



The PSRT Team

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Welcome to Safer Radiotherapy (RT). The aim of the newsletter is to provide a regular update on the analysis by PHE of radiotherapy error (RTE) reports. These anonymised reports are submitted on a voluntary basis through the National Reporting and Learning System (NRLS) of NHS Improvement and England or directly to PHE, to promote learning and minimise recurrence of these events. Safer RT is designed to disseminate learning from RTE to professionals in the RT community to positively influence local practice and improve patient safety.

Published 3 times a year, Safer RT contains key messages and trends from the analysis of RTE reports. Any comments and suggestions for inclusion in the newsletter can be sent to radiotherapy@phe.gov.uk and would be gratefully received. Thanks to all contributors to this issue. The next issue of Safer Radiotherapy will be published in January 2020 and will be available at www.gov.uk/government/collections/medical-radiation-uses-dose-measurements-and-safety-advice

Helen Best, Editor

PSIMS development update

The Patient Safety Incident Management System (PSIMS) will provide a new service that will replace the NRLS and Strategic Executive Information System. The alpha stage of this completed last year and the beta stage is underway. Using agile methodology, PSIMS will be built incrementally and iteratively, and tested with users. During the first half of the beta phase, work focused on the core functionality, creating a basic but functional end-to-end service which:

- captures a new data set both from risk management systems through Application Programming Interfaces (APIs) which facilitate two-way communication between local and national systems, and directly via online forms
- uses new algorithms to cleanse and anonymise the data
- stores the data on NHSI servers
- supports NHSI's statutory duties to survey for new and under recognised risks
- supports basic data analysis and outputs

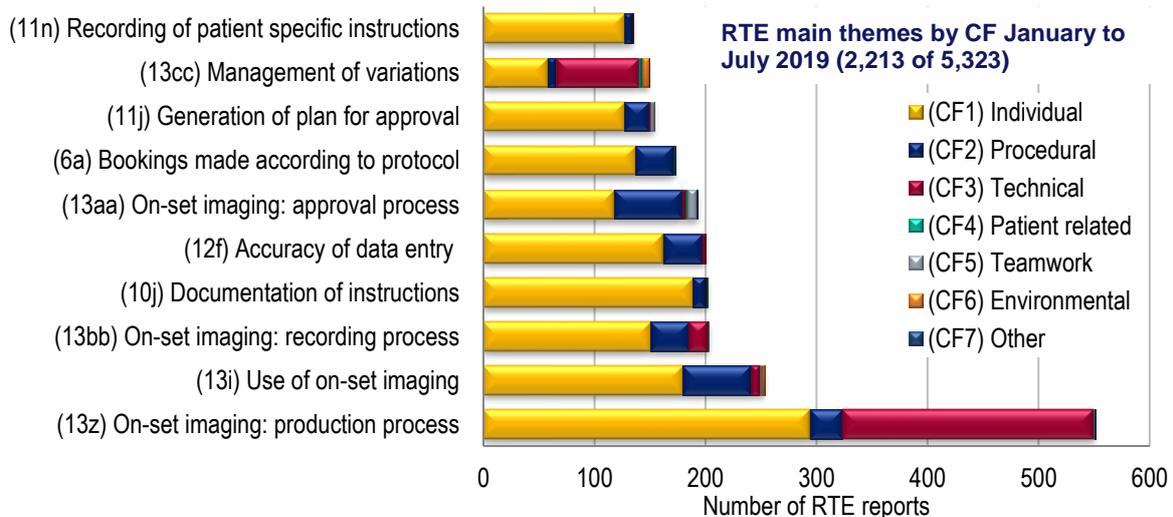
During the latter half of the beta phase, further tools and functionality will be gradually added, in line with prioritised user needs, and are expected to include patient/public reporting tools, incident investigation/review tools in line with the forthcoming Patient Safety Incident Response Framework (PSIRF) which will replace the previous Serious Incident Framework (SIF), self-service data access and analysis tools to support learning. The tools will continue to be tested and improved in line with user feedback. Further information is available: <https://improvement.nhs.uk/news-alerts/development-patient-safety-incident-management-system-dpsims/>

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Causative factor data

A causative factor (CF) can enable the identification of system problems or root causes. The graph below illustrates the most frequently reported pathway code by CF reported between January to July 2019.

The most frequently reported pathway code was ‘on-set imaging: production process’ making up 10.4% (551) of all RTE for this reporting period. The most frequently reported CF for this type of RTE was ‘individual’ (53.4%, n = 294), which includes slips and lapses and communication factors. The CF associated ‘technical’ factors including equipment or IT network failure and decide/product design was reported in 41% (n = 226) of the on-set imaging: production process RTE. All RTE associated with machine malfunction should also be reported to the MHRA and the relevant manufacturer.



NHS Patient Safety Strategy

NHS improvement have published the NHS Patient Safety Strategy (PSS) – it is available at <https://improvement.nhs.uk/resources/patient-safety-strategy/>

The strategy describes 3 strategic aims:

- **Insight**, improving understanding of safety and how the data is used
- **Involvement**, ensuring patient safety education and training. Include patients
- **Improvement**, develop how resources are used to improve systems.

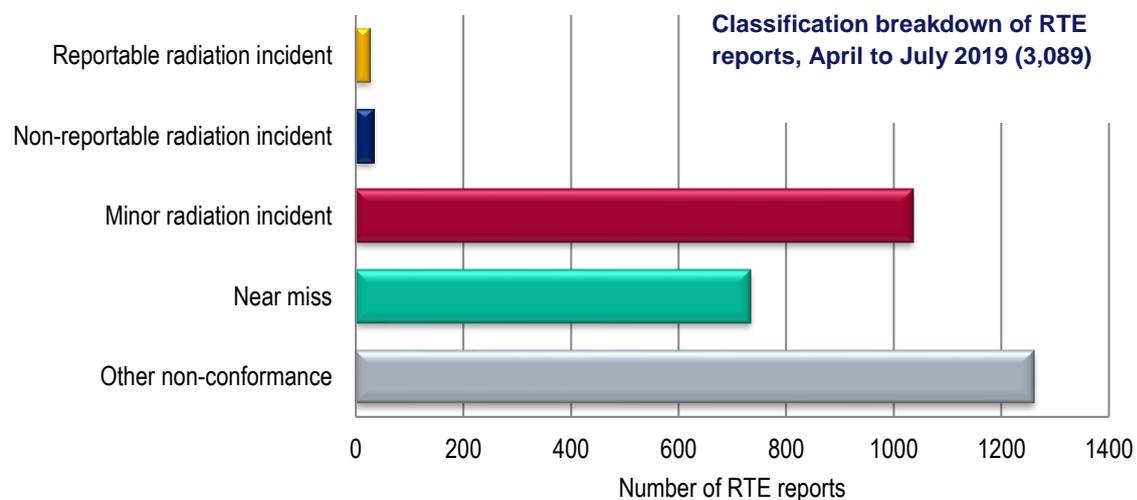
RT is well positioned to meet the aims of the PSS. The community has demonstrated a positive safety culture with the continuous regular reporting of RTE, this data is used for national analysis and learning to improve patient safety. The Patient Safety in Radiotherapy Steering Group (PSRT) aims to improve patient safety across the UK. Its members are drawn from the professional bodies, NHSEI and a patient representative, already working with the ethos of the PSS.

RTE Data analysis: April to July 2019

Submissions from 54 NHS UK providers out of 61 contributed to this issue's full data analysis, covering April to July 2019. Seven providers have not reported or used the TSRT9 trigger code to report RTE through the NRLS for this reporting period. Four providers have not reported RTE as part of this initiative for the year July 2018 to July 2019. Help with reporting is available at radiotherapy@phe.gov.uk.

The full data analysis is available at www.gov.uk/government/collections/medical-radiation-uses-dose-measurements-and-safety-advice and includes data on primary process coding, safety barriers, causative factors, methods of detection and the severity classification of the RTE.

Classification of RTE



Of those 3,089 RTE reported for the period April to July 2019, 3,031 reports (98.1%) were classified as minor radiation incidents, near misses or other non-conformances. These are lower-level incidents which would have no significant effect on the planning or delivery of individual patient treatments.

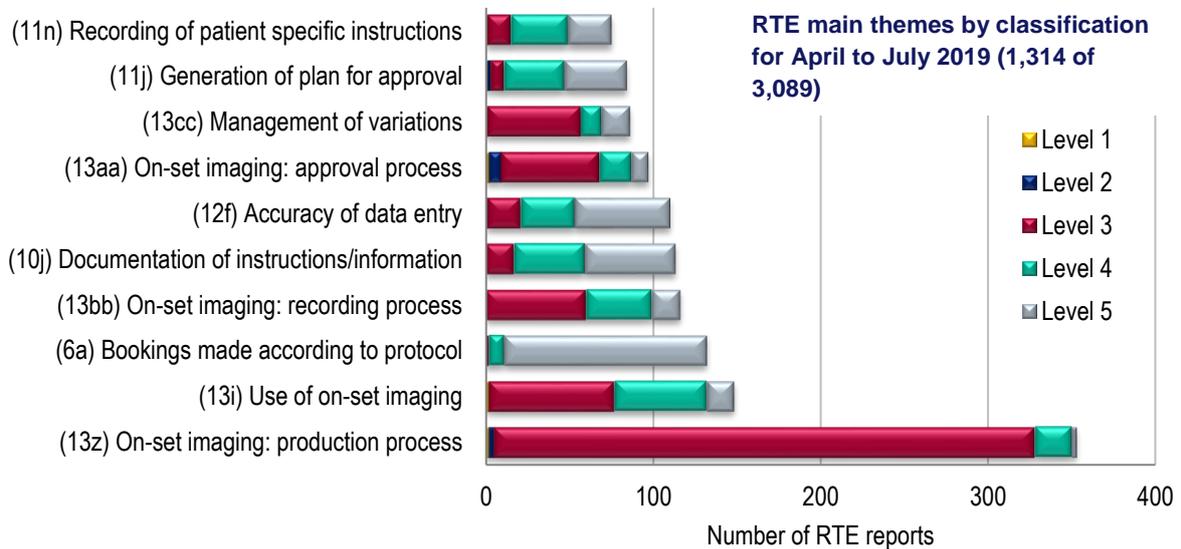
Reportable radiation incidents (level 1) made up 26 (0.8%) of all reports. 'Verification of diagnosis/extent/stage' comprised of 12.5% (n = 4) of these reportable radiation incidents. Non-reportable radiation incident reports (level 2) made up 32 (1%) of all reports. 'On-set imaging: approval process' comprised 7 (21.9%) of all level 2 RTE. Level 1 and 2 reports made up 58 (1.8%) for this reporting period which is consistent with the previous analysis (2%, n = 61).

Of the 1,036 minor radiation incidents (level 3) reported, 323 (31.2%) of this subset were related to the 'on set imaging: production process', making it the most frequently reported code in this classification. This is an increase from 25.3% (n = 242) in the previous 4 monthly analysis.

The most frequently reported RTE process code in the near miss (level 4) classification was 'use of on-set imaging' with 55 reports (7.5%). Within the non-conformance (level 5) classification 'bookings made according to protocol' comprised 121 reports (9.6%) making this the most frequently reported RTE in this classification.

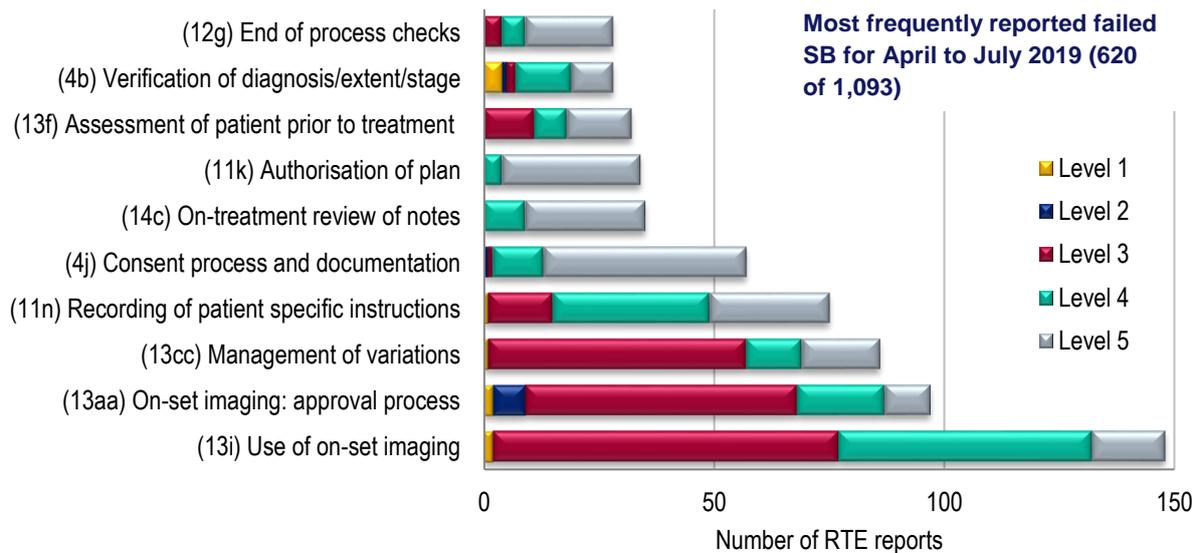
Primary process code

The main themes (points in the patient pathway where the majority of reported RTE occurred) for this dataset are shown below. Consistent with the previous 14 analyses ‘on-set imaging: production process’ is the most frequently occurring process code (10.5%, n = 323), examples of this include selecting the incorrect pre-set for an exposure. Guidance on this error can be found in issues 7 and 18 of Safer RT.

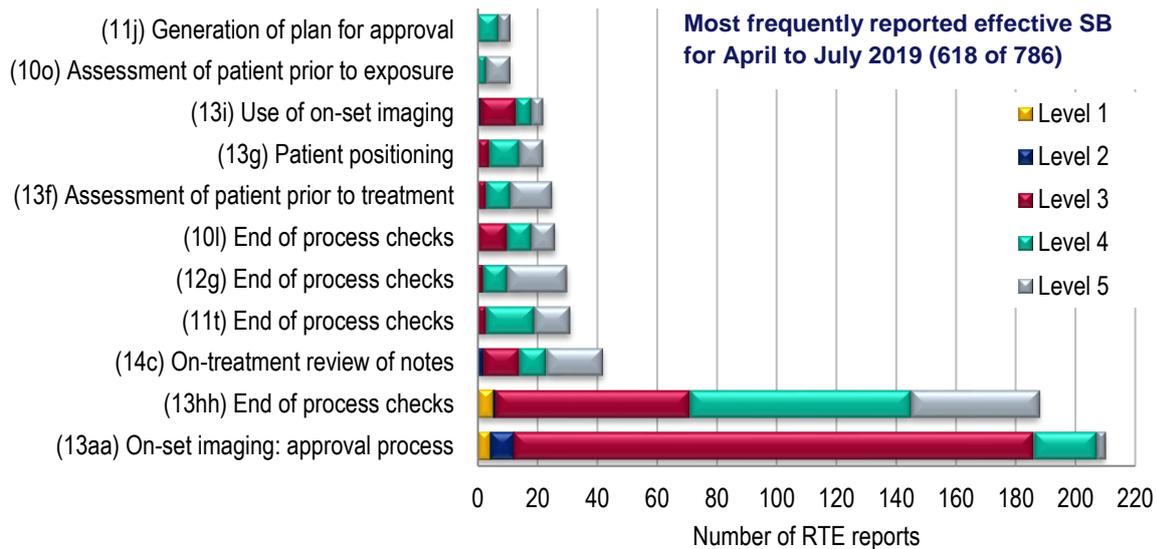


Safety Barriers (SB)

Several individual pathway codes can be allocated to each RTE report to identify all points in the pathway where the error was not picked up. All subcodes were analysed across the 3,089 RTE reports and a total of 1,093 subcodes were identified as failed safety barriers (SB). Only 30 (2.7%) of these RTE were Level 1 or 2 errors where the SB had failed. The most frequent failed SB reported is represented below broken down by classification. Treatment unit process ‘use of on-set imaging’ is the most frequently reported failed SB (13.5%, n=148).

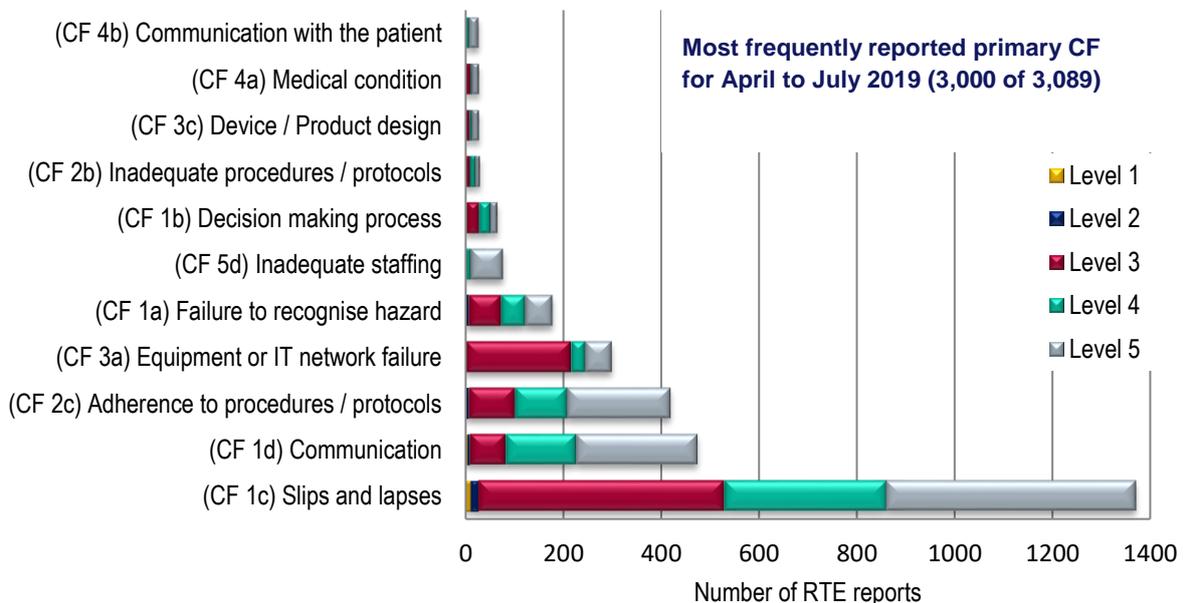


Effective safety barriers or methods of detection (MD) can now be identified utilising the safety barrier taxonomy. For the reporting period April to July 2019, 40 different providers indicated MD across 540 (17.5%) incidents. Following consistency checking, PHE coded a further 246 reports with MD, resulting in 786 reports containing MD for this analysis. The most frequently reported effective safety barrier for this reporting period was ‘on-set imaging: approval process’ (26.7%, n = 210).



Causative Factors (CF)

CF have been applied to 2,521 (81.6%) RTE reports by 45 (83.3%) providers for this reporting period. Following consistency checking, PHE coded a further 568 reports with CF taxonomy, resulting in all RTE reports containing CF taxonomy for the reporting period April to July 2019. The most frequently reported primary CF are shown below. The most frequent was individual ‘slips and lapses’ (44.4%, n = 1,372). Multiple CF can be associated with each RTE – the primary CF is the root cause and the subsequent CF are the contributory factors associated with an incident. Contributory factors were indicated across 805 reports – 77 of these contained multiple CF leading to 940 contributory factors. The most frequently reported contributory factor was ‘adherence to procedures/protocols’ (44.4%, n = 417).



Links to international patient safety resources

[ASTRO and AAPM RO-ILS Quarterly report Q3 to Q4 2018](#)

[Autorité De Sûreté Nucléaire \(French Nuclear Safety Authority\) Publications for Professionals](#)

[IAEA, SAFRON Updates on Patient Safety in Radiotherapy](#)

Case study – Verification of diagnosis/ extent/ stage

For this reporting period (April to July 2019) there have been 28 RTE associated with verification of diagnosis/ extent/ stage (4b). Of these 14.3% (n = 4) were classified as reportable radiation incidents, making it the most frequently reported level 1 RTE for this reporting period. The reportable radiation incidents associated with verification of diagnosis/ extent/ stage included incidents where patients received treatment that was not required.

A patient was referred for palliative radiotherapy to whole brain and upper c-spine based on CT scans of both areas. Local referral criteria require MR confirmation of diagnosis for palliative patients, which was not available. The patient received a CT planning scan and a treatment plan was produced and approved using the CT data. The patient received 2 out of 10# to spine and brain. On-treatment review of notes before #3 highlighted that a message had been included in the patients notes stating the patients c-spine was not to be treated until after the results of the MRI had been reported. Conversation with the original practitioner indicated that there was no disease in the c-spine area. No further treatment to the spine was given.

This might be coded as:

TSRT9/ Level 1/ 4b/ 7f/ 11e/ MD14c/ CF1d/ CF2c.

Things to consider for this type of RTE include:

- clearly define individuals roles and responsibilities
- have recommendations in place concerning referral criteria. They should be clearly documented in site procedures and protocols
- ensure all required diagnostic tests are completed and reported before referral
- ensure referrers provide sufficient clinical data so that the exposure can be justified
- review referrals ensuring safety critical elements are mandatory and checked against primary source data
- ensure all mandatory fields are completed
- consider a review of the palliative work flow from referral to follow up

Understanding IR(ME)R guidance

The RT Board update to the 2008 professional body guidance on the implementation of IR(ME)R is due to be published later this year. This will support the RT and nuclear medicine communities in understanding IR(ME)R.

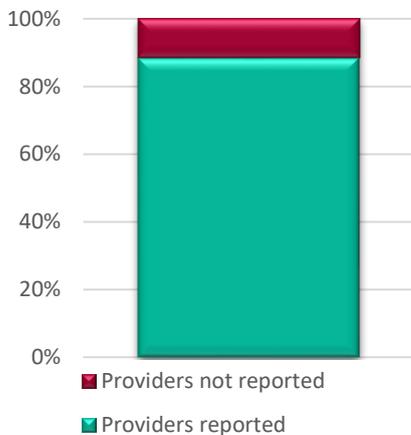
Dates for the diary

14 to 16 October	RCR19, Liverpool
29 October	IPEM, Ethics and research using ionising radiation, Bristol
5 November	IPEM, MR in radiotherapy pathway, Edinburgh
7 to 8 November	BIR, Annual congress 2019, London
24 to 25 January 2020	CoR, Annual radiotherapy conference, Brighton
January 2020	Safer Radiotherapy Issue 29

RTE reporting update, April to July 2019 (n = 3,089)

The PSRT set new targets to improve RTE reporting by September 2020. These include:

- **100%** providers to upload RTE a minimum of every 3 months



There are 61 NHS RT providers across the UK. All radiotherapy providers have reported – however, not all providers report on a regular basis. The graph to the left shows 7 providers have not reported any RTE in this reporting period.

Timely national reporting of RTE is in keeping with the ethos of IR(ME)R and the NHS PSS. NHSEI require English NHS RT providers to participate in national reporting of RTE.

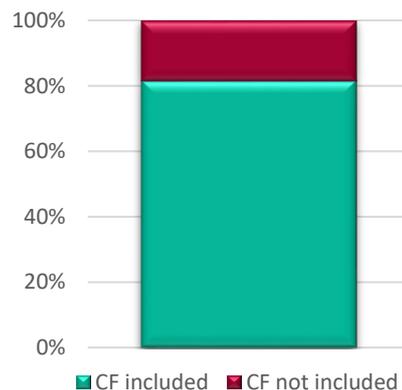
<https://www.engage.england.nhs.uk/consultation/radiotherapy-service-specification-consultation/>

- **100%** providers to apply the causative factor (CF) taxonomy

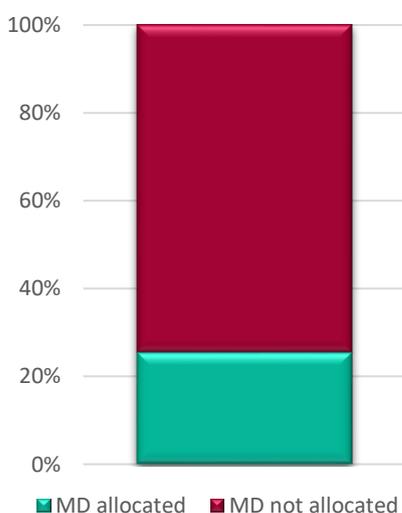
The graph to the right shows 81.6% (n = 2,521) of RTE from this reporting period contained a CF.

During consistency checking PHE were able to allocate CF to 568 incomplete RTE.

To strengthen learning opportunities and analysis of RTE the CF should be adopted locally and included in all national RTE reports submitted.



- **100%** providers to use the method of detection (effective safety barrier) coding



The use of the safety barrier taxonomy (SB) to identify failed SB was introduced with the DoL. The use of the SB taxonomy to identify effective SB or method of detection (MD) was recommended in January 2018.

In this reporting period, an MD code was assigned to 540 reports and 246 were allocated by PHE during consistency checking. This meant that 25.4% (n = 786) of RTE had an assigned MD.

To strengthen learning and analysis of RTE the CF should be adopted locally and included in all national RTE reports submitted. For example, **TSRT9/ Level 4/ 13c/ 13I/ MD13hh/ CF1c/ CF2c**

Help us achieve these targets. For advice contact radiotherapy@phe.gov.uk

Guest Editorial

Significant and Unintended Exposures – Implications for radiotherapy practice

Cliff Double

IR(M)ER Inspector, Care Quality Commission



The IR(ME)R inspection team at the Care Quality Commission (CQC) have developed new guidance to support notifications of ‘Significant Accidental and Unintended Exposures’, SAUE, in the IR(ME)R 2017, available at <https://www.cqc.org.uk/guidance-providers/ionising-radiation/saue-criteria-making-notification>. This replaces the definitions of ‘Much Greater than Intended’ (MGTI) from the 2000 regulations. The guidance applies across the UK, however there are minor differences within the guidance across the 4 nations. Further guidance has been commissioned by the Radiotherapy Board on “Understanding IR(ME)R” and will include suggested clinically significant.

As part of the work, a review of all medical radiation modalities was undertaken to consider what was ‘significant’. In radiotherapy, the CQC were able to build on previous work of the Radiotherapy Board, which was included in guidance on MGTI notifications published by DHSC in 2017.

The new guidance now includes the need to take account of ‘under-exposures’ to patients receiving a treatment exposure and following equipment malfunction. There is now a clear link in the notifications process to the guidance, and the inclusion of the Development of Learning pathway taxonomies.

Gaining universal agreement about what is a ‘significant’ exposure made in error was not easy. Initially the CQC leaned heavily on the earlier work of the Radiotherapy Board and took the view to not make radical changes, particularly in radiotherapy imaging. The new guidance revisits what the CQC defines as ‘significant’, perhaps arguing that if there is an error in the selection of a verification protocol for a single fraction where a CBCT protocol is selected rather than a planar kV protocol, the CQC would view this as ‘not significant’ in the context of the patient’s planned treatment exposures and not notifiable. The expectation would be instead, that this would be subject to normal local governance review processes with local actions such as reminders issued to staff, reviews of imaging work instruction and training and perhaps subject to audit.

The CQC asks employers to reflect on all the requirements of IR(ME)R Regulation 8, namely 8(4)(b)(iv) to provide an investigation report including corrective measures following the local investigation. The level of detail within the report, the report style and length are all largely down to the local employer to determine.

Finally, the CQC are reviewing how better to share more widely the learning arising from radiotherapy notifications. The CQC are considering a pilot exercise, requesting the inclusion of an additional anonymised paragraph within local SAUE investigation reports. The additional paragraph will describe what the organisation feels is the key learning they would want to share with colleagues elsewhere to try to prevent a repeat of the same error more widely. These will then be amalgamated and published anonymously.