Safer radiotherapy

Supplementary data analysis

Issue 30 – Full radiotherapy error data analysis August to November 2019
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Full radiotherapy error data analysis August to November 2019

This analysis has been undertaken by Public Health England (PHE) on radiotherapy errors and near misses (RTE) reported voluntarily by NHS radiotherapy (RT) providers. Reports are submitted from England and Wales to the National Reporting and Learning System (NRLS) at NHS England and NHS Improvement using the TSRT9 trigger code\(^1\) and directly to PHE from providers in Northern Ireland and Scotland.

The classification from Towards Safer Radiotherapy\(^2\) (TSRT) and the pathway coding from the Development of learning from radiotherapy errors\(^3\) (DoL) including safety barriers (failed & effective) and causative factor taxonomy were employed for the analysis. Where appropriate, comparisons have been drawn with previous issues of Safer Radiotherapy\(^4\) and the PHE supplementary data analyses\(^5\). The analysis has been reviewed by the Patient Safety in Radiotherapy Steering Group, whose comments have been incorporated into this document.

The overall analysis presented in this report will help providers to compare locally identified trends against the national picture. In doing so it is expected that these events might be minimised in the future. However, it should be noted this data is not adjusted to reflect individual provider activity or service specification. 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.

If individual providers would like to comment on the analysis or share experience of learning from RTE please email the RT team at radiotherapy@phe.gov.uk.

Number of reports

The average number of reports received by PHE each month for this reporting period was 897.8. When compared to the last reporting period the average number of reports per month has increased from 778.3\(^5\) (increase of 15.4%), this increase can also be seen when comparing the same reporting period in 2017 when 845.8 RTE (increase of 6.2%) were reported per month. A mature reporting culture is reflected in the continued participation by many providers in national reporting. This continued commitment of providers demonstrates the community’s drive to improve patient safety in RT.

According to the Radiotherapy Dataset\(^6\), the estimated number of attendances in NHS providers across England and Wales for this reporting period was 614,351. Across England and Wales 3,425 RTEs were detected and reported by NHS providers,
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equating to 0.6% of all attendances for this reporting period; this is similar to the previous reporting period\(^{(5)}\). The estimated number of prescriptions was 57,878 equating to RTE detected in 5.9% of prescriptions. Similar activity data is not yet available for an estimated reported error rate to be calculated for Northern Ireland and Scotland. Also, it is worth noting that the clear majority of these events did not impact on the patients’ planning, treatment or outcome.

There is some disparity in frequency of reporting across providers, with a wide variance shown when comparing the incident date with the date reported to the national voluntary reporting scheme. This time lag ranges from a minimum of 0 day to a maximum of 594 days for this reporting period, with a mode of 14 days and a mean of 53.7 days. This is a difference in the mean since the last reporting period (mean = 41 days), however the same mode of 14 days\(^{(5)}\). This variance in timeliness of reporting is also reflected in the overall patient safety incident reports received by the NRLS\(^{(7)}\). To ensure timely learning from RTE reports continues to be shared nationally, providers are asked to make submissions at the earliest opportunity for inclusion in the monthly data uploads by PHE and 4-monthly analyses. Issue 26\(^{(4)}\) of Safer Radiotherapy provides further information on the frequency of reporting.

**Monitoring of TSRT classification and coding by radiotherapy providers**

All providers are asked to apply a trigger code, classification, coding, including failed and effective (detection method) safety barriers and causative factor to their RTE reports to facilitate both local and national analysis. For example TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c. Failed and effective safety barriers and how to include them in report submissions are discussed further in Issue 24 and 28 of Safer Radiotherapy\(^{(4)}\).

Consistency checking was undertaken by PHE staff on the application of the TSRT\(^{(2)}\) classification and DoL\(^{(3)}\) coding system by RT providers. During consistency checking the coding is reviewed for all RTE classified as reportable through to near miss (levels 1 – 4) and 10% of non-conformances (level 5) RTE are audited. A complete report (Figure 1) contains the classification, pathway code, including safety barriers and causative factor taxonomies. From the 2,819 RTE reports classified and coded locally, 1,729 were classified as levels 1-4, 270 of these were amended (complete fixed); an 84.4% level of consistency was achieved for the levels 1-4 RTE. Some of the amendments were due to the incorrect allocation of classification and pathway codes to imaging associated RTE. The DoL guidance document gives examples of the application of the classification, pathway and causative factor coding\(^{(3)}\). In addition, 744 RTE were classified or coded by PHE staff using the supporting text supplied by the local providers, (incomplete fixed in Figure 1), this is an increase since the last reporting period when 568 RTE were reported incomplete (31% increase). A further breakdown of incomplete fixed reports by provider can be seen in figure 1. There were 42 providers who reported incomplete reports, however; 71.1% (n = 529) of the incomplete fixed RTE
were reported from just 4 providers. There were 33 providers who each reported less than 15 incomplete RTE, this was only 16.1% \((n = 120)\) of all incomplete fixed reports. Only one incomplete report did not contain enough information to allocate all required taxonomies, a causative factor taxonomy could not be applied; therefore, this is included in the analysis with the omission of the causative factor taxonomy.

Non-RTE reports submitted with the TSRT9 trigger code formed 0.8% \((n = 27)\) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI). This is consistent with previous analyses\(^{(5)}\). A PSI 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’\(^{(8)}\); further information on PSI can be found in issue 5 of Safer Radiotherapy\(^{(4)}\). Non-RTE reports were excluded from the detailed analysis.

**Figure 1. Breakdown of reports, August to November 2019 \((n = 3,591)\)**

In total, 3,564 RTE for the reporting period from August to November 2019 were included for analysis. The analysis is presented here.

**Number of reports per provider**

There are now 60 NHS RT providers across the UK. For this reporting period, August to November 2019, 90.0% \((n = 54)\) of providers have submitted RTE reports using the TSRT9 trigger code, this is similar to the last reporting period (88.5%, \(n = 54\))\(^{(5)}\). The RTE reports received at PHE are anonymised and received as part of a voluntary reporting scheme. New and existing NHS and independent RT providers are welcome to contact PHE at radiotherapy@phe.gov.uk for advice on how to submit data for inclusion in these national analyses.
Figure 2 shows the number of RTE reported by providers during August to November 2019. The number of reports per provider ranged from 1 to 331 reports with a mode of 18 reports and mean of 59.4 reports for this subset of data. There were 6 providers who did not submit any reports for this reporting period, of the 54 providers who reported 63.0% (n = 34) reported less than the national mean. It should be noted that those centres reporting higher numbers of RTE represent providers with mature reporting cultures and should be encouraged to continue reporting. Figure 2 also indicates the classifications of reports received per provider. The majority of providers reporting higher numbers of RTE reports include all classification of reports. One of the providers who reported 309 RTE did not report any level 5 RTE. Furthermore, it is essential that the local reporting and learning system is readily accessible and offers an efficient solution to enable reporting.

The third in a series of surveys of UK RT providers in 2014\(^9\) on reporting culture demonstrated that those departments with fully electronic single reporting and learning solutions, which were accessible in all areas of the clinical department, were most likely to submit greater numbers of RTE. The intention in sharing this data is to allow providers to benchmark themselves against other UK NHS radiotherapy providers. Furthermore, a survey on the current reporting culture can be seen in issue 27 of Safer Radiotherapy\(^4\).

Figure 2. Number of RTE reported per RT provider, August to November 2019 (n = 3,564)
Breakdown of process codes

The 3,564 RTE reports were categorised by process code according to DoL\textsuperscript{(3)} irrespective of classification, so that the main themes could be derived. Figure 3 shows 43.5\% (n = 1,550) of the RTE were reported to have occurred during treatment unit processes. It is expected that the treatment unit process code is to be the most frequently reported code as RT treatments can span several visits, providing additional opportunities during the treatment unit process for RTE to occur. New equipment was featured for the first time for this reporting period within the main activity codes (n = 75). An appropriate risk assessment should be conducted as part of commissioning new equipment.

Figure 3. Breakdown of RTE main activity codes reported, August to November 2019 (n = 3,346/3,564 subset of RTE)

The most frequently reported process subcodes in the RT pathway are presented in Figure 4. This subset of data was also broken down by classification. The most frequently occurring RTE reported was ‘on-set imaging: production process’ at 14.5\% (n = 518) of all the reports. This has increased from 11.4\% (n = 353) from the previous reporting period\textsuperscript{(5)}. Of this subset 94.8\% (n = 491) reports were level 3 events. The second most frequently occurring RTE was ‘documentation of instructions/ information’ at 4.8\% (n = 173). 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 on-set imaging associated RTE made up
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26.3% of all RTE reported for this reporting period. Further guidance on these types of incident can be seen in the PHE good practice guidance series\(^{(10)}\).

**Figure 4. Breakdown of RTE main themes by classification level reported, August to November 2019 (n = 1,565/3,564 subset of RTE)**

Classification of radiotherapy errors

Each of the 3,564 RTE reports was classified as ‘other non-conformance’, ‘near miss’, ‘minor radiation incident’, ‘non-reportable radiation incident’ or ‘reportable radiation incident’ (Figure 5).

**Figure 5. Breakdown by classification of RTE reports, August to November 2019 (n = 3,564)**

Of the RTE reports, 98.5% (n = 3,510) were minor radiation, near miss or other non-conformities with little or no impact on patient outcome. Of the remaining 1.5% (n = 54) RTE reports, only 1.1% (n = 38) were reportable under the Ionising Radiation (Medical
Exposure) Regulations (IR(ME)R) to the appropriate authority. For this reporting period the most frequently reported RTE was classed as a minor radiation incident (39.3%, n = 1,400), this prevalence may be due to a single provider who reported 309 RTE and did not report any level 5 RTE. The national survey on reporting culture in issue 27 of Safer Radiotherapy\(^{(4)}\) indicates that providers are more likely to submit RTE reports of higher classification levels (levels 1 – 3) to the national voluntary reporting system. It was found RTE reports of lower classification (level 4 – 5) are less likely to be shared due to resource constraints and inefficient reporting and learning systems\(^{(4)}\).

**Reportable radiation incident**

Reportable radiation incidents as defined in *TSRT*\(^{(2)}\) fall into the category of reportable under IR(ME)R\(^{(11-13)}\). These incidents will generally be clinically significant, although they may be correctable within the course of treatment. The majority of these higher-level incident reports affected a single exposure. This meant that corrective action could be taken over the remaining treatment fractions, so the incident did not have a significant impact on the patient or the outcome of their treatment.

There were 38 reportable radiation incidents submitted to the voluntary system from August to November 2019 (Figure 5), comprising 1.1% of the RTE reviewed; this is a slight increase from 26 (0.8%) reportable radiation incidents in the previous 4-monthly analysis\(^{(5)}\). Further analysis of the reports indicates the points in the pathway at which the reportable incidents occurred (Figure 6).

**Figure 6. Breakdown of reportable radiation incidents (level 1) by process subcode reported, August to November 2019 (n = 16/38 subset of RTE)**

‘On-set imaging: approval process’ comprised of 10.5% (n = 4) of these reportable radiation incidents. An example of this type of reportable RTE includes the incorrect matching of a verification image, including the mis match of vertebrae leading to a geographical miss. The mismatch of the verification images for the 4 RTE reported associated with ‘on-set imaging: approval process’ only affected a single fraction of
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Each treatment. Further guidance on verification of diagnosis/extent/stage can be seen in issue 28 of Safer Radiotherapy\(^4\). All other events were spread across 15 different subcodes.

**Non-reportable radiation incident**

A non-reportable radiation incident is defined as a radiation incident which is not reportable, but of potential or actual clinical significance\(^2\).

Non-reportable radiation incidents comprised 0.4 % \((n = 16)\) of the RTE reported from August to November 2019 (Figure 5); this is a slight decrease since the previous 4-monthly analysis when non-reportable radiation incidents comprised 1.0% \((n = 32)\)\(^5\). Further analysis indicates the points in the pathway at which non-reportable radiation incidents occurred (Figure 7). The reports were spread across 14 different subcodes.

‘On-set imaging: approval process’ comprised 25.0% \((n = 4)\) and was the most frequently occurring event within the non-reportable radiation incidents. An example of RTE associated with ‘on-set imaging: approval process’ includes the mismatch of reference and verification imaging which does not lead to a total geographical miss. This was also the most frequently occurring non-reportable radiation incident in the previous 4-monthly analysis \((21.9\%, n = 7)\)\(^5\). Further guidance on reducing this type of event can be seen in issue 3 of Safer Radiotherapy\(^4\). Singular events reported are spread across 13 different subcodes. ‘IT infrastructure’, ‘commissioning’ and ‘daily consistency checks – dosimetric parameters’ are 3 of the singular events in the non-reportable RTE, these have not featured in previous analysis.

**Figure 7. Breakdown of non-reportable radiation incidents (level 2) by process subcode reported, August to November 2019 \((n = 16)\)**
Minor radiation incident

A minor radiation incident is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance\(^{(2)}\).

Minor radiation incidents comprised 39.3\% (n = 1,400) of the RTE reported from August to November 2019 (Figure 5); this is an increase from 1,036 (33.5\%) minor radiation incidents in the previous 4-monthly analysis\(^{(5)}\). The most frequently occurring level 3 process subcodes (Figure 8) consisted mainly of treatment unit processes 66.9\% (n = 936). ‘On-set imaging: production process’ was the most frequently occurring event (35.1\%, n = 491) within this subset; this is an increase from 31.2\% (n = 323) in the previous 4-monthly analysis\(^{(5)}\). Examples of this type of minor radiation incident included setting the incorrect jaw position for kV imaging. The pathway subcode ‘critical examination under IRR99’ (now IRR17) featured in the most frequently reported minor radiation incidents, this subcode was reported by a single provider and has not featured in the most frequently occurring minor radiation incidents in previous analysis.

Figure 8. Breakdown of most frequently occurring minor radiation incidents (level 3) by process subcode reported, August to November 2019 (n = 1,007/1,400 subset of RTE)

A large proportion of the reports in this classification were related to on-set imaging, these included ‘use of on-set imaging’, ‘on-set imaging: production process’, ‘on-set imaging: approval process’ and ‘on-set imaging: recording process’ (51.3\%, n = 718). This is an increase since the previous 4-monthly analysis\(^{(5)}\) when 49.9\% (n = 517) of minor radiation incidents were associated with on-set imaging. Further guidance on these types of incident can be seen in the PHE good practice guidance series\(^{(10)}\). Several minor radiation incidents with the primary code ‘on-set imaging: production process’ were attributed to equipment malfunction, (49.7\%, n = 244); examples of this
type of RTE include CBCT faults during acquisition. Equipment malfunction and on-set imaging: production process is discussed further in issue 18 of Safer Radiotherapy(4).

Near miss

A near miss is defined as a potential radiation incident that was detected and prevented before treatment delivery(2).

Near misses comprised 23.1% (n = 822) of the RTE reported from August to November 2019 (Figure 5). This is a similar to the previous 4-month analysis(5) (734 (23.8%).

Figure 9 shows the most frequently occurring process subcodes across this level of RTE. ‘Documentation of instructions’ comprised of 9.6% (n = 79) followed by ‘use of on-set imaging’ 7.5% (n = 62); An example of RTE associated within ‘documentation of instructions’ includes the incorrect entry of information regarding the set-up, positioning and immobilisation of a patient at pretreatment, this error is then not recognised until patient set up at treatment. An example of RTE associated with ‘use of on-set imaging’ includes the omission of verification imaging on fractions required in the imaging protocol. Further details on ‘documentation of instructions’ can be found in issue 8 of Safer Radiotherapy(4) and issue 7 contains further details on the ‘use of on-set imaging’.

The top 8 most frequently reported near miss RTE within this reporting period also featured in a different order as the most frequently reported near miss RTE within the previous 4-month period(5). The most frequently occurring near miss RTE graph shown in Figure 9, includes a pathway subcode ‘critical examination under IRR99’ (now IRR17), this subcode was reported by a single provider and has not featured in the most frequently occurring near miss RTE in previous analysis.

Figure 9. Breakdown of the most frequently occurring near misses (level 4) by process subcode reported, August to November 2019 (n = 389/822 subset of RTE)
Other non-conformance

Other non-conformance is defined as a non-compliance with some other aspect of a documented procedure, but not directly affecting radiotherapy delivery\(^{(2)}\).

Other non-conformance comprised 36.1\% (n = 1,288) of the RTE reported from August to November 2019 (Figure 5). This is a decrease from 1,261 (40.8\%) non-conformances in the previous 4-monthly analysis\(^{(5)}\). This decrease may be due to a single provider who reported 309 RTE but did not report any level 5 RTE.

The most frequently occurring subcode was ‘communication of appointments to patients’ (6.2\%, n = 80), (Figure 10) within this classification. Examples of other non-conformance RTE associated with communication of appointments to patients include; the incorrect communication of appointments to patients, including omitting appointments or incorrect communication of timings of appointments. This was followed by ‘bookings made according to protocol’ (5.7\%, n = 73). An example of other non-conformances associated with ‘bookings made according to protocol’ includes; the incorrect booking of appointments or not including electronic check lists and on treatment review appointments. All non-conformances are then detected before any effect on the patient’s pathway can occur. The booking process features 6 different pathway subcodes, these subcodes feature in 19.8\% (n = 255) of non-conformances for this reporting period. The most frequently reported non-conformances within this reporting period also each featured within the most frequently reported non-conformances for the previous reporting period\(^{(5)}\).

Figure 10. Breakdown of the most frequently occurring non-conformances (level 5) by process subcode reported, August to November 2019 (n = 532/1,288 subset of RTE)
Safety barriers and method of detection

A safety barrier (SB) is a critical control point, detection method or defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow\(^{14}\).

Several SB embedded in the pathway coding\(^{3}\) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). All subcodes were analysed across the 3,564 RTE reports for the reporting period August to November 2019, and a total of 1,173 subcodes were identified as failed (SB). Only 2.5% \((n = 29)\) of failed SB led to a Level 1 or 2 RTE. SBs associated with treatment unit processes were attributed to 37.8% \((n = 443)\) of all failed SB. The most frequently failed SB are represented in Figure 11. Treatment process ‘use of on-set imaging’ was the most frequently reported failed SB (13.5%, \(n = 159\)), this was also the most frequently reported failed SB from the previous 4-month analysis\(^{5}\). Most RTE 99.4% \((n = 158)\) associated with the failed SB ‘use of on-set imaging’ were minor radiation, near miss or other non-conformities with little or no impact on patient outcome.

Figure 11. Breakdown of failed safety barriers by classification level reported, August to November 2019 \((n = 655/1,173\) subset of RTE data)

Effective safety barriers or method of detection (MD) can now be identified also utilising the safety barrier taxonomy. For the reporting period August to November 2019, 44 providers indicated MD in 24.6% \((n = 878)\) reports. This is an increase from the previous 4-month reporting period where 40 providers indicated MD in 17.5% \((n = 540)\) reports. Issue 24 and 28 of Safer Radiotherapy\(^{4}\) includes guidance on the application of MD coding. Following consistency checking, PHE coded a further 338 reports with SB taxonomy, resulting in 1,216 reports containing effective SB taxonomy for the analysis. The most frequently reported effective safety barriers can be seen in
Figure 12. For this reporting period, the most frequently reported effective safety barrier was ‘on-set imaging: approval process’ (19.1%, n = 232), 83.6% (n = 194) of these were reportable, non-reportable and minor radiation incidents.

Figure 12. Breakdown of method of detection (effective safety barriers) by classification level reported, August to November 2019 (n = 818/1,216 subset of RTE data)

Causative factors

The use of a causative factor taxonomy enables identification of system problems or root causes that could precipitate a range of different incidents\(^{(15)}\).

The new causative factor (CF) taxonomy has been applied to 2,886 (81.0%) RTE reports by 47 (87.0%) providers for this reporting period. This is a similar to the last reporting period, when 45 (83.3%) of providers applied the CF taxonomy to 2,521 (81.6%) RTE\(^{(5)}\). Following consistency checking, PHE coded a further 677 reports with CF taxonomy, resulting in 3,563 RTE reports containing CF taxonomy for this analysis.

Figure 13 shows the most frequently occurring primary CFs which are the root cause of an incident. Consistent with the previous analysis, the most frequently occurring primary CF was individual ‘slips and lapses’ (45.0 %, n = 1,602), followed by ‘communication’ (15.4%, n = 547). ‘Slips and lapses’ was most frequently attributed to ‘on-set imaging: production process’ (12.5%, n = 200), and ‘communication’ was most frequently attributed to ‘documentation of instruction’ (12.6%, n = 69). Issue 22 of Safer Radiotherapy\(^{(4)}\) includes guidance on minimising the occurrence of RTE caused by a
slip or lapse of an individual. Most RTE (99.3%, n = 1,590) associated with CF ‘slips and lapses’ were minor radiation, near miss or other non-conformities with little or no impact on patient outcome.

**Figure 13. Breakdown of most frequent primary causative factors by classification level, August to November 2019 (n = 3,431/3,563 subset of data)**

Several CF codes can be attributed to each individual RTE. A review of the second to fifth CF codes indicate the contributory factors associated with an incident. Contributory factors were indicated across 844 reports; 108 of these contained multiple CF leading to 982 contributory factors. Figure 14 shows the most frequently occurring contributory factors. The most frequently occurring was ‘adherence to procedures/protocols’ (45.2%, n = 444).

**Figure 14. Breakdown of most frequent contributory factors, August to November 2019 (n = 904/982 subset of data)**
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Brachytherapy errors

Errors coded with brachytherapy process codes as the primary code account for 0.7% (n = 24) of radiotherapy errors for the reporting period August to November 2019 this is similar to the previous 4-monthly report\(^5\) (1.0%, n = 31). Brachytherapy is a specialised practice within radiotherapy, therefore the number of brachytherapy associated RTE would be expected to be low. Many of the brachytherapy errors reported were near misses or non-conformances (79.2%, n = 19) and only 16.7% (n = 4) were classified as minor radiation incidents; 4.1% (n = 1) incidents associated with brachytherapy were classified as reportable radiation (Figure 15).

The most frequently occurring subcode associated with brachytherapy incidents was ‘initial positioning of applicators/ sources’, comprising 16.7% (n = 4) of all brachytherapy incidents. An example of this type of RTE included the application of seeds in the incorrect position. This was followed by ‘management of variations’ and ‘use of on-set imaging’ each comprising 12.5% (n = 3). Issue 20 of Safer Radiotherapy\(^4\) includes further guidance on brachytherapy RTE.

Multiple pathway subcodes can be assigned to each RTE. A total of 40 subcodes were identified across the 24 brachytherapy RTE reports; only 16 subcodes were identified as failed SB. The most frequently failed SB was ‘management of variations/ unexpected events/ errors’, comprising 17.5% (n = 7) of all brachytherapy subcodes. Only 3 method of detection subcodes were assigned to 5 brachytherapy associated RTE; these were ‘end of process checks’ (n = 3), ‘management of variations and ‘planning of treatments’.

Figure 15. Breakdown of brachytherapy errors coded ‘15’ by classification level, August to November 2019 (n = 24)
The CF were reviewed within this dataset; all 31 brachytherapy RTE were attributed to 6 different CF as shown in Figure 16. The most frequently reported CF associated with brachytherapy RTE was ‘equipment or IT network failure’ (41.7%, n = 10), and this was spread across 7 different pathway subcodes.

**Figure 16. Breakdown of brachytherapy primary causative factors, August to November 2019 (n = 24)**
References