

# **Safer Radiotherapy**

# Triannual RTE analysis and learning report

Issue 37 – Full radiotherapy error data analysis December 2021 to March 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) (previously Public Health England (PHE)) on radiotherapy errors (RTE) including near misses, reported voluntarily by NHS radiotherapy (RT) providers. Anonymised reports were submitted from England and Wales to the National Reporting and Learning System (NRLS) at NHS England and Improvement using the TSRT9 trigger code (<u>3</u>), and directly to UKHSA from providers in Northern Ireland and Scotland. In future, reports from Wales will also be received via the Once for Wales Concerns Management Sysem. In England, the NRLS will be replaced by the Learn from Patient Safety Events Service (LFPSE) (<u>4</u>). 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</u> <u>Radiotherapy (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.

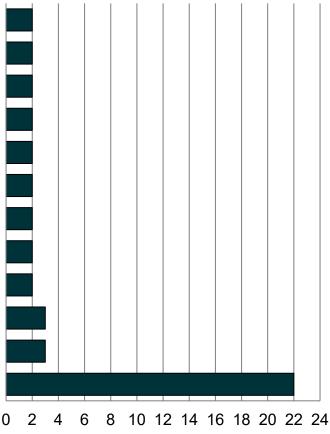
The classification from <u>TSRT</u> (8), the pathway coding, safety barrier, methods of detection and causative factor taxonomies from the <u>Development of Learning (DoL) from Radiotherapy</u> <u>Errors (9)</u> were employed for the analysis. Where appropriate, comparisons have been drawn with previous data analyses (<u>10</u>). The analysis has been reviewed and added to by the PSRT. If individual providers would like to comment on the analysis or share experience of learning from RTE please email the RT team at <u>radiotherapy@phe.gov.uk</u>

## Inspectorate data

A breakdown of the inspectorate data for this reporting period can be seen in Figure 1. The inspectorates shared 66 anonymised closed synopses of reported SAUE for analysis. The most frequently reported notifications were associated with 'on-set imaging: production process' (33.3%, n = 22), These are similar to the previous reporting period (10) when 67 were shared and 'on-set imaging:production process' was the most frequently reported at 35.8%, n = 24). A case study of this type of event is included in <u>issue 32</u> of the triannual analysis (10). Further guidance on mitigating RTE associated with imaging is also available (11).

# Figure 1. Breakdown of most frequently reported inspectorate process subcodes from closed notifications (n = 46/66 subset of data)

(4b) Verification of diagnosis/extent/stage (4a) Identification of patient (13q) Setting of couch position/angle (13l) Movements from reference marks (13j) Transfer of marks (13bb) On-set imaging: recording process (13aa) On-set imaging: approval process (11i) Target and organ at risk delineation (10b) Positioning of patient (13cc) Management of variations (11j) Generation of plan for approval (13z) On-set imaging: production process



Number of RTE reports

# Case study 7: Brachytherapy, initial positioning of applicator or sources

Analysis of brachytherapy (BRT) RTE shows the proportion of level 1 RTE is larger in BRT (3.4%) in comparison to all radiotherapy errors (1.3%). The hypo-fractionated nature and level of human involvement in BRT may be factor in this. Better monitoring and analysis of BRT RTE is essential to mitigate these events. The following case study has been developed with the support of the PSRT, a special thank you to Pauline Humphrey at Bristol Cancer Institute.

#### Synopsis

A new applicator, intrauterine tube and cervical ring was introduced locally. On first use 2 of the catheters were connected to the wrong channels on the HDR brachytherapy afterloader. This meant that catheter 1 was connected to channel 2 and catheter 2 was connected to channel 1. This was detected at the end of treatment whilst removing the catheters from the afterloader.

A dosimetry review was undertaken which detected the total sigmoid dose delivered was 77.2Gy, rather than the intended 75Gy. As the error occurred on the first fraction, a replan was completed with a clinically acceptable composite plan. This resulted in no significant volume of overdose and the volume underdose was corrected for. The patient was informed of the error by the consultant clinical oncologist.

During the investigation it was noted that all training records were up to date and included the use of the new applicator. The individuals who completed the brachytherapy tasks were deemed competent and appropriately entitled.

However, there were no amendments to the work instructions reflecting the use of the new applicator. The work instructions still contained photographs and a diagram of the old applicator. Further review indicated that no risk assessment was carried out before the introduction of the new applicator.

On completion of the investigation the work instructions were updated and issued through the quality management system and a risk assessment produced. This was communicated to all staff via an update email and during staff meetings.

Coding: TSRT9/ Level 1/ 15g/ 15s/ 19a/ MD15s/ CF2a/ CF1a/ CF5f

#### **Causative factors**

The root cause for this case study was identified as 'procedural', due to the lack of up to date work instructions. Further causative factors included the individual 'failure to recognise hazard'. This was the first time the new applicator was used and the incorrect assignment of catheters to channels was not identified prior to treatment. As no proactive risk assessment was completed prior to use of this new applicator, the causative factor 'inadequate risk assessment' was also attributed.

#### Safety barriers

The 'end of process checks' did not identify this error. The final check before leaving the room did not detect that the incorrect channels had been selected. The work instructions had not been updated to reflect the new applicator, which may have reduced the likelihood of its incorrect use.

### Method of detection

On completion of treatment when the catheters were being removed, it was noticed the catheters were connected to the incorrect channels.

#### **Corrective actions**

Corrective actions include:

- minimum criteria for checking should be reviewed to ensure safety critical elements are included
- when placing the applicator, consideration should be given to catheter allocation and confirmation of the correct catheter and applicator by the operators, this should be a discrete part of the end of process checks
- an independent check on the catheter to applicator connections should be completed by a separate individual
- end of process checks should include the confirmation of catheter allocation against the treatment plan
- a run through using new equipment such as applicators should be completed during end-to-end testing before utilising new equipment
- when introducing new equipment or techniques consider using a template for an end of project report which includes a checklist, this should include completion of risk assessment, quality system changes, handover and training, lessons learnt and follow on actions.

### Learning from excellence and published guidance

Learning from excellence includes:

- prior to introducing change to practice, new techniques or technology a risk assessment should be carried out (<u>12</u>)
- all written procedures should be updated at agreed intervals and when there is significant change (<u>8</u>)
- embed simulator training into the introduction of new techniques and technology (<u>13</u>)
- purpose built brachytherapy suites are recommended with all necessary equipment co-located. Where this is not possible reduce transfer distance between theatre and treatment room (<u>14</u>)
- use of 3D imaging (computed tomography (CT), magnetic resonance imaging (MRI) or ultrasound(US)) should be routine to verify position of applicator (<u>15</u>)
- use of real time US during a procedure to verify intrafraction positioning (15)

Further guidance and national tools to aid investigations are available ( $\underline{16}$ ,  $\underline{17}$ ). Following a simple risk matrix ( $\underline{12}$ ) a study of risk was produced for this case study and other (15g) initial positioning of applicator/ sources related RTE.

#### Table 1. Study of risk matrix

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

	Initial risk			Risk following mitigations		
Area of risk	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Incorrect connection of applicator to catheter for treatment	3	2	6 (G)	3	1	3 (G)
Applicator moved between applicator insertion and treatment - detected prior to treatment	1	2	2 (G)	1	1	1 (G)
Applicator moved between applicator insertion and treatment - not detected prior to treatment	3	2	6 (G)	3	1	3 (G)
Applicator not fixed to bed or other area prior to treatment leading to geographical miss	3	2	6 (G)	3	1	3 (G)
Incorrect placement of applicator - detected prior to treatment	2	3	6 (G)	2	1	2 (G)
Incorrect placement of applicator leading to geographical miss	4	2	8 (A)	4	1	4 (G)

# December 2021 to March 2022 data analysis

## Number of RTE reports

A monthly average of 828 reports were received between December 2021 and March 2022. This was an increase from 777 (6.2%), when compared to the <u>previous reporting period</u> (10) and 719, (13.2%) when compared to the same reporting period published in <u>2021</u>. However, this is similar to the same time period in <u>2020</u> (830.5, 0.3% decrease).

According to the <u>Radiotherapy Data Set (18</u>), the estimated number of attendances in NHS providers across England and Wales for this reporting period was 452,111 (as of May 2022). There has been a decrease (7.9%) in activity since the <u>previous reporting period (10</u>), when the estimated number of attendances was 490,902.

Across England and Wales 3,143 RTE were detected and reported by NHS providers, equating to 7 per 1,000 attendances for this reporting period. This is the same as the <u>previous</u> reporting period (10). Similar activity data is not yet available for the reported error rate to be calculated for Northern Ireland and Scotland.

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 798 days, with a mean of 49 days and a mode of 7 days. 23 reports from 7 providers had a greater lag time than 365 days, 5 of which were due to the original incident learning reporting form being mislaid. Although the average lag time (47 days) is similar to the previous reporting period (10), the lag time range was 0 to 462 days with just 4 reports with a greater lag time than 365 days. 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 26 of Safer Radiotherapy (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, pathway coding (including failed safety barriers) and causative factors (including root cause and contributory factors) and a method of detection to their RTE reports to facilitate both local and national analysis.

The <u>DoL</u> guidance document (9) and <u>good practice in RTE reporting</u> (11) include examples of the application of the classification, pathway and causative factor coding. Safety barriers and method of detection are discussed further in the May 2021 issue of <u>Safer Radiotherapy</u> (20). 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. A complete report includes the trigger code, classification, pathway code, including failed safety barriers and causative factor taxonomies. All future analysis will include the method of detection taxonomy within complete reports.

From the 2,661 RTE reports classified and coded locally, 1,672 were classified as levels 1 to 4. A total of 326 of these were amended (complete fixed in Figure 2 includes level 5 data (n = 195)). Thus, an 80.5% level of consistency was achieved for levels 1 to 4 RTE. This is the same as the previous reporting period (10) when an 80.5% level of consistency was achieved. Some amendments were made to reports to ensure consistent allocation of the taxonomies. Of the 411 complete fixed reports 28.2% (n = 116) had the classification amended, 74.2% (n = 305) had the pathway subcode amended and 9.5% (n = 39) had the causative factor amended.

The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (64.7%, n = 75). 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 17.7% (n = 54) of all the amended codes. This was most frequently amended to 'management of variations/ unexpected events/ errors'. 60.3% (n = 184) of all primary pathway subcodes were amended 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 <u>e-Bulletin edition 3</u> (20).

Of the 2,661 RTE reported classified and coded locally, only 1,078 contained a MD code. In future analyses, the MD taxonomy will be included in the count of completed reports. Any reports received without a MD will be assigned as incomplete and UKHSA staff will assign a MD code where possible.

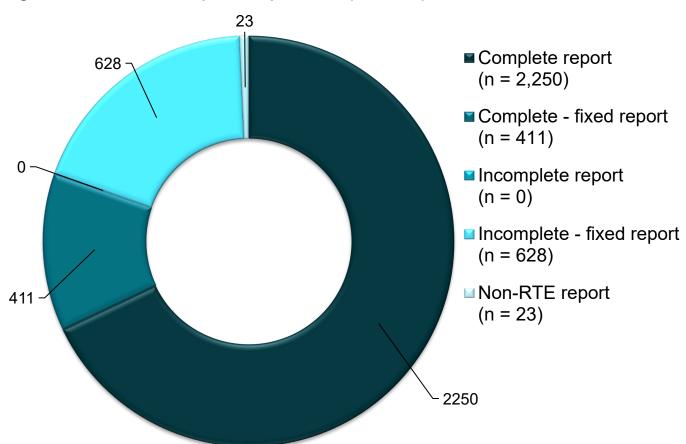


Figure 2. Breakdown of report completeness (n = 3,312)

A total of 628 (19.0%) RTE were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed in <u>Figure 2</u>). This is a slight increase since the <u>previous reporting period</u> (10) when 540 (17.4%) RTE were incomplete. Incomplete reports were submitted by 39 providers. However, 43.8% (n = 275) of the incomplete fixed RTE were reported from a single provider.

If providers would like advice or support with coding RTE please email the RT team at <a href="mailto:radiotherapy@phe.gov.uk">radiotherapy@phe.gov.uk</a>.

Non-RTE reports submitted formed 0.7% (n = 23) 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> (10). 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' (21). Further information on PSI can be found in <u>issue 5 of Safer</u> Radiotherapy (20). Non-RTE reports were excluded from the detailed analysis.

In total, 3,289 RTE for the reporting period from December 2021 to March 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, 84.7% (n = 50) of providers have submitted RTE reports using the TSRT9 trigger code, this is a slight decrease to the <u>previous reporting period</u> (86.4%, n = 51) (10).

Figure 3 shows the number of RTE reports submitted by provider. This ranged from one to 336 reports, with a mean of 56. A total of 9 providers did not submit any reports for this reporting period. Of the 50 providers who reported, 54.0% (n = 27) 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 92 RTE did not report any level 5 RTE.

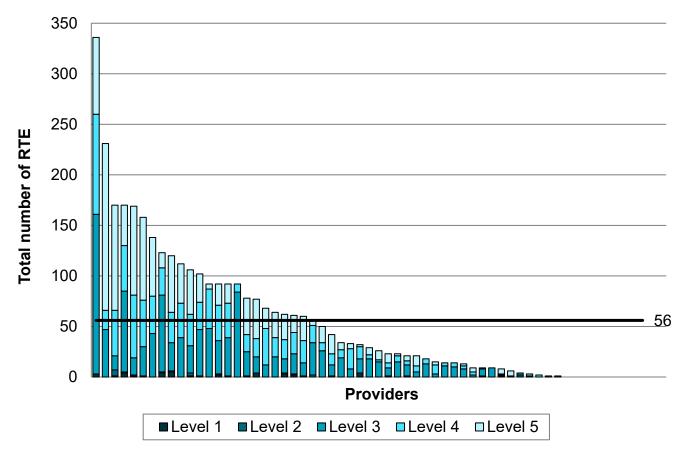


Figure 3. Number of RTE reported by provider (n = 3,289)

There may be several reasons for this disparity in reporting. Reporting culture varies across providers. Reporting and learning systems are not always easily accessible. Additional resource may be required to support a full reporting and learning system. Finally, a local requirement to use more than one reporting 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</u> (20). This survey demonstrated that those providers with requirements to use more than one reporting and learning solutions were less likely to submit

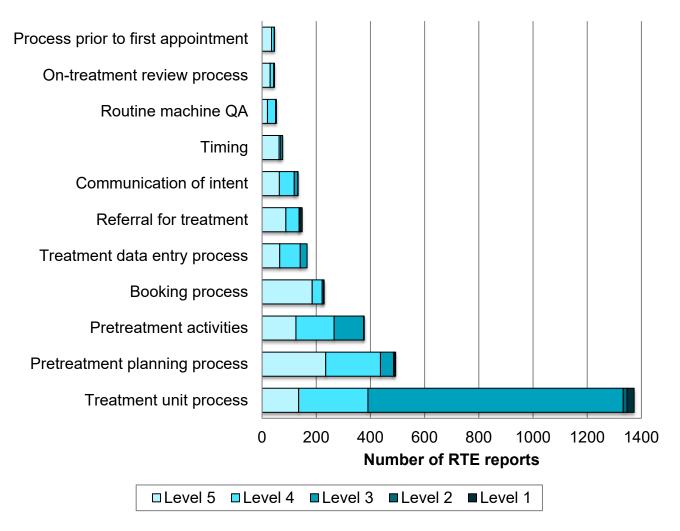
all classification of RTE. Furthermore, only 64.3% stated their local incident learning system was linked for data transfer to the wider hospital/trust risk management incident learning system.

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 3,289 RTE reports were categorised by process code according to  $\underline{DoL}$  (9) and level so the main themes could be derived. Figure 4 shows 41.7% (n = 1,373) 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.

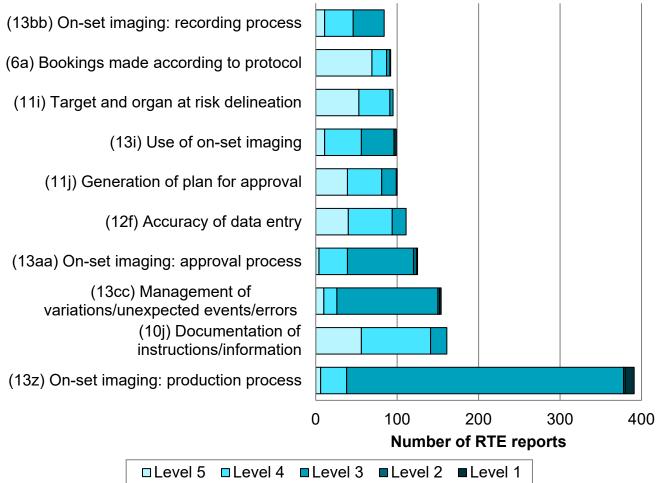
#### Figure 4. Breakdown of RTE process code by level (n = 3,140/3,289 subset of RTE)



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 11.9% (n = 391) of all the reports. This shows that the proportion of the current report is statistically significantly (p = 0.04) lower than the previous reporting period (13.6%, n = 421) (10). Of this subset, 96.7% (n = 378) of the reports were minor radiation, near miss or other non-conformities with little or no impact on patient care. The second most frequently reported RTE was 'documentation of instructions or information' at 4.9% (n = 161), of these 87.6% (n = 141) were classified as level 4 or 5 indicating that the majority of this type of RTE were detected before treatment occurred. This was followed by 'management of variations/unexpected events/errors' at 4.7% (n = 154). All but one ('bookings made according to protocol') of the most frequently reported process subcodes were seen in the previous reporting period (10).

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 21.3% (n = 699) 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 (11).

# Figure 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,412/3,289 subset of RTE)

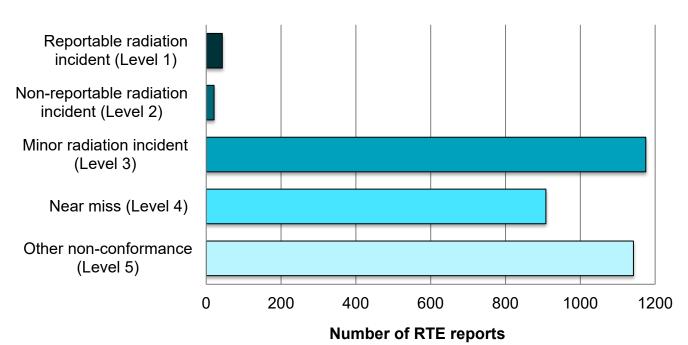


# Classification (level) of RTE

Each of the 3,289 RTE reports was classified as 'other non-conformance', 'near miss', 'minor radiation incident', 'non-reportable radiation incident' or 'reportable radiation incident' (Figure <u>6</u>).

Of the RTE reports, 98.1% (n = 3,225) were minor radiation, near miss or other nonconformities with little or no impact on patient outcome. Of the remaining 1.9% (n = 64) reports, only 1.3% (n = 43) 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</u> (20) 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 (20). 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 = 3,289)

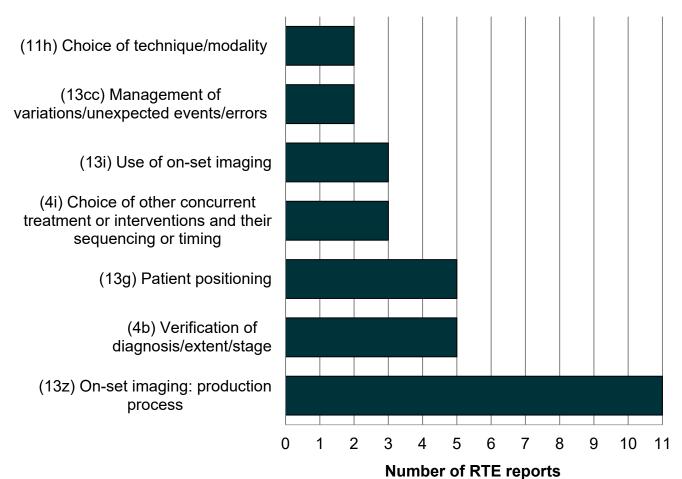
## Reportable radiation incident (Level 1) RTE

Reportable radiation incidents, as defined in <u>TSRT</u> (8) fall into the category of reportable under 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 43 reportable radiation incidents submitted by 21 providers to the voluntary system for this reporting period (Figure 6), comprising 1.3% of the RTE reviewed. This proportion is slightly lower than the previous analysis (10) (1.5%, n = 47) and the differences are not statistically significant (p = 0.50). 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 25.6% (n = 11) and was the most frequently reported event within the reportable radiation incidents. These 11 events were reported by just 9 different providers. This was also the most frequently reported Level 1 event within the inspectorate data (Figure 1) and within the previous analysis (10), comprising 34.0% (n = 16) of all reportable radiation incidents for that time period. An example of 'on-set imaging: production process' reportable RTE is when repeat verification cone beam computed tomography (CBCT) are taken multiple times due to either machine malfunction and, or setting the incorrect position for the CBCT. Taking 3 or more images in one fraction due to machine malfunction meets the reportable threshold of the inspectorates (22). Further guidance on reducing this type of event can be seen in case study 2 in issue 32 and good practice guidance series (11, 20).

# Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 31/43 subset of RTE)



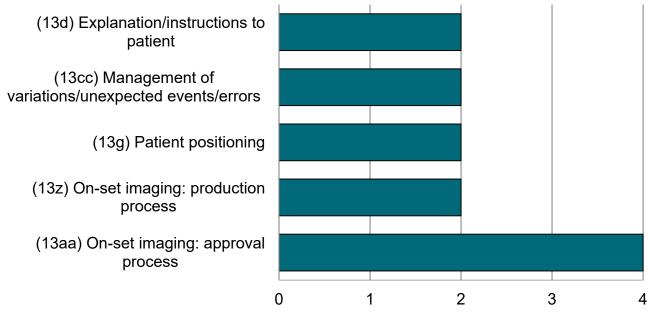
'Verification of diagnosis/extent/stage' and 'patient positioning' each comprised of 11.6% (n = 5) of the reportable radiation incidents. An example of 'verification of diagnosis/extent/stage' level 1 RTE is when an urgent treatment of spinal metastasis is referred without the confirmation of diagnosis, the CT planning scan and treatment are carried out, after completion of treatment the MRI report confirms there is no disease in the area, the patient has received CT planning scan and treatment when not required. Further guidance on reducing these type of events can be seen in <u>Issue 29</u> of Safer Radiotherapy (<u>20</u>).

Only 3 of the process subcodes within the most frequently reportable radiation incidents were also featured in the most frequently reported reportable RTE within the <u>previous analysis</u> (10). The level 1 RTE were spread across 19 different process subcodes. Of these, 12 were singular events and 8 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 is defined as a radiation incident which is not reportable, but of potential clinical significance ( $\underline{8}$ ). Non-reportable radiation incidents comprised 0.6 % (n = 21) of the RTE reported for this time period (Figure 6). The number of non-reportable radiation incidents is reduced since the previous analysis (10) (0.8% (n = 26)), however, the differences in proportion are not statistically significant (p = 0.34). 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 = 21/12 subset of RTE)



Number of RTE reports

The reports were spread across 14 different subcodes, 9 of which were singular and not shown within (Figure 8). 'On-set imaging: approval process' was the most frequently reported event within the non-reportable radiation incident reports comprising of 19.0% (n = 4). 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 (22).

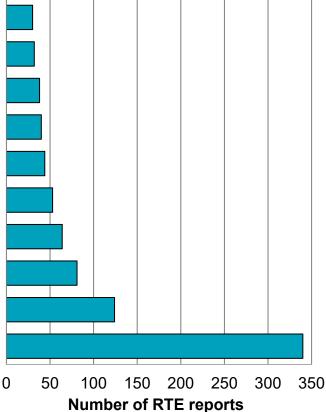
Only the 2 process subcodes reported within the non-reportable radiation incidents reported during this period were also featured in the non-reportable RTE within the <u>previous analysis</u> (<u>10</u>).

## Minor radiation incident (Level 3) RTE

A minor radiation incident is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance (8). Minor radiation incidents comprised 35.7% (n = 1,175) of the RTE reported for this reporting period (Figure 6). The proportion is similar to the corresponding proportion of the previous analysis (10) (36.1%, n = 1,119) and the differences are not statistically significant (p = 0.74). 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 = 846/1,175 subset of RTE)

(13u) Use of compensators (13q) Setting of couch position/angle (13bb) On-set imaging: recording process (13i) Use of on-set imaging (13r) Use of immobilisation devices (13g) Patient positioning (13l) Movements from reference marks (13aa) On-set imaging: approval process (13cc) Management of variations/unexpected events/errors (13z) On-set imaging: production process



'On-set imaging: production process' was the most frequently reported event (28.9%, n = 340) within this subset. This is a decrease since the <u>previous analysis</u> (10) (34.0%, n = 380).

Examples of this type of minor radiation incident include using the incorrect filter for a single CBCT imaging. A total of 51.8% (n = 176) level 3 RTE with the primary process subcode 'on-set imaging: production process' were attributed to equipment failure. Examples of this type of RTE include CBCT faults during acquisition. Equipment failure and on-set imaging: production process is discussed further in <u>issue 18 of Safer Radiotherapy</u> (20). All of the most frequently reported level 3 RTE occurred during treatment unit processes, this is reflective of the data shown in <u>Figure 4</u>.

All of the most frequently reported minor radiation incident RTE process subcodes also featured in the most frequently reported near miss RTE within the <u>previous analysis</u> (10). A large proportion of the level 3 reports were related to on-set imaging, (42.5%, n = 499), this is a decrease since the <u>previous analysis</u> (10) at 46.3% (n = 518). Further guidance on mitigating these types of RTE is <u>available</u> (11).

# Near miss (Level 4) RTE

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

Near misses comprised 27.6% (n = 908) of the RTE reported (Figure 6). The number of near miss RTE is similar to the previous analysis (10) (26.3%, n = 908) and no significant difference is observed in proportion between the 2 reports (p = 0.24). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

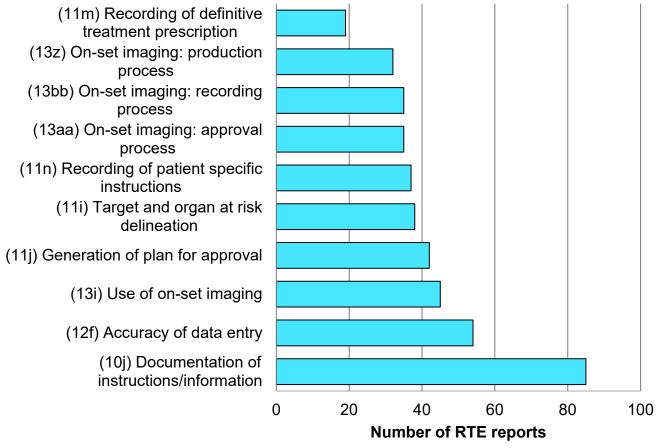
'Documentation of instructions/information' comprised 9.4% (n = 85) of level 4 RTE, followed by 'accuracy of data entry' at 5.9% (n = 54). An example of RTE associated with 'documentation of instructions/information' is the incorrect immobilisation information annotated at pre-treatment and detected during treatment unit patient positioning. An example of RTE associated with 'accuracy of data entry' is the omission of detail from data entry, including set up information or patient preparation information, this is then detected during treatment unit processes. Further details on 'documentation of instructions/ information' and 'accuracy of data entry' related RTE can be found in <u>issues 2 and 8</u> of Safer Radiotherapy (<u>20</u>).

All but one ('recording of definitive treatment prescription') 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> (10).

The most frequently reported level 4 RTE shown in <u>Figure 10</u>, includes the pathway subcodes associated with on-set imaging (16.2%, n = 147). Examples of 'use of on-set imaging'

associated RTE includes the omission of imaging to confirm patient position before treatment. 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.

# Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 422/908 subset of RTE)

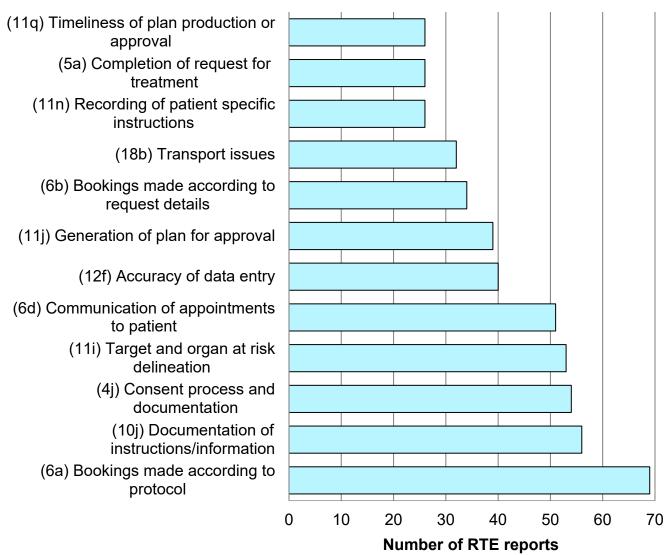


### Other non-conformance (Level 5) RTE

Other non-conformance 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 34.7% (n = 1,142) of all RTE reported for this period (Figure 6). The number of other non-conformances is increased in comparison with the previous analysis (10) (35.3%, n = 1,093), the proportion is similar with no significant differences in proportion (p = 0.62). The most frequently reported level 5 process subcodes were 'bookings made according to protocol' comprising of 6.0% (n = 69) of all level 5 RTE (Figure 11).

# Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 506/1,142 subset of RTE)



An example of a RTE associated with 'bookings made according to protocol' includes the incorrect scheduling of patient appointments, such as once per week rather than daily treatments or booking appointments starting on the incorrect date. The booking process includes 6 different process subcodes, which were reported in 14.8% (n = 169) of level 5 RTE.

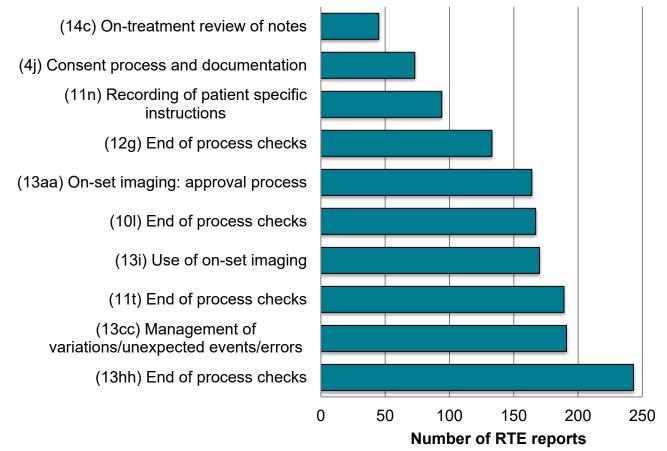
Examples of level 5 RTE associated with 'documentation of instructions, information' include the incorrect documentation of instructions and information from the pre-treatment area. This can include the incorrect patient set-up information or the incorrect patient preparation instructions. These are detected during an end of process check, before treatment occurs.

There are no treatment process subcodes contained within the most frequently reported level 5 RTE as shown within <u>Figure 11</u>. Eight of the most frequently reported process subcodes in the other non-conformances RTE were also seen in the <u>previous analysis</u> (<u>10</u>).

## 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 (23). 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 2,196 failed safety barriers (FSB) were identified across the RTE reported (Figure 12).





Treatment unit processes were attributed to 39.8% (n = 873) of all FSB. The most frequently reported FSB are represented in Figure 12. Treatment unit processes 'end of process checks' was the most frequently reported FSB (11.1%, n = 243). An example of an RTE with FSB 'end of process checks' is where an independent end of process check has either been omitted or carried out incorrectly at the end of the process. All but one ('on-treatment review of notes/ data according to protocol) of the failed safety barriers were also seen in the previous analysis (10).

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised of 33.7% (n = 741) of all FSB. The PSRT are currently undertaking a piece of work to look at the use of end of process checks which is highlighted in the January 2022 issue of <u>Safer Radiotherapy (20)</u>.

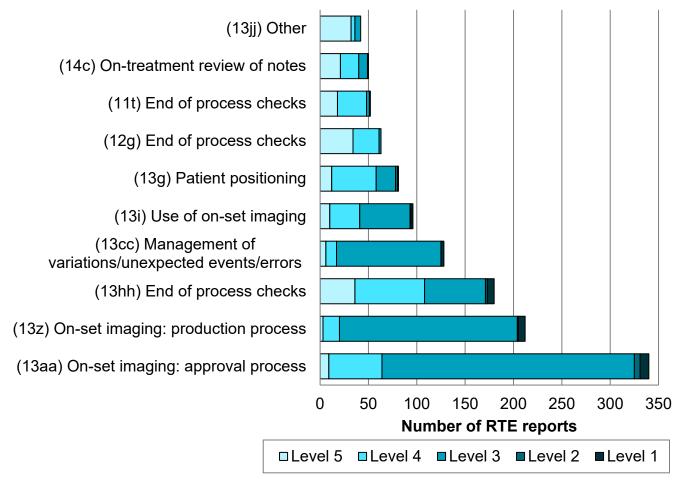
## Method of detection

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 33 providers indicated MD in 35.0% (n = 1,152) of reports. This is an increase in providers but decrease in MD since the <u>previous analysis</u> (10), where 30 providers indicated MD in 40.0% (n = 1,240) of reports. Method of detection are discussed further in the May 2021 issue of <u>Safer Radiotherapy</u> (20). Following consistency checking, UKHSA coded a further 820 reports with SB taxonomy, resulting in 1,972 reports for analysis.

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

# Figure 13. Breakdown of method of detection by level (n = 1,244/1,972 subset of RTE data)



For this reporting period, the most frequently reported MD was 'on-set imaging: approval process' (17.2%, n = 340). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (27.9%, n = 95). Seven 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 = 334) of all FSB, of which 70.1% (n = 234) detected the error for either near miss or other-non-conformance RTE.

For each part of the pathway there are 'other' pathway subcodes. Before consistency checking 14.2% (n = 164/1,152) of MD were assigned an 'other' pathway subcode. After consistency checking this was reduced to 7.5% (n = 87). It is recommended the entire pathway coding should be considered when assigning a MD. Further information on the allocation of the pathway coding for MD can be seen in the January 2022 issue of <u>Safer Radiotherapy</u> (20).

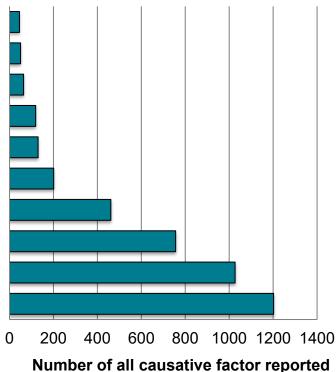
## **Causative factors**

The use of a causative factor (CF) taxonomy enables identification of system problems or root causes that could precipitate a range of different incidents ( $\underline{24}$ ).

From the 3,289 RTE reported 85.8% (n = 2,823) contained CF coding. These were reported from 47 providers, this is an increase since the <u>previous analysis</u> (10),when 83.6% (n = 2,590) of RTE contained CF. Multiple CF can be assigned to a single RTE, across the 3,289 RTE reported 848 contained multiple CF totalling 4,240 CF codes. <u>Figure 14</u> shows the most frequently reported CF codes.

#### Figure 14. Breakdown of most frequently reported CF (n = 4,055/4,240 subset of data)

(CF 4a) Medical condition (CF 3c) Device / Product design (CF 2b) Inadequate procedures / protocols (CF 5d) Inadequate staffing (CF 1b) Decision making process (CF 1a) Failure to recognise hazard (CF 3a) Equipment or IT network failure (CF 1d) Communication (CF 2c) Adherence to procedures / protocols (CF 1c) Slips and lapses

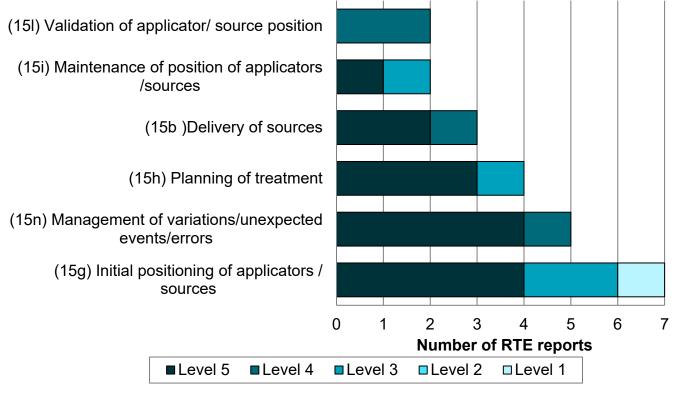


The most frequently reported CF was 'slips and lapses' making up 28.3% (n = 1,202) of all CF reported (Figure 14). Issue 22 of Safer Radiotherapy (20) includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual.

# Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to the treatment area (25). BRT makes up less than 3% of all RT episodes (<u>16</u>). Therefore, the number of BRT associated RTE would be expected to be low. RTE coded with BRT process subcodes as the primary code account for 0.9% (n = 29) of reports, a slight increase to the <u>previous analysis</u> (<u>10</u>) (0.5%, n = 17). A breakdown of the brachytherapy RTE can be seen in <u>Figure 15</u>.

# Figure 15. Breakdown of most frequently reported brachytherapy RTE coded '15' by level (n = 23/29 subset of data)



There were just 11 providers who reported BRT RTE for this reporting period. As this number is very small, this may skew the data presented in the analysis below.

The most frequently reported BRT process subcode was 'initial positioning of applicators, sources', comprising 24.1% (n = 7) of all BRT RTE. An example BRT RTE associated with 'initial positioning of applicators, sources' is when the applicator is not positioned correctly, further detail on this can be seen in the case study included at the beginning of this document.

An example of BRT RTE associated with 'management of variations/ unexpected events/ errors' is when the seeds from a treatment cartridge cannot be expelled due to machine malfunction. <u>Issue 20 of Safer Radiotherapy</u> (20) includes further guidance on mitigating BRT RTE.

Multiple pathway subcodes can be assigned to each RTE. A total of 39 subcodes were identified across the 29 BRT RTE reports. Only 14 subcodes were identified as FSB.

The most frequently reported FSB was 'management of variations/ unexpected events/ errors' comprising of at 50.0% (n = 7) of all the BRT FSB as seen in <u>Figure 16</u>.

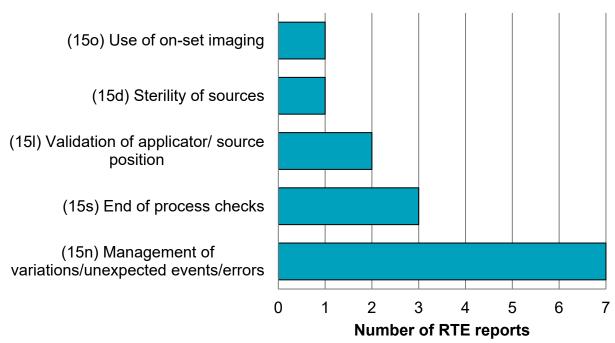


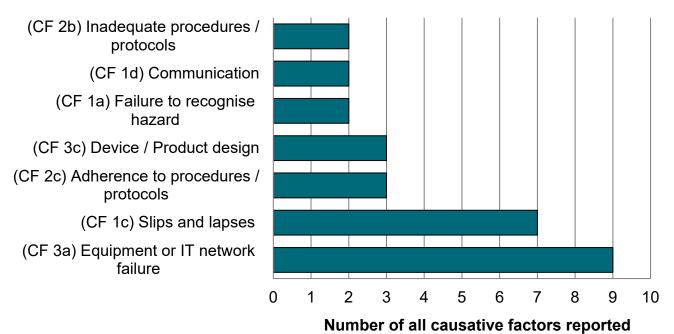
Figure 16. Breakdown of brachytherapy failed safety barriers (n = 14)

The FSB seen across the entire pathway shown in <u>Figure 12</u> indicate imaging associated FSB. This difference is due to a percieved greater uptake of IGRT in external beam RT than in BRT.

Only 15 MD subcodes were assigned to the BRT RTE. The most frequently reported BRT MD was 'management of variation/ unexpected events/ errors' (24.1%, n = 7). All CF were reviewed within this subset of the data. From the 29 BRT RTE there were 33 CF reported as shown in Figure 17.

The most frequently reported CF associated with BRT RTE was 'equipment or IT network failure' comprising of 27.3% (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.

#### Figure 17. Breakdown of brachytherapy RTE CF (n = 28/33 subset of RTE)



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