

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 38: Full radiotherapy error data analysis April to July 2022

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Full radiotherapy error data analysis

The fundamental role of reporting and learning systems is to enhance patient safety by learning from failures of the healthcare system (<u>1</u>). 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 minimised in the future.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) on radiotherapy errors and near misses (RTE), reported voluntarily by UK NHS radiotherapy (RT) providers. Anonymised reports were submitted through multiple routes, from England to the National Reporting and Learning System (NRLS) at NHS England and from Wales via the Once for Wales Concerns Management System (OfW) using the TSRT9 trigger code (<u>3</u>), directly to UKHSA from providers in Northern Ireland and Scotland. In England, the NRLS will be replaced by the Learn from Patient Safety Events Service (LFPSE) (<u>4</u>) by autumn 2023. In the interim, UKHSA will continue to receive reports from the NRLS.

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>5</u>, <u>6</u>, <u>7</u>) inspectorates of significant accidental or unintended exposures (SAUE) (or 'reportable radiation incidents' (level 1) as defined in <u>Towards Safer Radiotherapy</u> (<u>TSRT</u>) (<u>8</u>). 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 significant accidental or unintended exposures (SAUE) for analysis. It should be noted there may be a significant time lag between notification of an event to the inspectorates, it being closed and then shared with UKHSA for inclusion in the analysis.

The classification level from <u>TSRT</u> (8), the pathway coding, safety barrier, methods of detection and causative factor taxonomies from the <u>Development of Learning (DoL) from Radiotherapy</u> <u>Errors (9)</u> were employed for the analysis. SB and MD are discussed further in the May 2021 issue of the <u>Safer Radiotherapy e-bulletin (10</u>). A series of <u>presentations</u> have been developed to support the RT community, these include an introduction to learning from RTE, a description of the nationally agreed terminology and taxonomies used within this report, how the taxonomies should be applied to RTE reports, the sharing of examples of the types of analysis that can be done on RTE to maximise learning opportunities and the requirements and methodologies for a study of risk of accidental or unintended exposures. More learning resources will be added to the pages shortly $(\underline{11})$

The analysis has been reviewed and added to 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 red <a href="mailto:red" red <a href="mailto:red" <a href="mailto:red" <a href="mailto:red" <a href="mailto:red" <b href="mailto:red"

Inspectorate data

A breakdown of the inspectorate data for this period can be seen in <u>Figure 1</u>. The inspectorates shared 49 anonymised closed synopses of reported SAUE for analysis. The most frequently reported notifications were associated with 'on-set imaging: production process' (36.7%, n = 18). Of these, 77.8% (n = 14) were associated with equipment malfunction as shown in <u>Figure 1</u>. This is a slight decrease to the <u>previous analysis</u> (12) when 66 reports were shared. 'On-set imaging: production process' was still the most frequently reported at 33.3% (n = 24). A case study of this type of event is included in <u>issue 32</u> of the triannual analysis (<u>13</u>). Further guidance on mitigating RTE associated with imaging is available (<u>14</u>).

Figure 1. Breakdown of most frequently reported inspectorate process subcodes from closed notifications (n = 36/49 subset of data)



Case study 8: generation of plan for approval

'Generation of plan for approval' is one of the most frequently reported pathway subcodes. This involves the generation of the plan for treatment as part of pretreatment planning process. It includes virtual simulation and replans.

Synopsis

A paediatric patient's brain treatment was prescribed ph1 24Gy in 15#, 6MV plus ph2 16Gy in 10#, 6MV to the 100% isodose. The treatment was planned using a non-standard beam configuration (that is, not based on a pre-existing script or template within the treatment planning system). It consisted of 2 VMAT arcs. One arc had the treatment couch at zero and a full 360° arc. The second had the treatment couch at 270° and a 60° sagittal arc starting at 350°. The starting point of this arc was modified by the checker so that it started at 30° and continued until the gantry was at 90° ensuring that the beam did not enter or exit through the patient's eyes. However, in focussing on sparing the eye dose, the checker hadn't realised that the beam was exiting through the patient's neck and thoracic cavity. This resulted in the dose to the thyroid exceeding local dose tolerances as an OAR. Following the authorisation of the plan a linac based verification was completed using an anamorphic phantom. The checker noted 'acceptable doses to OAR near the tumour but missed the thyroid'. The error was noted some months later when another similar plan was carried out.

The clinical impact of this dose was assessed to be an additional approximate 0.9Sv whole body dose.

The subsequent review noted there was no written record of the checker adjusting the arc, the original planner was on annual leave therefore this change was not taken back to the original planner and no subsequent independent check was carried out after the adjustment was made. This was against local protocol. There was very short timescale for review and checking of a complex plan (2 days) it was also reported the checker was frequently interrupted and did not raise the adjustment to the arc with the original planner.

The report recommended the default setting within the treatment planning settings were changed to ensure low dose isodoses in planned distributions for paediatric patients. It was also noted that there had been 4 similar treatments, this has led to the introduction of a new clinical protocol for this type of treatment. This would include constraints on beam or couch arrangement to avoid such an error. Further recommendations included amending the wording in existing planning work instructions to remind staff to monitor exit beams. A new planning system has since been deployed which includes the capability to create algorithm or scripts to include a warning to check total body dose and OAR when the couch is rotated through 90°.

Coding: level1/11j/11k/11t/MD11j/CF1a/ CF2c/ CF1d/ CF6a/ CF2d

Causative factors

The first causative factor (CF) for this synopsis was 'failure to recognise hazard' (CF1a) as staff were so focussed on reducing the dose to the patient's eyes, they missed that the beam was exiting through the patients' neck into the thoracic cavity. The checker did not record a justification for the adjustment for the second arc (CF 1d 'communication'). After the adjustment the checker did not send the plan for an independent check which was against local protocol (CF2c 'adherence to protocols'). Further contributory factors included CF6a 'physical (distractions)' as it was stated the checker was interrupted and had insufficient time to complete the check (CF2d process design).

Safety barriers

The 'verification of the plan' using a phantom may have helped identify this. The final 'end of process check' on the plan was not carried out as per local protocol. Therefore, this did not detect the error as the OAR doses near the target volume were acceptable.

Method of detection

The completion of a similar plan for the same condition some months later highlighted the need to review similar plans and identified the error.

Corrective actions

Corrective actions include:

- reduce interruptions
- utilise standard planning and treatment nomenclature across the pathway
- implement inclusion of low dose isodoses in templates or scripting for paediatric patients
- ensure minimum criteria for checking includes a section on assessing exit doses for all plans
- clarification of responsibilities within the planning area to ensure the integrity of the independent check
- regular review of process design and work rotas
- consider mapping of workflow using the OMS to ensure all critical checks are completed
- share the error with the wider department for learning

Learning from excellence and published guidance

Learning from excellence include:

- create an appropriate environment for planning and checking processes (8)
- checking procedures should be regularly reviewed to ensure that they add value and to eliminate those that have become redundant (<u>8</u>)
- develop 'intuitive' procedures where possible as part of Human Factors approach

Further guidance and national tools to aid investigations are available (<u>15</u>, <u>16</u>). Following a simple risk matrix (<u>17</u>) a study of risk was produced for this case study and other (11j) generation of plan for approval related RTE.

Table 1. Study of risk matrix

In this table an A in brackets indicates amber risk, a G in brackets indicates green risk.

Area of risk	Initial risk			Risk following mitigations (corrective action examples shown above)		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
OAR exceeded tolerance dose, detected at end of process check	3	2	6 (G)	3	1	3 (G)
OAR exceeded tolerance patient treated	4	2	8(A)	4	1	4(G)
Laterality incorrectly transcribed onto patient plan, detected at treatment	1	2	2 (G)	1	1	1 (G)
Treatment fields labelled incorrectly, detected at treatment pause and check	3	2	6 (G)	3	1	3 (G)
Treatment delivery of arc treatment timed out during treatment	3	2	6 (G)	3	1	3 (G)
User origin not set correctly leading to incorrect shifts, detected at verification imaging	2	3	6 (G)	2	1	2 (G)
User origin not set correctly leading to geographical miss for single fraction	4	2	8 (A)	4	1	4 (G)

April to July 2022 data analysis

Number of RTE reports

A monthly average of 1,052 reports were received between April and July 2022. This was an increase from 828 (27.5%), when compared to the <u>previous analysis</u> (12) and 890 (18.2%) when compared to the same reporting period published in 2021 (18). This slight increase in reporting since the previous reporting period may be due to the receipt of data on the establishment of the OfW reporting system.

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 days to 1,724 days, with a mean of 41 days and a mode of 0 days, reflecting that 271 were reported nationally on the same day as the incident. If the outlier of 1,724 days is removed the maximum lag time is reduced to 455 days, with the same mean and mode. 11 reports from 7 providers had a greater lag time than 365 days, the outlier of 1,724 was detected due to ongoing surveillance of a patient. This variation in timeliness of reporting is also reflected in the overall patient safety incident reports received by the <u>NRLS</u> who encourage organisations to report incidents monthly (<u>19</u>). To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. <u>Issue</u> <u>26 of Safer Radiotherapy</u> (<u>20</u>) provides further information on reporting frequency.

Monitoring of RTE coding by radiotherapy providers

All providers are asked to apply a trigger code, classification level, pathway coding (including failed safety barriers (FSB)), method of detection (MD) and causative factors (CF) (including root cause and contributory factors) 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 reporting and learning system where possible.

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. For the first time within this analysis a complete report includes the MD taxonomy. A complete report includes the trigger code, classification, pathway code, including FSB, MD, and CF taxonomies

From the 1,420 RTE reports classified and coded locally with all the taxonomies, 955 were classified as levels 1 to 4. A total of 175 of these were amended (complete fixed in Figure 2 includes level 5 data (n = 240)). Thus, an 81.7% level of consistency was achieved for levels 1

to 4 RTE. This is similar to the <u>previous analysis</u> (12) when an 80.5% level of consistency was achieved. Some amendments were made to reports to ensure consistent allocation of the taxonomies. Of the 240 complete fixed reports 14.6% (n = 35) had the classification amended, 54.2% (n = 130) had the pathway subcode amended and 8.3% (n = 20) had the causative factor amended.





The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (54.3%, n = 19). If a verification image is required to be repeated this should be classified as a radiation incident (level 1-3) and not a near miss (level 4) or non-conformance (level 5). The most frequently amended primary pathway subcode was treatment unit process 'other', making up 19.2% (n = 25) of all the amended pathway subcodes. This was most frequently amended to 'management of variations/ unexpected events/ errors. 65.4% (n = 85) of all primary pathway subcodes amended were from an 'other' primary pathway subcode. It is recommended the entire pathway subcoding should be considered when allocating primary pathway subcodes. Further information on the consistent allocation of pathway codes can be seen in e-Bulletin edition 3 (21).

A total of 2,710 RTE reported did not contain one of the required taxonomies, including MD. A total of 2,202 RTE were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed in <u>Figure 2</u>). A total of 1,000 of these contained the trigger code, classification, pathway code, including FSB and CF taxonomies but no MD (in previous analysis these would have been categorised as complete reports) From the remaining 508 RTE reports 507 contained sufficient information to assign a classification, pathway code

and CF but not a MD. 1 RTE report did not contain sufficient information to assign any taxonomies and has been excluded from the detailed analysis.

Non-RTE reports submitted formed 1.9% (n = 81) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI) but not RTE. This is consistent with <u>previous analysis</u> (12). A <u>PSI</u> is defined by the NRLS as 'any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving care' (22). Further information on PSI can be found in <u>issue 5 of Safer Radiotherapy</u> (23). Non-RTE reports were excluded from the detailed analysis.

In total, 4,129 RTE for the reporting period from April to July 2022 were included for analysis. The analysis is presented here.

Number of reports per provider

There are currently 59 NHS RT providers across the UK. For this reporting period, 94.9% (n = 56) of providers have submitted RTE reports using the TSRT9 trigger code, this is an increase to the <u>previous analysis</u> (84.7%, n = 50) (<u>12</u>).

Figure 3 shows the number of RTE reports submitted by provider. This ranged from one to 439 reports, with a mean of 70. A total of 3 providers did not submit any reports for this reporting period. Of the 56 providers who reported, 69.6% (n = 39) reported less than the national mean. Figure 3 also indicates the classification of reports received per provider. The majority of providers that submitted higher numbers of RTE reports included all classification levels of reports. However, one provider who reported 155 RTE did not report any level 5 RTE.



Figure 3. Number of RTE reported by provider (n = 4,129)

There may be several reasons for this disparity in reporting. 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 RT providers on reporting culture is published in the January 2022 issue of <u>Safer Radiotherapy e-bulletin (24</u>). This survey demonstrated that those providers required to use more than one system were less likely to submit all classification of RTE. Furthermore, only 64.3% stated their local incident learning system.

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.

Breakdown of process codes

The 4,129 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 4 shows 42.6% (n = 1,759) of the RTE were reported to have occurred during treatment unit processes. The treatment 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 prevalence of RTE within treatment unit processes.



Figure 4. Breakdown of RTE process code by level (n = 3,888/4,129 subset of RTE)

Breakdown of process subcodes

The most frequently reported process subcodes in the RT pathway are presented in Figure 5. This subset of data was also broken down by level.

The most frequently reported RTE reported was 'on-set imaging: production process' at 12.9% (n = 534) of all the reports similar to the <u>previous analysis</u> (11.9%, n = 391) (<u>12</u>).

Of this subset, 97.8% (n = 522) of the reports were minor radiation, near miss or other nonconformities with little or no impact on patient care. The second most frequently reported RTE was 'documentation of instructions or information' at 4.6% (n = 190) of these 83.2% (n = 158) were classified as level 4 or 5 indicating that the majority of this type of RTE were detected before treatment occurred. All but one ('patient positioning') of the most frequently reported process subcodes were seen in the previous analysis (12).

On-set imaging associated RTE include 'on-set imaging: production process', 'use of on-set imaging', 'on-set imaging: recording process' and 'on-set imaging: approval process'. These combined RTE made up 21.9% (n = 904) of all RTE reported for this period. Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy good practice guidance series (14).

Figure 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,718/4,129 subset of RTE)



□Level 5 □Level 4 ■Level 3 ■Level 2 ■Level 1

Classification (level) of RTE

Each of the 4,129 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 6).

Of the RTE reports, 98.0% (n = 4,047) were minor radiation, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 2.0% (n = 82) reports, only 1.0% (n = 40) were reportable under IR(ME)R to the appropriate authority. The national survey on reporting culture published in the January 2022 issue of <u>Safer</u> <u>Radiotherapy e-bulletin</u> (24) indicates that providers are less likely to submit all levels of RTE reports to the national voluntary reporting system. It was found RTE reports of classification level 4 to 5 are less likely to be shared due to resource constraints and use of multiple reporting systems. This trend is also reflected in <u>Figure 3</u> which shows providers who report a higher number of RTE report all levels of RTE.

Figure 6. Classification (level) of RTE reports (n = 4,129)



Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in <u>TSRT</u> (8) fall into the category of reportable under $\underline{IR(ME)R}$ (5, 6, 7). These incidents will generally be significant, although they may be correctable within the course of treatment. The majority of these incident reports related to a single exposure. This meant that corrective action could be applied to the remaining treatment fractions, so the incident did not have a significant impact on the patient or the outcome of their treatment.

There were 40 level 1 incidents submitted by 24 providers to the voluntary system for this reporting period (Figure 6), comprising 1.0% of the RTE reviewed. This proportion is slightly

lower than the <u>previous analysis</u> (12) (1.3%, n = 43) but not statistically significant (p = 0.23). Further analysis of the reports indicates the points in the pathway at which the reportable incidents occurred (Figure 7).

'On-set imaging: production process', comprised 17.5% (n = 7) and was the most frequently reported event within the reportable radiation incidents. This was also the most frequently reported event within the inspectorate data (Figure 1) and within the previous analysis (12), comprising 25.6% (n = 11) of all level 1 incidents for that time period. An example of an 'on-set imaging: production process' reportable RTE is when repeat verification image is taken multiple times due to either machine malfunction and or setting the incorrect position for the image panel. Taking 3 or more images in one fraction due to machine malfunction meets the reportable threshold of the inspectorates (25). Further guidance on reducing this type of event can be seen in case study 2 in issue 32 and good practice guidance series (13, 14).

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 25/40 subset of RTE)



'Patient positioning' comprised of 11.6% (n = 4) of the reportable radiation incidents, these each only affected a single fraction of treatment. An example of this type of event is when the patient is not in the correct position for treatment leading to a geographical miss.

Only 4 of the process subcodes within the most frequently level 1 incidents were also featured in the most frequently reported level 1 RTE within the <u>previous analysis</u> (12). The level 1 RTE were spread across 23 different process subcodes. Of these, 11 did not occur during a patient attendance. A review of checking processes to ensure they contain a minimum criteria for checking is recommended, this may mitigate RTE propagating through the pathway to the patient treatment process.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined as a radiation incident which is not reportable, but of potential clinical significance ($\underline{8}$). Non-reportable radiation incidents comprised 1.0 % (n = 42) of the RTE reported for this time period (Figure 6). The number of level 2 RTE has increased since the previous analysis (12) (0.6% (n = 21)) but is not statistically significant (p = 0.06). Further analysis indicates the points in the pathway at which non-reportable radiation incidents occurred (Figure 8).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 24/42 subset of RTE)



The reports were spread across 26 different subcodes, 18 of which were singular and not shown in Figure 8. 'On-set imaging: approval process' and 'on-set imaging: production process' each comprised of 11.9% (n = 5) of all the non-reportable radiation incident reports. An example of RTE associated with '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. An example of RTE associated with 'on-set imaging: production process' is when multiple on-set

images are taken, either in a single fraction or across a course of treatment but do not meet the tolerance threshold for reporting to the inspectorates (25).

Only the 3 process subcodes reported within the non-reportable radiation incidents reported during this period were also featured in the non-reportable RTE within the <u>previous analysis</u> (<u>12</u>).

Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance (8). Minor radiation incidents comprised 37.2% (n = 1,536) of the RTE reported for this reporting period (Figure 6). The proportion is similar to the corresponding proportion of the previous analysis (12) (35.7%, n = 1,175) and the differences are not statistically significant (p = 0.18). 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 = 1,083/1,536 subset of RTE) *equipment failure discussed further in text



'On-set imaging: production process' was the most frequently reported event (31.8%, n = 488) within this subset. This is a slight increase in proportion since the <u>previous analysis</u> (<u>12</u>) (28.9%, n = 340).

Examples of this type of minor radiation incident can include setting the jaws incorrectly for a single image, leading to an additional image. A total of 56.8% (n = 277) level 3 RTE with the primary process subcode 'on-set imaging: production process' 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 in issue 18 of Safer Radiotherapy (26). All of the most frequently reported level 3 RTE occurred during treatment unit processes, this is reflective of the data shown in Figure 4 and also reflects the previous analysis (12). Further guidance on mitigating these types of RTE is available (14).

Near miss (level 4) RTE

A near miss (level 4) is defined as a potential radiation incident that was detected and prevented before treatment delivery ($\underline{8}$).

Near misses comprised 25.5% (n = 1,053) of the RTE reported (Figure 6). The proportion of the current report is statistically significantly (p = 0.04) lower than the <u>previous analysis</u> (12) (27.6%, n = 908). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 453/1,053 subset of RTE)



'Documentation of instructions/information' comprised 7.5% (n = 79) of level 4 RTE, followed by 'use of on-set imaging' at 6.8% (n = 72). An example of RTE associated with 'documentation of instructions/information' is the incorrect immobilisation information annotated at pre-treatment and detected during treatment unit patient positioning. An example of RTE associated with 'use of on-set imaging' is the omission of verification imaging, this is detected during treatment, the verification image is then taken and confirms the correct treatment positioning. Further details on 'documentation of instructions/ information' and 'accuracy of data entry' related RTE can be found in <u>issue 8 and 7</u> of Safer Radiotherapy (27, 28).

All but one (treatment data entry 'end of process checks') of the most frequently reported process subcodes within the near misses (level 4) RTE also featured in the most frequently reported near miss RTE within the <u>previous analysis</u> (<u>12</u>).

Similar to the minor radiation incidents (level 3), the most frequently reported level 4 RTE shown in Figure 10, includes the pathway subcodes associated with on-set imaging (16.3%, n = 172). Examples of 'on-set imaging: production process' associated RTE include using a kV image for verification when a CBCT should have been acquired, the kV image is used for treatment verification and no additional exposure is given. An example of 'on-set imaging: approval process' RTE includes when the second review of a verification image has not been completed, this is then detected whilst performing end of process checks during the next fraction of treatment. An example of 'on-set imaging: recording process' RTE includes the actions following image review not being undertaken, where this does not lead to incorrect or additional exposure.

Other non-conformance (level 5) RTE

Other non-conformance (level 5) is defined as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery ($\underline{8}$).

Level 5 RTE comprised 35.3% (n = 1,458) of all RTE reported for this period (Figure 6). The number of other non-conformances is increased in comparison with the previous analysis (12) (34.7%, n = 1,142), the proportion is similar with no significant differences in proportion (p = 0.59). The most frequently reported level 5 process subcodes were 'documentation of instructions/information' comprising of 5.4% (n = 79) of all level 5 RTE (Figure 11).

An example of a RTE associated with 'documentation of instructions/information' include the incorrect documentation of instructions and information from the pre-treatment area. This can include the incorrect patient set-up information or the incorrect patient preparation instructions. These are detected during an end of process check before treatment exposure.

The booking process includes 6 different process subcodes, which were reported in 17.2% (n = 251) of level 5 RTE.

There are no treatment process subcodes contained within the most frequently reported level 5 RTE as shown in Figure 11. Eight of the most frequently reported process subcodes in the other non-conformances RTE were also seen in the <u>previous analysis</u> (<u>12</u>).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 561/1,458 subset of RTE)



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 (29). SB embedded in the pathway coding (9) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). Multiple SB codes can be attributed to each individual RTE. A total of 2,348 failed safety barriers (FSB) were identified across the RTE reported (Figure 12).



Treatment unit processes were attributed to 37.2% (n = 874) of all FSB. The most frequently reported FSB are represented in Figure 12. Treatment unit processes 'use of on-set imaging' was the most frequently reported FSB (8.8%, n = 207). An example of an RTE with this FSB includes when a verification image is not taken when required, this then has the potential for required corrections to be missed. All but one ('availability of staff) of the FSB were also seen in the previous analysis (12).

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised of 31.0% (n = 729) of all FSB. The PSRT have undertaking a piece of work to look at the use of end of process checks which is highlighted in the <u>January</u> and <u>September</u> 2022 issue of Safer Radiotherapy e-bulletin (<u>24</u>, <u>30</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 36 providers indicated MD in 34.4% (n = 1,420) of reports. This is similar to the <u>previous analysis</u> (<u>12</u>), where 33 providers indicated MD in 35.0% (n = 1,152) of reports. Following consistency checking, UKHSA coded a further 2,202 reports with MD taxonomy, resulting in 3,622 reports for analysis.

The most frequently reported MD can be seen in Figure 13.





For this reporting period, the most frequently reported MD was 'on-set imaging: approval process' (16.3%, n = 593). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (23.9%, n = 142). Six 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 pathway and include 6 different pathway subcodes. These comprised of 16.9% (n = 611) of all MD, of which 65.0% (n = 397) detected the error, stopping the RTE from propagating across the pathway.

For each part of the pathway there are 'other' pathway subcodes. Before consistency checking 14.2% (n = 192/1,420) of MD were assigned an 'other' pathway subcode. After consistency checking this was reduced to 5.4% (n = 77). It is recommended the entire pathway coding should be considered when assigning a MD as described in the January 2022 issue of <u>Safer</u> Radiotherapy e-bulletin (24).

Causative factors

The use of a causative factor (CF) taxonomy enables identification of system problems or contributory factors that could precipitate a range of different incidents (31).





From the 4,129 RTE reported 83.2% (n = 3,436) contained CF coding. These were reported from all providers who reported for this time period. This is an increase in providers since the <u>previous analysis (12)</u>, when 47 providers reported 85.8% (n = 2,823) of RTE contained CF. Multiple CF can be assigned to a single RTE, across the 4,129 RTE reported 915 contained multiple CF totalling 5,200 CF codes. Figure 14 shows the most frequently reported CF codes.

The most frequently reported CF was 'slips and lapses' making up 29.5% (n = 1,534) of all CF reported (Figure 14). <u>Issue 22 of Safer Radiotherapy</u> (32) includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual.

Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to the treatment area (<u>33</u>). BRT makes up less than 3% of all RT episodes (<u>34</u>). Therefore, the number of BRT associated RTE would be expected to be low and should be interpreted with caution. RTE coded with BRT process subcodes as the primary code accounted for 1.3% (n = 55) of reports, a slight increase to the <u>previous analysis</u> (<u>12</u>) (0.9%, n = 29). BRT

RTE were submitted from just 16 providers for this reporting period. A breakdown of the brachytherapy RTE can be seen in Figure 15.

Figure 15. Breakdown of most frequently reported brachytherapy RTE coded '15' by level (n = 52/55 subset of data)



The most frequently reported BRT process subcodes was 'initial positioning of applicator/ sources' comprising 18.2% (n = 10) of all BRT RTE. An example BRT RTE associated with 'initial positioning of applicator/ sources' includes when the seeds are incorrectly positioned for treatment.

From the 55 BRT RTE, 32 subcodes were identified as FSB. The most frequently reported BRT FSB are shown <u>Figure 16</u>.

The most frequently reported was 'correct applicator/ sources' and, 'management of variations' each comprising 12.7% (n = 7) The FSB seen across the entire pathway shown in <u>Figure 12</u> indicate imaging associated FSB. This difference is due to a perceived greater uptake of IGRT in external beam RT than in BRT.



Figure 16. Breakdown of brachytherapy failed safety barriers (n = 32)

Of the 55 BRT RTE, 60.0%, (n = 33) were assigned a MD subcode, during consistency checking the remaining 22 were also assigned a MD using the text within the report. These are shown in Figure 17.

Figure 17. Breakdown of brachytherapy method of detection by level (n = 43/55 subset of RTE)



All CF codes were reviewed within this subset of the data and 66 CF identified (Figure 18). The most frequently reported CF associated with BRT RTE was 'adherence to procedures' comprising of 33.3% (n = 22) 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.

Figure 18. Breakdown of brachytherapy RTE CF (n = 59/66 subset of RTE)

(CF 1d) Communication (CF 1b) Decision making process (CF 5a) Inadequate leadership (CF 2b) Inadequate procedures / protocols (CF 1c) Slips and lapses (CF 1a) Failure to recognise hazard (CF 3a) Equipment or IT network failure (CF 2c) Adherence to procedures / protocols



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