

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 45: full radiotherapy error data analysis, August to November 2024

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Full radiotherapy error data analysis

Incident learning systems are a widely accepted safety tool advocated internationally by professional groups, bodies, agencies, and regulators in radiotherapy (<u>1</u>). Analysis of reported data facilitates the identification of possible areas for improvement and informs the direction of future refinements and improvements. It is imperative errors and near misses are learned from, and effective preventative measures are implemented (<u>2</u>).

The Safer Radiotherapy publication series facilitates comparison of locally identified trends against the national picture. The Patient Safety in Radiotherapy Steering Group (PSRT) recommends implementing learning from this analysis locally. In doing so it is expected that these events might be mitigated in the future.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) on radiotherapy errors (RTE) reported voluntarily by UK radiotherapy (RT) providers. Anonymised reports were submitted through multiple routes. In Wales from the <u>Once for Wales Concerns Management</u> <u>System (OfW)</u>, and directly to UKHSA from providers in Northern Ireland, Scotland and the independent sector. In England, the National Reporting and Learning System was replaced in June 2024 by the <u>Learn from Patient Safety Events Service (LFPSE)</u>, therefore all RTE from English NHS providers have been received via LFPSE for this reporting period. MEG continues to work in collaboration with NHS England (NHSE) to ensure timely sharing of reports with completed investigations including the radiotherapy trigger code (TSRT9) and corresponding coding taxonomy.

As with any voluntary reporting system, the data will only reflect those incidents that are reported and may not necessarily be representative of the actual level of occurrence. As such, this data needs interpreting with care.

There is a requirement for RT providers to notify the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (<u>3</u>, <u>4</u>) inspectorates of significant accidental or unintended exposures (<u>SAUE</u>) or 'reportable radiation incidents' (Level 1) as defined in <u>Towards Safer Radiotherapy</u> (TSRT). The UK inspectorates for IR(ME)R; Care Quality Commission, Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority, shared anonymised closed synopses of reported SAUE for analysis.

The classification level from <u>TSRT</u>, the pathway coding, failed safety barriers (FSB), methods of detection (MD) and contributory factor taxonomies from the <u>Development of Learning (DoL)</u> from Radiotherapy Errors were employed for the analysis. FSB and MD are discussed further in the May 2021 issue of the <u>Safer Radiotherapy E-bulletin</u>. A series of <u>presentations</u> have been developed as free educational tools to support the RT community in engaging with this work. The analysis has been reviewed by the PSRT. If individual providers would like to comment on the analysis, share experience of learning from RTE or application of the coding please email the RT team at <u>radiotherapy@ukhsa.gov.uk</u>

Inspectorate data

A breakdown of the inspectorate data for this reporting period can be seen in Figure 1. As $IR(ME)R(\underline{3}, \underline{4})$ applies to both NHS and independent RT providers, this data covers all RT providers. It should also be noted there may be a time lag between notification of an event to the inspectorates, completion of the detailed investigation and the subsequent sharing of information with UKHSA for inclusion in the analysis. Therefore, this data is analysed separately from the voluntary data.

The inspectorates shared 66 anonymised closed synopses of reported SAUE. This is an increase since the <u>previous analysis</u> (issue 44) when 59 reports were shared.

The most frequently reported notifications were associated with 'on-set imaging: production process' (20.3% n = 13). This also represents an increase since the <u>previous analysis</u> (issue 44) where 8 reports (13.6%) were associated with 'on-set imaging: production process'.

A number of case studies have been included in Safer Radiotherapy publications such as the <u>triannual analysis</u>, the <u>E-bulletin</u>, the <u>unseen pathway</u> and <u>good practice guidance</u>. Relevant published case studies are shown with an asterisk (*) in Figure 1.

Figure 1. Breakdown of most frequently reported inspectorate Level 1 process subcodes from closed notifications (n = 37/66 subset of data)



Case study 15: Authorisation to irradiate (IR(ME)R): authorisation of additional imaging (5k)

Authorisation is the documentation confirming that justification of a patient's pretreatment, treatment and verification exposures has taken place. Authorisation can be carried out by either a practitioner or operator following authorisation guidelines issued by the practitioner ($\underline{3}, \underline{4}$).

In terms of concomitant verification imaging, justified and authorised exposures may be acquired in accordance with a verification imaging protocol or equivalent. These protocols include expected site-specific frequencies and maximum number of additional images permitted. If further imaging is required, justification and authorisation must be sought from an appropriately entitled practitioner, prior to exposure ($\underline{5}$).

The CQC have commented in their <u>annual report</u> that confusion continues to exist around justifying and authorising medical exposures. Pathway subcode 5k 'authorisation to irradiate (IR(ME)R)' is indicated in incidents where concomitant verification imaging exposures are undertaken without prior justification and authorisation, often due to inadequate adherence to, or failure to follow, imaging verification or IGRT protocols.

Synopsis

Departmental verification imaging protocol requires a daily CBCT verification image to be taken prior to each treatment. The departmental protocol also allows one additional exposure per fraction, if required, and states the maximum number of additional CBCTs is limited to 20% of the prescribed fractions. The protocol states that any further verification imaging required per fraction, or beyond the 20% threshold, requires additional justification and authorisation from an appropriately entitled practitioner.

A newly implemented retrospective imaging audit identified a patient completed 60Gy/20# to the prostate and received 6 additional CBCT images, taken on separate occasions through their treatment course. In accordance with the corresponding verification imaging protocol this exceeds the maximum number of CBCT's (<u>4</u>), justified and authorised by the practitioner. The audit did not identify any evidence to suggest separate justification had been sought prior to each of the 2 additional CBCT verification exposures, therefore it was concluded these exposures had been undertaken without prior justification.

As 2 CBCT images were not justified and authorised by an appropriately entitled practitioner prior to the exposure, the RTE was notified to the IR(ME)R regulator.

The practitioner was informed and reviewed the corresponding images. A retrospective imaging audit was carried out on a large sample of patient imaging over the past 6 months and determined that similar RTE had occasionally occurred.

A trend analysis and subsequent study of risk of unauthorised exposures associated with on-set imaging was also undertaken. The system-based investigation confirmed that current mandatory verification imaging training modules would benefit from greater focus on practical scenario problem solving. Furthermore, clarity was required within the departmental verification imaging protocol on when escalation to the practitioner for further justification of repeat CBCT images was required. In addition, communication channels between radiographers and clinicians would benefit from being strengthened. The RTE has been reported and will be shared internally and nationally for learning.

Coding: TSRT9/ Level 1/ 5k/ 13bb/ 14c/ MD14c/ CF2c/ CF2b/ CF5b/ CF5e/ CF1d

Contributory factors

Following investigation, a contributory factor (CF) for this synopsis was identified as 'adherence to procedures/protocols'. The investigation reviewed external and internal environmental factors, as well as corresponding tasks and safeguards, and determined that within the department occasionally duty holders were unclear of their responsibilities (CF5b), that training materials could be strengthened (CF5e), communication channels could be improved (CF1d) and protocols benefit from being written with greater clarity (CF2b). Mechanisms that monitor the number of concomitant images and signify a requirement to alert practitioners when approaching tolerance levels were also considered in need of enhancement (CF2b).

Safety barriers

The local management of verification imaging included multiple safety barriers:

- end of process check at the completion of each fraction includes documentation of imaging including any follow-up actions required
- weekly on-treatment review of notes/data including monitoring of imaging activity

On this occasion the safety barriers in place failed to detect that concomitant imaging frequency had approached, and then breached, the maximum number of exposures authorised.

Method of detection

The error was detected during a retrospective imaging audit.

Corrective actions

Corrective actions for this type of RTE include:

• ensure staff are adequately trained, competent, and appropriately entitled to undertake necessary tasks

- consider review of departmental IR(ME)R training to ensure roles, responsibilities, and IR(ME)R processes such are justification and authorisation are clearly understood and consistent compliance is achieved
- review of relevant imaging protocols and/or authorisation guidelines to ensure responsibility, entitlement and triggers for escalation are clearly defined, easily understood and clinically practicable. In addition, strengthen protocols relating to treatment end of process checks and weekly review of patient data
- establish more effective communication pathways to inform practitioners regarding requirements to review requests for further justification and authorisation of concomitant exposures
- consider contingency plans when practitioners are not available to review urgent requests for additional concomitant verification exposures, outside of protocol or authorisation guidelines
- regular review or audit to assess adherence to departmental verification imaging protocols to assist in the identification of thematic trends or areas for improvement
- ensure a positive safety culture is embedded within department, facilitating unambiguous multidisciplinary communication
- ensure learning themes and corresponding corrective actions are shared with relevant staff
- share learning from the event with the wider department
- where thematic trends are identified consider appropriate action and escalation, for example review of procedures and corresponding risk management tools.
- although this incident relates to verification imaging there is transferable learning for other imaging modalities, for example CT Simulators, and relevant pretreatment protocols should be reviewed

Learning from excellence and published guidance

Learning from excellence includes:

The CQC IR(ME)R annual report 2023 to 2024

This advised that confusion exists around justification and authorising of medial exposures. As more advanced practice qualified radiographers are working in clinical areas it is important to differentiate between:

- individuals who are adequately trained and entitled under an approved scope of practice to justify and authorise
- those who are authorising an exposure under guidelines

On target 2: updated guidance for image-guided radiotherapy

This recommends that scope for repeat imaging should be included within site-specific protocols. These protocols should include clear guidance on where imaging is justified by the IR(ME)R practitioner and detail specific imaging protocols that should be used.

Further guidance and national tools to aid investigations are available ($\underline{6}$, $\underline{7}$). Following a simple risk matrix ($\underline{8}$), a study of risk was produced for this case study and the process sub-code (5k) 'authorisation to irradiate (IR(ME)R)'.

Table 1. Study of risk matrix

In this table, a G (green) in brackets indicates low risk, an A (amber) in brackets indicates a moderate risk.

Area of risk	Initial risk			Risk following mitigations (corrective action examples shown above)		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Duty holders fail to fully understand departmental protocols and guidelines, with regards to IR(ME)R roles, responsibilities, inclusion criteria and imaging thresholds (per fraction and over the course of treatment)	3	2	6 (G)	3	1	3 (G)
Inadequate checking procedures departmentally to identify scenarios whereby verification imaging frequency approaches maximum threshold	3	3	9 (A)	3	2	6 (G)
Failure to escalate requirement for additional imaging exposures to practitioner appropriately	3	3	9 (A)	3	2	6 (G)
Inadequate communication channels between operator and practitioner lead to delays in requested review on images	3	3	9 (A)	3	2	6 (G)
Inadequate resources, such as available staff with required training and entitlement to justify and authorise additional verification imaging exposures when required	3	2	6 (G)	3	1	3 (G)

August to November 2024 data analysis

Number of RTE reports

A total of 3,887 reports were received between August 2024 and November 2024. Of those, 132 were not RTE reports, resulting in 3,755 RTE reports received. This equates to a monthly average of 939 RTE reports, reflecting a decrease of 12.1% (n = 1,060) when compared to the <u>previous analysis</u> (issue 44) and an decrease of 6.2% (n = 999) when compared to the same reporting period between August 2023 and November 2023 (<u>issue 42</u>).

The transition to LFPSE for English NHS providers may have contributed to the decrease in reporting volume. If a report does not contain the **TSRT9** trigger code, it will not be shared by LFPSE with UKHSA. UKHSA encourage reporters to include the **TSRT9** trigger codes for all RTE once the required investigation is complete and coding taxonomy has been applied. Similarly, **TSRT9** should not be used for patient safety incidents (PSI) that are not considered RTE. <u>E-Bulletin edition 15</u> has further information on this subject.

There is some disparity in frequency of reporting across providers. A wide variation is seen when comparing the incident date with the date reported to the national voluntary reporting scheme. This time lag ranges from 0 to 3,804 days, with a mean of 18 days and a mode of 0 days, reflecting that 1,402 were reported nationally on the same day as the incident. There were 28 outliers with a lag time greater than 365 days, reported from 6 providers. Often there was no reason associated with the delay, and it is possible some may be due to date transcription error. The greatest lag time of 3,804 days was due to a previous RTE being detected when a patient was referred for treatment for recurrent cancer.

To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. <u>Issue 26 of Safer Radiotherapy</u> provides further information on reporting frequency.

Monitoring of RTE coding by radiotherapy providers

All providers are asked to apply a trigger code (TSRT9), classification level, primary pathway subcode, additional pathway subcoding (including failed safety barriers (FSB)), method of detection (MD) and contributory factors (CF) to their RTE reports to facilitate both local and national analysis.

The format of coding for submission is TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c. This should be included in the opening section of the first open text field of the local incident learning system where possible. Providers within England may add this information to the "What is the radiotherapy error code?" field of the local incident learning system.

Consistency checking was undertaken by UKHSA staff on the application of the RTE coding by RT providers. The coding was reviewed for all RTE classified as reportable through to near miss (levels 1 to 4) and 10% of non-conformances (level 5) RTE were audited. A complete report includes the trigger code, classification, pathway code (including FSB), MD, and CF taxonomies.

From the 2,367 RTE reports classified and coded locally with all the taxonomies, 1,534 were classified as levels 1 to 4. A total of 366 levels 1 to 4 reports were amended (complete fixed in Figure 2 includes level 5 data (n = 431)). Thus, a 76.1.% level of consistency was achieved for levels 1 to 4 RTE. This reflects an increase since the <u>previous analysis</u> (issue 44) when an 70.9% level of consistency was achieved.



Figure 2. Breakdown of report completeness (n = 3,887)

A total of 1,388 RTE reported did not contain one of the required taxonomies. A total of 965 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed report in Figure 2).

It is recommended that the entire pathway subcoding should be considered when allocating pathway subcodes. Further information on the consistent allocation of pathway codes can be seen in <u>E-bulletin edition 3</u>.

Non-RTE reports submitted formed 3.4% (n = 132) of all the reports for this reporting period. Data and accompanying text indicate that these were PSI but not RTE. This reflects an increase of 131.6% since the <u>previous analysis</u> (issue 44) when non-RTE made up 1.3% of the submitted reports (n = 57). A <u>PSI</u> is defined by NHS England as 'Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm' (9). Further information on PSI can be found in <u>issue 5 of Safer Radiotherapy</u>. Non-RTE reports were excluded from the detailed analysis.

Of the incomplete reports, 6 RTE did not contain sufficient supporting text to assign any classification or coding taxonomy, therefore these have not been included in the detailed analysis. This is an decrease from 20 in the <u>previous analysis</u> (issue 44).

In total, 3,749 RTE for the reporting period from August 2024 to November 2024 were included for analysis. The analysis is presented below.

Number of reports per provider

Data was received from NHS providers and from the independent sector. For this reporting period 57 RT providers have reported. This is broadly consistent with the <u>previous analysis</u> (issue 44) (n=58). There were 253 anonymised reports received which did not indicate the RT provider, these have been included in Figure 3 as a single default provider.



Figure 3. Number of RTE reported by provider (n = 3,749)

Figure 3 shows the number of RTE reports submitted by provider. This ranged from 2 to 307 reports, with a mean of 66. Of the 57 providers who reported, 66.7% (n = 38) reported less than the national mean. Figure 3 also indicates the classification of reports received per provider.

The providers that submitted higher numbers of RTE reports were more likely to include all classification levels of reports. Ten providers did not report any level 5 RTE.

There may be several reasons for reporting variance. Reporting culture varies across providers. Incident learning systems are not always easily accessible. Additional resource may be required to support a full incident learning system. Finally, a local requirement to use more than one system may disincentivise reporting. Findings of the most recent survey of UK incident learning and local management of RTE is published in the September 2024 issue of <u>Safer Radiotherapy</u> <u>E-bulletin</u>. This survey demonstrated that 89.1% (n = 41) of respondents reported all classification levels of RTE locally. Of those 41 respondents who reported all levels of RTE locally only 29.3% (n = 12) shared all levels of RTE with their trust/board risk management team, however 48.8% (n = 20) shared nationally for inclusion in the national database. The additional time required for applying coding was given as an explanation for not reporting level 4 and 5 reports.

The number of reports per provider has not been normalised to account for the variation in provider capacity or service specification. It should be noted that those providers reporting higher numbers of RTE represent providers with mature reporting cultures and should be encouraged to continue reporting.

Classification (level) of RTE

Each of the 3,749 RTE reports was classified as 'other non-conformance (level 5)', 'near miss (level 4)', 'minor radiation incident (level 3)', 'non-reportable radiation incident (level 2)' or 'reportable radiation incident (level 1)' (Figure 4).

Figure 4. Classification (level) of RTE reports (n = 3,749)



Of the RTE reports, 96.9% (n = 3,631) were minor radiation incident, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 3.1% (n = 118) of reports, 2.4% (n = 91) were reportable under IR(ME)R to the appropriate enforcing authority (level 1).

Breakdown of process codes

The 3,749 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 5 shows 43.5% (n = 1,630) of the RTE were reported to have occurred during treatment unit processes. The treatment set-up process represents the last opportunity to identify errors. Accurate treatment relies on the correct interpretation of the treatment plan and set up details which need to be replicated at each fraction of treatment. This might explain the high prevalence of RTE within treatment unit processes. The most frequently reported process codes remain consistent with the previous analysis (issue 44), with the addition of 'pretreatment: preparation of patient'.

Figure 5. Breakdown of RTE process code by level (n = 3,534/3,749 subset of RTE)



Breakdown of process subcodes

The most frequently reported process subcodes in the RT pathway are presented in Figure 6. This subset of data was also broken down by level.

The most frequently reported RTE was 'on-set imaging: production process' at 16.2% (n = 607) of all reports. This is an increase from the <u>previous analysis</u>, issue 44 (12.5%, n = 526). Of this

subset, 97.5% (n = 592) of the reports were minor radiation, near miss or other non-conformities with little or no impact on patient care. The majority of the reports were associated with contributory factor 'equipment or IT network failure' (66.6%, n = 404). The second most frequently reported RTE was 'management of variations, unexpected events or errors' at 7.1% (n = 266). The most frequently reported process subcodes during the current review period are similar to the previous analysis (issue 44), although 'consent process and documentation' has increased in proportion from 2.4% to 3.4%, whilst 'documentation of instructions/information' has reduced from 4.1% to 3.1%.

Figure 6. Breakdown of most frequently reported RTE process subcodes by level (n = 1,689/3,749 subset of RTE)



Three of the most frequently reported RTE process subcodes shown in <u>Figure 6</u> relate to on-set imaging; 'on-set imaging: production process', 'on-set imaging: approval process', and 'use of on-set imaging'. When these are combined with the fourth imaging code, 'on-set imaging: recording process', they constitute nearly a quarter of all RTE reported for this period (23.8%, n = 891). Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy <u>good practice guidance series</u>.

Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in <u>TSRT</u>, fall into the category of reportable under IR(ME)R ($\underline{3}, \underline{4}$), in accordance with <u>SAUE</u> guidance. These incidents will generally be significant, although they may be correctable within the course of treatment. The majority of these incident reports relate to a single treatment exposure or multiple verification imaging exposures. As a result, corrective action may be applied to the remaining treatment fractions

where required, so the incident does not have a significant impact on the patient or the outcome of their treatment.

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 61/91 subset of RTE)





There were 91 level 1 incidents submitted by 34 providers to the voluntary system for this reporting period, comprising 2.4% of the RTE reviewed (Figure 4). This is broadly consistent with the previous analysis, issue 44 (2.5%, n = 104) and the variance is not considered significant (p = 0.77). The most frequently reported level 1 reports are shown in Figure 7. 'Onset imaging: production process' was the most frequently reported level 1 event comprising of 16.5% (n = 15) of reports. In addition, 'On-set imaging: production process' has been the most frequently reported event within 7 of the last 8 previous analysis (issues 37 to 44). An example of an 'on-set imaging: production process' reportable RTE is when verification images are repeated multiple times due to set-up error and/or hardware or software failure.

Further information on radiotherapy verification imaging IR(ME)R notification criteria may be found within the <u>SAUE</u> guidance. Practical advice on reducing this type of event can be seen in case study 14 in <u>issue 44</u>, case study 2 in <u>issue 32</u>, the <u>good practice guidance series</u> and the <u>biennial report</u>.

'Patient positioning' and 'Management of variations/unexpected events/errors' each comprised of 9.9% (n = 9) of reported level 1 incidents, both increasing in proportion from the previous analysis (issue 44), from 5.8% (n = 6) and 3.8% (n = 4) respectively.

In the <u>previous analysis</u> (issue 44) 'authorisation to irradiate (IR(ME)R)' was highlighted as an emerging theme. It comprised of 3.8% (n = 4) of all level 1 incidents and had not featured within issue 43 or the <u>biennial report</u> (report number 8). In this current reporting period 'authorisation to irradiate (IR(ME)R)' has increased in proportion to 7.7% (n = 7). A <u>case study</u> of risk and suggested corrective actions to mitigate this type of RTE occurring can be found above.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined within <u>TSRT</u> as a radiation incident which is not reportable, but of potential clinical significance. Non-reportable radiation incidents comprised 0.7% (n = 27) of the RTE reported for this time period (Figure 4). This is consistent with the previous analysis, issue 44 (0.6%, n = 26) (p = 0.07).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 14/27 subset of RTE)



Three pathway codes were cited multiple times as primary pathway points where non-reportable radiation incidents initially occurred (Figure 8). The remainder of Level 2 primary pathway codes were listed once (n = 13) and are not shown within Figure 8. 'On-set imaging: approval process' comprised of 22.2% (n = 6) of all non-reportable radiation incident reports. An example of 'on-set imaging: approval process' is the incorrect approval of an on-set verification image which leads to a partial geographical miss which is non reportable.

Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined within <u>TSRT</u> as a radiation incident in the technical sense, but of no potential or actual clinical significance. Minor radiation incidents comprised 41.1% (n = 1,541) of the RTE reported for this reporting period (Figure 4). This is similar to the <u>previous analysis</u> (issue 44) (40.5% (n = 1,709) and not statistically significant (p = 0.59). A breakdown of level 3 RTE by process subcode can be seen in Figure 9.

Figure 9. Breakdown of most frequently reported level 3 RTE by process subcode (n = 1,179/1,541 subset of RTE) includes equipment failure related



'On-set imaging: production process' was the most frequently reported event with a proportion of 35.0% (n=539) of the total level 3 RTE reported. This is an increase on the previous analysis (issue 44) (27.1%, n = 463). Examples of this type of minor radiation incident can include selecting an incorrect CBCT preset setting the jaws incorrectly for a single image, leading to an additional image. A total of 67.3% (n = 363) of the reported 'on-set imaging: production process' primary process subcode were attributed to equipment failure, this is shown in Figure 9. Examples of this type of RTE include CBCT faults during acquisition. Equipment failure and 'on-set imaging: production process' is discussed further within case study 14 featured in the previous analysis (issue 44).

'Management of variations, unexpected events or errors' made up 14.3% (n = 220) of all minor radiation incidents, and of these 89.5% (n = 197) were attributed to equipment failure. Examples of this type of event includes when treatment equipment failure leads to a patient requiring transfer to a matched treatment machine. The re-set of the patient positioning then requires additional verification imaging. Further information on this type of event can be seen in Safer Radiotherapy the <u>unseen pathway</u>.

Near miss (level 4) RTE

A near miss (level 4) is defined within <u>TSRT</u> as a potential radiation incident that was detected and prevented before treatment delivery.

Near misses comprised 21.7% (n = 813) of the RTE reported (Figure 4). This reflects a statistically significant decrease in proportion in comparison to the <u>previous analysis</u>, issue 44 (24.1% (n = 1,016) (p = 0.01). Figure 10 shows the most frequently reported Level 4 subcodes.

Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 353/813 subset of RTE)



'Accuracy of data entry' comprised 8.0% (n = 65) of level 4 RTE. An example of this type of RTE would be incorrect documentation of isocentric shifts during pretreatment prep that is not detected until patient positioning at the treatment unit.

There is 1 addition to the most frequently reported process subcodes within the near miss (level 4) RTE when compared to the <u>previous analysis</u> (issue 44); 'management of variations/unexpected events/errors'. Examples of this type of event includes occasions where treatment planning has not taken place immediately after a patient rescan due to replan task not being scheduled. However, this omission is identified during pretreatment review of outstanding tasks and replan is expedited to ensure no delay in start date.

Other non-conformance (level 5) RTE

Other non-conformance (level 5) is defined within <u>TSRT</u> as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery.

Level 5 RTE comprised 34.1% (n = 1,277) of all RTE reported for this period (Figure 4). This is an increase in proportion in comparison to the <u>previous analysis</u>, issue 44 (32.3%, n = 1,364), although not considered statistically significant (p = 0.09).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 515/1,277 subset of RTE)



The most frequently reported level 5 process subcode was consent process and documentation with a proportion of 7.0% (n = 90). This is an increase from the previous analysis (4.7%, n = 64). Examples where this subcode might be used include occasions where the consenting clinician has failed to sign the consent form. 'Communication of appointments to patient' is the second most frequently reported pathway subcode within the other non-conformances (5.8%, n = 74). This is comparable with the previous analysis (issue 44) when the subcode made up 5.4% (n = 74). An example of this type of RTE includes when appointments are amended during treatment, however the patient is not informed. Of note 'bookings made according to protocol' has reduced in proportion to 5.6% (n = 72) from 6.0% (n = 82) in the previous analysis (issue 44), and 7.1% (n = 92) in the analysis featured in issue 43.

Failed safety barriers

A safety barrier (SB) is a critical control point, defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow (<u>10</u>). SB embedded in the pathway coding (<u>11</u>) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). Multiple FSB codes can be

attributed to each individual RTE. A total of 2,055 failed safety barriers (FSB) were identified from the RTE reported (Figure 12).

Figure 12. Breakdown of failed safety barriers (n = 1,417/2,055 subset of RTE data)



Treatment unit processes were attributed to 44.6% (n = 916) of all FSB. The most frequently reported FSB are detailed in <u>Figure 12</u>. Treatment unit processes 'management of variations, unexpected events or errors' was the most frequently reported FSB (15.4%, n = 317). An example of an RTE with this FSB includes when a machine failure occurs at the treatment unit, and the correct course of action is not taken in accordance with departmental protocol.

All but one of the FSB were also seen in the <u>previous analysis</u> (issue 44), 'On-treatment review of notes/data to according protocol' was the addition to the most frequent FSB for this reporting period.

'End of process checks' occur at the end of each discrete part of the patient pathway and include 6 different pathway subcodes. These comprised of 24.9% (n = 511) of all FSB. The PSRT provided further information on the use of end of process checks in the January (#6) and September (#7) 2022 issues of <u>Safer Radiotherapy E-bulletin</u>.

Method of detection

A method of detection (MD) is the process that identified the error and can be coded using the entire pathway taxonomy. For this reporting period 49 providers indicated MD in 63.1% (n =

2,367) of reports. Following consistency checking, UKHSA coded a further 1,070 reports with MD taxonomy, resulting in 3,437 reports for analysis. The most frequently reported MD can be seen in Figure 13.





The most frequently reported MD was 'on-set imaging: production process' (14.6%, n = 502). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (86.5%, n = 434) and a contributory factor of 'equipment or IT network failure' (73.1%, n = 367). Eight of the most frequently reported MD occurred at the treatment unit process.

'End of process checks' occur at the end of each discrete part of the patient pathway and include 6 different pathway subcodes. These comprised of 9.9% (n = 340) of all MD, of which 77.9%% (n = 265) were classified as either near miss or other non-conformances, stopping the RTE from propagating across the patient pathway.

For each part of the patient pathway there are 'other' pathway subcodes. 'Other' pathway subcodes attribute 7.1% (n = 245) of assigned MD. It is recommended the entire pathway coding should be considered when assigning a MD as described in the January 2022 issue of <u>Safer Radiotherapy E-bulletin</u>.

Contributory factors

Including contributory factors (CF) within a RTE taxonomy enables identification of system problems that could precipitate a range of different incidents ($\underline{12}$).

From the 3,749 RTE reported, 89.7% (n = 3,364) included CF coding. These were reported from 55 providers. This reflects an increase in the total frequency of CF coding reported since the <u>previous analysis</u> (issue 44), when 53 providers included CF coding in 76.5% of RTE reports (n = 3,229). UKHSA were able to assign a further 280 primary CF, resulting in 3,644 primary CF for analysis. Multiple CF can be assigned to a single RTE, 799 contained multiple CF, and a total of 4,603 CF codes were assigned to the 3,644 RTE.

Figure 14. Breakdown of most frequently reported CF (n = 4,310/4,603 subset of data)



The most frequently occurring CF codes are illustrated within Figure 14. The most frequently reported CF was 'slips and lapses' making up 27.8% (n = 1,280) of all CF (Figure 14). <u>Issue 22</u> of <u>Safer Radiotherapy</u> includes guidance on minimising the occurrence of RTE which may be attributed to a slip or lapse of an individual. The ranking of CF is broadly similar to the <u>previous</u> <u>analysis</u> (issue 44). Of note, 'equipment or IT network failure' increased in proportion from 14.5% (n = 751) in the <u>previous analysis</u> (issue 44) to 16.4% (n = 753) in the current analysis.

Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves radiotherapy treatment inside or close to the treatment area. BRT makes up less than 3% of all RT episodes (<u>13</u>). Therefore, the number of BRT associated RTE would be expected to be low and should be interpreted with caution. Further learning from BRT RTE can be seen in a separate <u>learning resource</u>.

RTE coded with BRT process subcodes as the primary code accounted for 1.1% (n = 42) of reports, reflecting a small increase from the <u>previous analysis</u>, issue 44 (1.0%, n = 41). Providers reporting BRT RTE remained consistent at 14 compared to 12 within the <u>previous analysis</u>. A breakdown of the BRT RTE can be seen in <u>Figure 15</u>.

The most frequently reported BRT process subcode was 'management of variations/unexpected events/errors' comprising 19.0% (n = 8) of all BRT RTE. This reflects an increase from the previous analysis, issue 44, where 9.8% (n = 4) of all BRT RTE were attributed to 'management of variations/unexpected events/errors'.

During the current review period 4.8% (n = 2) BRT RTE were classified as reportable radiation incidents (level 1), reflecting a decrease from the <u>previous analysis</u>, issue 44 (9.8%, n = 4). Both level 1 BRT RTE were attributed to 'maintenance of position of applicators /sources'. An example of this type of BRT level 1 RTE may include the displacement of an applicator during treatment, affecting the planned delivery.

From the 42 BRT RTE, there were 45 subcodes reported. Of these, 11 were FSB, the most frequently reported was 'correct applicators / sources' comprising 45.5% (n = 5).

Figure 15. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 42)



A MD subcode was supplied for 26 of the BRT RTE. Following UKHSA consistency checking a MD subcode was assigned to 13 more BRT RTE, totalling 39 MDs (92.9%) for the current reporting period. The most frequently reported BRT MD are illustrated in Figure 16.

Figure 16. Breakdown of BRT method of detection by level (n = 36/39 subset of RTE)



All CF codes were reviewed within this subset of the data and 42 CF were identified (Figure 17). The most frequently reported CF associated with BRT RTE was 'slips and lapses' comprising of 21.4% (n = 9) of all the CF for BRT RTE. The trends of these BRT CF are slightly different when compared to the entire data as in Figure 14, which may be indicative of differences in the equipment, skill mix and workflow between areas.

Figure 17. Breakdown of BRT RTE CF by level (n = 37/42 subset of data)



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Prepared by: Medical Exposures Group For queries relating to this document, please contact: <u>radiotherapy@ukhsa.gov.uk</u>

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