

Uncertainties in Radiotherapy (and what to do about it)

Tomas Kron

Potential conflicts of interest (that could introduce a systematic uncertainty in my deliberations)

- Varian Medical Systems Research Collaborative Agreement
- RefleXion funded project

Objectives

- Define Uncertainties
- Explore where uncertainties can arise in radiotherapy
- Discuss the link between uncertainties and accuracy required
- Consider which uncertainties can be managed by physicists
- Explore the relation between uncertainties and risk
- Establish a link to risk management (and FMEA)

Uncertainties and errors

- Not the same
- Errors are known and should be corrected for
- Uncertainties provide a range of estimation how wrong one can be
- This is most useful in the context of measurable quantities

ISO/IEC Guide 98-6:2021

- Uncertainty of measurement

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Abstract

[Preview](#)

This document provides guidance on developing and using a measurement model and also covers the assessment of the adequacy of a measurement model. The document is of particular interest to developers of measurement procedures, working instructions and documentary standards. The model describes the relationship between the output quantity (the measurand) and the input quantities known to be involved in the measurement. The model is used to obtain a value for the measurand and an associated uncertainty. Measurement models are also used in, for example, design studies, simulation of processes, and in

2.2 The term “uncertainty”

The concept of uncertainty is discussed further in Clause [3](#) and Annex [D](#).

2.2.1 The word “uncertainty” means doubt, and thus in its broadest sense “uncertainty of measurement” means doubt about the validity of the result of a measurement. Because of the lack of different words for this *general concept* of uncertainty and the specific quantities that provide *quantitative measures* of the concept, for example, the standard deviation, it is necessary to use the word “uncertainty” in these two different senses.

2.2.2 In this *Guide*, the word “uncertainty” without adjectives refers both to the general concept of uncertainty and to any or all quantitative measures of that concept. When a specific measure is intended, appropriate adjectives are used.

2.2.3 The formal definition of the term “uncertainty of measurement” developed for use in this *Guide* and in the VIM [\[6\]](#) (VIM:1993, definition 3.9) is as follows:

uncertainty (of measurement)

parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

rounding and numerical overflow. It is demonstrated how such problems can often be alleviated by expressing a model differently so that it performs well in calculations. It is also shown how a reformulation of the model can be used to eliminate the effects of numerical overflow and underflow.

ISO/IEC Guide 98-6:2021

- Uncertainty of measurement

2.2.4 The definition of uncertainty of measurement given in [2.2.3](#) is an operational one that focuses on the measurement result and its evaluated uncertainty. However, it is not inconsistent with other concepts of uncertainty of measurement, such as

- a measure of the possible error in the estimated value of the measurand as provided by the result of a measurement;
- an estimate characterizing the range of values within which the true value of a measurand lies (VIM:1984, definition 3.09).

Although these two traditional concepts are valid as ideals, they focus on *unknowable* quantities: the “error” of the result of a measurement and the “true value” of the measurand (in contrast to its estimated value), respectively. Nevertheless, whichever *concept* of uncertainty is adopted, an uncertainty component is always *evaluated* using the same data and related information. (See also [E.5](#).)

specific measure

2.2.3 The formal

uncertainty

parameter, a

NOTE 1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

NOTE 2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which also can be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

NOTE 3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.



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Two types of uncertainty

Type A

- based on the statistical analysis of a series of measurements (for example, statistical data obtained from quality control results).
- Repeated measurements reduce the uncertainty

Type B

- obtained by non-statistical procedures and may include: Information associated with an authoritative published numerical quantity.
- Generally requires an expert who is very familiar with the objective of the measurement and the method

Two types of uncertainty

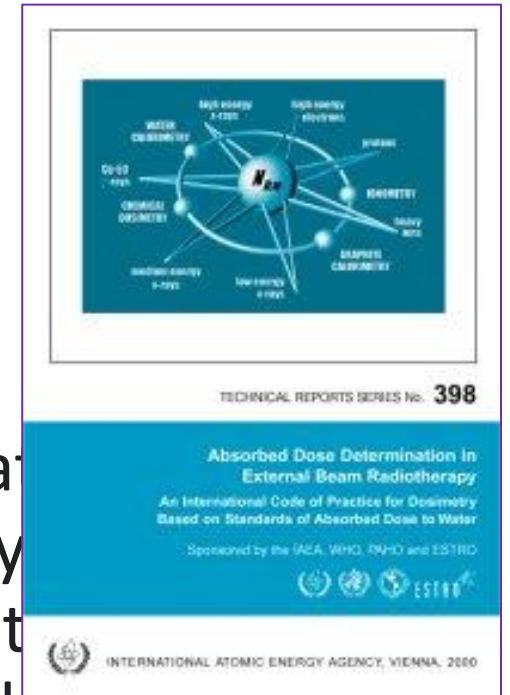
Type A

- based on the statistical analysis of a series of measurements (for example, statistical data obtained from quality control results).
- Repeated measurements reduce the uncertainty

Who but the
medical physicist?

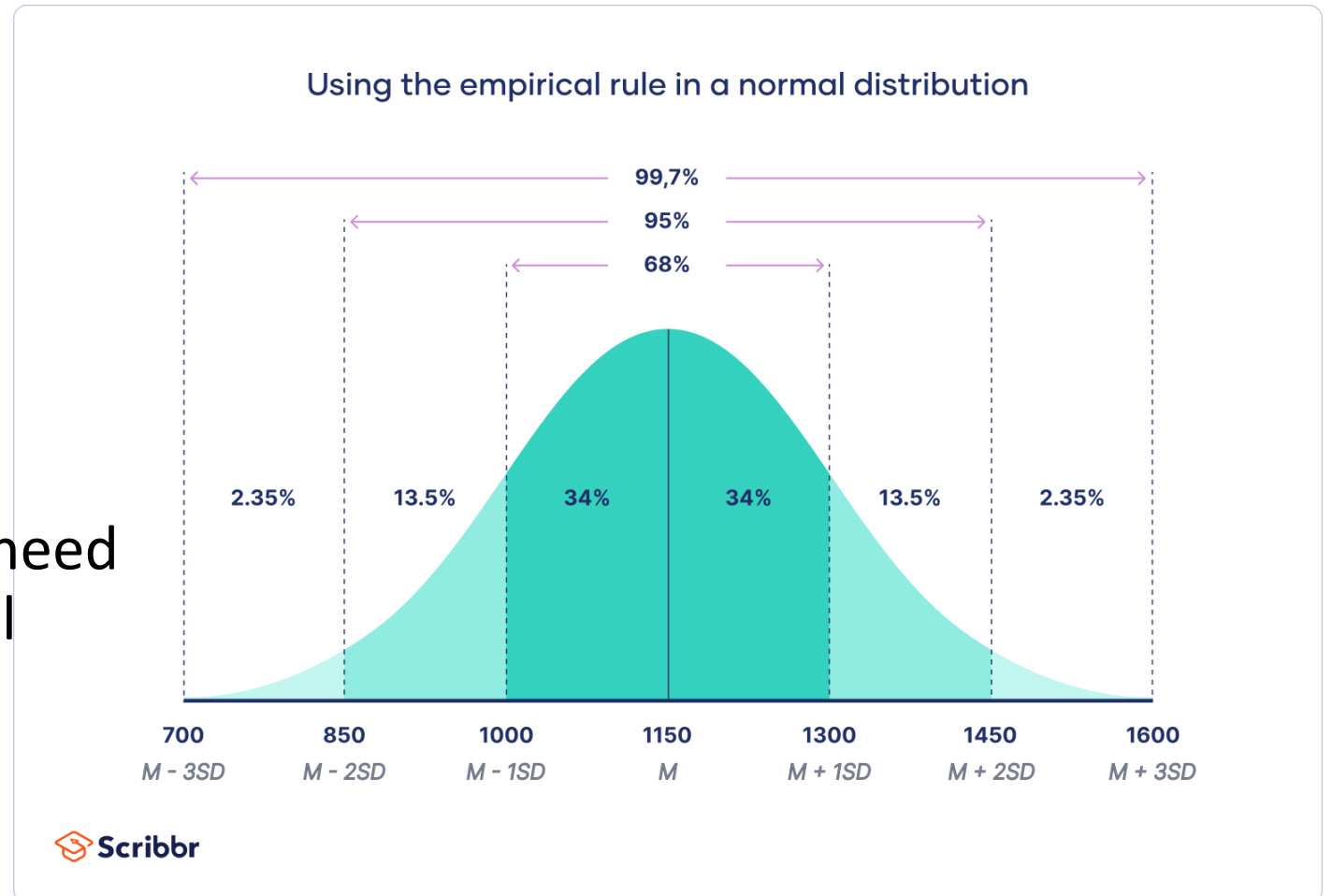
Type B

- obtained by non-statistical procedures and may be numerical or qualitative information associated with a numerical quantity.
- Generally requires an expert who is very familiar with the objective of the measurement and the method



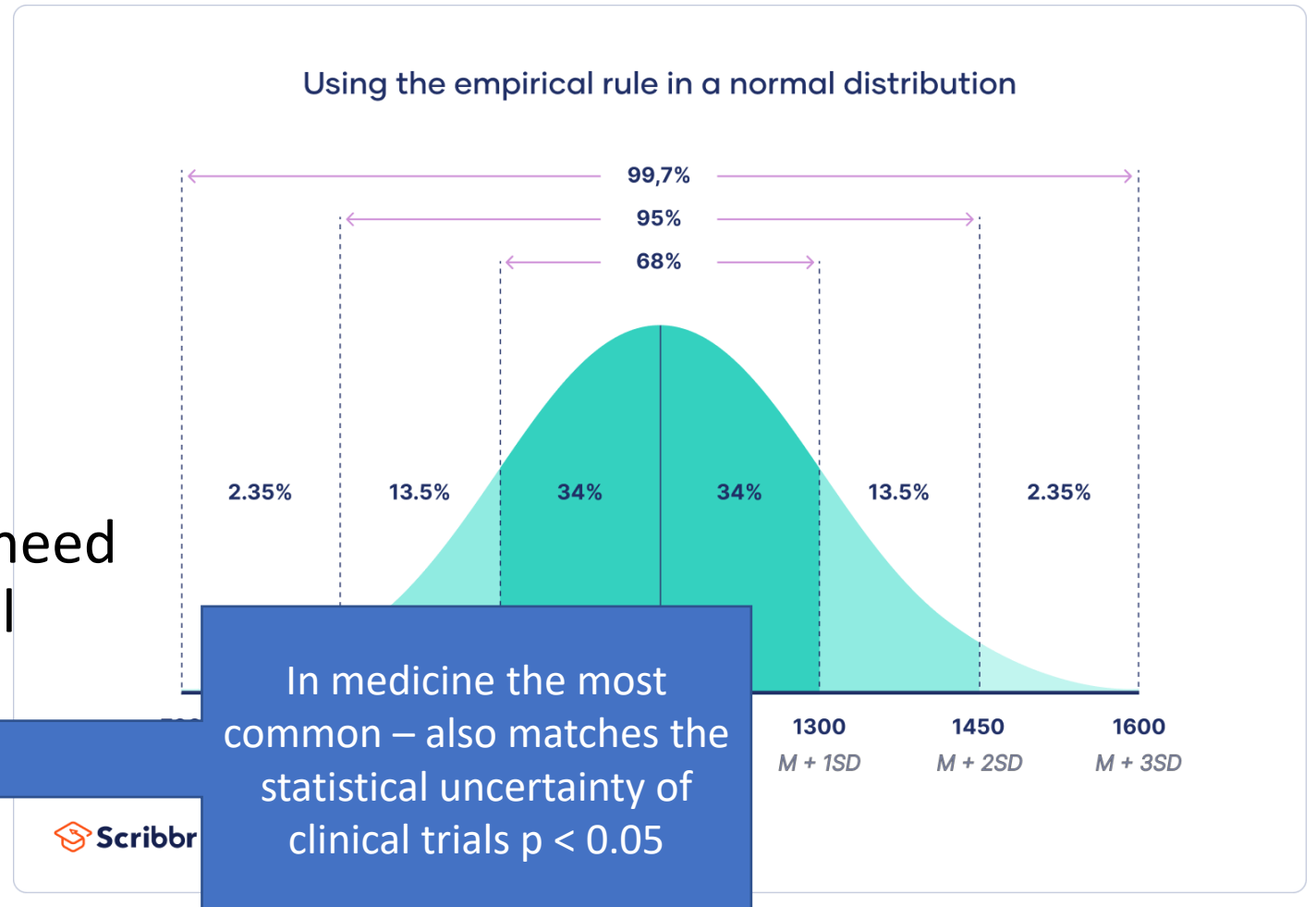
Random uncertainties (Type A)

- Normal distribution
- Characterised by mean and standard deviation
- Generally be assumed to be bidirectional
- When specifying uncertainty need to specify the confidence level
 - $K = 1 \rightarrow 68\%$ confidence
 - $K = 2 \rightarrow 95\%$ confidence



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 - $K = 2 \rightarrow 95\%$ confidence



Clinical evidence

“Significance”

- Clinical
- Statistical
 - $P < 0.05$ means that there is a 95% chance that a new treatment is actually better than the old
 - The degree of ‘evidence’ typically required by journal editors, governments and insurance companies



Clinical evidence

“Significance”

- Clinical
- Statistical
 - $P < 0.05$ means that there is a 95% chance that a new treatment is actually better than the old
 - The degree of ‘evidence’ typically required by journal editors, governments and insurance companies

- What if we run the same trial 20 times?
 - Assume the new is not better
 - One of the trials is likely to show that it is better
 - Is this the trial that will be published?

Clinical evidence

“Significance”

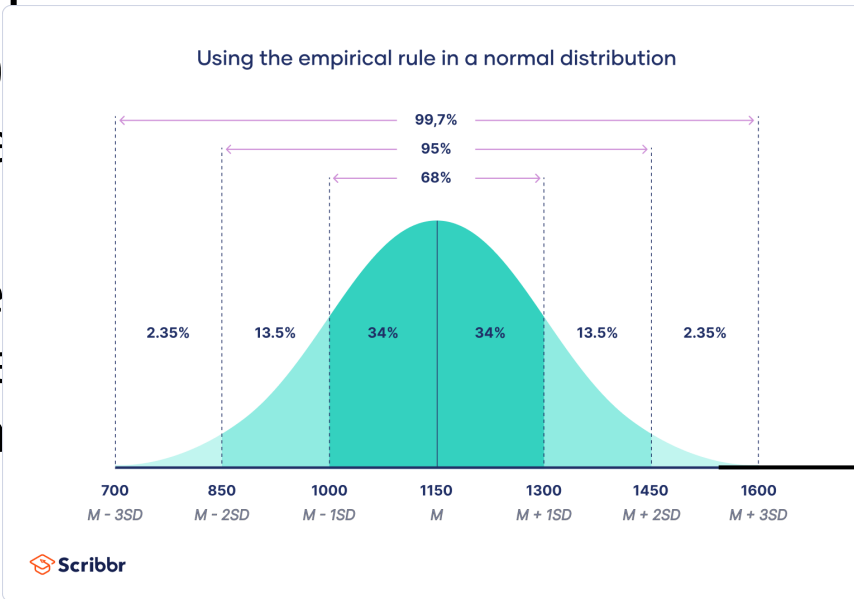
- Clinical
- Statistical
 - $P < 0.05$ means that there is a 95% chance that a new treatment is actually better than the old
 - The degree of ‘evidence’ typically required by journal editors, governments and insurance companies

- What happens if we ask more than one question?
 - Eg: What determines toxicity?
 - Mean dose, maximum dose, 90% volume dose,...
 - Minimum dose, average dose to organ 20Gy, ...
 - Each has a 5% chance of randomly being shown statistically significantly linked to toxicity
 - Confidence level needs to be adjusted

Clinical evidence

“Significance”

- Clinical
- Statistical
 - $P < 0.05$
 - chance
 - actually
 - The de
 - require
 - govern
 - compa



- What happens if we ask more than one question?

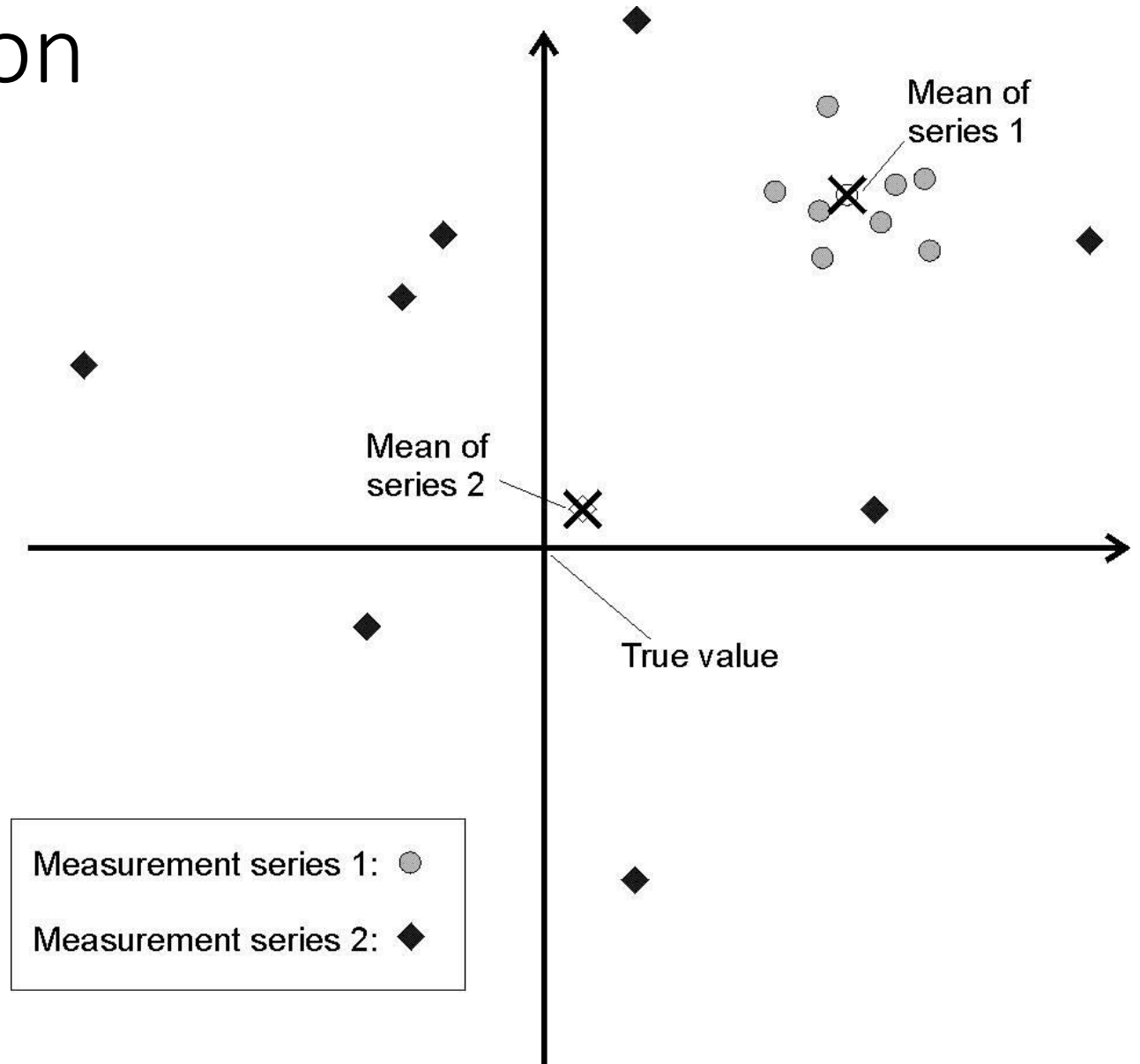
- Note aside:
Society accepts different levels of confidence:
Nuclear power plant incident $k > 10$
New particle found? Need at least 10^5 probability that the finding is correct (error probability < 0.00001)

significantly lin toxicity

- Confidence adjusted be

Accuracy and precision

- Series 1 has high precision (reproducibility)
- Series 2 has better accuracy (and if we were to repeat the measurement many many times the average will be close to the truth)



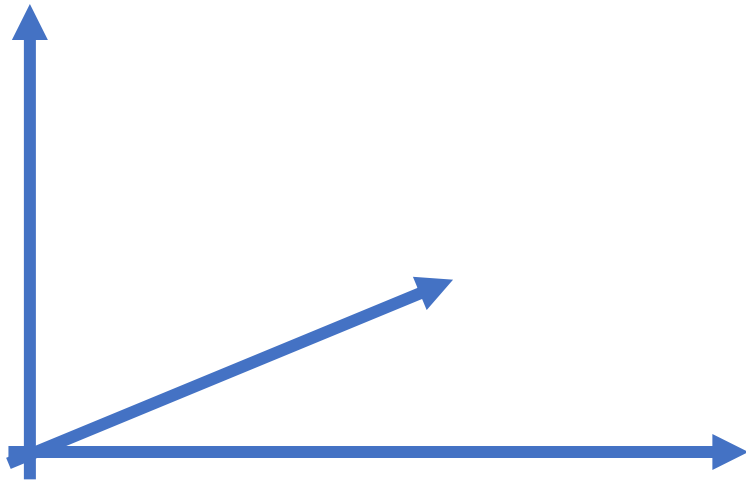
Multiple uncertainties

Independent

- “orthogonal”
- Changing one does not affect the other

Dependent

- More difficult
- Need quantitative measure of correlation



Operating with independent uncertainties

Addition

- Quantity 1 + Quantity 2
- Add the absolute uncertainties

Multiplication

- Quantity 1 x Quantity 2
- Add relative uncertainties

Operating with independent uncertainties

Addition

- Quantity 1 + Quantity 2
- Add the absolute uncertainties

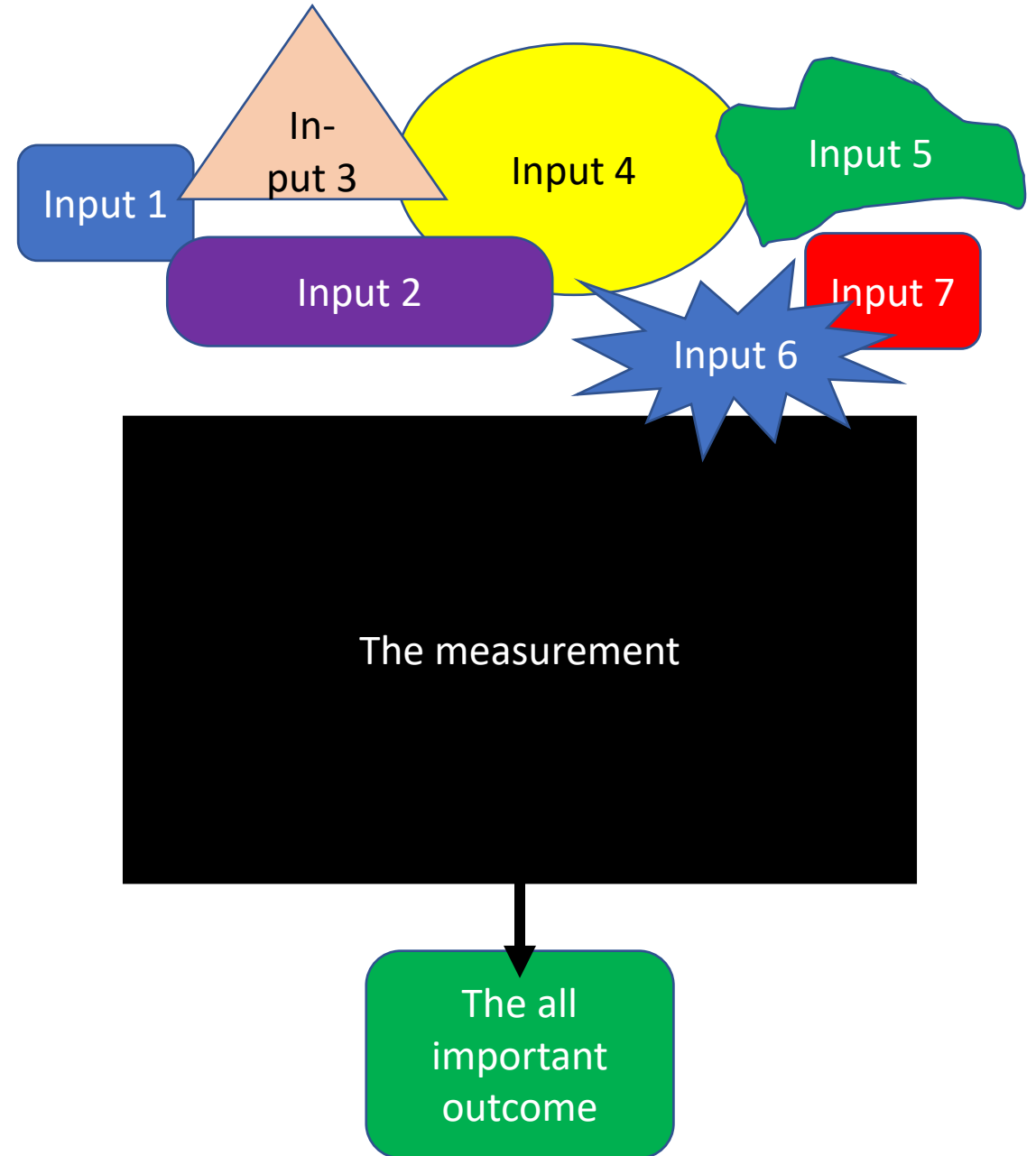
Multiplication

- Quantity 1 x Quantity 2
- Add relative uncertainties

- This is a rule of thumb
- Make sure you use the same confidence level (usually 2SD)
- It makes sense to quantify uncertainties and address the biggest one first

Sensitivity analysis

- If it all gets to difficult
 - Many uncertainties
 - Not always quantifiable
 - Combine in different ways
 - Depend on each other (possibly)
 - Some of them may not be known
- Vary each input (one at a time) and see how much the output changes

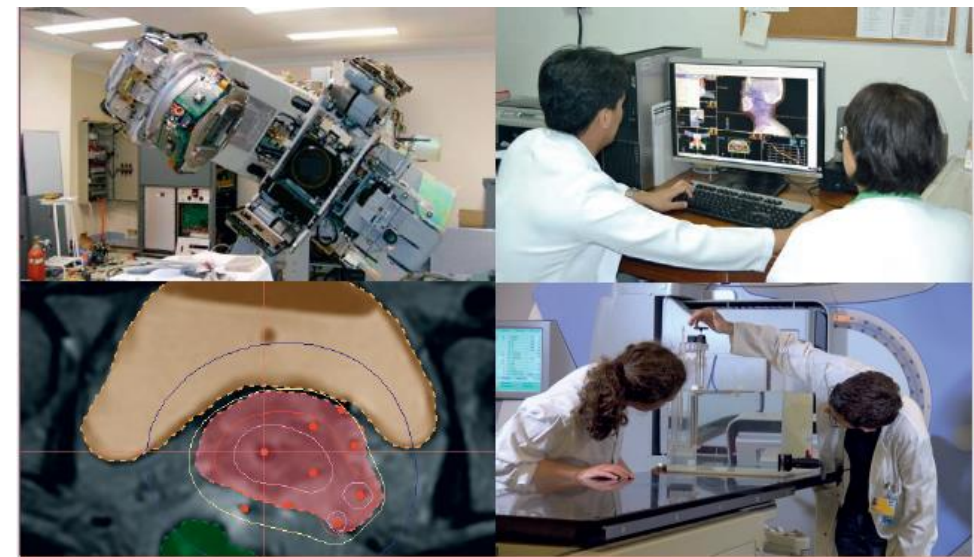


Uncertainties in life

- Measurement often difficult
- Mathematics often fails us
- Typically uncertainties are judged smaller when we can control them
- Unknown uncertainties that cannot be influenced (eg allow to discharge radioactive water from Fukushima) are often seen as catastrophic

Uncertainties in Radiotherapy

- Typically considered more dangerous than medical imaging
 - More physicists employed in RT
- Considering stochastic effects and the overall dose to population, this is not necessarily correct in particular as medical exposures (excluding RT) contribute up to 50% to population dose



IAEA HUMAN HEALTH SERIES

No. 31

**Accuracy Requirements
and Uncertainties in
Radiotherapy**



IAEA

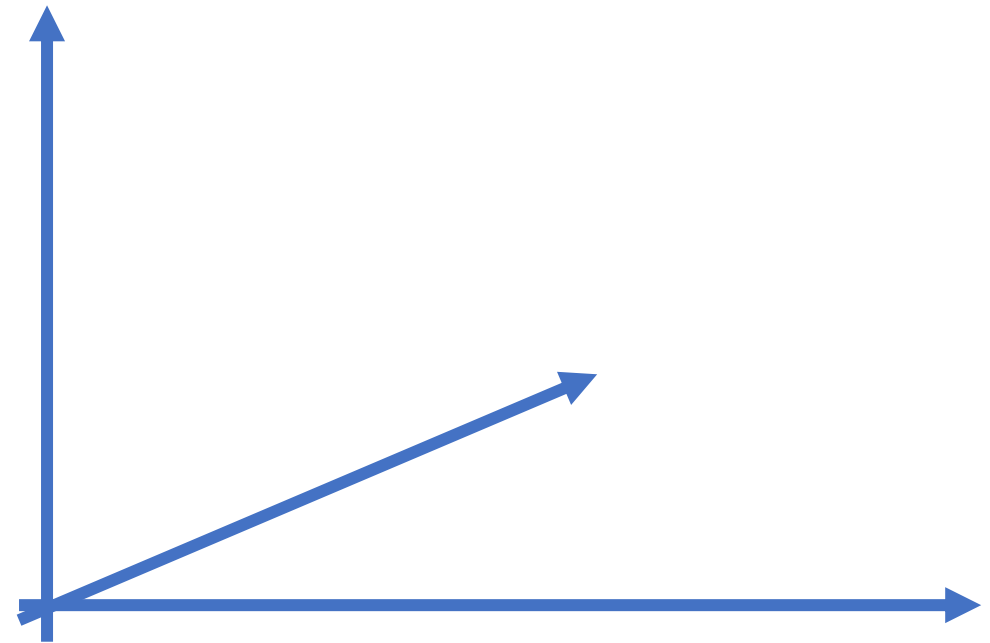
International Atomic Energy Agency

Uncertainties specifically in radiotherapy

- Different ways to manage them
 1. Look at different domains separately
 2. Follow patient pathway/
Develop a process map
 3. Risk management

1. Domains of uncertainty in radiotherapy

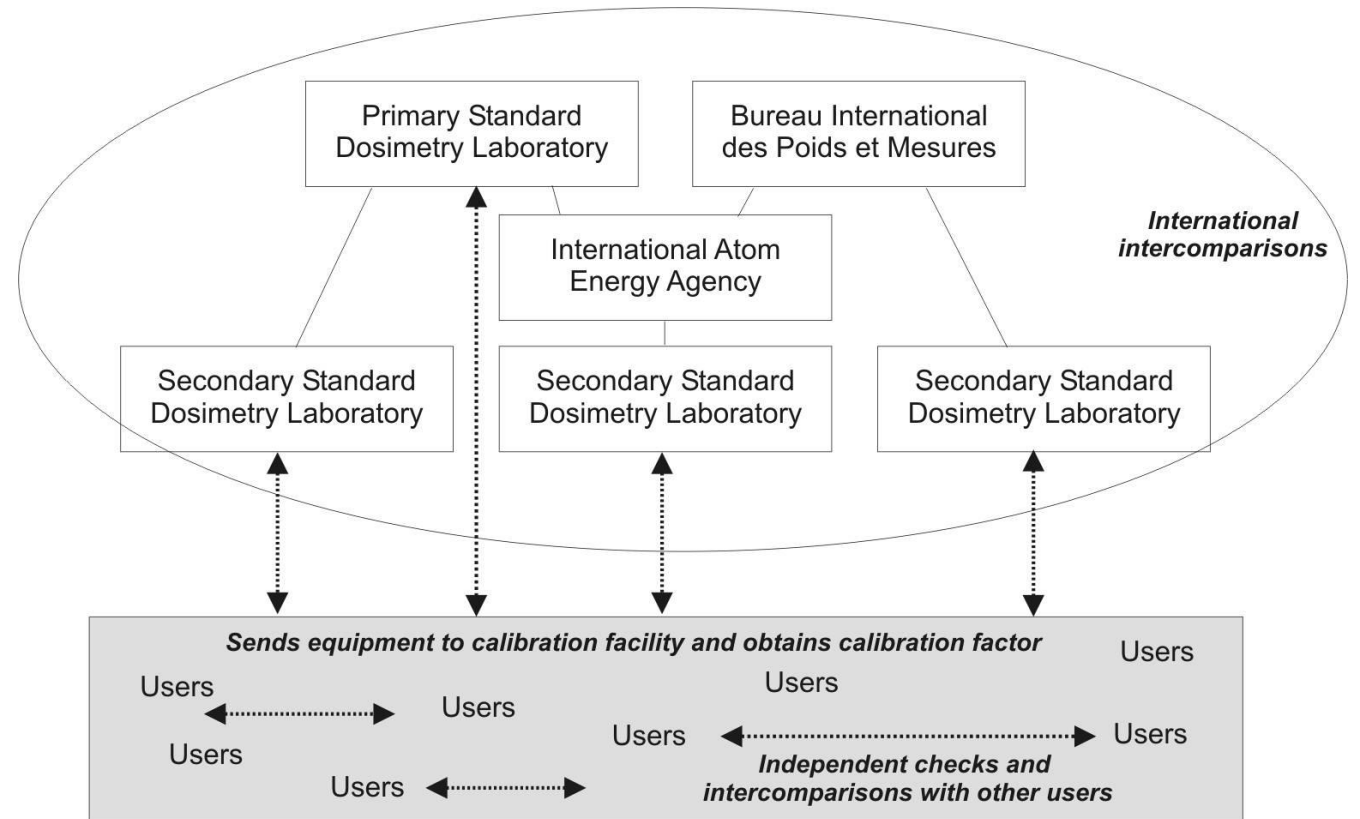
- Dose
- Location/Volume
- Time
- Effect of interest



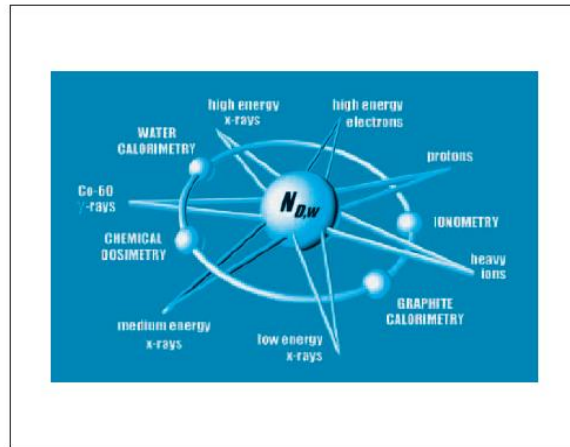
Independent of each other

Dose starts with traceability

- Units mean the same all over the world
- 1Gy in NY = 1Gy in Trieste = 1Gy in Melbourne
 - Under reference conditions



Uncertainty Budget



TECHNICAL REPORTS SERIES No. **398**

**Absorbed Dose Determination in
External Beam Radiotherapy**
An International Code of Practice for Dosimetry
Based on Standards of Absorbed Dose to Water

Sponsored by the IAEA, WHO, PAHO and ESTRO



INTERNATIONAL ATOMIC ENERGY AGENCY, VIENNA, 2000

TABLE 15. ESTIMATED RELATIVE STANDARD UNCERTAINTY^a OF $D_{w,Q}$ AT THE REFERENCE DEPTH IN WATER AND FOR A HIGH ENERGY PHOTON BEAM, BASED ON A CHAMBER CALIBRATION IN ^{60}Co GAMMA RADIATION

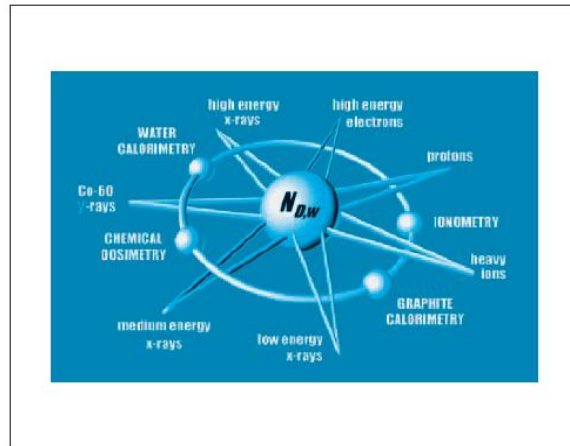
Physical quantity or procedure	Relative standard uncertainty (%)
<i>Step 1: Standards laboratory^b</i>	
$N_{D,w}$ calibration of secondary standard at PSDL	0.5
Long term stability of secondary standard	0.1
$N_{D,w}$ calibration of the user dosimeter at the standard laboratory	0.4
<i>Combined uncertainty of step 1</i>	<i>0.6</i>
<i>Step 2: User high energy photon beam</i>	
Long term stability of user dosimeter	0.3
Establishment of reference conditions	0.4
Dosimeter reading M_Q relative to beam monitor	0.6
Correction for influence quantities k_i	0.4
Beam quality correction k_Q (calculated values)	1.0 ^c
<i>Combined uncertainty of step 2</i>	<i>1.4</i>
Combined standard uncertainty of $D_{w,Q}$ (steps 1 + 2)	1.5

^a See the ISO Guide for the expression of uncertainty [32], or Appendix IV. The estimates given in the table should be considered typical values; these may vary depending on the uncertainty quoted by standards laboratories for calibration factors and on the experimental uncertainty at the user's institution.

^b If the calibration of the user dosimeter is performed at a PSDL, then the combined standard uncertainty in step 1 is lower. The combined standard uncertainty in D_w should be adjusted accordingly.

^c If k_Q is measured at a PSDL for the user chamber, this uncertainty is approximately of the order of 0.7%.

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APPENDIX IV. EXPRESSION OF UNCERTAINTIES 210

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IV.4. COMBINED AND EXPANDED UNCERTAINTIES

Because type A and type B uncertainties are both estimated standard deviations, they are combined using the statistical rules for combining variances (which are squares of standard deviations). If u_A and u_B are the type A and type B standard uncertainties of a quantity, respectively, the combined standard uncertainty of that quantity is

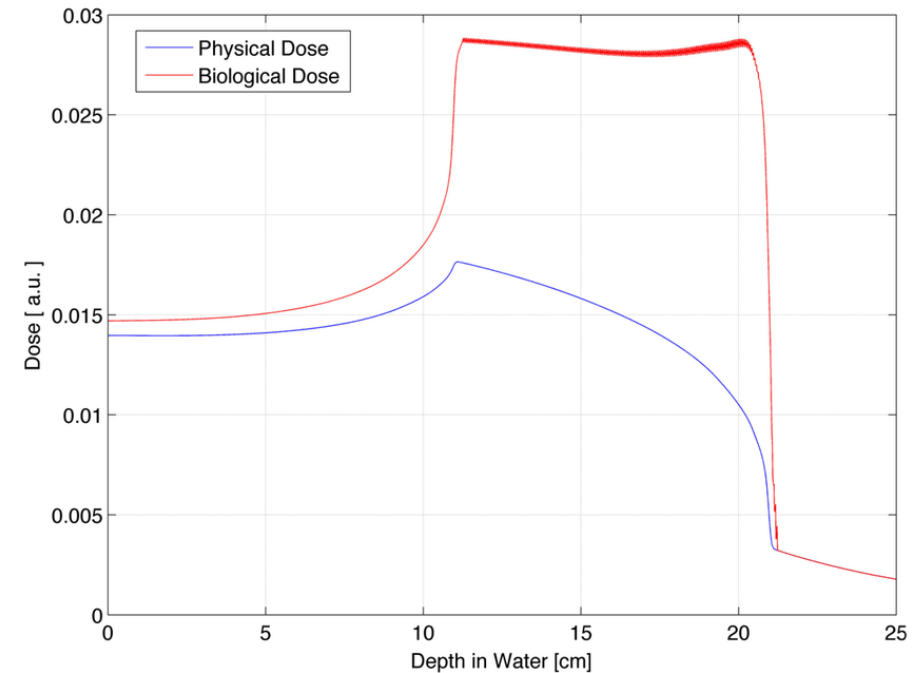
$$u_c = \sqrt{u_A^2 + u_B^2} \tag{83}$$

Radiation Dose

- Absorbed dose: $1\text{Gy} = 1\text{J/kg}$
- Biologically effective dose
- Equivalent dose
- Effective dose: $1\text{Sv} = 1\text{J/kg} \times \text{radiation and tissue weighting factor}$
- Biological dose



Breakfast cereal:
 1000kJ/kg



Carbon radiotherapy

Radiation Dose

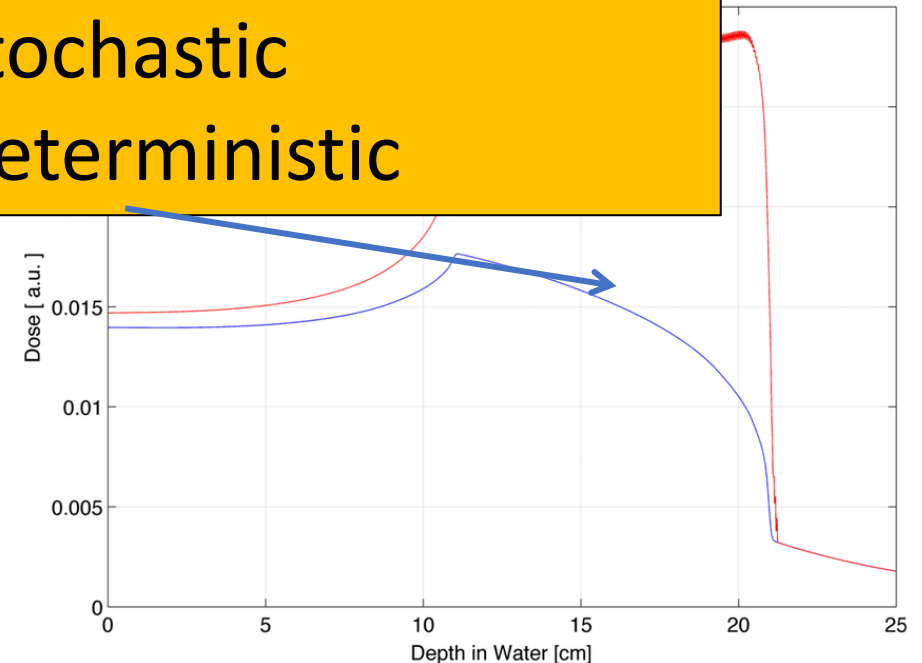
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- Biological dose



Breakfast cereal:
1000kJ/kg

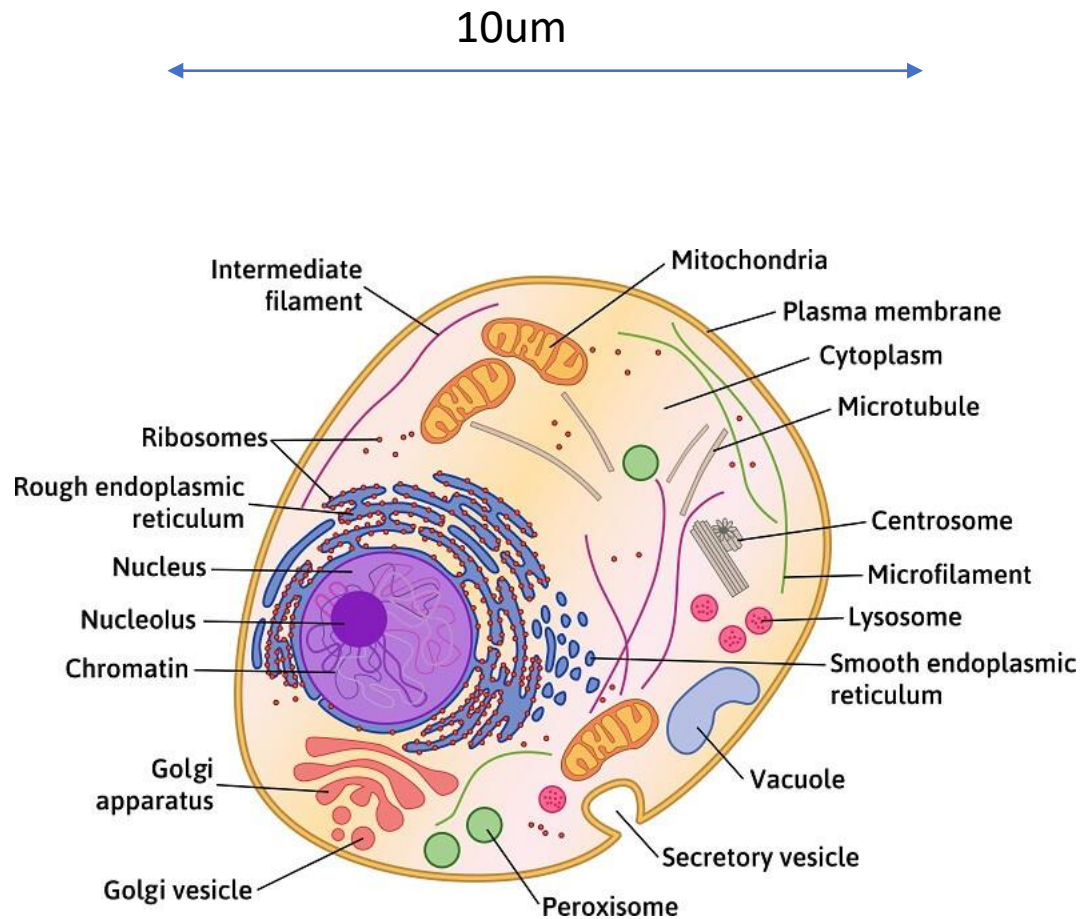
Depends on dose effects

- Stochastic
- Deterministic

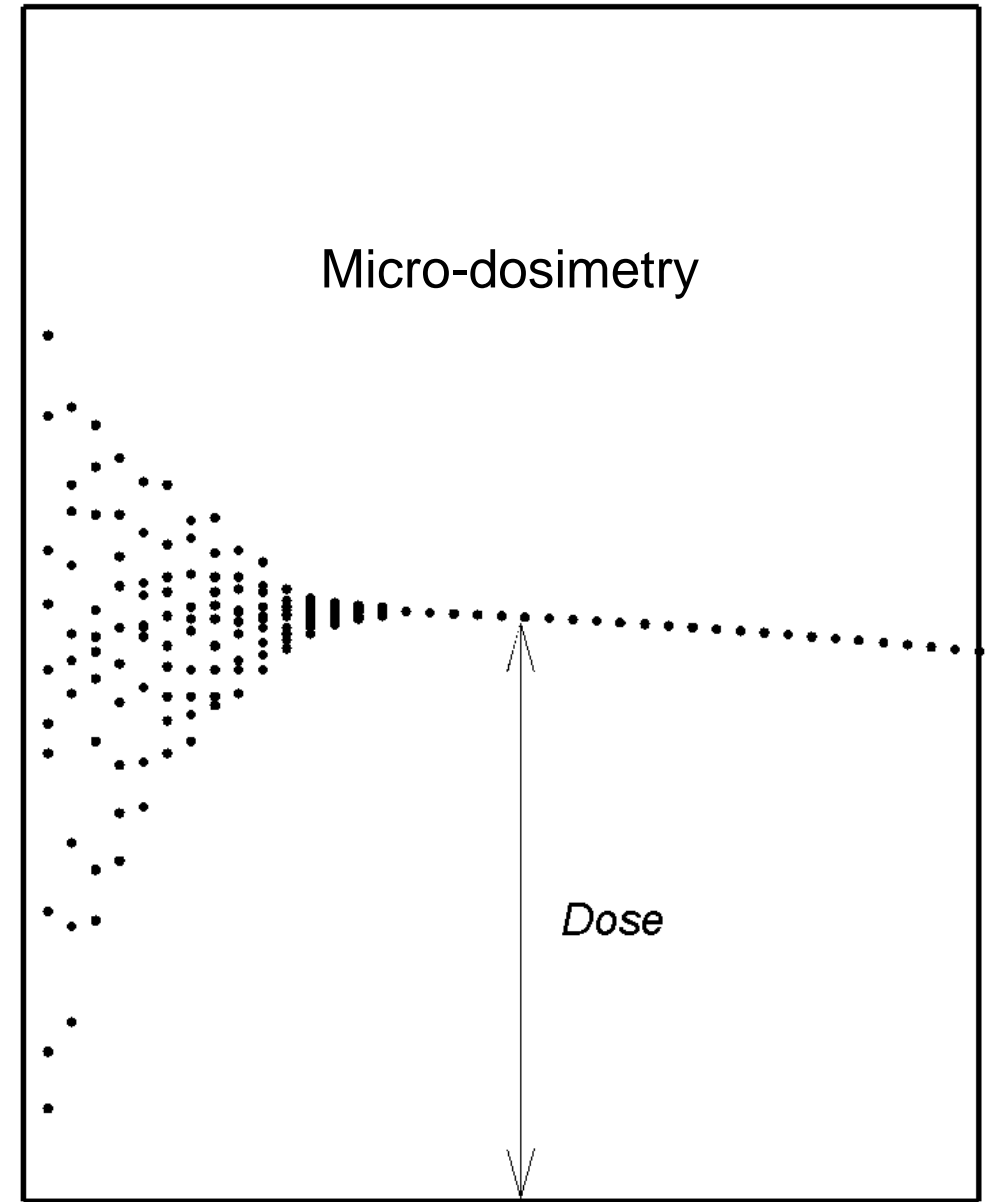


Carbon radiotherapy

What dose distribution in space and time?

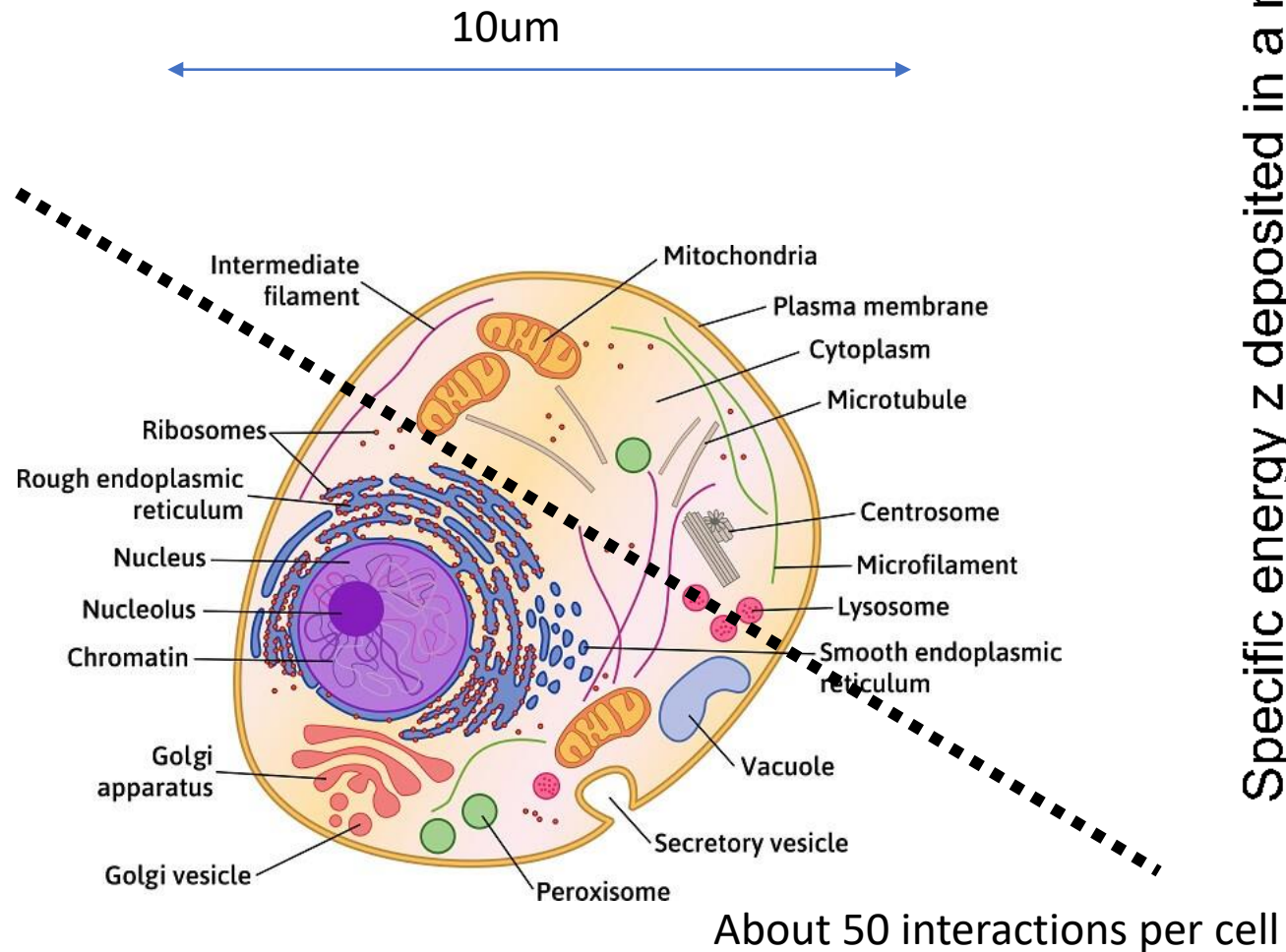


Specific energy z deposited in a mass m

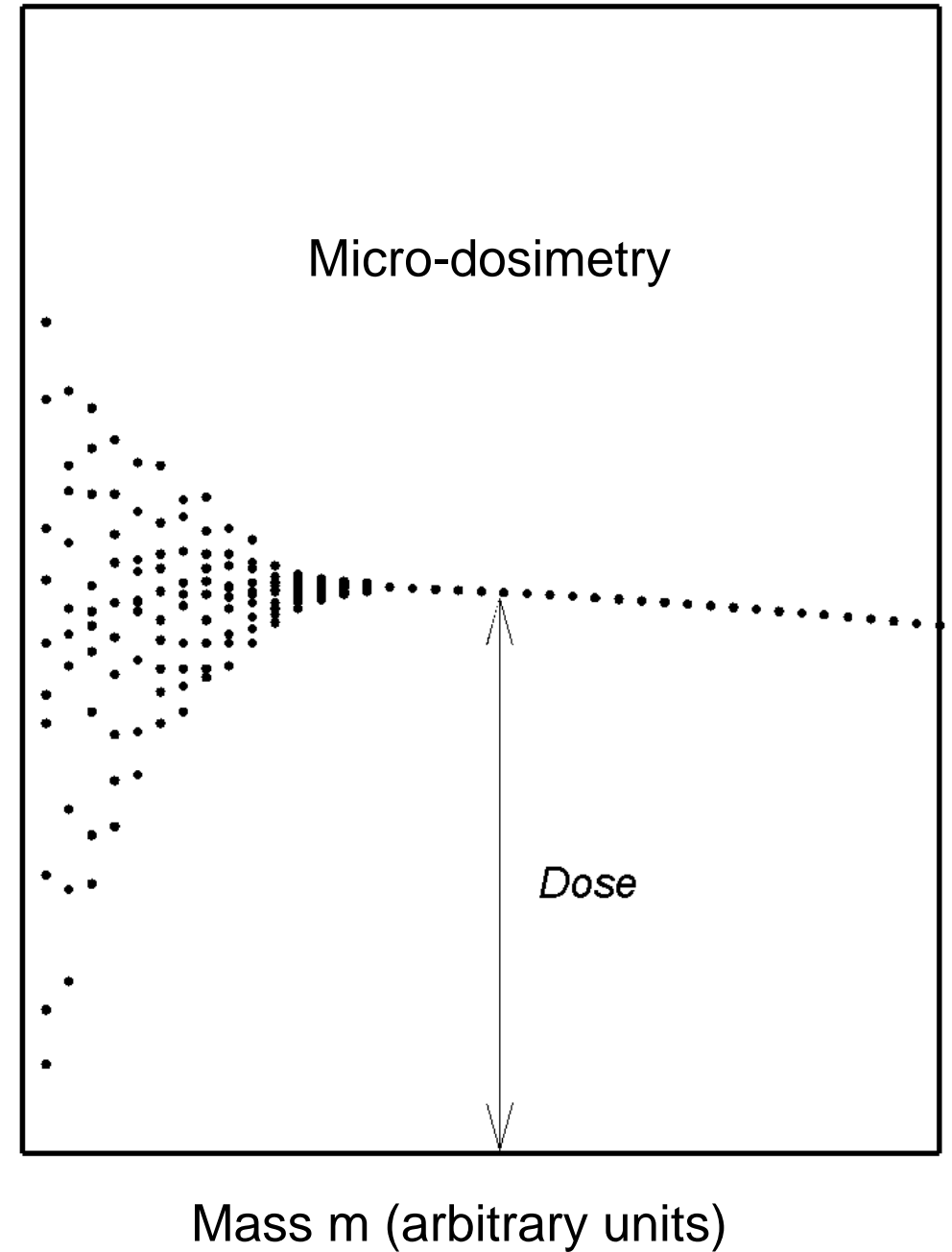


Mass m (arbitrary units)

What dose distribution in space and time?

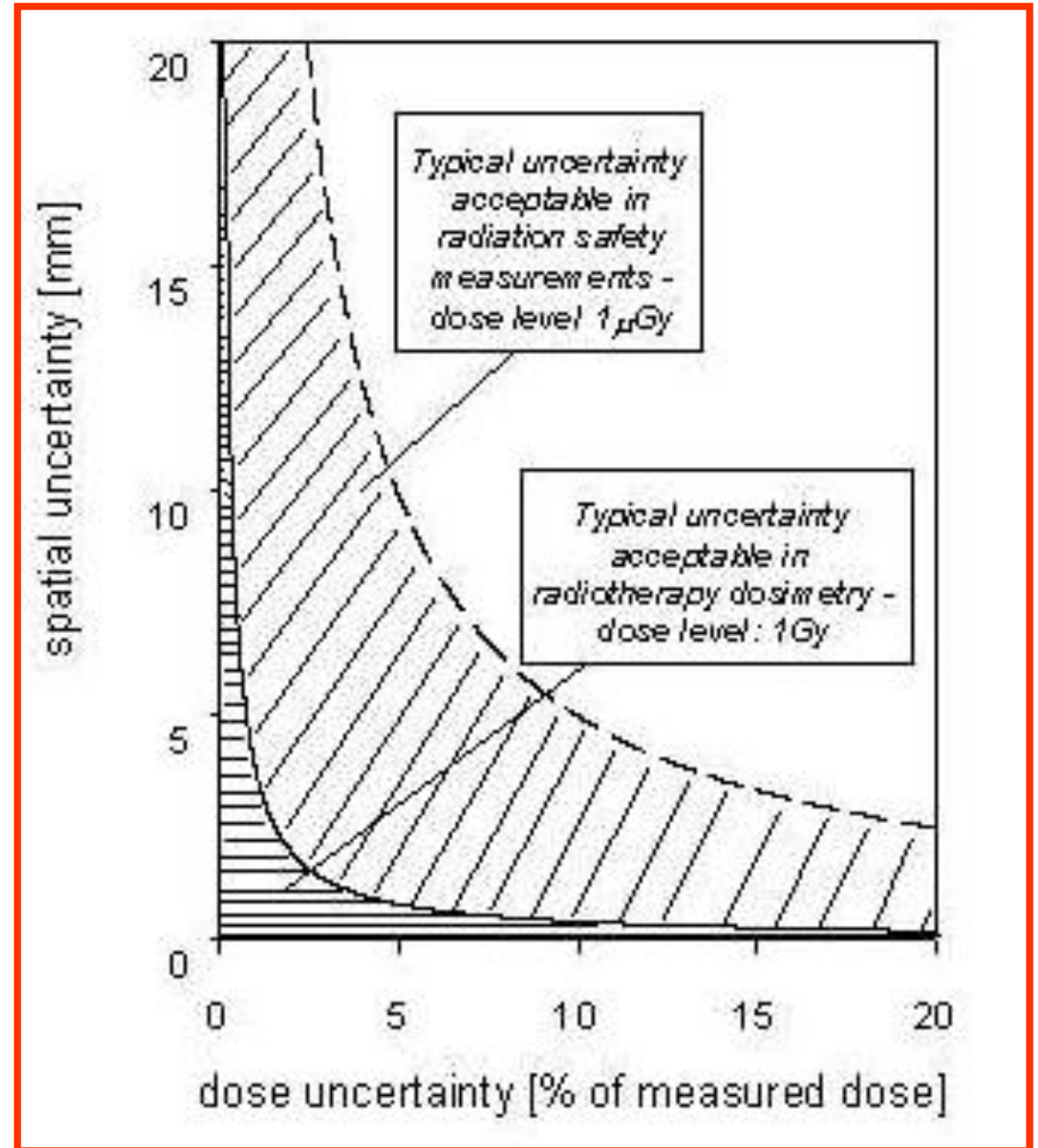


Specific energy z deposited in a mass m



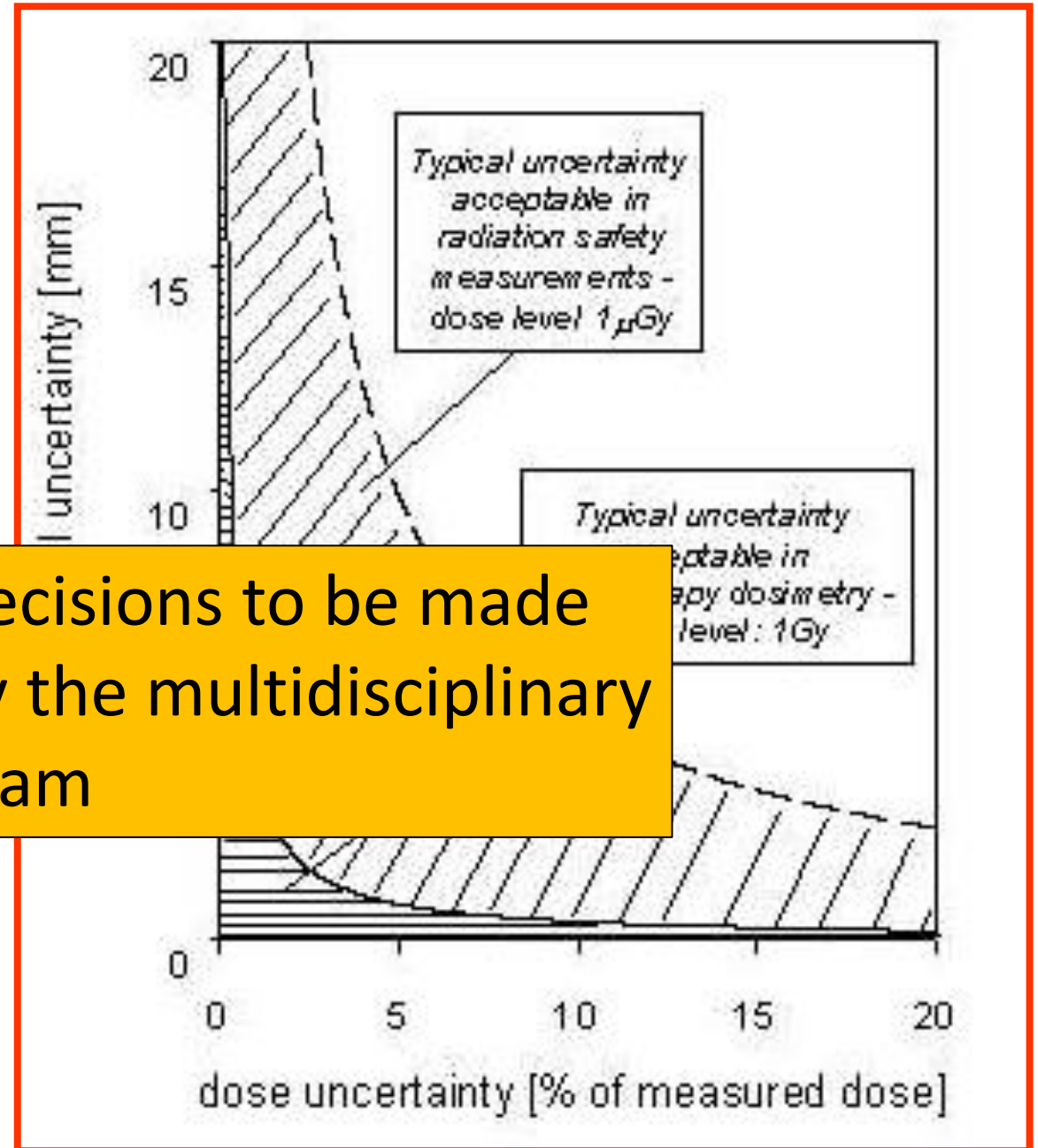
Dimensions can be “traded”

- There is a compromise between spatial resolution, sensitivity and precision
- Depends on measurement purpose and location
- Time can reduce uncertainty through repeat measurements
- Time adds cost and reduces patient comfort
- Reduced comfort increases motion



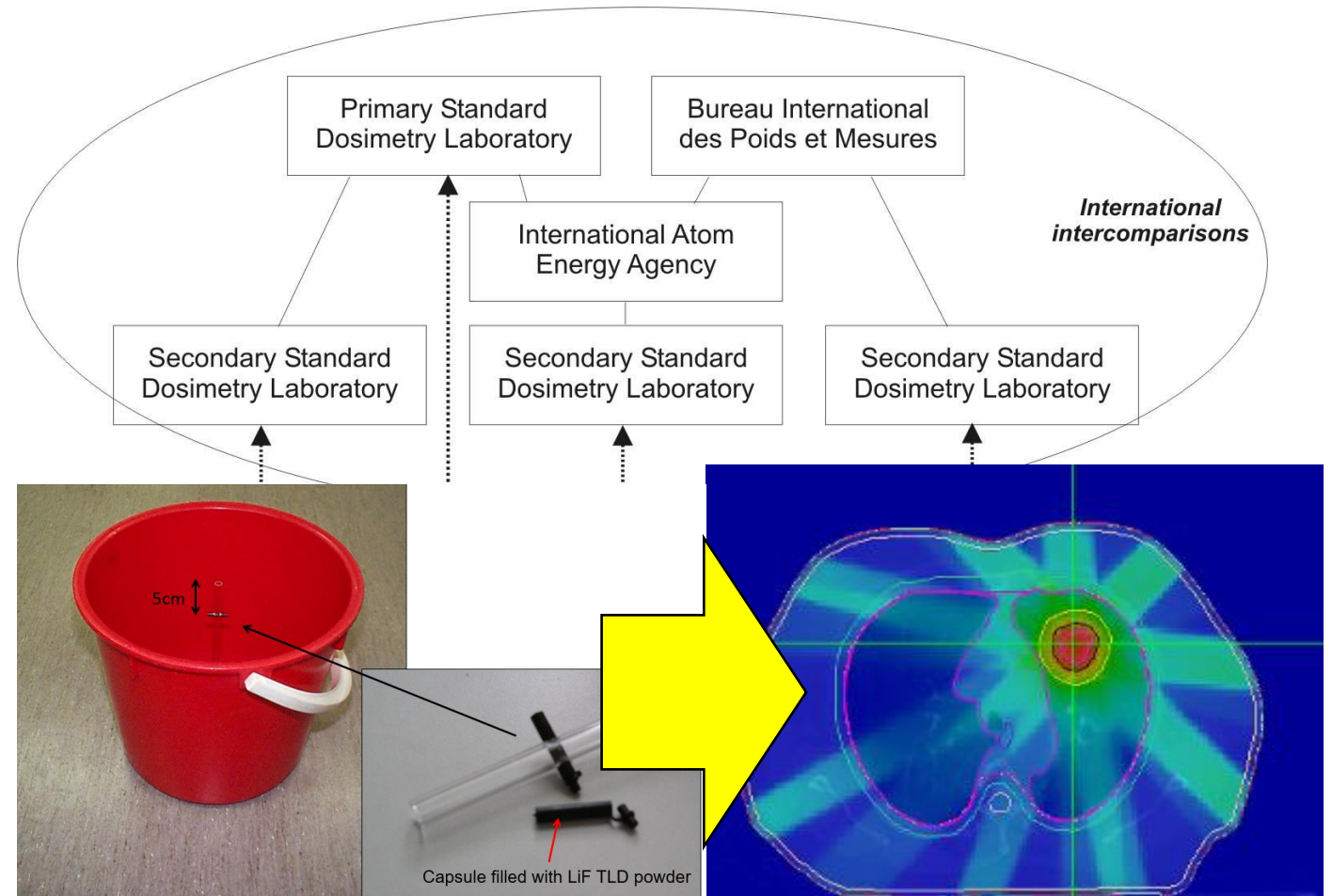
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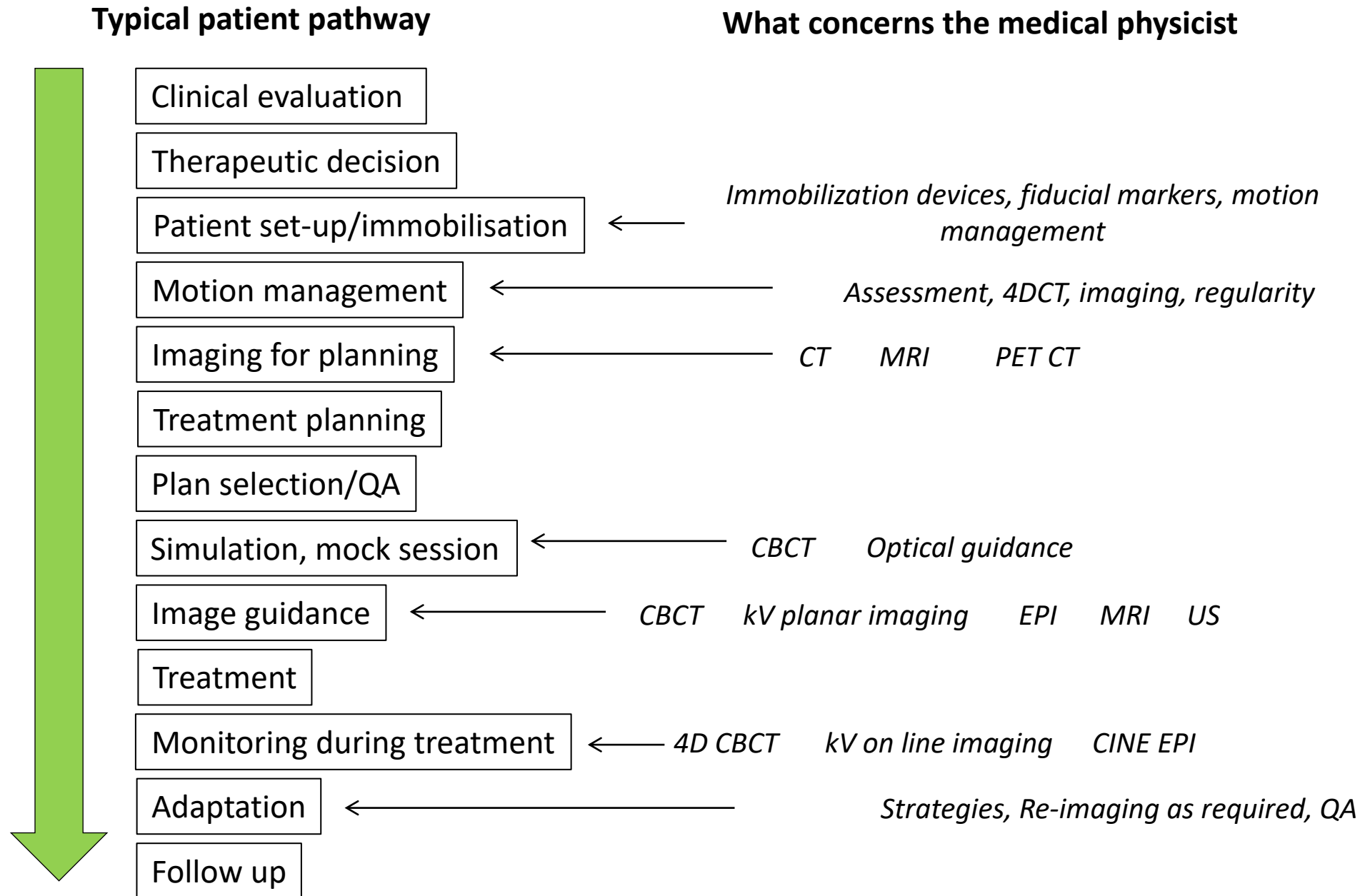


Dose starts with traceability

- Units mean the same all over the world
- 1Gy in NY = 1Gy in Trieste = 1Gy in Melbourne
 - Under reference conditions
 - For a VMAT lung SBRT treatment (?)

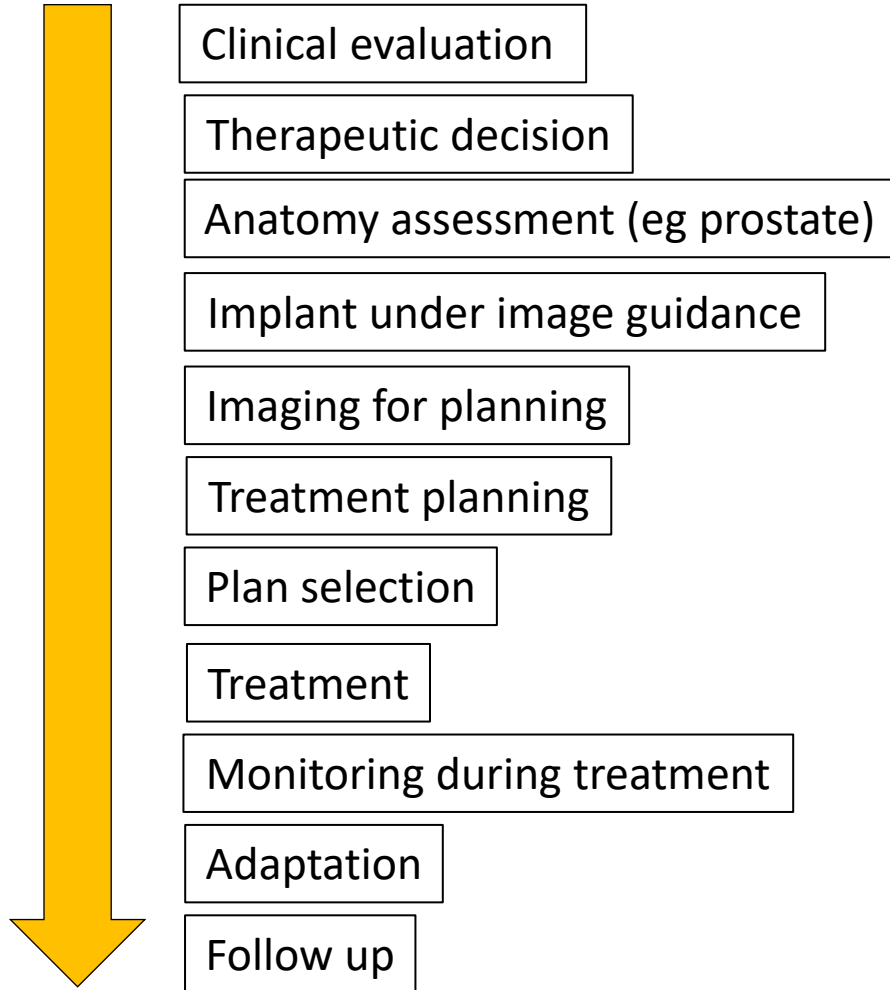


2. Uncertainties in the External Beam Radiotherapy Patient Pathway



Uncertainties in the Brachytherapy Patient Pathway

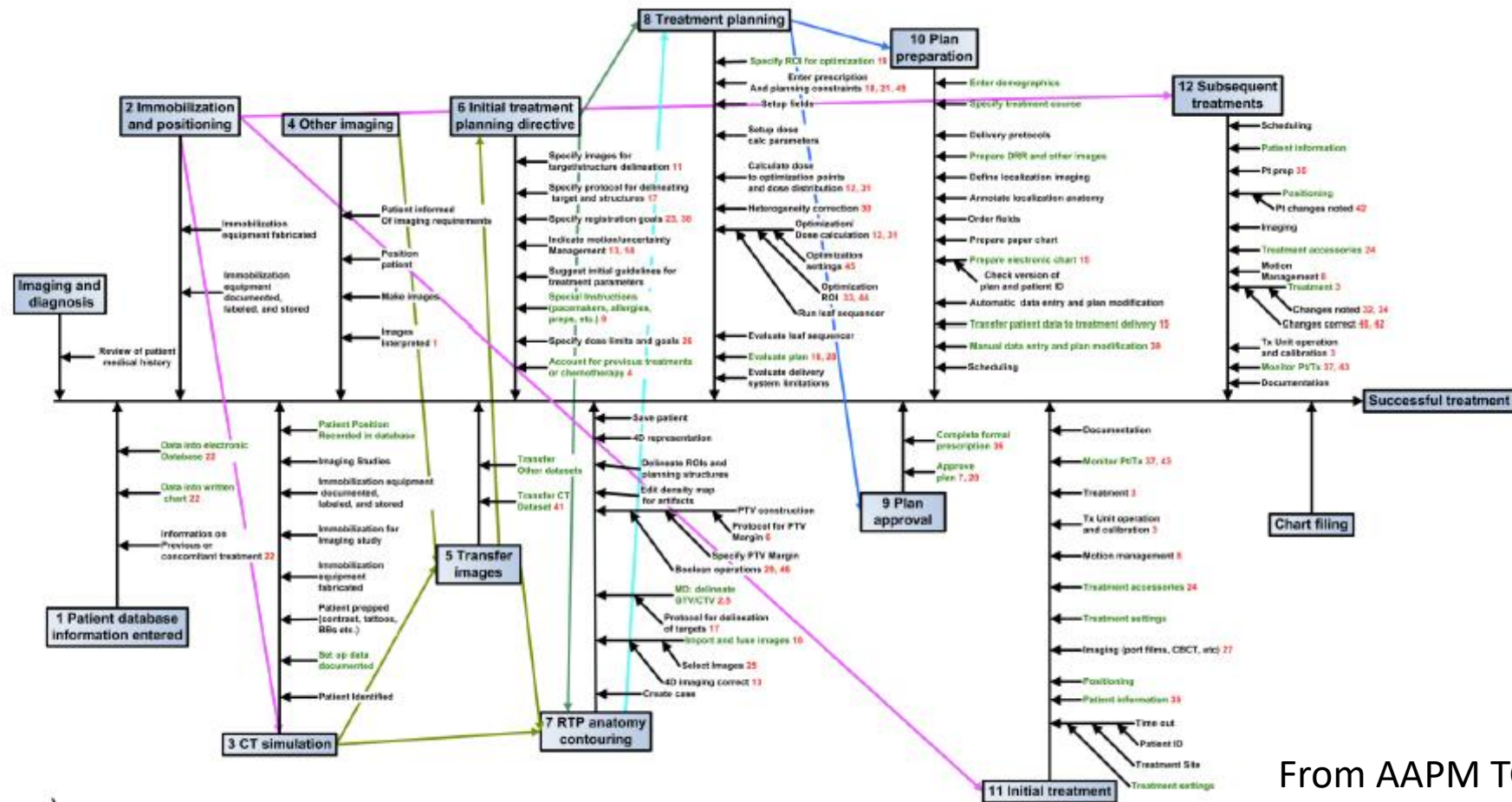
Typical patient pathway



What concerns the medical physicist?

Process maps for each step of patient journey

Here IMRT following AAPM TG 100



From AAPM TG100

a)

3. Risk management

- ISO 31000 group of standards
- Unified approach to principles and generic guidelines on risk management
- Risk defined as: “Effect of uncertainty on objectives”
- Uncertainty can in principle have positive and negative effects on the objectives
- Compare genetic mutations...

Two 'broad' approaches

- Retrospective:

- Root Cause Analysis
- Based on what has gone wrong in the past
- Requires past incidents
- Typically based on incident reporting



- Prospective

- Failure Mode and Effect Analysis (FMEA)
- Based on understanding and analysis of the process



Original article

Risk factors for radiotherapy incidents and impact of an online electronic reporting system

David W. Chang^{a,*}, Lynn Cheetham^b, Luc te Marvelde^c, Mathias Bressel^c, Tomas Kron^d, Suki Gill^a, Keen Hun Tai^{a,e}, David Ball^{a,e}, William Rose^f, Linas Silva^c, Farshad Foroudi^{a,e}

^a Division of Radiation Oncology and Cancer Imaging; ^b Department of Radiation Therapy Services; ^c Centre for Biostatistics and Clinical Trials; ^d Department of Physical Sciences, Peter MacCallum Cancer Centre; ^e Sir Peter MacCallum Department of Oncology, The University of Melbourne; and ^f Department of Information Technology, Peter MacCallum Cancer Centre, Melbourne, Australia

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ABSTRACT

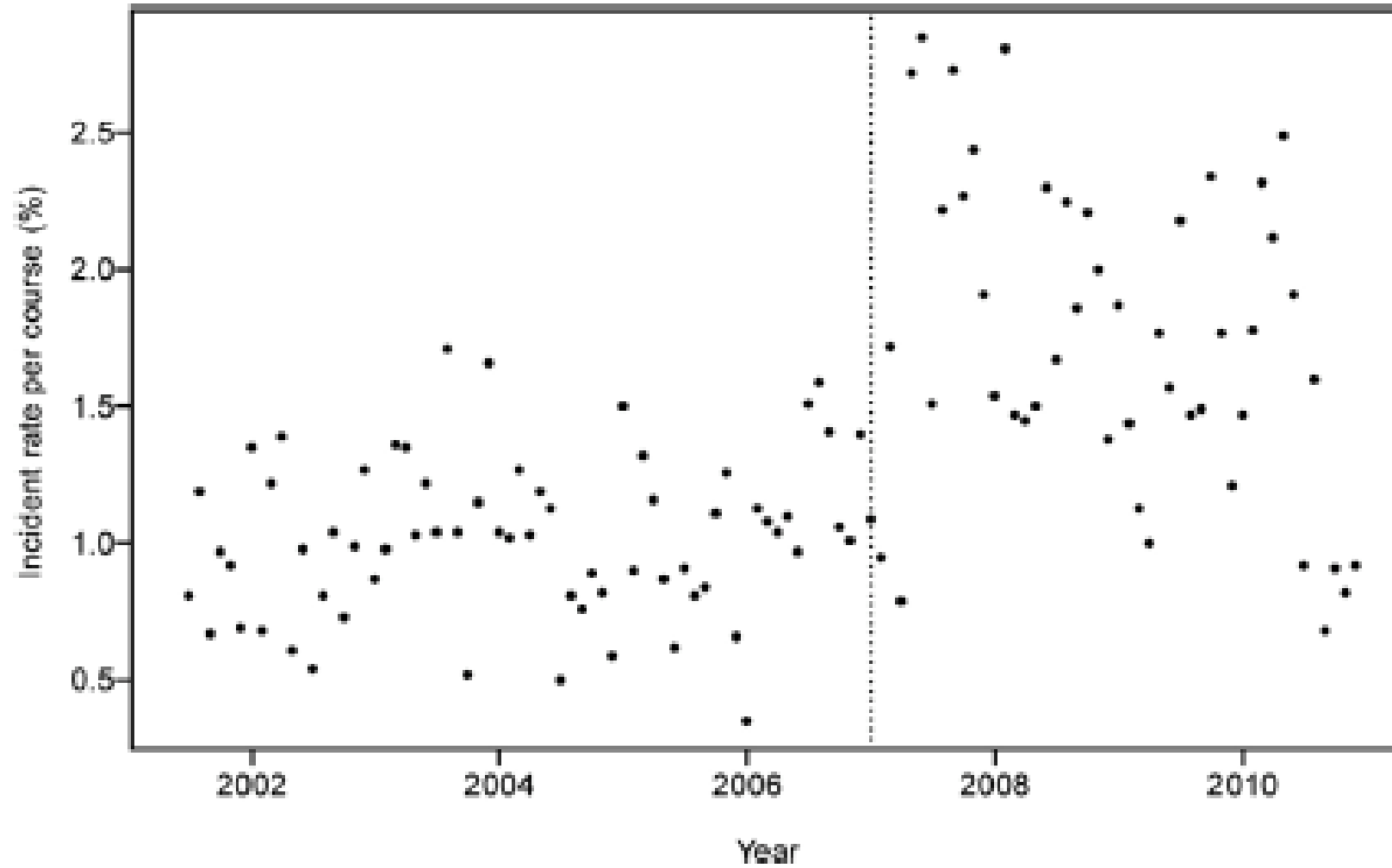
Background and purpose: To ascertain the rate, type, significance, trends and the potential risk factors associated with radiotherapy incidents in a large academic department.

Materials and methods: Data for all radiotherapy activities from July 2001 to January 2011 were reviewed from radiotherapy incident reporting forms. Patient and treatment data were obtained from the radiotherapy record and verification database (MOSAIQ) and the patient database (HOSPRO). Logistic regression analyses were performed to determine variables associated with radiotherapy incidents.

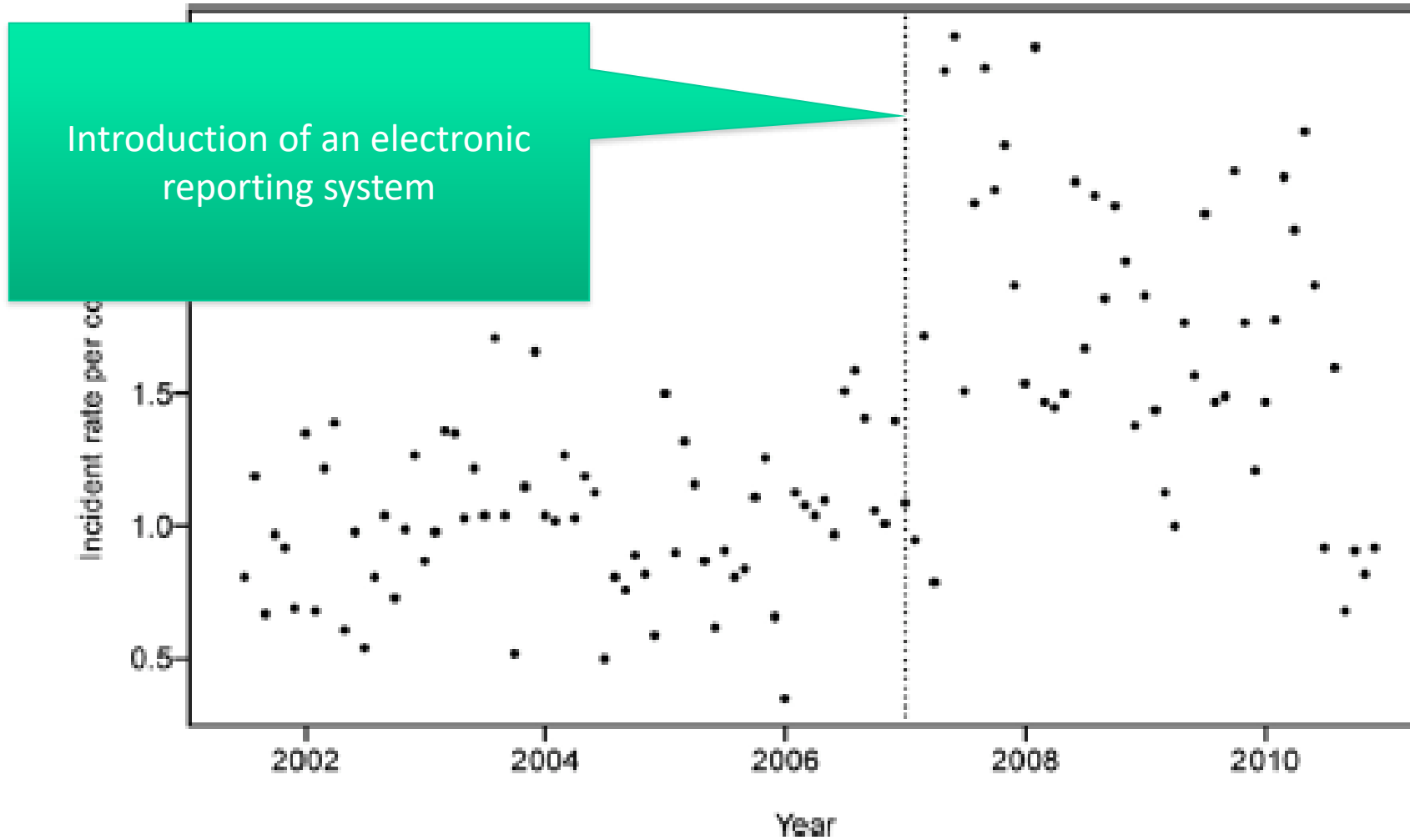
Results: In that time, 65,376 courses of radiotherapy were delivered with a reported incident rate of 2.64 per 100 courses. The rate of incidents per course increased (1.96 per 100 courses to 3.52 per 100 courses, $p < 0.001$) whereas the proportion of reported incidents resulting in >5% deviation in dose (10.50 to 2.75%, $p < 0.001$) had decreased after the introduction of an online electronic reporting system. The following variables were associated with an increased rate of incidents: afternoon treatment time, paediatric patients, males, inpatients, palliative plans, head-and-neck, skin, sarcoma and haematological malignancies. In general, complex plans were associated with higher incidence rates.

Conclusion: Radiotherapy incidents were infrequent and most did not result in significant dose deviation. A number of risk factors were identified and these could be used to highlight high-risk cases in the future. Introduction of an online electronic reporting system resulted in a significant increase in the number of incidents being reported.

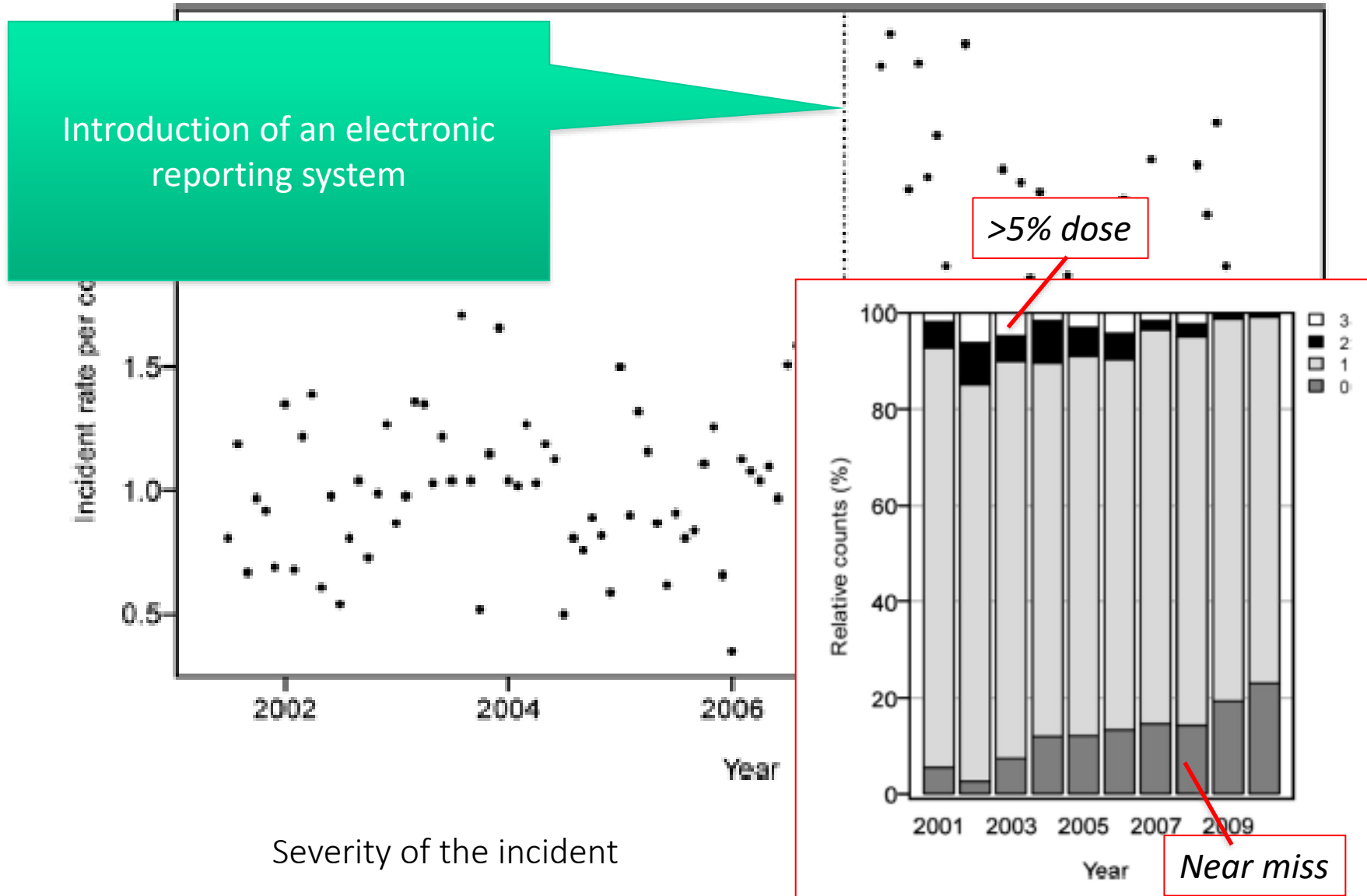
Findings



Findings



Findings



Which treatments are affected (by the largest uncertainty)?

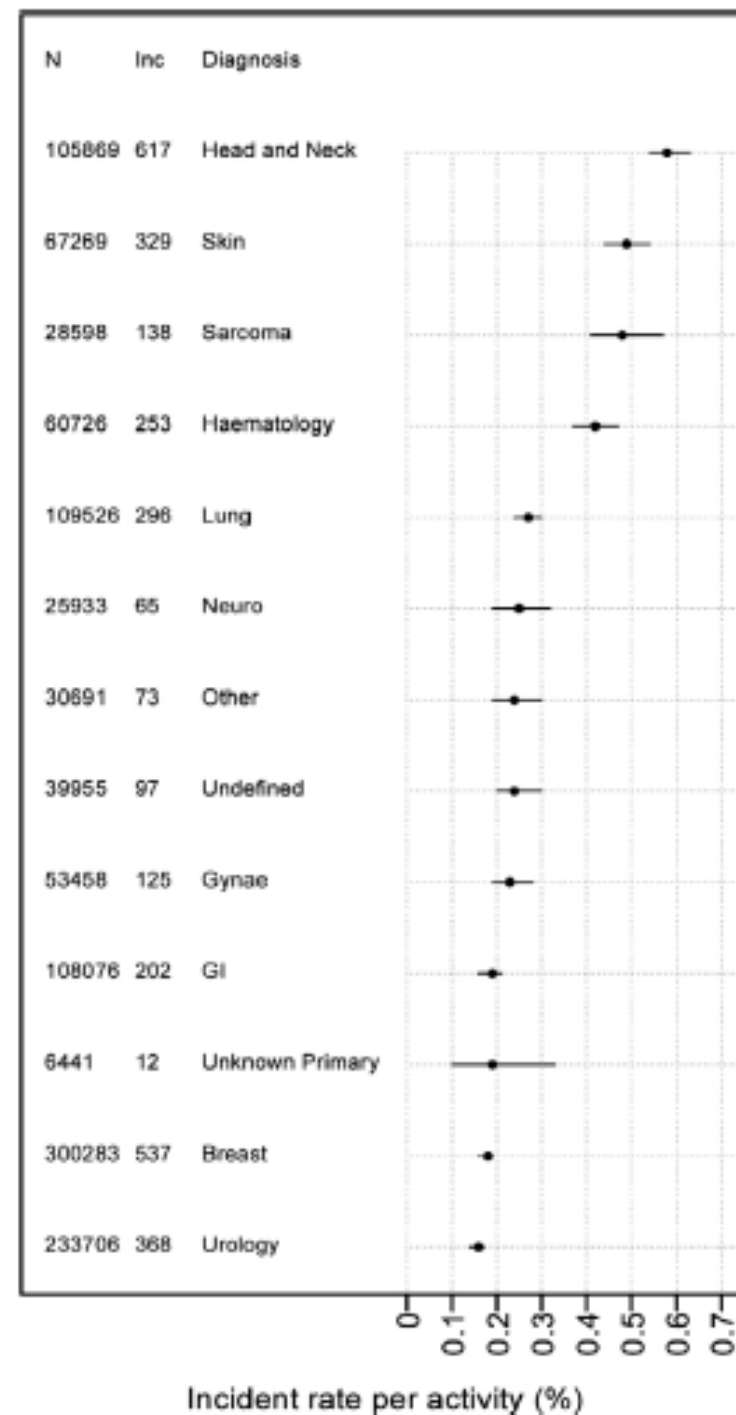


Fig. 5. Mean incident rate per activity with exact 95% confidence intervals per diagnosis region. *N* - total number of activities, *Inc* - total number of activities in which at least one incident occurred.

Impact of complexity and computer control on errors in radiation therapy

B.A. Fraass

Department of Radiation Oncology, Cedars-Sinai Medical Center, 8700 Beverly Blvd., AC1085, Los Angeles, CA 90048, USA; e-mail: benedick.fraass@cshs.org

Abstract—A number of recent publications in both the lay and scientific press have described major errors in patient radiation treatments, and this publicity has galvanised much work to address and mitigate potential safety issues throughout the radiation therapy planning and delivery process. The complexity of modern radiotherapy techniques and equipment, including computer systems, as well as radiation therapy, image-guided systems, and intensity modulated radiation therapy, are there- umetric modulated issues related to that complex computer control, and vari- scribes studies that address the issue of these modern techniques and whether their complexity does, in fact, result in more errors or safety-related problems. Clinical implications of these results are discussed, as are some of the ways in which the field should respond to the ongoing concerns about errors and complexity in radiation therapy.

In brief:

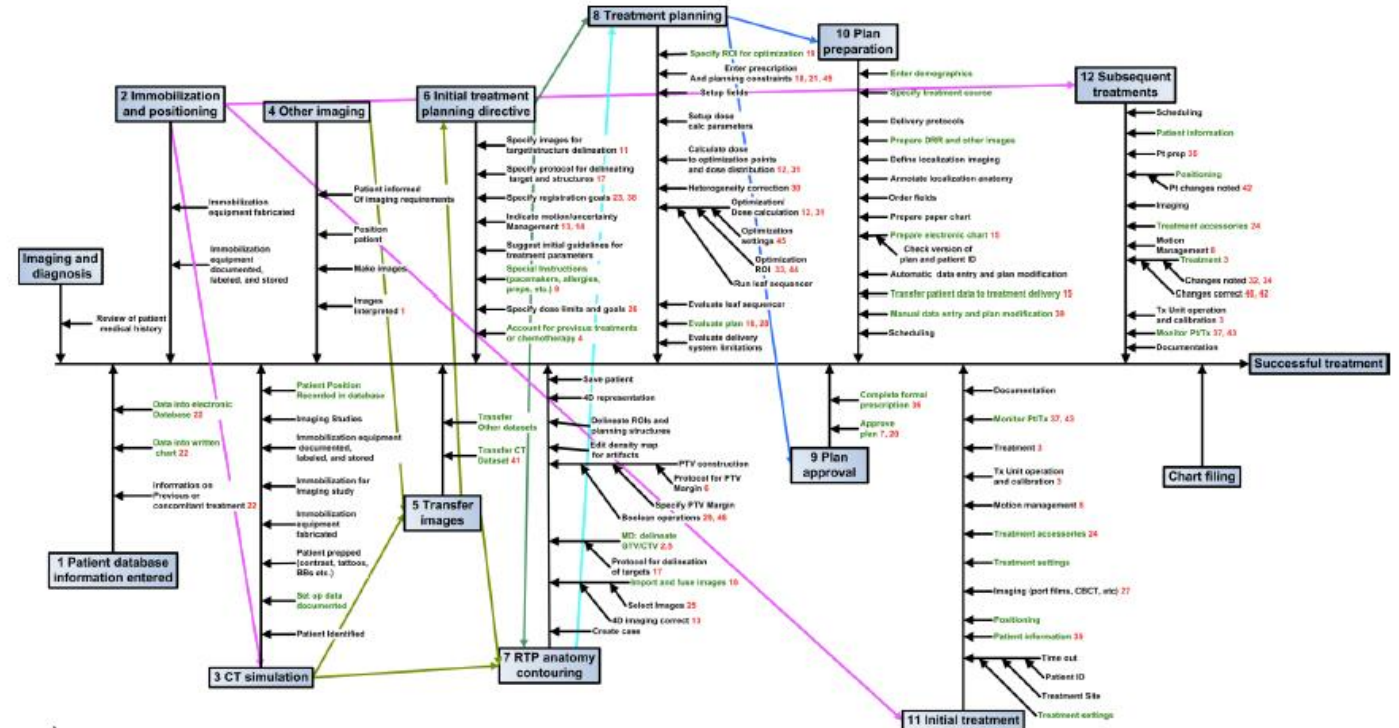
Complexity does not increase error rate

Computers generally increase safety

Error type changes: random → systematic

Prospective Risk management: Failure Mode and Effect Analysis

- Requires a process map
- IMRT example from AAPM TG100

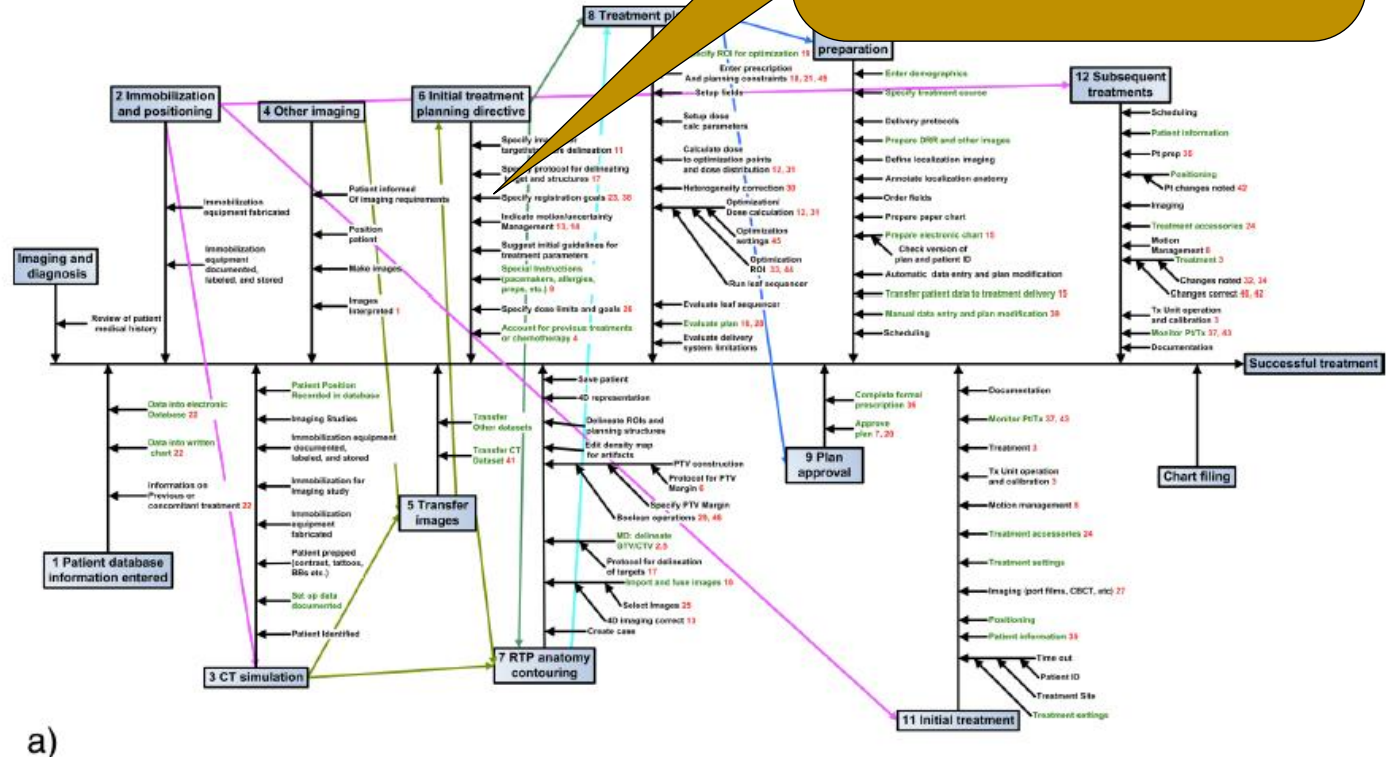
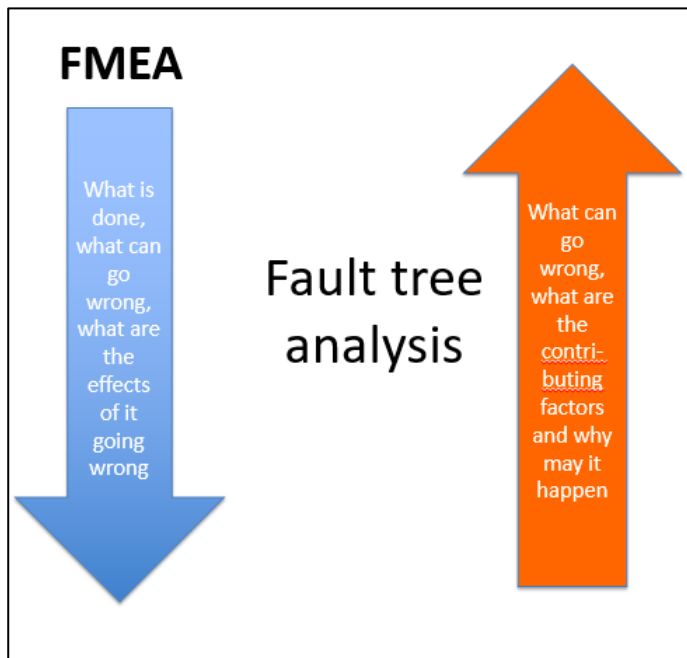


a)

Prospective Risk management: Failure Mode and Effect Analysis

- Requires a process map
- IMRT example from AAPM TG100

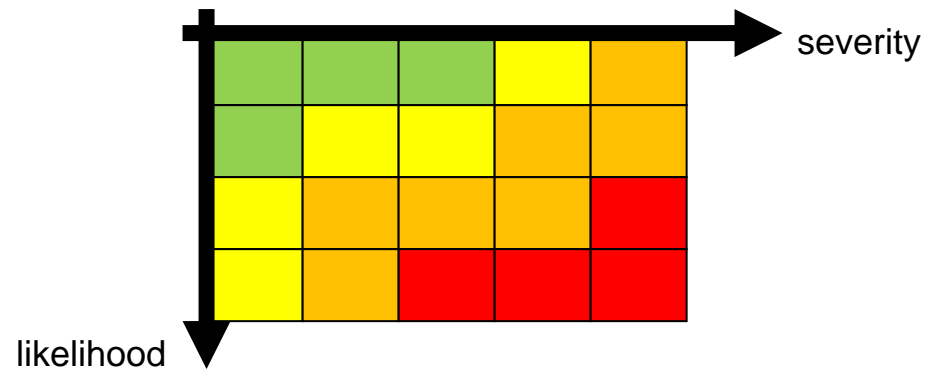
Each step decide what failure modes exist, how likely they are and how significant their impact is



a)

How can we rationally decide on how much QC is required?

- Likelihood that something goes wrong, O
- Severity of the consequences, S
- Ease and feasibility of checking, D



Risk Priority Number = O x S x D

Guidance by TG100

TABLE II. Descriptions of the *O*, *S*, and *D* values used in the TG-100 FMEA.

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

Guidance by TG100

Who but the medical physicist can determine what D is?

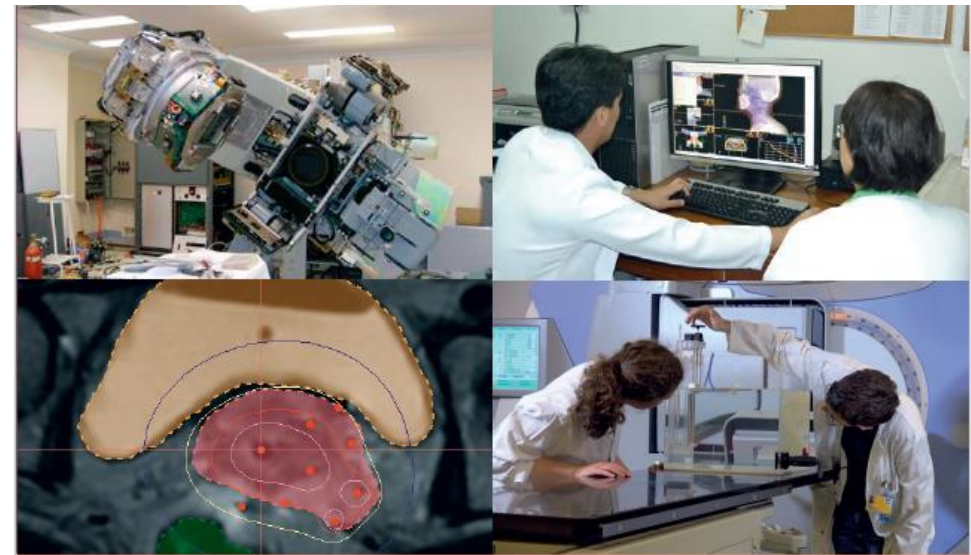
4222 Huq *et al.*: TG 100 report

TABLE II. Descriptions of the *O*, *S*, and *D* values used in the TG-100 FMEA.

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

Uncertainties in Radiotherapy

- Accuracy requirements determine the allowable uncertainty



IAEA HUMAN HEALTH SERIES

No. 31

**Accuracy Requirements
and Uncertainties in
Radiotherapy**



IAEA

International Atomic Energy Agency

How accurate can we want to be?

- How accurate can we be in dose and location (and time)?
- What is the purpose of the measurement?
- What dose makes a difference
 - For cancer cure?
 - For normal tissue toxicity?
 - For achieving the imaging purpose?
 - For cancer induction?
 - For regulatory purposes?
 - For clinical research?
- How much can it cost?



What accuracy is required in treatment planning?

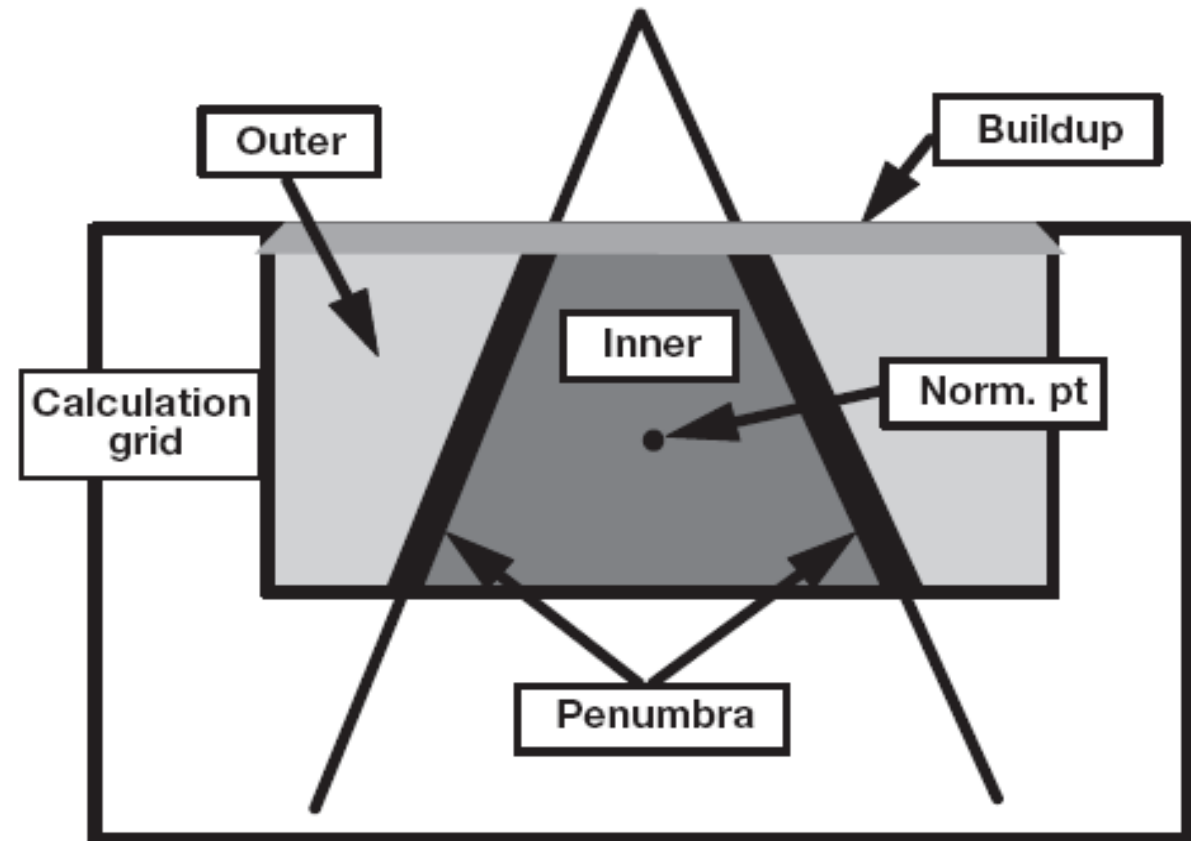
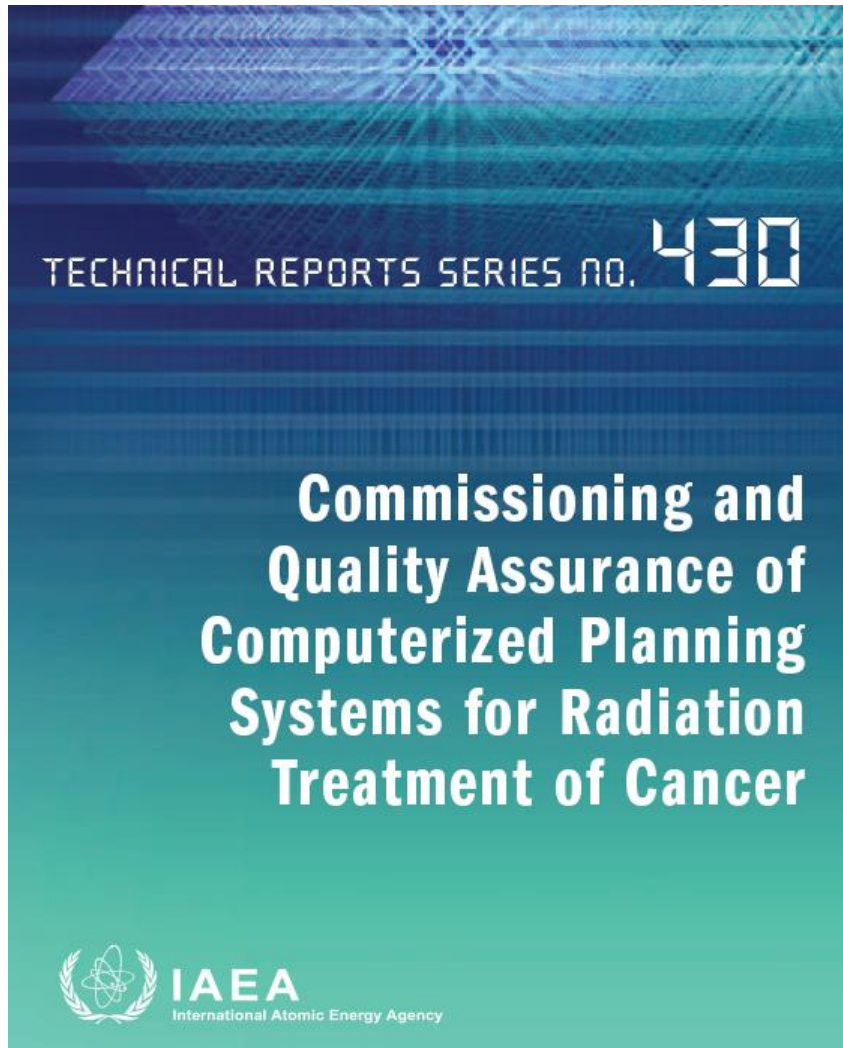


FIG. 11. Regions of different accuracy capabilities for photon beam dose calculations. Reproduced, with permission, from Ref. [18].

TABLE 17. SAMPLE CRITERIA OF ACCEPTABILITY FOR EXTERNAL DOSE CALCULATIONS

(Adapted, with permission, from Ref. [18].)

Situation	Absolute dose at normalization point (%) ^a	Central ray (%)	Inner beam (%)	Penumbra (mm)	Outer beam (%)	Buildup region (%)
Homogeneous phantoms						
Square fields	0.5	1	1.5	2	2	20
Rectangular fields	0.5	1.5	2	2	2	20
Asymmetric fields	1	2	3	2	3	20
Blocked fields	1	2	3	2	5	50
MLC shaped fields	1	2	3	3	5	20
Wedged fields	2	2	5	3	5	50
External surface variations	0.5	1	3	2	5	20
SSD variations	1	1	1.5	2	2	40
Inhomogeneous phantoms^b						
Slab inhomogeneities	3	3	5	5	5	—
3-D inhomogeneities	5	5	7	7	7	—

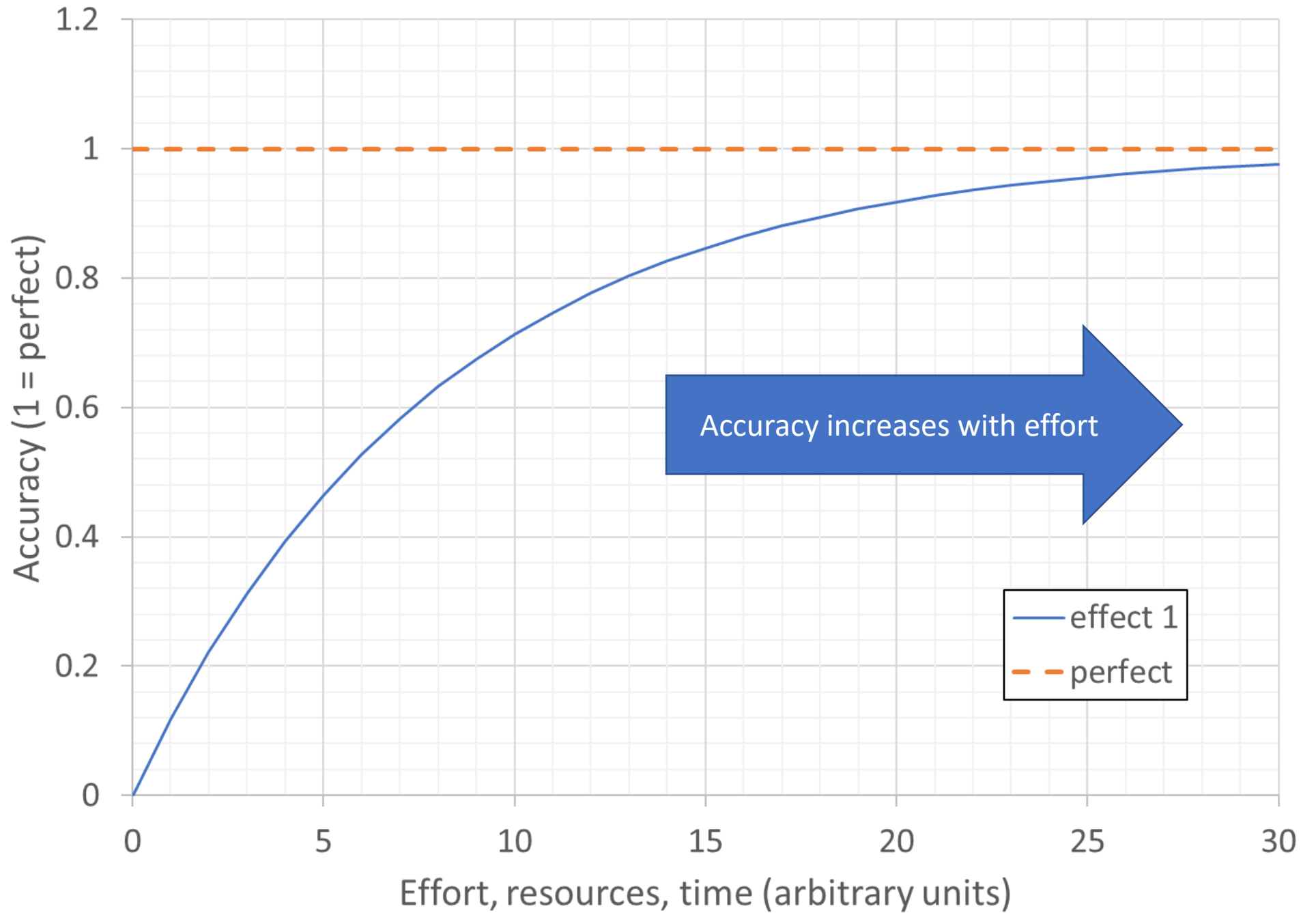
Note: Percentages are quoted as per cent of the central ray normalization dose.

^a Absolute dose values at the normalization point are relative to a standard beam calibration point.

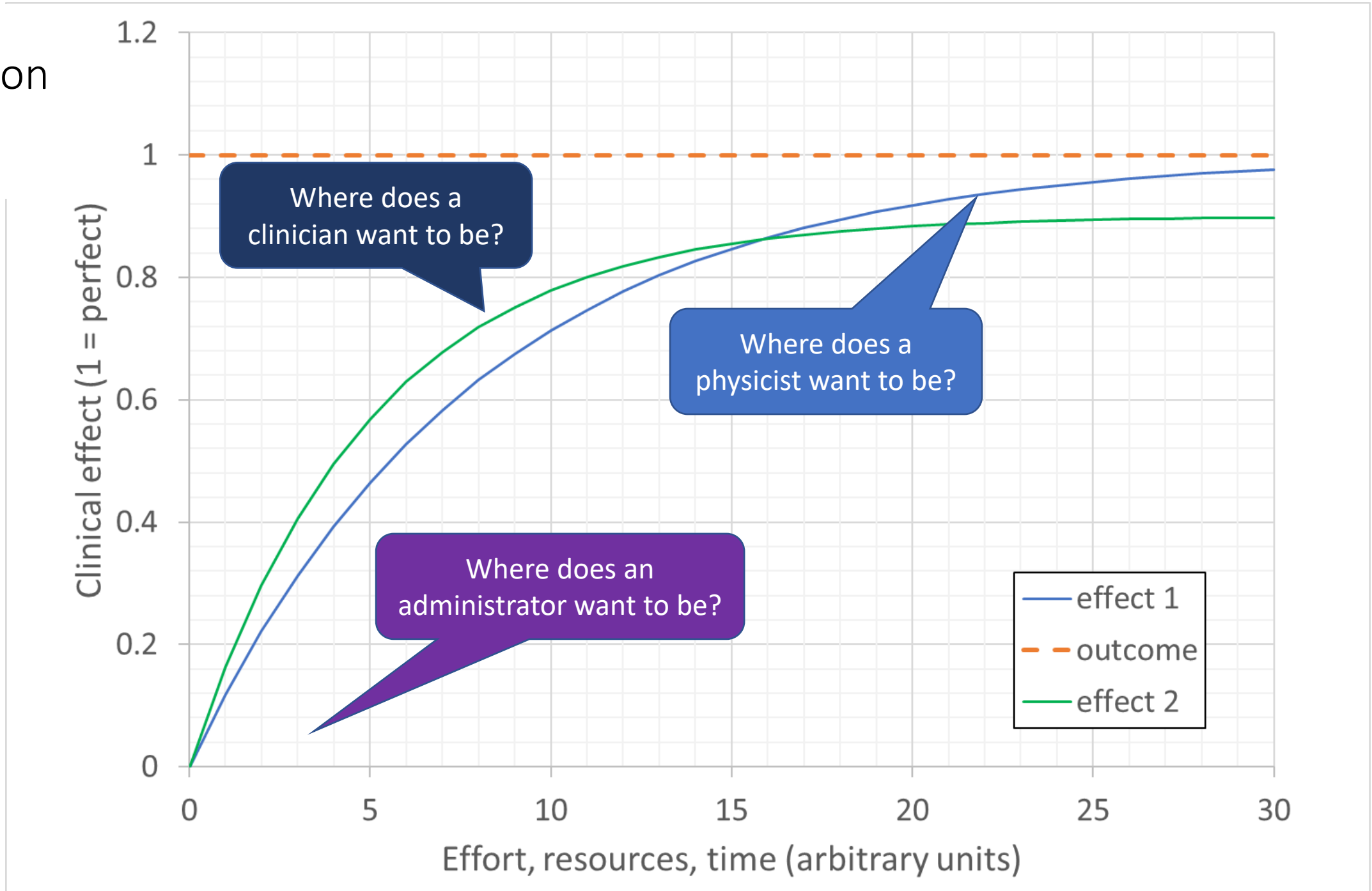
^b Excluding regions of electronic disequilibrium.

What are we expected to achieve?

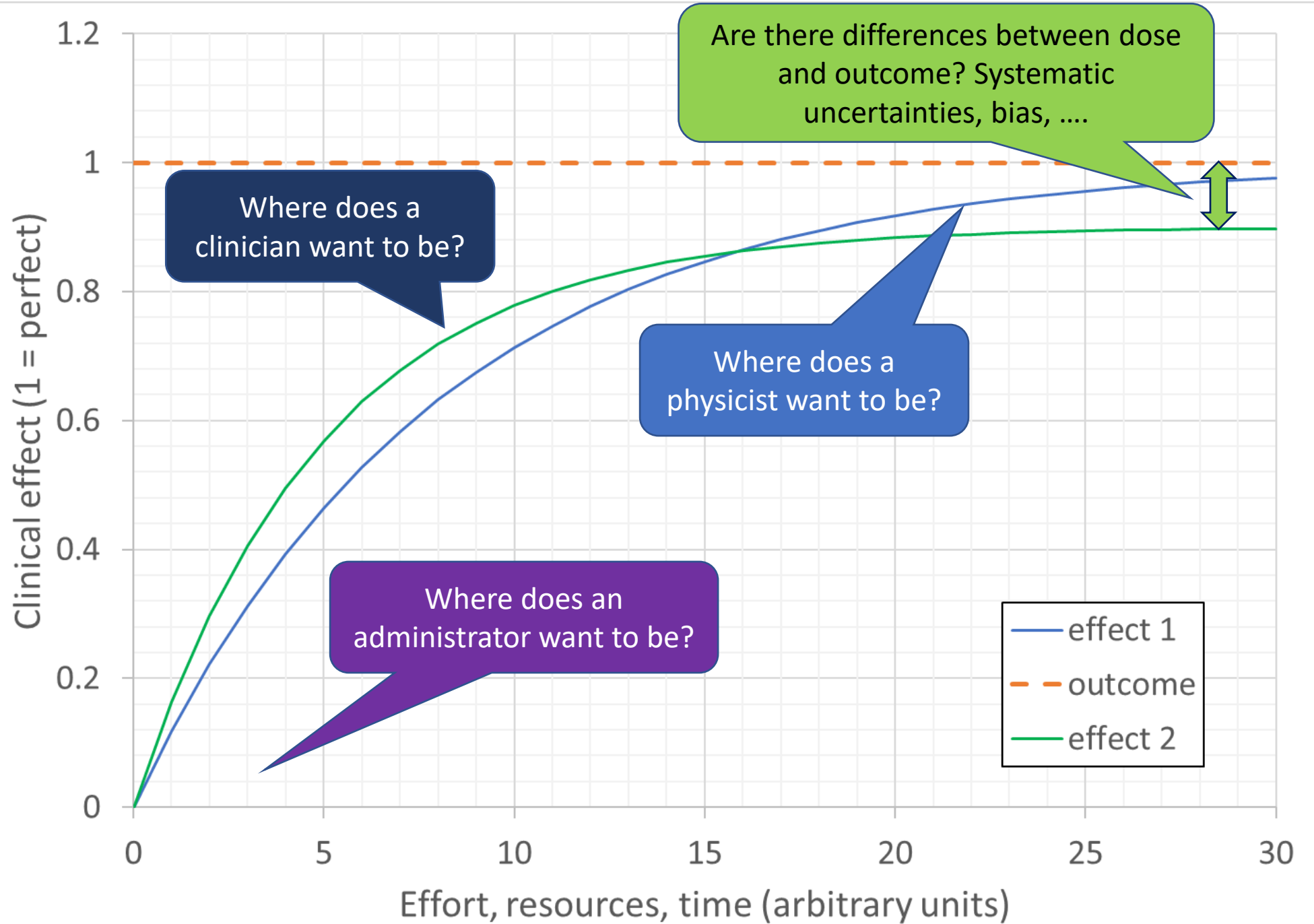
Optimisation
problem



Optimisation problem

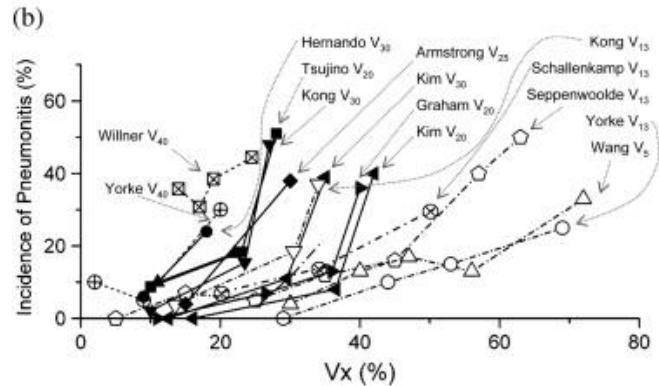
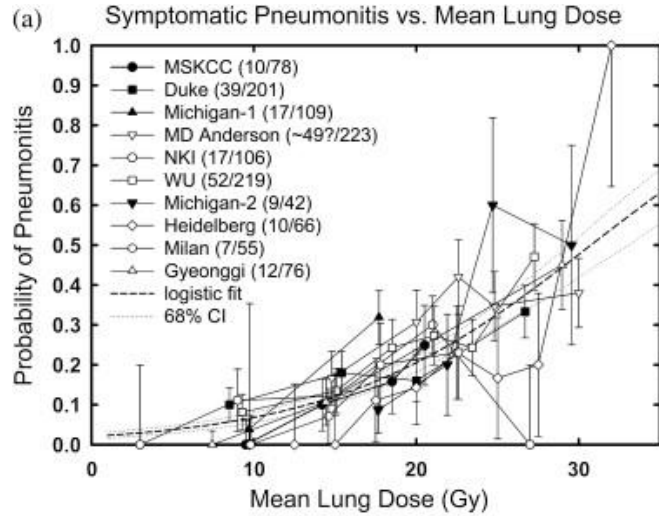


Optimisation problem

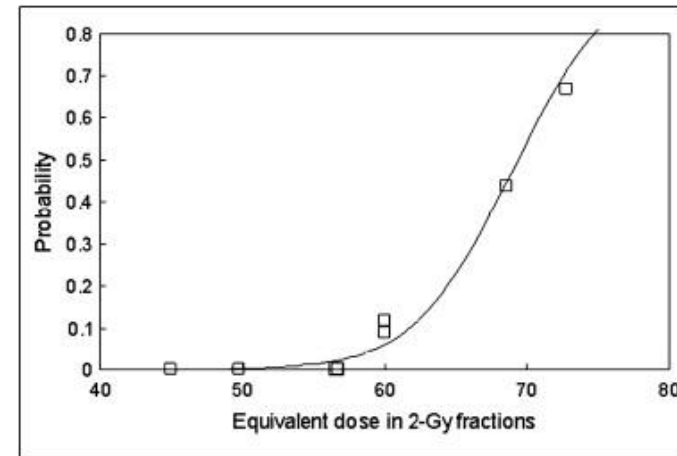
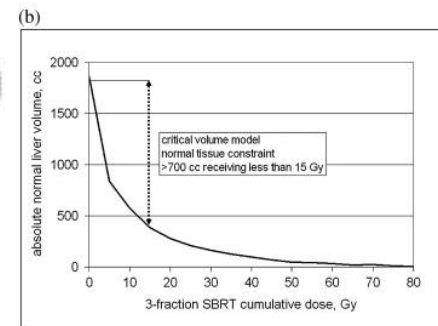
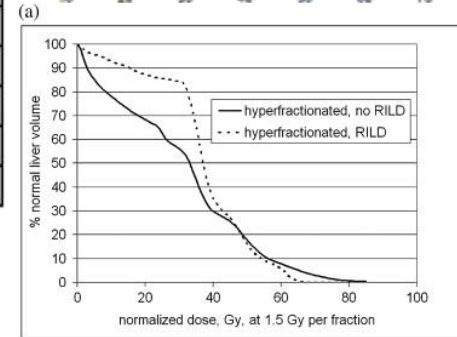
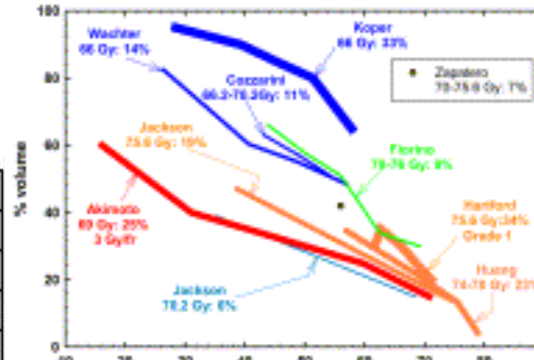


Does dose make a difference?

- QUANTEC




Dose-volume limits for \geq grade 2 rectal toxicity with LQ corrected doses ($\alpha/\beta = 3$ Gy)



Measurements: how accurate can they be?

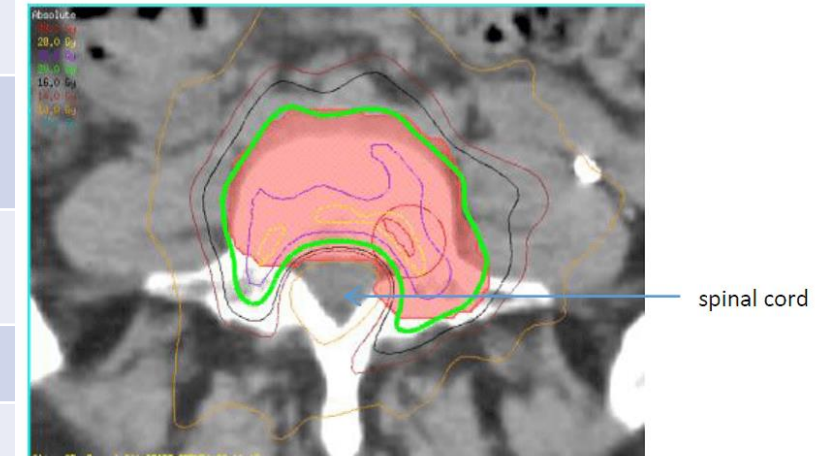
Assume homogenous medium, dose to water, radiotherapy dose level (2 Gy), $k=1$

Radiation effect	Dosimetric method	Reproducibility (%)	Accuracy (%)
Ionization in gases	Ionization chamber	0.2	1
Ionization in liquids	Liquid filled ionization chamber	0.3	
Ionization in solids	Semiconductors	0.5	
	Diamond detectors	0.3	
Luminescence	Thermoluminescence dosimetry	1	2
	OSL	0.8	
Fluorescence	Scintillators	0.8	
Chemical transitions	Radiochromic film	5	2
	Chemical dosimetry	2	
	NMR/gel dosimetry	5	
Heat	Calorimetry	0.5	
Biological effects	Erythema	20	
	Chromosome damage	20	

Measurements: how accurate can they be?

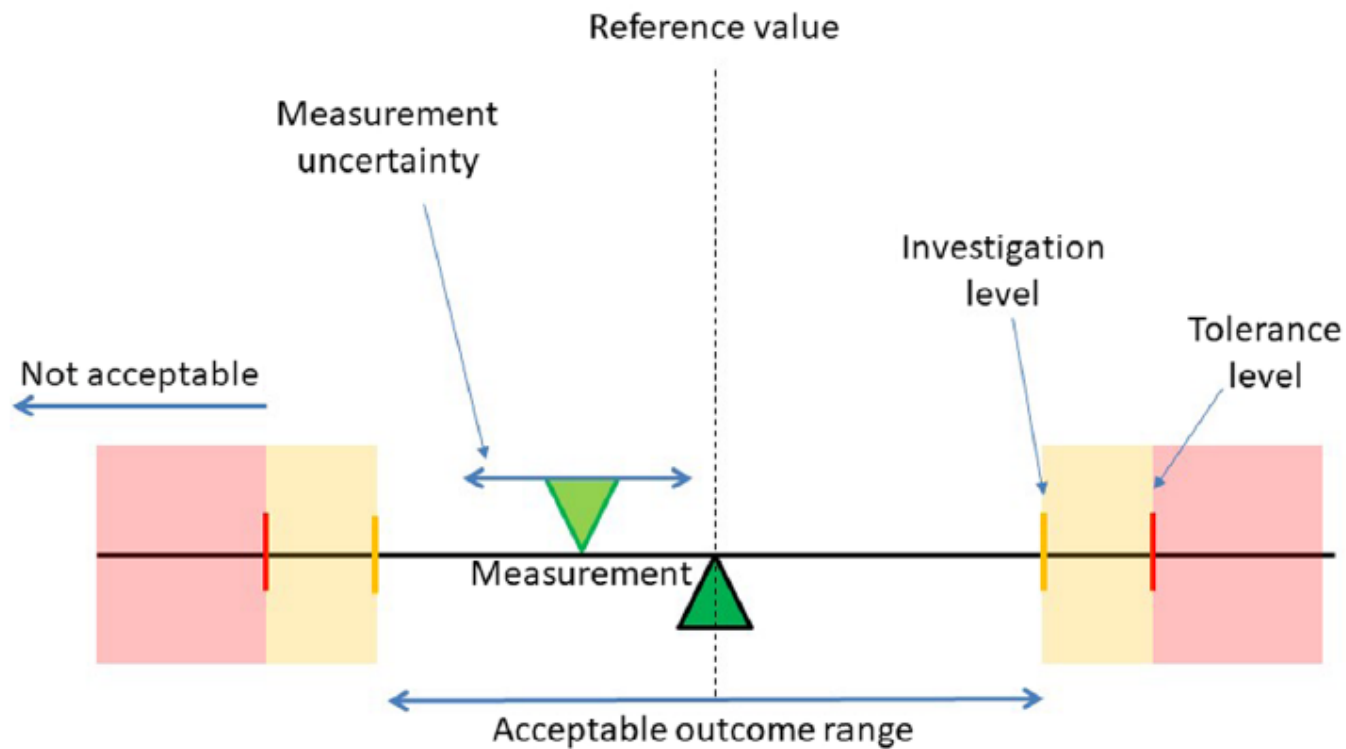
Assume inhomogenous medium, dose to medium, complex dose distribution with VMAT FFF beam and radiotherapy dose level (20 Gy), $k=2$

Radiation effect	Dosimetric method	Reproducibility (%)	Accuracy (%)
Ionization in gases	Ionization chamber	5	???
Ionization in liquids	Liquid filled ionization chamber		
Ionization in solids	Semiconductors	5	
	Diamond detectors	5	
Luminescence	Thermoluminescence dosimetry	5	
	OSL		
Fluorescence	Scintillators		
Chemical transitions	Radiochromic film	8	???
	Chemical dosimetry		
	NMR/gel dosimetry		
Heat	Calorimetry		
Biological effects	Erythema	20	
	Chromosome damage	20	



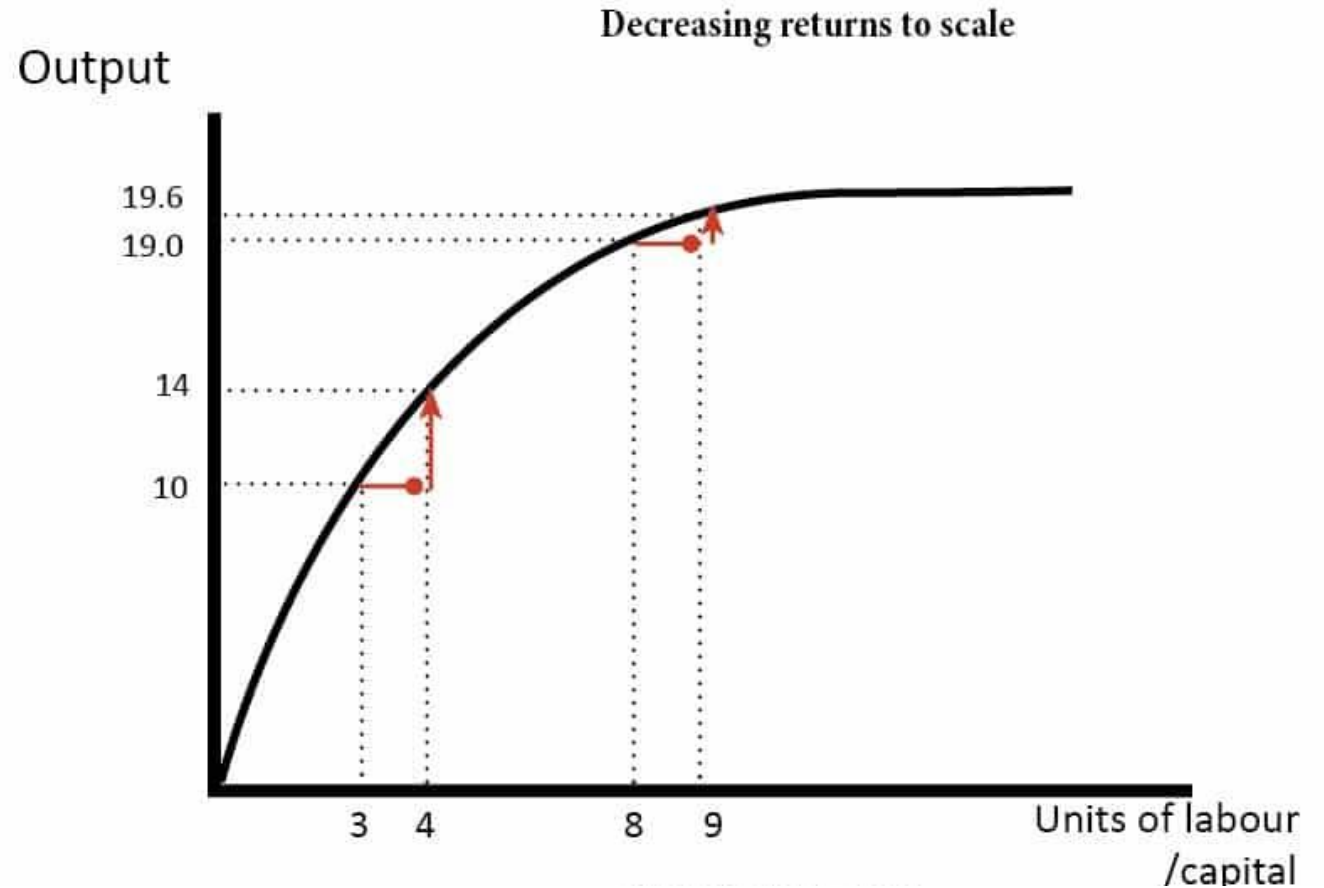
Need to adjust actions based on measurement to the outcome

- How much uncertainty do we have
- Our QA criteria (gamma index) change:
 - VMAT/IMRT: 2mm/3%, 90%, threshold 10%
 - SABR/SRS: 1mm/5%, 90%, threshold 10%
- Variation depending on modulation, IGRT and clinical need



Why don't we want to be perfect?

- Type B uncertainties are difficult to overcome and lead to systematic errors
- The effort/resources increase dramatically
- Other uncertainties dominate the outcome



Summary

- Everything is affected by uncertainty
- Measurements should have a quantifiable uncertainty
- Uncertainties come in two flavours: Type A and Type B
- Medical physicists are required to understand all aspects of patient treatment to appreciate where efforts are best directed to
- It has implications for patient care, access to treatment, workload and clinical research