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
3. Towards Integrating Operations with Risk Analysis: Risk Management
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

Premise

We can meet patients' expectations and providers' obligations by

- maximizing benefit to patients
- minimizing harm to patients

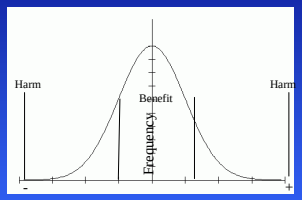
while, at the same time,

- staying within resource constraints
- acknowledging other stakeholders

if

- we quantitatively understand the characteristics of the systems within which patients and providers interact.

Benefit and Harm



Deviation from optimum dose

Harm results from an unacceptable deviation from a "quality treatment"

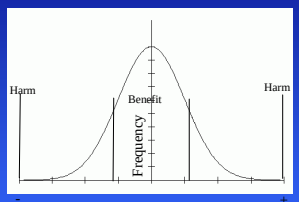
Benefit and Harm

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)



Deviation from optimum dose

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

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

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.

Current Approaches: Comparison of Alternatives

	Method						
Criterion	*Ad hoc*	*Descriptive statistics*	*RCA*	*FMEA*	*Microsystems modeling*	*PRA*	*Decision analysis*
Systematic	-	+	+	+	+	+	+
Proactive/predictive	-	-	-	+	-	+	+
System-oriented	-	-	+	+	+	+	+
Quantitative	-	+	-	Semi +	Semi +	+	+
Addresses parameter uncertainty	-	Semi +	-	-	-	+	+
Addresses variability	-	+	-	-	-	+	+
Can model rare incidents	-	-	-	-	-	+	+
Addresses multiple objectives	-	-	-	-	-	-	+
Addresses resource constraints	-	-	-	-	-	-	+
Addresses changes to the system	-	-	-	-	-	-	+

HTA Initiative #15. Alberta Heritage Foundation for Medical Research. www.ahfmr.ab.ca

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**

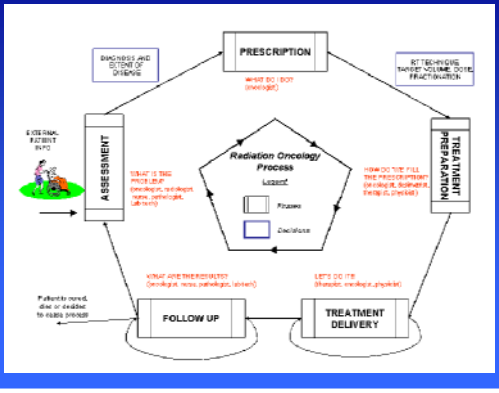
$$r = f(\mathbf{p}, c)$$

- Development of a fault tree will be facilitated by a taxonomy
- Development of a taxonomy will be facilitated by a process map

Thomadsen et al. 2003 IJROBP 57, 1492-1508

Chang et al. 2005 IJQHC 17, 95-105

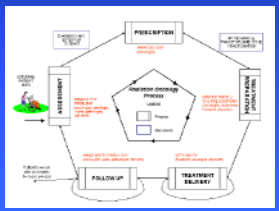
Process Map



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

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: 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.

A Digression: Uncertainties in Radiation Therapy

We have undertaken a study of the probability of a woman with breast cancer being assigned to the inappropriate treatment technique due uncertainties in staging.

A Bayesian approach was followed and included staging based on imaging, pathology and physical examination.

Lee et al. Medical Decision Making, to be published

A Digression

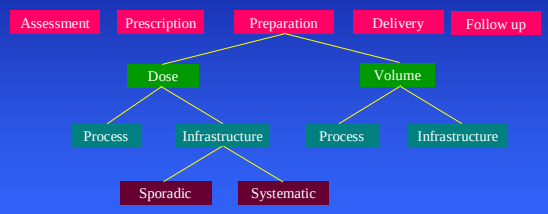
Simulation results for RT treatment technique prescription

Required true treatment	Prescribed treatment			
	'none'	'2-field'	'4-field'	'palliative'
none	**100.0**	0.0	0.0	0.0
2-field	0.0	**98.3**	0.0	0.0
4-field	0.0	1.5	**92.3**	1.9
palliative	0.0	0.2	7.7	**98.1**

NOTE: Results are mean percentages.

Risk Analysis

Taxonomy



Risk Analysis

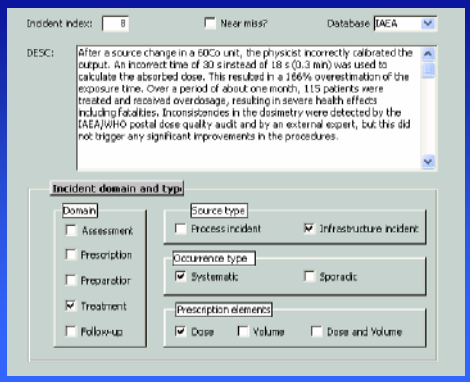
Analysis of existing databases

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

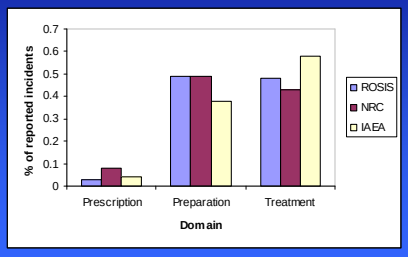
1. NRC database
2. IAEA "Lessons learned from accidental exposures in radiotherapy" 2000
3. ROSIS database

And categorized them according to the taxonomy

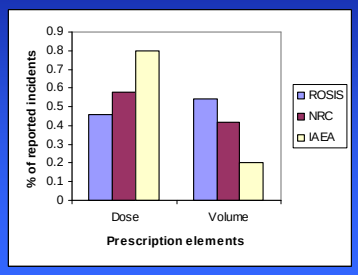
Risk Analysis



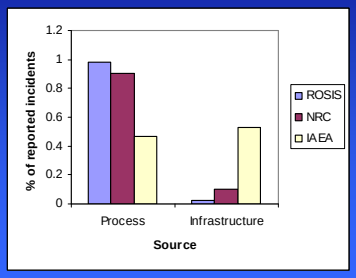
Reported Incidents by Domain



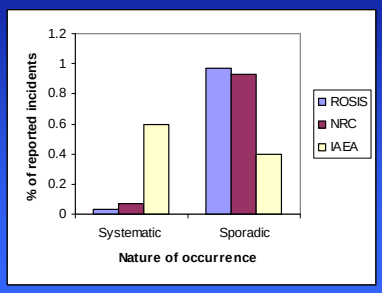
Reported Incidents by Prescription Element



Reported Incidents by Source



Reported Incidents by Occurrence



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 associated a consequence denoted by **c**

$$r = f(p,\mathbf{c})$$

Metrics that have been used include:

- Death
- Disability
- Unexpected hospitalization
- Life years lost
- Quality adjusted life years lost

Consequence Metrics

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.

$$EUD \left[\frac{1}{N}\sum_i D_i^a\right]^{1/a}$$

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

Niemerko 1997 Med Phys 24, 103-110

EUD as a consequence metric, c

Standard two field tangential breast treatment

Treatment Configuration	EUD Breast	EUD Lung
Prescribed Treatment	51.0	12.8
15MV instead of 6MV – whole course	55.7	14.0
SAD + 10cm – whole course	42.3	10.7
SAD + 10cm – one fraction	50.6	12.7
Missing wedge - whole course	55.1	12.9
Missing wedge – one fraction	51.1	12.8
Coll. Rotation 10^0 – whole course	50.6	12.7
Coll. Rotation 10^0 – one fraction	51.0	12.7

With thanks to Sandy Iftody C.M.D. and Nicolas Ploquin M.Sc.

Risk Analysis

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.

Risk Management

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

Risk Management

Integrating Operations with Risk Analysis: Responsibilities

Responsibilities in conventional external beam radiation therapy			
Domain	**Procedures**	**Primary Responsibility**	
		Infrastructure	**Process**
Assessment	Diagnosis		Radiation oncologist
	Staging		Pathologist
Prescription	Dose and Volume	Physicist	Radiation oncologist
Preparation	Treatment aids	Physicist	Mould room staff
	Treatment planning	Physicist	Dosimetrist
	Simulation	Physicist	Simulator therapist
Delivery	Treatment delivery	Physicist	Delivery therapist
	Verification	Physicist	Radiation oncologist Delivery therapist
Follow-up			Radiation oncologist

Risk Management

Integrating Operations with Risk Analysis: Responsibilities

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.

Risk Management

Integrating Operations with Risk Analysis: Quality Control

Monthly			
ML1	Emergency off	Functional	
ML2	Wedge, tray cone interlocks	Functional	
ML3	Accessories integrity and centering	Functional	
ML4	Gantry angle readouts	0.5	1
ML5	Collimator angle readouts	0.5	1
ML6	Couch position readouts	1	2
ML7	Couch isocentre	1	2
ML8	Couch angle	0.5°	1°
ML9	Optical distance indicator	1	2
ML10	Crosswire centering	1	2
ML11	Light/radiation coincidence	1	2
ML12	Field size indicator	1	2
ML13	Relative dosimetry	1%	2%
ML14	Central axis depth dose reproducibility	1%/2mm	2%/3mm
ML15	Beam flatness	2%	3%
ML16	Beam symmetry	2%	3%
ML17	Records	Complete	

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.

Risk Management

Integrating Operations with Risk Analysis: Incident Learning

Incident Characteristics (CLINICAL)

Impact:
patients affected: _____
fractions per patient affected:_____
fields per fraction affected: _____
Deviation from prescribed dose: _____
Deviation from prescribed volume: _____
Dosimetrist/medical physicist who analyzed incident:
Name:_____ Date: _____
Signature: _____
Name:_____ Date: _____
Signature: _____
Domain:
For clinical incidents

Domain	Discovery of incident	Origin of incident
Assessment		
Prescription		
Preparation		
Treatment		
Follow up		
Other: _____		

Risk Management

Integrating Operations with Risk Analysis: Incident Learning

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