Received:
15 November 2017

Revised:
19 December 2017

Accepted:
21 December 2017

<https://doi.org/10.1259/bjr.20170863>

Cite this article as:

Eaton DJ, Byrne JP, Cosgrove VP, Thomas SJ. Unintended doses in radiotherapy—over, under and outside?. *Br J Radiol* 2018; **91**: 20170863.

COMMENTARY

Unintended doses in radiotherapy—over, under and outside?

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ABSTRACT

Radiotherapy is a safe treatment; nevertheless, national reporting of serious incidents allows investigation of potential harm to individuals and failing safety culture. UK guidance has previously been limited to overexposures, but underexposures will be included in the new legislation, and positioning errors have also been explicitly included in recent guidance. This commentary reviews current guidance and suggests practical approaches to the additional categories, including the definition of a local error margin.

INTRODUCTION

Radiotherapy is a safe treatment. In the UK, previous estimates suggest that 1 in 2500 treatment courses led to an error serious enough to be “reportable” to national enforcement agencies, on the basis of potential harm to the individual or as an indicator of failing safety culture.¹ Only 8% of these (or 1 in 30,000 overall) were predicted to result in a significant adverse clinical outcome. However, it is recognized there will also be many minor incidents and near misses, and within these categories patterns of failure or predictable risks may be identified. Therefore, all UK incidents are voluntarily submitted with standard classifications for central analysis, to aid national learning.² Similar international systems for error reporting are listed in Table 1.

Guidance for reporting serious radiation incidents in the UK has accompanied legislation on radiation safety, as described in Table 2.^{3,4} Previous reporting has focused on overexposures (those “much greater than intended”), but underexposures and positioning errors (geographic misses) can also have serious consequences.⁵ This commentary suggests practical approaches for these latter categories, maintaining the same philosophy to “ensure that the majority of significant incidents would be notifiable ... while retaining a level of simplicity and transparency”.³

OVERDOSES: THERAPY AND IMAGING

Overdoses of radiation therapy can lead to serious injury and death, with some high profile incidents in recent years.⁵ UK guidance provides factors for reporting incidents when the delivered therapeutic dose is 1.1 times (whole course) or 1.2 times (any fraction or administration) that of the intended dose.^{3,4} Such overexposures are likely to be clinically significant and these factors apply to both the planned treatment volume and any organs at risk. Appropriate organs at risk should be identified by local protocols and national guidance, and intended doses taken as those calculated in the approved treatment plan.

2017 guidance also clarifies the reporting of planning and verification imaging, based on a factor of 2.5 times the intended dose per imaging episode.⁴ It is recognized that in radiotherapy an imaging episode may comprise multiple planar or volumetric exposures, and the guideline factors are to be applied to the total episode dose and not to an individual exposure within the episode. If a protocol specifies that a number of repeat exposures may be given until the patient position is verified then repeats according to the protocol are not reportable. Such exposures would be reasonable repeats for optimization purposes. However, if the reason for additional exposures is a failure to correctly execute the procedure, then the incident should be reported if the total episode dose is

Table 1. International systems for radiotherapy error reporting

Reporting system	Supporting bodies	Reference
National Reporting and Learning System (NRLS)	Public Health England (PHE, UK)	https://report.nrls.nhs.uk/nrlsreporting
Radiotherapy Incident Reporting and Learning System (PSO)	Center for Assessment of Radiological Sciences (CARS, Madison, USA)	http://www.cars-psy.org
Radiation Oncology Incident Learning System (RO-ILS)	American Society for Radiation Oncology (ASTRO, Arlington, USA) & American Association of Medical Physicists (AAPM, Alexandria, USA)	http://www.astro.org/roils
Radiation Oncology Safety Education and Information System (ROSIS)	European Society for Radiotherapy and Oncology (ESTRO, Brussels, Belgium)	https://roseis.estro.org
Safety in Radiation Oncology (SAFRON)	International Atomic Energy Agency (IAEA, Vienna, Austria)	https://rpop.iaea.org/SAFRON

greater than or equal to 2.5 times the intended dose. Therefore, a single repeat exposure will not usually be reportable, unless a much higher dose procedure was selected in error. In calculating the multiplying factor, the dose for the exposures given should be compared to the dose for the exposures required to verify the particular patient, not the maximum that the protocol permits.

Finally, under current guidance all unintended planning or verification exposures are to be reported, as well as scheduling errors where there is an unintended clinical impact or compromise, regardless of dose. Examples of this could include starting treatment without diagnostic results or decision, daily imaging where weekly was intended, or an electron boost given concurrently when sequentially was intended. If several people have been exposed to greater than intended dose this should be reported even if the dose increase does not reach the normal reporting guideline dose factor. The guidance also contains the specific case where five repeat imaging exposures are necessary for an individual patient, because of human or procedural error, even if each episode was within the factor of 2.5 times intended.⁴ Such situations indicate a systematic process or clinical failure and hence could cause further over-exposures if not addressed.

Errors leading to exposures greater than intended (but not much greater) do not need to be reported to regulatory bodies. However, it is recommended that these are subject to local audit and reported to the National Reporting and Learning System (NRLS, or equivalent) to aid collective learning.⁴

UNDERDOSES: NON-CORRECTABLE ONLY

Underdoses in radiotherapy can also have clinically significant consequences in terms of loss of tumour control,⁵ but most will be correctable if they occur for a limited number of fractions. Currently there is no guidance on this situation. We suggest that a factor of less than 0.9 times the intended dose would be a reasonable complement to the overdose factors, but only when applied to the planned treatment volume and only for the whole treatment.

It is possible that doses less than intended but with a factor between 0.9 and 1.0 could also have a clinical impact, or be indicative of systematic process failures. However, small variations in delivered dose are part of the accepted uncertainties in treatment delivery (e.g. linac output variation). Also, repeated failure to deliver an intended treatment episode can be counted as a scheduling error, which is also currently recommended for reporting “*when there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose*”.⁴

Table 2. UK legislation for reporting serious radiation incidents

Legislation	IRR 1999	IRR 2017	IRMER 2000	IRMER 2017
Individuals relating to radiotherapy exposures	Employees and trainees Members of the public Women of reproductive capacity Comforters and carers	Employees and trainees Members of the public Carers and comforters (within medical exposures)	Patients	Patients Carers and comforters
Type of error ^a	Equipment malfunction (overdoses only)	Accident requiring immediate action to limit exposure	Human and procedural error (overdoses only)	Accidental and unintended exposures, because of equipment or procedural failure
Guidance	Guidance note PM77 (v3) ³	–	Much greater than intended guidance ⁴	To be developed

IRR, Ionising Radiation Regulations; IRR, Ionising Radiation (Medical Exposure) Regulations.

^aSafety or performance issues with equipment should also be reported to the appropriate medical device regulator, for example, the Medicines & Healthcare products Regulatory Agency in England and Wales (www.mhra.gov.uk).

OUTSIDE: GEOGRAPHIC MISS

Total geographic miss can clearly have a significant impact on effectiveness of treatment, but partial geographic misses are harder to quantify than errors in dose magnitude.⁶ Current UK guidance recommends that “any errors resulting in a partial geographical miss that exceeds the locally defined error margin and the guideline dose factor above for the tissue unintentionally exposed, should be reported. Local error margins should be anatomical site specific...”⁴ Local error margins (LEMs) are not equivalent to a planning target volume margin, or an imaging tolerance for positional correction, but have more in common with the concept of “gross error” described in joint professional guidance *On target: ensuring geometric accuracy in radiotherapy*.⁷ This recommends “the action level for immediate intervention (that is, a gross error) may be set at 3× the random set-up uncertainty that will typically come to around 1 cm for a wide range of treatment sites”. However, the achievable accuracy has improved in the last 10 years, so a value of 1 cm will no longer be applicable for some sites. The current guidance does not specify how the LEMs should be defined but it is clear that they should be related to clinical significance. There is, at the time of writing, no national specification of LEMs and so various approaches to determine LEMs are proposed here, based on the practice at the authors’ own centres.

In Leeds reporting is based on incorrect field placements of whatever cause, which produce partial geographic misses of more than 2 cm from any intended field edge (this may include omission of shielding). This excludes brachytherapy where medical physics expert advice should be sought. An extension to this approach would be to use different values for different types of treatment, such as 0.5 cm for stereotactic brain radiosurgery or body radiotherapy, and 1 cm for radical treatments with regular imaging.

In Newcastle the LEM is taken to be 2.5 times the setup tolerance, or 0.5 cm for the case of stereotactic brain radiosurgery

where no setup tolerance is used. This approach gives more flexibility to treatments where it has already been decided locally that there is less significance in delivering dose to the surrounding tissue and inherently includes improvements in accuracy and precision of delivery.

Alternatively, in Cambridge the LEM is taken to be 20% of the field dimension in the direction of the error (single fraction) or 10% (whole course). For example, a 10 × 10 cm field would be reportable if a positional error of 2 cm occurred for a single fraction. Whilst not explicitly considering anatomy, this implicitly allows for the fact that small treatment fields (such as in stereotactic radiotherapy) are more sensitive to geographical inaccuracies than treatments of large volumes.

Additional reporting of underdoses, as required by Ionising Radiation (Medical Exposure) Regulations 2018, has little impact on partial geographic misses. The most likely form of geographic miss is for the field size and shape to be as intended, but to be positioned incorrectly. A lateral or longitudinal shift will create an area receiving more than intended at the same time as producing an area receiving less than intended. A change in distance from the radiation source of a linear accelerator that is large enough to give a field dimension that is 10% smaller than intended will (by the inverse square law) result in a reportable overdose of 20% and so will be reportable as reaching the 1.2 guideline factor. The one new class of reportable errors would be when too small a field size is set; if such an error is discovered too late to be correctable, then it would be consistent to regard it as reportable if 10% or more of the intended volume is unintentionally underdosed.

ONLINE CORRECTION: 19 MARCH 2018

This article was originally published online with some data omitted from Table 2. This has now been corrected.

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