td>
<td>Physicist</td>
<td>Staging</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>Diagnosis</td>
<td>Physicist</td>
<td>Assessment</td>
</tr>
</tbody>
</table>

On the basis of a risk analysis and by being very specific about responsibilities of the different members of the radiation therapy team we can direct limited continuing education resources to those areas where risk is the highest.
Integrating Operations with Risk Analysis:
Quality Control

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Emergency off</td>
<td>Functional</td>
</tr>
<tr>
<td>2</td>
<td>Wedge, crosswire/interleaf</td>
<td>Functional</td>
</tr>
<tr>
<td>3</td>
<td>Awin/wedge shape and position</td>
<td>Functional</td>
</tr>
<tr>
<td>4</td>
<td>Couch angle reproducibility</td>
<td>±0.5</td>
</tr>
<tr>
<td>5</td>
<td>Couch reproducibility</td>
<td>±1</td>
</tr>
<tr>
<td>6</td>
<td>Couch reproducibility</td>
<td>±1</td>
</tr>
<tr>
<td>7</td>
<td>Couch reproducibility</td>
<td>±1</td>
</tr>
<tr>
<td>8</td>
<td>Optic distance indicator</td>
<td>±1</td>
</tr>
<tr>
<td>9</td>
<td>Crosswire centering</td>
<td>±1</td>
</tr>
<tr>
<td>10</td>
<td>Light/radiation coincidence</td>
<td>±1</td>
</tr>
<tr>
<td>11</td>
<td>Field size indicator</td>
<td>±2%</td>
</tr>
<tr>
<td>12</td>
<td>Relative dosimetry</td>
<td>±2%</td>
</tr>
<tr>
<td>13</td>
<td>Central axis depth dose reproducibility</td>
<td>±1%/3mm</td>
</tr>
<tr>
<td>14</td>
<td>Beam flatness</td>
<td>±2%</td>
</tr>
<tr>
<td>15</td>
<td>Beam symmetry</td>
<td>±2%</td>
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<tr>
<td>16</td>
<td>Records</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Risk Management
Integrating Operations with Risk Analysis: Quality Assurance

By linking quality assurance to a formal risk analysis we can direct limited resources to those areas where the risk is highest. (Evidence Based Quality Assurance)

For example, certain high risk activities may be subjected to more intense verification than others.

Integrating Operations with Risk Analysis: Incident Learning

Incident Characteristics (CLINICAL)

- # Patients affected
- # Fractions per patient affected
- # Fractions per fraction affected
- Central axis reproducibility
- Distance medical physicist
- Prescriber
- Name
- Date
- Signature
- Signature
- Follow-up
- Other

By linking incident learning to a formal risk analysis we can develop and refine the risk analysis to reflect local circumstances.
Conclusions

1. Opportunities exist for improving the way we collect and analyze reports of incidents in radiation therapy.
2. With a better understanding of risk in radiation therapy we will be better able to meet patients’ expectations and providers’ obligations.

Final Thought

Incidents are like photons
You can reduce the number
You can reduce the energy or impact
But you can never get rid of them all