UK Health Security Agency

Safer radiotherapy

Biennial radiotherapy error data analysis and learning report

Report number 8: full radiotherapy error data analysis, January 2022 to December 2023

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Executive summary

Radiotherapy remains a safe practice whose working community is acutely aware of their responsibility in maintaining a safe, secure environment where patients receive the best care possible. This is evidenced in the tens of thousands of radiotherapy exposures undertaken accurately and safely every day. However, on occasion things do go wrong and it is important that we learn from these events.

The fundamental role of an incident learning system is to enhance patient safety by learning from failures of the healthcare system (1). The value of near miss and error reporting and learning processes is well appreciated in the UK radiotherapy (RT) community with 100% of NHS RT providers subscribing to a national voluntary system of reporting of RT error and near miss events. In 2023, data started to be submitted from the independent sector to the system.

This report is the eighth in a series of 2-year reports, providing an overview of Radiotherapy Error (RTE) data reported voluntarily to UKHSA between January 2022 and December 2023 (n = 22,113). The report compares data with that from the previous 2-year period between January 2020 and December 2021 (n = 18,681) and contains aggregate data from January 2019 to December 2023 (n = 50,587). Finally, this report includes data received from each of the UK inspectorates for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (2 to 4) (n = 406).

The analysis undertaken uses the taxonomies from ‘Towards Safer Radiotherapy’ (TSRT) (5) and the ‘Development of Learning from RTE’ (DoL) (6) thus allowing comparisons of national RTE trends with both local and network or regional findings.

Of the 22,113 RTE reports reviewed, analysis of the severity of the reports showed 97.5% (n = 21,569) were minor radiation incidents (Level 3), near misses (Level 4) or other non-conformances (Level 5) with little or no impact on patient outcome. Of the remaining reports, 0.9% (n = 194) did not reach the notification threshold whilst 1.6% (n = 350) were notifiable under IR(ME)R (2 to 4) to the inspectorates (Level 1). Of the Level 1 RTE reported, most involved planning or on-set verification imaging, with only 28.6% (n=100) affecting the delivery of radiotherapy, commonly for only one fraction of a course of treatment. This permits corrective action to be taken over the remaining treatment fractions.

Extrapolating data from the Radiotherapy Dataset (RTDS) (7), an estimated 3,861,707 RT attendances and 405,585 RT prescriptions were delivered in the UK in this reporting period. An estimated reported RTE rate of 5.7 per 1,000 attendances was calculated, up from 5 per 1,000 for the previous reporting period. This was calculated as 0.9 per 1,000 prescriptions for reportable radiation incidents (Level 1) up from 0.5 for the previous reporting period. Please note this is a measure of number of errors reported as opposed to occurrence of errors.

The volume of RTE reported increased by 18.4% compared to the previous 2-year period. Extrapolating data from the Radiotherapy Dataset (RTDS) (7), attendance and radiotherapy prescription numbers were estimated. Whilst the 11.5% increase in attendance (11.7% in prescriptions) between the 2-year periods can account for a proportion of the rise it does not account for the entirety. Furthermore, estimated reporting rates of 5.7 RTE per 1,000 attendances and 0.9 Level 1 RTE per 1,000 prescriptions for this reporting period represents notable increases from an estimated RTE rate of 5 per 1,000 attendances and 0.5 Level 1 RTE events per 1,000 prescriptions for the previous 2-year period. It is possible that providers commitment to patient safety is leading to a commensurate increase in reporting, a trend very much to be welcomed.

Another possibility is that changes in activity have impacted upon reporting levels. Providers may be experiencing staffing issues at a time when cancer incidence and referrals are rising (8, 9). This may lead to increasing work pressures for radiotherapy staff, making them more suspectable to burnout (10), increasing the likelihood of preventable incidents (11). Certainly, the causes are multifactorial and, ultimately, challenging to ascribe proper relevance to with any great certainty.

The proportion of Level 1 reports of all received RTE has increased. A notable trend within Level 1 RTE is the increase in proportion of ‘patient positioning’ from 3.6% in the previous 2-year period to 10.9% for the current 2-year period. It is the second most frequently reported Level 1 RTE behind ‘on-set imaging: production process’ which comprised 22.0% of all Level 1 reports, a similar proportion (21.2%) to the previous 2-year period.

‘On-set imaging: production process’ was also the most frequently reported Level 3 RTE and the second most common Level 2 RTE pathway code behind ‘on-set imaging: approval process’. The suite of four on-set imaging pathway codes combined made up 22.7% of all RTE.

The reported trends in Level 5 data differs from Level 1-4 RTE reports. The most frequently occurring Level 5 subcode was ‘bookings made according to protocol’ at 6.4% (n = 475).

Over the past 5 years there has been a statistically significant increase in the percentage of RTE associated with ‘management of variations/unexpected events/errors’ across levels. The majority of which were associated with ‘equipment or IT network failure’.

Changes in trends over time demonstrate the importance of ongoing cyclic monitoring of RTE. RT is ever evolving with new techniques and technology; therefore, these trends should continue to be reported and learnt from. The move to increased hypo-fractionation of external beam RT will reduce the opportunities to correct for RTE. The role of incident learning systems will continue to play a part in helping identify and address RTE.

Reporting of RTE is only effective if there is a willingness to learn from errors and to alter practice accordingly. Employers should share the outcomes of analyses with all relevant staff and apply lessons learnt to mitigate these events in future. Staff are more likely to report RTE

where there is an open, just reporting culture and where the clear aim of reporting is to learn and to improve patient safety (12, 13).

Participation in the national voluntary incident learning system (1, 12) is indicative of an open and transparent safety culture. As providers continue to contribute to a mature and growing national RTE dataset this allows robust local and regional comparison of events to the national picture and strengthens provider safety programmes. Further increases in voluntary reporting numbers are to be welcomed and must be unequivocally supported by employers.

Local provider recommendations:

1. All NHS UK providers should continue to use the national taxonomies, including classification, pathway subcodes, failed safety barriers, method of detection and contributory factors, to code all levels of RTE for local analysis, learning and practice.
2. Local employers should provide adequate resourcing to support the development and maintenance of effective patient safety systems and processes. Likewise, they should encourage national reporting of all classification Levels of RTE on a monthly basis to ensure timeliness of shared learning.
3. Equipment-related incidents should be reported to the relevant regulator, manufacturer and UKHSA. If equipment faults persist a risk assessment should be undertaken for the ongoing use of the device.
4. Local learning should be compared with national data and used to inform local and regional practice.
5. Outputs from local RTE analysis should be used to inform prospective risk assessments as part of a study of the risk of accidental and unintended exposures.

National recommendations:

1. Learning from RTE should be used by the Patient Safety in Radiotherapy Steering Group (PSRT) and individual RT providers as part of a risk-based approach to allocating resources for improving patient safety in RT and to inform audit and research.
2. PSRT should engage the relevant agencies and vendors in developments to monitor and reduce the rate of RTE related to imaging equipment failure.
3. Following the review of safety barrier data analysis, the PSRT will provide updated guidance and refine future safer RT publications. Future trend analysis will not be limited to failed safety barriers but consider the multiple pathway codes detailed within RTE reports to reflect the multifaceted nature of a full systems analysis.
4. The taxonomies used for the coding of RTE were last updated in 2017, these should be reviewed by the PSRT to ensure they continue to reflect contemporary practice in RT.
5. Providers utilising molecular radiotherapy (MRT) or diagnostic MRI facilities are encouraged to use the National taxonomy for incident learning in clinical imaging, magnetic resonance imaging and nuclear medicine guidance. A mechanism to report these incidents nationally to UKHSA will become available later this year.

6. Working with stakeholders the PSRT will develop guidance for UK RT providers to support the advancement of safer RT through the adoption of contemporary thinking in the field.

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Introduction

Radiotherapy is an effective treatment for cancer and some other diseases. It is also a highly complex tool, involving many highly skilled professional groups, constantly evolving and driven by innovative technological and radiobiological advances.

Within this dynamic environment, patient safety, defined as the avoidance of excessive morbidity or sub-optimal tumour control (1), can never be assumed given the potential consequences of failure. Many elements contribute to safe working practice and a strong safety culture is a prerequisite. It is essential in ensuring that the risk of error occurrence and magnitude are minimised. A positive safety culture in radiotherapy is a culture in which risks are considered, evaluated, and minimised. Providers must be proactive and learn from when things have gone right to achieve better practice. To that end, delivering the safest treatment possible to patients require providers to engage in a continual process of review and refinement of existing clinical workflows. As new technologies and techniques are introduced, providers must ensure procedures and processes are in place to monitor safe practice through evaluation and learning.

Incident learning systems are a widely accepted safety tool, advocated for by professional groups, bodies, agencies, and regulators in radiotherapy (2). Analysis of incidents allow organisations to identify weaknesses in operational systems and inform the direction of future refinements and improvements. Evidence of correlation between initiation of local incident learning systems and subsequent reduction in serious incidents has been reported by many groups (3-7) indicating their efficacy.

For incident systems to be effective and ultimately, improve patient outcomes, organisations must monitor safety events by promoting and nurturing a strong reporting culture. Organisations with robust reporting cultures have demonstrated raised staff safety awareness and better work practices and improved patient experience (8). When local incident learning systems contribute to national systems, emerging trends that might not be immediately apparent within individual provider data can be identified early. Providing trend analysis at a national level enables providers to compare local analysis of incidents against a national benchmark and allows more confidence in setting realistic aims when working to develop patient safety initiatives.

This report details analysis and learning from radiotherapy errors, reported over a 2-year period, submitted to the UK national reporting and learning system within the UK Health Security Agency (UKHSA). Radiotherapy errors (RTE) are characterised as unintended divergences between radiotherapy treatment delivered, or process followed, and that defined as correct by local protocol, near misses; where the anomaly is detected prior to the delivery of radiation, and other non-conformance; a non-compliance with some other aspect of a documented procedure but not directly affecting radiotherapy delivery are reported and collated within such systems (9).

Background

In the context of this report, radiotherapy (RT) is defined as the use of high energy ionising radiation in the treatment of disease. Many RT approaches exist and are included in the data analysis of this report. They include external beam, superficial, orthovoltage, brachytherapy, and some molecular radiotherapy.

This report is the eighth in a series of 2-year reports, providing an overview and analysis of anonymised RTE data reported voluntarily between January 2022 and December 2023. The report also contains trend analysis for RTE data extending from January 2019 to December 2023. This analysis has been undertaken by the UKHSA on RTE reported by NHS and independent RT providers, and the relevant enforcing authorities for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (10 to 12). The analysis has been reviewed by the Patient Safety in Radiotherapy Steering Group (PSRT).

The purpose of the PSRT is to lead a collaborative programme of work improving patient safety in RT and is composed of representatives from the Institute of Physics and Engineering in Medicine (IPEM), Royal College of Radiologists (RCR), Society of Radiographers (SoR), a lay representative, and UKHSA. The group provides a forum for discussion, review and progression of current matters associated with the safety of patients within radiotherapy. The PSRT recommends employing the analysis contained within this report, and of UKHSA triannually published analyses (13), to facilitate local learning and comparison of locally identified trends against the national picture.

Obtaining the data

UKHSA has a data sharing agreement with NHS England and under this agreement RTE data is extracted and shared with UKHSA for analysis. Over the past 2-year period data was obtained from either the National Reporting and Learning System (NRLS) or Learn from Patient Safety Events (LFPSE) patient safety reporting platforms in England. English NHS providers are currently transitioning from NRLS to LFPSE, and it is anticipated that LFPSE will replace NRLS entirely during 2024.

Welsh NHS providers transitioned from NRLS to the Once for Wales Concerns Management System (OfWCMS), NHS Wales Shared Services Partnership: Welsh Risk Pool in 2022. Since then, OfWCMS has shared RTE data for analysis. RTE data is shared directly by providers in Northern Ireland, Scotland and from the independent sector.

In addition, anonymised synopses of closed reportable radiation incidents are shared by the UK IR(ME)R (10 to 12) enforcing authorities with UKHSA for inclusion in the analysis. The relevant enforcing authorities will be referred to as inspectorates here after.

Data

The data presented in this report is anonymised and received as part of a voluntary reporting scheme. As with any voluntary reporting system, the data only reflects those incidents reported and may not necessarily be representative of the actual levels of occurrence, and as such, this data requires interpreting with care.

Data for the reporting period January 2022 to December 2023 forms the focus for the analysis. Where possible, comparisons are drawn against the previous 2-year reporting period and data for annual reporting periods going back over 5 years.

Inspectorate data

RT providers are required to notify the IR(ME)R inspectorates of significant accidental or unintended exposures (SAUE) or 'reportable radiation incidents' (Level 1) as defined in *Towards Safer Radiotherapy (TSRT)* (9). The UK inspectorates for IR(ME)R: Care Quality Commission, Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority, shared anonymised closed synopses of reported SAUE for analysis. This data is analysed separately from the voluntary data to reduce replication of Level 1 reports within the data. As IR(ME)R applies to both NHS and independent RT providers, this data covers both sectors.

Data quality

All providers are asked to apply the full coding taxonomy to each RTE report including; trigger code (TSRT9), classification level, pathway coding (including failed safety barriers (FSB)), method of detection (MD) and contributory factors (CF) to facilitate both local and national analysis.

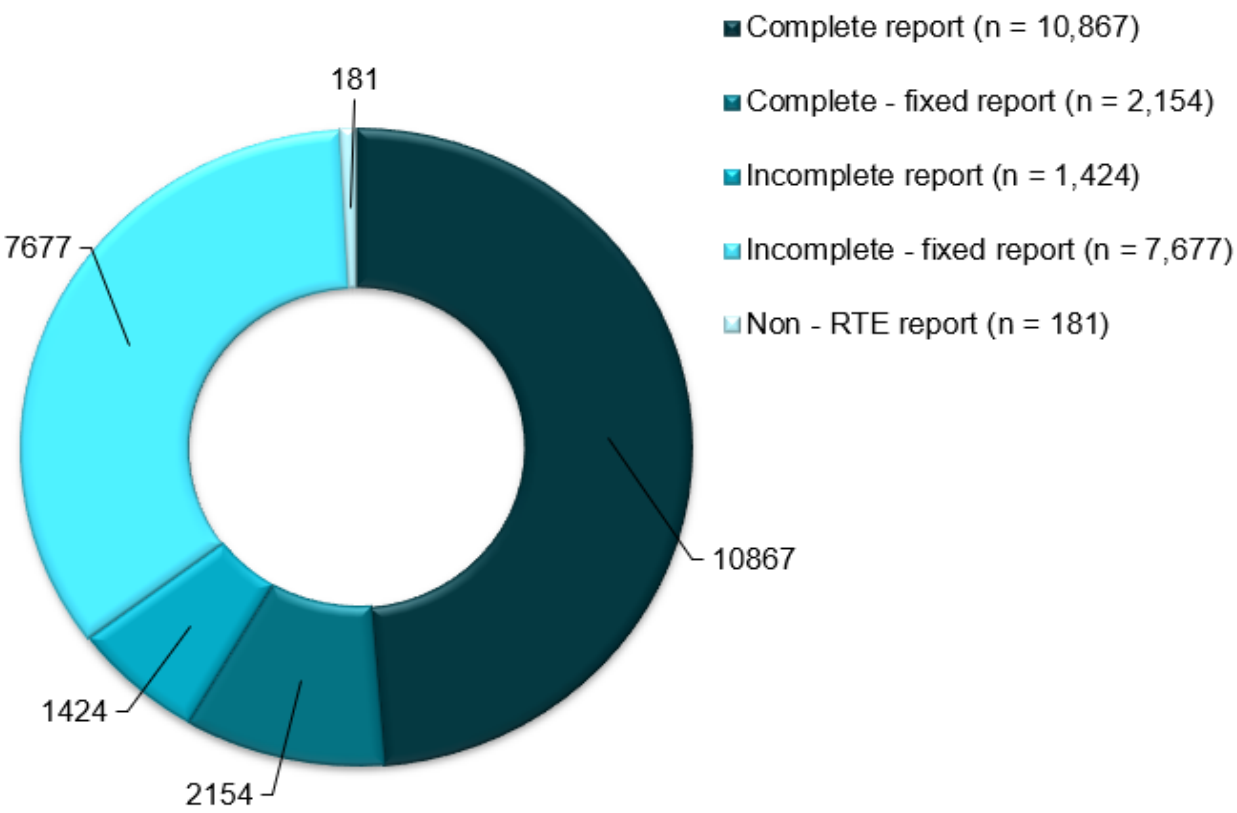
The format of coding for submission is TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c. This should be included in the opening section of the first open text field of the local incident learning system where possible.

On receipt of the reports, UKHSA staff with clinical RT expertise performed consistency checking of local coding application. The coding was reviewed for all RTE classified as reportable through to near miss (Levels 1 to 4) whilst 10% of non-conformances (Level 5) were audited. This formed part of the data quality assurance process completed prior to analysis of the reports.

Reports were categorised into complete, incomplete, or non-RTE:

- complete reports contain the classification level, pathway coding, method of detection and contributory factors
- complete fixed reports are defined as complete reports which have had one or more of the RTE taxonomies amended for consistency reasons
- incomplete reports are reports submitted without the full classification and coding applied and without the requisite text to assign full coding
- incomplete fixed reports are reports which had sufficient text descriptors to assign the classification and/or pathway coding
- non-RTE reports are reports which are considered not RTE as defined in *TSRT* (9)

Figure 1. Breakdown of report completeness (n = 22,303)



During this review period 22,303 incident reports were received, reflecting a 18.8% increase in the total volume of reports compared to the previous 2-year period (n = 18,772). Of the 22,303 RTE reports received, 58.4% (n = 13,021) were classified and coded by local RT providers (Figure 1). This is a marked reduction in proportion from the previous 2-year period (79.6%, n = 14,940).

Of those reports in this review period 16.5% (n = 2,154) were amended (complete fixed), an increase from 15.3% in previous 2-year period. Of the complete fixed reports, 19.1% (n = 411) had the classification amended, 59.2% (n = 1,275) the pathway subcode (see Table 1), 6.6% (n = 143) the contributory factor and 59.3% (n = 1,277) had the method of detection amended.

The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (57.4%, n = 236 out of 411), where an additional verification image was required, and these reports had been classified as Level 4 or 5 instead of Level 3.

The most frequently amended primary pathway subcodes can be seen in Table 1. ‘Use of on-set imaging’ made up 11.1% (n = 239) of all amended codes. Based on the information shared in the free text description field, this was most frequently amended to ‘on-set imaging: production process’. A total of 56.9% (n = 726) of all amended primary pathway subcodes were originally assigned one of the ‘other’ pathway subcodes.

Table 1. Amendments made to pathway process subcodes

Initial pathway subcode	Most frequently amended to
13i ‘use of on-set imaging’ (11.1%, n = 239)	13z ‘on-set imaging: production process’ (46.4%, n = 111)
13jj treatment unit process ‘other’ (10.2%, n = 220)	13cc ‘management of variations/unexpected events/errors’ (33.2%, n = 73)
13z ‘on-set imaging: production process’ (3.8%, n = 82)	13cc ‘management of variations/unexpected events/errors’ (28%, n = 23)
10n pretreatment activities ‘other’ (3.6%, n = 78)	10f ‘production of images demonstrating correct detail’ (17.9%, n = 14)
11v pretreatment planning process ‘other’ (3.4%, n = 73)	11j ‘generation of plan for approval’ (54.8%, n = 40)

A total of 143 (6.6% of the 2,154 complete fixed RTE) were amended. Of these 51.0% (n = 73) were amended from CF7a ‘other’ to an alternate contributory factor code.

The treatment unit process ‘other’ code was the most frequently amended method of detection code (43.1%, n = 434). It was most commonly replaced by treatment unit process code ‘end of process checks’ (24.7%, n = 107).

The analysis excluded 181 non-RTE reports (0.8%). These were largely slips, trips or falls that occurred within the RT setting. There were 1,424 incomplete reports received from 54 different providers. A further 9 reports failed to provide any RTE taxonomy and contained insufficient information for UKHSA to assign coding and therefore also were excluded from the analysis. These deductions left a total of 99.1% (n = 22,113) RTE reports included in the analysis.

Lag time for reporting

A lag time between the date of the RTE and the date on which it was reported to the national voluntary reporting systems or directly with UKHSA was calculated for each report included in the dataset. This measures the time from date of RTE discovery to date shared with the national system. A minimum reporting lag of 0 days and a maximum 3,017 days was found for individual RTE. There was an average lag time of 49 days and a mode of 0 days across providers.

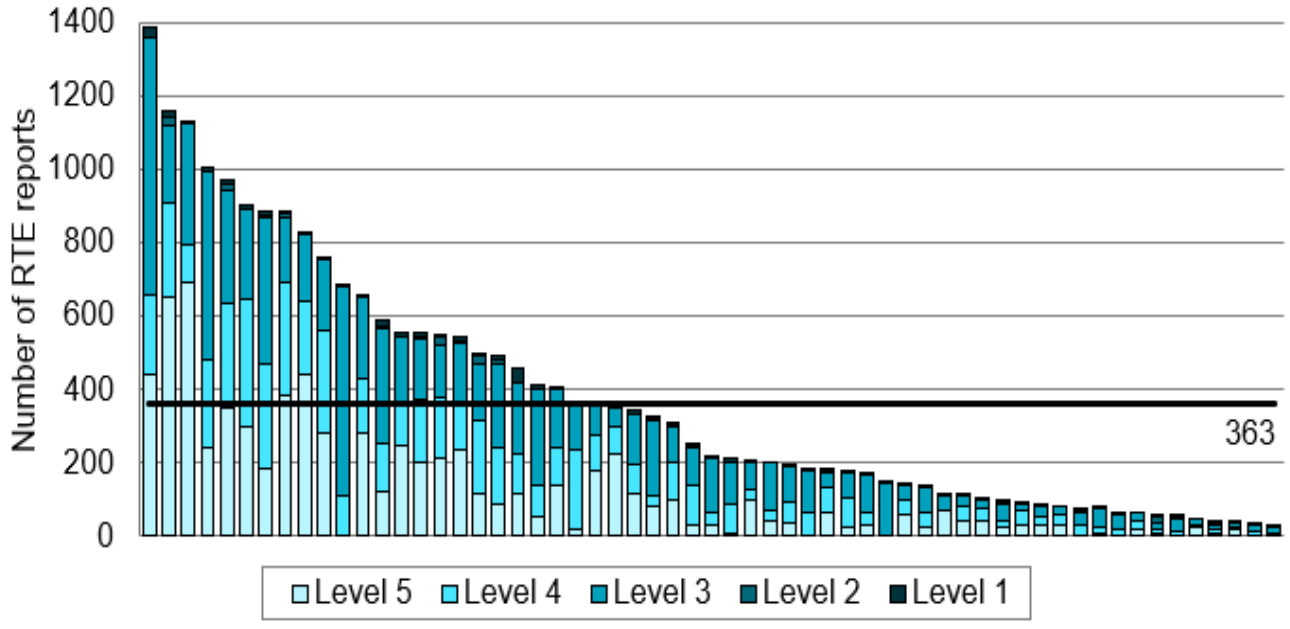
A total of 166 reports were received with a lag time of over 365 days. There were several reasons noted to explain the extended lag time. These included the RTE being detected during audit, at re-treat appointment, or initial report lost leading to a delay in submission to local incident learning system. A number of these reports did not include an explanation within the text descriptor for the large lag time. Of the reports received 5 did not include incident date and were not included within the average lag time.

The average lag time of 49 days for submitting reports has increased from 31 days in the previous 2-year report. However, the mode has decreased from 21 days to 0 days. This may be in part due to the transition English organisations have been undergoing between national NHS reporting platforms.

Number of reports per provider

For this 2-year period, reports were received from all NHS RT providers (n=59). In addition, reports were received from the independent sector. Some 80 anonymised reports received did not indicate the RT provider, these have been included in Figure 2 as a single provider. Overall, this makes a total of 61 reporting providers.

Figure 2. Number of RTE reported by provider (n = 22,113)



There is some variance in the number of reports submitted by providers as seen in Figure 2. The number per provider ranged from 7 to 1,390. The average number of RTE reported by providers increased by 14.9% from 316 per provider during the previous 2-year period to 363 for the current period. Of note 62.3% (n = 38) of providers reported less than the average of 363 RTE over the 2-year period.

Results

A total of 22,113 RTE reports were submitted to the voluntary reporting scheme between January 2022 and December 2023, with an average 921 reports received per month. This reflects a slight increase in comparison to the previous 2-year period, whereby 18,681 RTE reports were received, with a monthly average of 778 reports. The 22,113 RTE reports were categorised so main themes could be derived. The data analysis has been presented using graphs, bar charts and pie charts to facilitate local replication of the analysis using local data to enable data comparison.

With any voluntary incident learning system, it is appropriate to acknowledge that there will be some variance in reporting levels across providers. Figures presented in the report only reflect those RTE submitted to the national system as opposed to the actual occurrence of RTE. The data also does not consider the size and capacity of individual providers and the complexity of services they deliver; hence, it should be interpreted with care.

Between January 2019 and December 2023, UK NHS RT providers submitted 50,587 RTE to the national incident learning system. The annual breakdown of the number of reports submitted for last 5-year period can be seen in Table 2.

Table 2. Number of RTE reports submitted to the incident learning system by year

Year	2019	2020	2021	2022	2023
Number of reports	9,793	9,137	9,544	11,471	10,642

A z-test statistic has been used in some parts of the analysis to compare 2 proportions (or rates) to see if they are the same. A linear regression analysis has been performed to estimate the slope for RTE classifications using yearly data and a t-test to determine whether the slope of the fitted trend model is significantly different from zero. For both tests $p<0.05$ is considered statistically significant. All the statistical tests and regression analyses were carried out using Microsoft® Office Excel.

Breakdown of process codes

The dataset was categorised by process code according to established *Development of Learning* (14) and *TSRT* (9) methodology so the main themes could be derived.
RTE reports were spread across all 21 categories of process code and level.

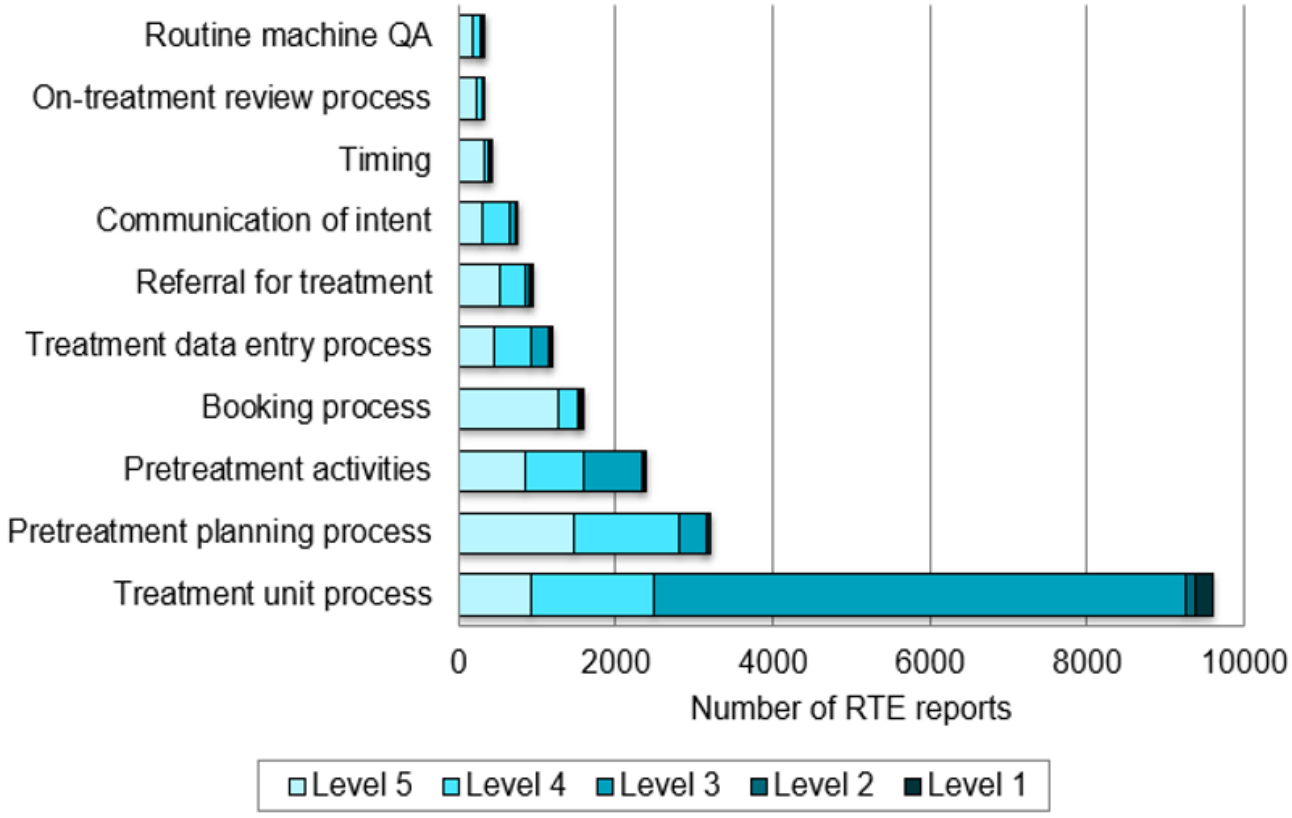
The most frequently reported RTE process code was ‘treatment unit process’ (43.5%, n = 9,614), and the proportion of reports comprised of this code remained the same as the previous 2-year report (43.5%, n = 8,134). The ‘treatment unit process’ represents the last opportunity to identify errors prior to delivery. Accurate treatment relies on the correct interpretation of the treatment plan and set-up details and these need to be replicated during each treatment. Due to

the fractionated nature of radiotherapy this presents more frequent opportunities for errors to occur compared to other steps in the pathway which may attribute to its high proportion of RTE reports.

'Treatment unit process' process code reports were made up of 'minor radiation incidents' (Level 3) at 70.6% (n = 6,789), 'near misses' (Level 4) at 16.3% (n = 1,567) and 'other non-conformance' (Level 5) at 9.5% (n = 914). The remaining 3.6% (n = 344) of 'treatment unit processes' process code reports comprised of Level 2 'non-reportable radiation incidents' (n = 110) and Level 1 'reportable radiation incidents' (n = 234).

The second most frequently reported RTE process code was 'pretreatment planning process' which comprised 14.4% (n = 3,193) (Figure 3). The proportion of reports comprised of this code have decreased in comparison to the previous 2-year report (15.2%, n = 2,844).

Figure 3. Breakdown of RTE process code by Level (n = 20,619 out of 22,113 subset of RTE)

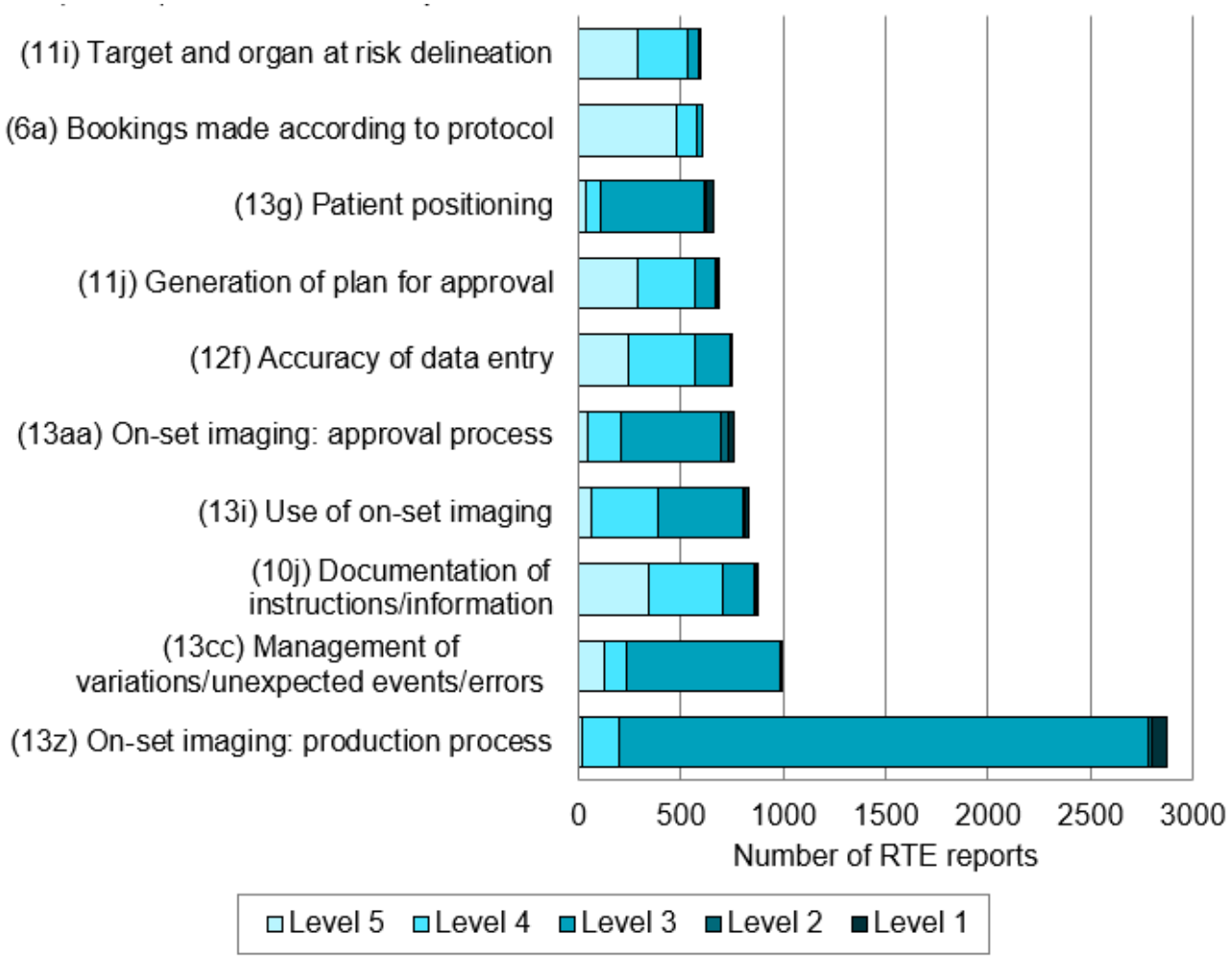


Breakdown of process subcodes

The most frequently reported process subcodes are presented in Figure 4 and broken down by Level. The most frequently reported RTE was 'on-set imaging: production process' at 13.0% (n = 2,875). Of this subset, 90.0% (n = 2,587) were classified as minor radiation incidents (Level 3). The second most frequently reported RTE was 'management of variations/unexpected events/errors' at 4.5% (n = 998). Of these 75.6% (n = 754) were classified as Level 3, whilst 71.8% (n = 717) were attributed to 'equipment or IT network failure' as a contributory factor.

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 made up 22.6% (n = 5,006) of all RTE reported.

Figure 4. Breakdown of most frequently reported RTE process subcodes by Level (n = 9,629 out of 22,113 subset of RTE)

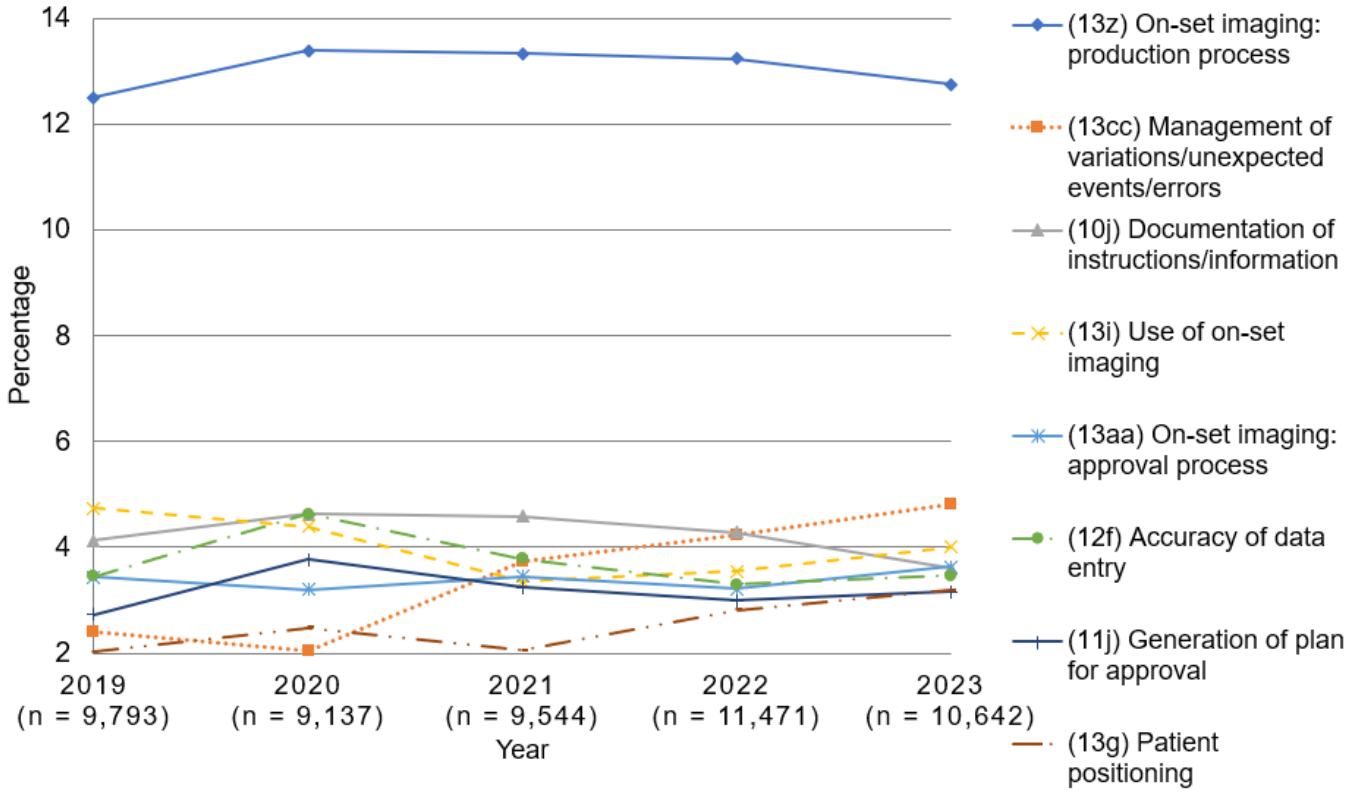


The 8 most frequently reported process subcodes were reviewed across the preceding 5-year period as shown in Figure 5. The subcode ‘on-set imaging: production process’ has shown a slight drop of 0.6% in its overall reporting proportion from 2020 to 2023 (13.4% to 12.8%) but remains higher than its 2019 percentage (12.4%). The overall trend for this subcode was not statistically significant (p = 0.84).

Pathway subcodes ‘management of variations/unexpected events/errors’ and ‘patient positioning’ both increased their percentage proportion of RTE reporting. ‘Management of variations/unexpected events/errors’ proportion has risen since 2020 from 2% to 4.8% in 2023 and the overall trend was statistically significant (p = 0.02). ‘Patient positioning’ has increased from 2.1% in 2021 to 3.2% in 2023. In contrast ‘Documentation of instructions/information’ dropped from 4.6% in 2020 and 2021 to 3.6% in 2023. In both circumstances the overall trend was not statistically significant (p = 0.07 and p = 0.40 respectively).

A separate UKHSA publication, ‘Safer Radiotherapy: the unseen pathway’, highlighted an increase in RTE associated with the ‘management of variations/unexpected events/errors’ since 2009 (15). Other frequently reported pathway subcodes in Figure 5 appear broadly consistent in reporting frequency and therefore fail to demonstrate any statistically significant trends.

Figure 5. Trends of most frequently reported RTE by process subcodes (January 2019 to December 2023)



Classification (Level) of RTE

Each of the 22,113 RTE reports were 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). A breakdown of these can be seen in Figure 6. Of the RTE reports, 97.5% (n = 21,569) were minor radiation, near miss or other non-conformances with little or no impact on patient outcome. Of the remaining 2.5% (n = 544) reports, 1.6% (n = 350) were reportable under IR(ME)R (10 to 12) to the inspectorates.

Figure 6. Classification (Level) of RTE reports (n = 22,113)

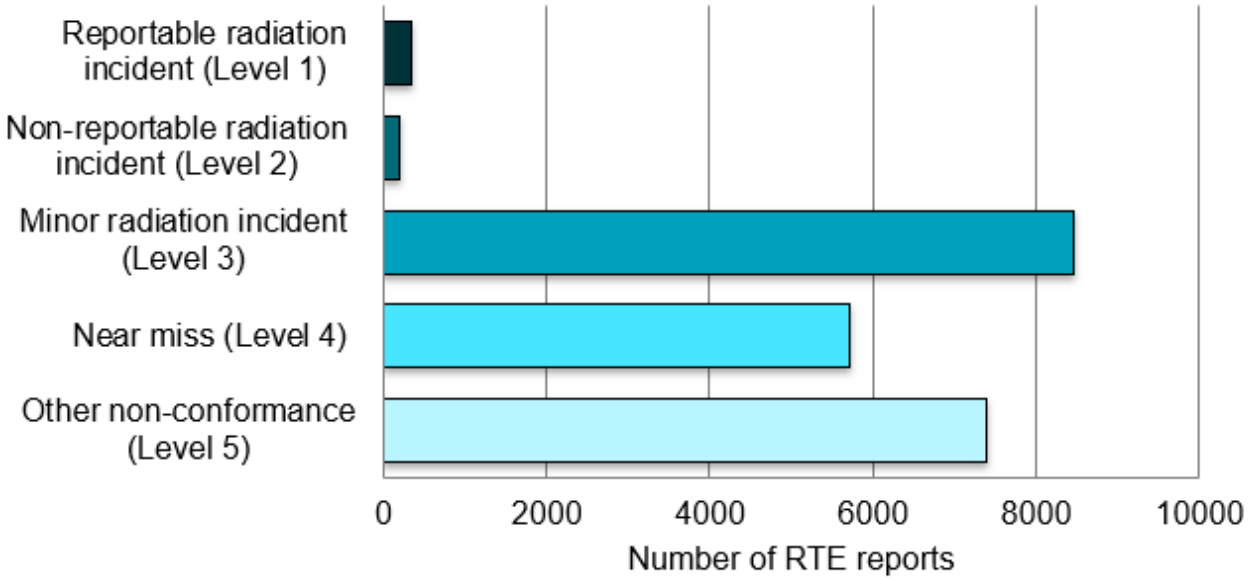


Table 3 shows trends across the different classifications for the current 2-year period, the previous 2-year reporting period and the 5 year period. Reportable radiation incidents comprised 1.6% of all RTE from January 2022 to December 2023 (n = 350), which is a marked increase from the previous 2, and 5 year periods.

Table 3 Classification (Level) as a percentage of RTE reports

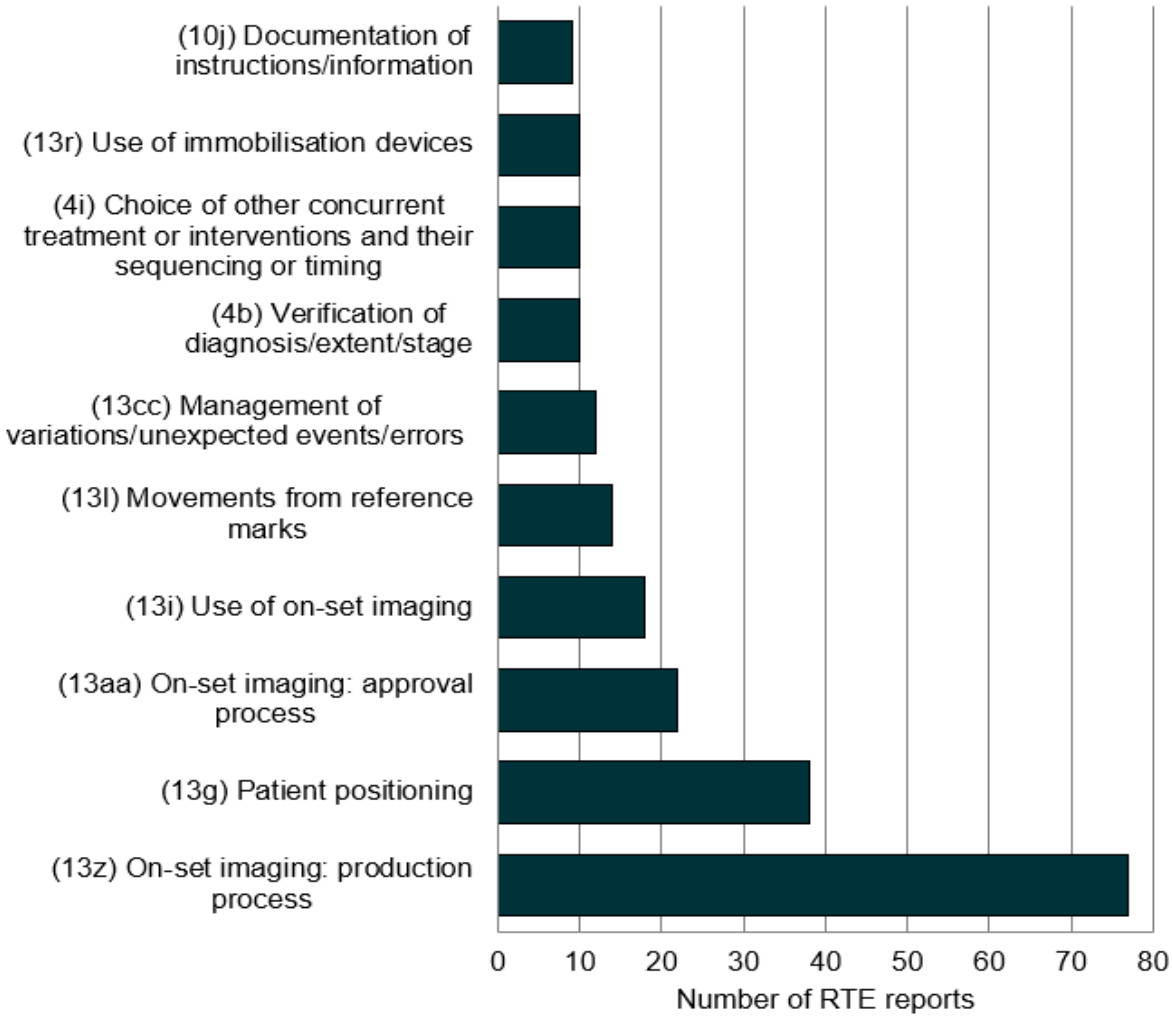
Classification	January 2017 to December 2021	January 2020 to December 2021	January 2022 to December 2023
Other non-conformance (Level 5)	37.9	36.7	33.4
Near miss (Level 4)	24.4	25.6	25.9
Minor radiation incident (Level 3)	35.9	36.2	38.3
Non-reportable radiation incident (Level 2)	0.9	0.7	0.9
Reportable radiation incident (Level 1)	0.9	0.9	1.6

Reportable radiation incident (Level 1) RTE

Reportable radiation incidents, as defined in *TSRT* (9), fall into the category of reportable under IR(ME)R (10 to 12). These incidents will generally be significant, although they may be correctable within the course of treatment. Of the Level 1 RTE reported, most of them involved planning or on-set verification imaging, with only 28.6% (n=100) affecting the delivery of radiotherapy, commonly for only one fraction of a course of treatment. This meant that corrective action could be taken over the remaining treatment fractions.

There were 66 different subcodes associated with the 350 Level 1 RTE (Figure 7), an increase of 40.4% compared to the previous 2-year reporting period, where 47 different process subcodes were reported. 56 of the 61 providers submitted Level 1 data for analysis.

Figure 7. Breakdown of most frequently reported Level 1 RTE by process subcode (n = 220 out of 350 subset of RTE)

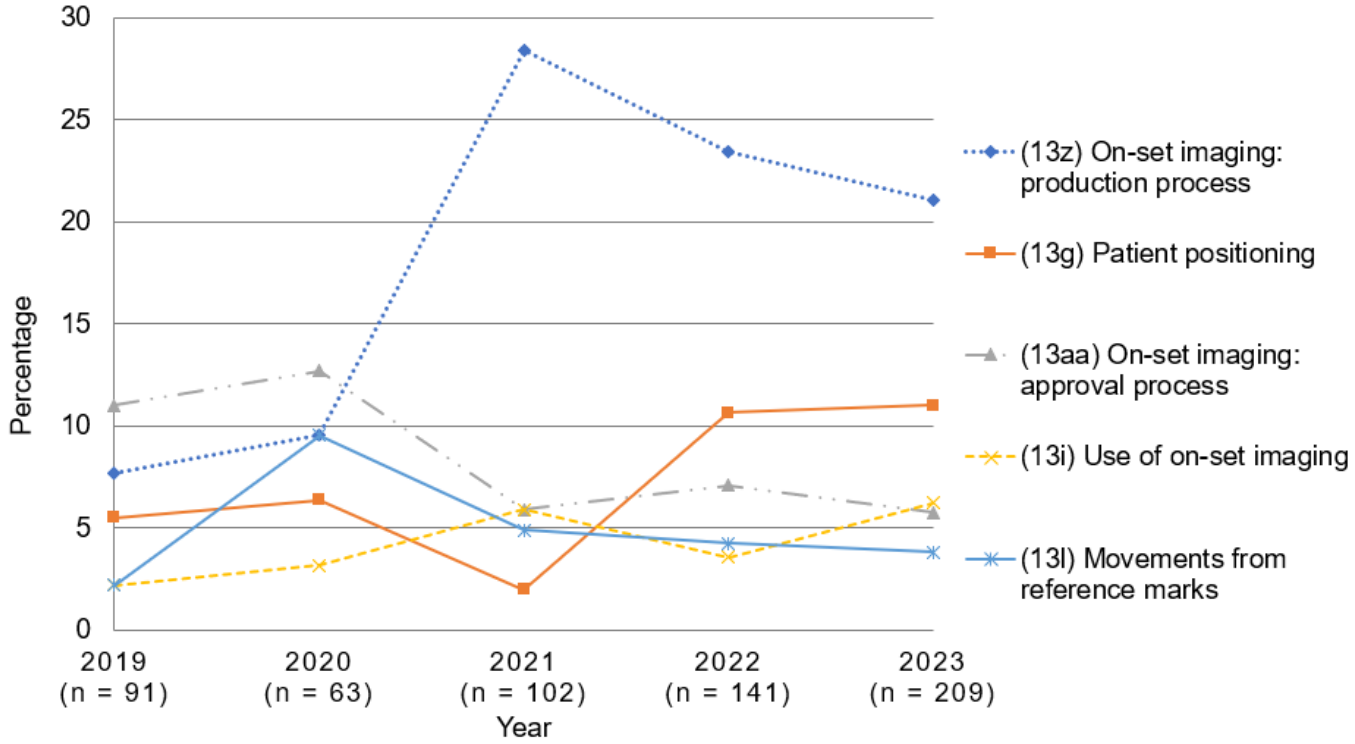


The most frequently reported subcode was ‘on-set imaging: production process’ comprising 22.0% (n = 77) of all Level 1 reports. The most commonly attributed contributory factor for this subcode was ‘equipment or IT network failure’ (54.5%, n = 42). An example of this type of RTE is when a verification CBCT is initiated and part way through the arc the machine malfunctions, therefore additional verification images are required. The second most commonly attributed contributory factor for the subcode ‘on-set imaging: production process’ was ‘slips and lapses’ (14.2%, n = 11). An example of this type of reportable RTE includes repeat verification cone beam computed tomography (CBCT) taken due to procedural failures such as incorrect positioning of the imaging panel or use of an incorrect filter, resulting in the need for repeat exposures.

The second most frequently reported Level 1 RTE was associated with ‘patient positioning’ at 10.9% (n = 38). The most common contributory factor was ‘slips and lapses’ (42%, n = 16) and examples of this type of RTE include where mobile anatomy, such as a limb, was incorrectly positioned during set up causing it to be unnecessarily irradiated.

Figure 8 shows changes in reported RTE as a proportion by year across the 5-year period from 2019 to 2023. After reaching a peak in 2021 (28.4%), 'on-set imaging: production process’ has reduced as a percentage to 21.1% in 2023. By contrast, ‘patient positioning’ has increased its proportion from 5.5% in 2019 to 11% in 2023. However, in both situations the overall trend was not statistically significant (p = 0.18 and p = 0.25 respectively).

Figure 8. Trends for most frequently reported Level 1 RTE by process subcode (January 2019 to December 2023)



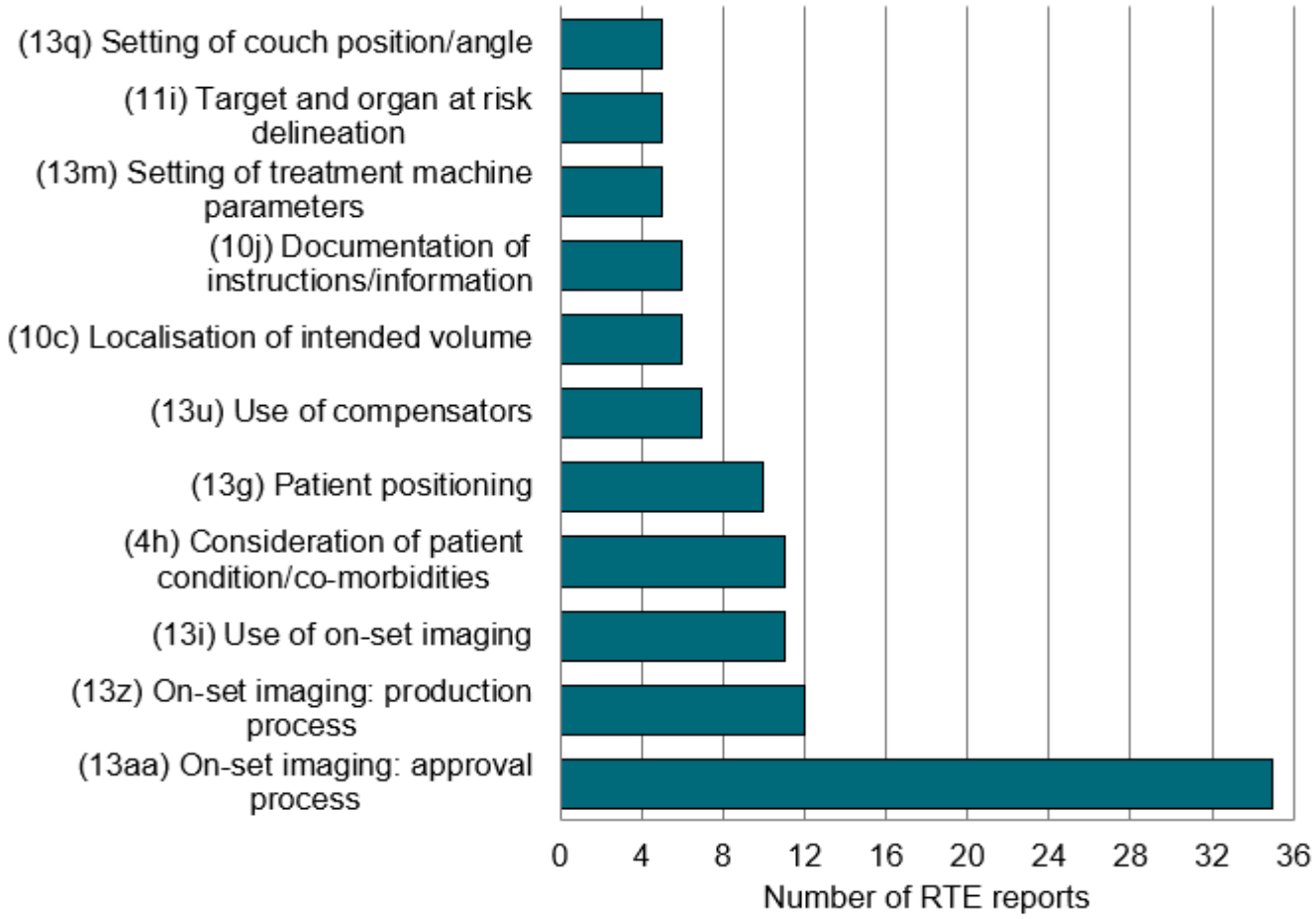
Other changes noted are an overall reduction in proportion of ‘on-set imaging: approval process’ from 11.0% in 2019 to 5.7% in 2023 and an increase in proportion of ‘use of on-set imaging’ from 2.2% in 2019 to 6.2% in 2023. Again, no evidence of a trend was observed in either process (p = 0.10 and p = 0.14 respectively).

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 (9).

There were 47 different subcodes associated with Level 2 reports. The most frequently reported Level 2 RTE can be seen in Figure 9. These were reported by 39 of the 61 providers that submitted data for analysis.

Figure 9. Breakdown of most frequently reported Level 2 RTE by process subcode (n = 113 out of 194 subset of RTE)

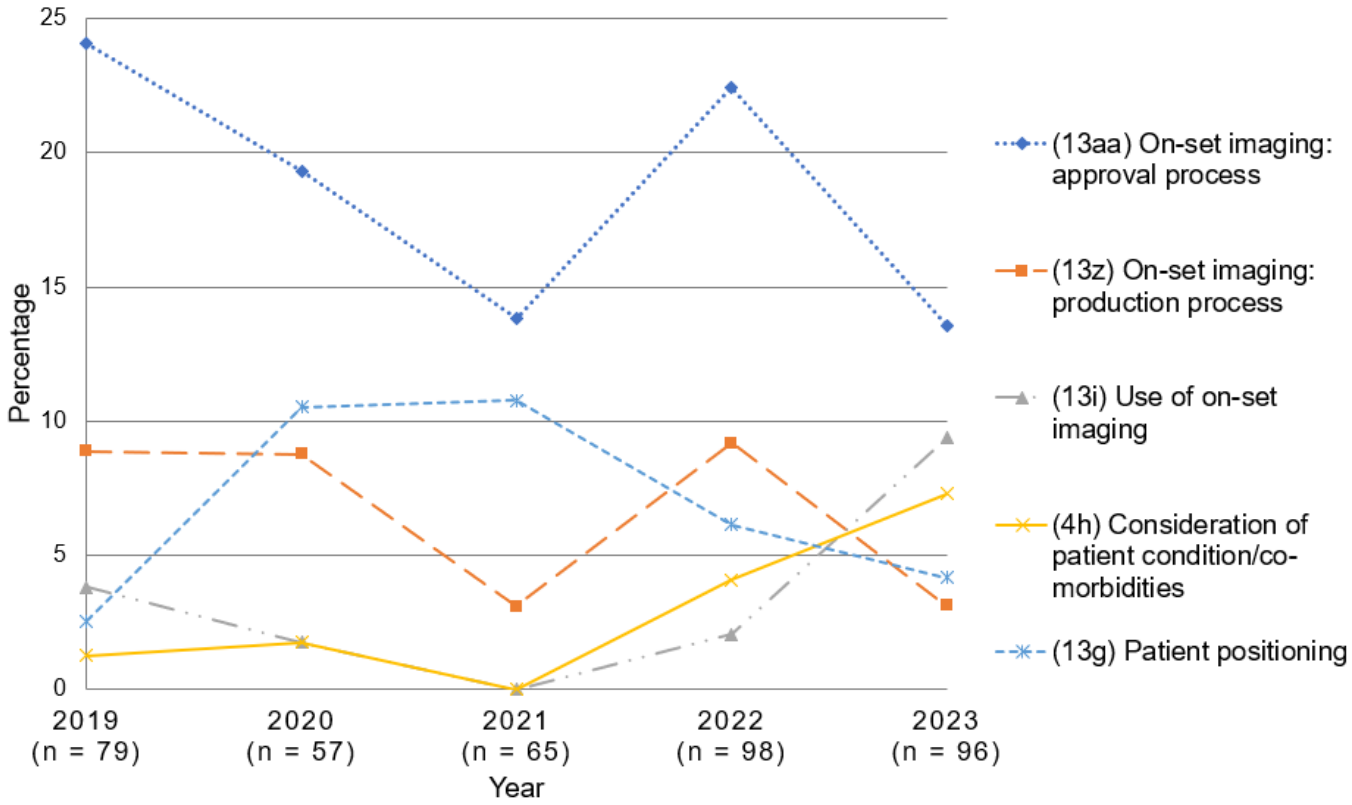


The most frequently reported Level 2 reports were associated with ‘on-set imaging: approval process’ at 18.0% (n = 35) of all Level 2 RTE. An example of RTE associated with ‘on-set imaging: approval process’ includes the mismatch of reference and verification imaging, subsequently treated, but did not lead to a total or partial geographical miss.

This was followed by ‘on-set imaging: production process’ with 6.2% (n = 12) of submitted Level 2 reports. An example of this type of RTE includes an incorrect cone beam filter selected for use over a number of fractions and the subsequent dosimetric evaluation considers it of potential clinical significance but not reportable.

Figure 10 identifies trends by year across the preceding 5-year period. For the Level 2 RTE related to ‘on-set imaging: approval process’ the highest rate was observed in 2019 (24.1%) and has varied over the 5-year period, with the lowest proportion in 2023 (13.5%) although the overall decreasing trend was not statistically significant (p = 0.30).

Figure 10. Trends for most frequently reported Level 2 RTE by process subcode (January 2019 to December 2023)



'Patient positioning' associated reports increased between 2019 to 2020, remained stable in 2021 but has subsequently reduced in 2022 and 2023. 'Use of onset imaging' and 'consideration of patient condition/comorbidities' pathway codes have both increased in proportion (9.4%, n = 9 and 7.3%, n = 7, in 2023 respectively) since 2021 when, notably, neither had any reports submitted. Trends for these process subcodes was not statistically significant (p = 0.94, p = 0.39 and p = 0.11 respectively). The Level 2 classification receives the smallest proportion of reports for any classification and due to the small sample size considerable year to year variations are seen for some pathway codes.

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 (9).

There were 142 different subcodes associated with Level 3 reports. The most frequently reported RTE in this sub-group can be seen in Figure 11. These were reported by 60 of 61 providers that submitted data for analysis. Of note, all the most frequently reported Level 3 RTE occurred during the treatment unit process.

'On-set imaging: production process' made up 30.6% (n = 2,587) of all Level 3 RTE. An example of this type of RTE included repeated verification imaging due to incorrect field size or

equipment malfunction during image acquisition. As illustrated in Figure 11, 55.9% (n = 1,446) of these errors were attributed to equipment or IT failure during image acquisition.

This was followed by 'management of variations/unexpected events/errors', accounting for 12.5% (n = 754). The contributory factor 'equipment or IT network failure' was associated with 83.3% (n = 628) of reports with this process subcode. An example is when a patient is imaged and VMAT treatment initiated, however a machine fault occurs midway through an arc, so the patient is taken to a different treatment unit, receiving a further imaging exposure and remaining treatment delivered.

Figure 11. Breakdown of most frequently reported Level 3 RTE by process subcode (n = 6,044 out of 8,459 subset of RTE) includes equipment failure related

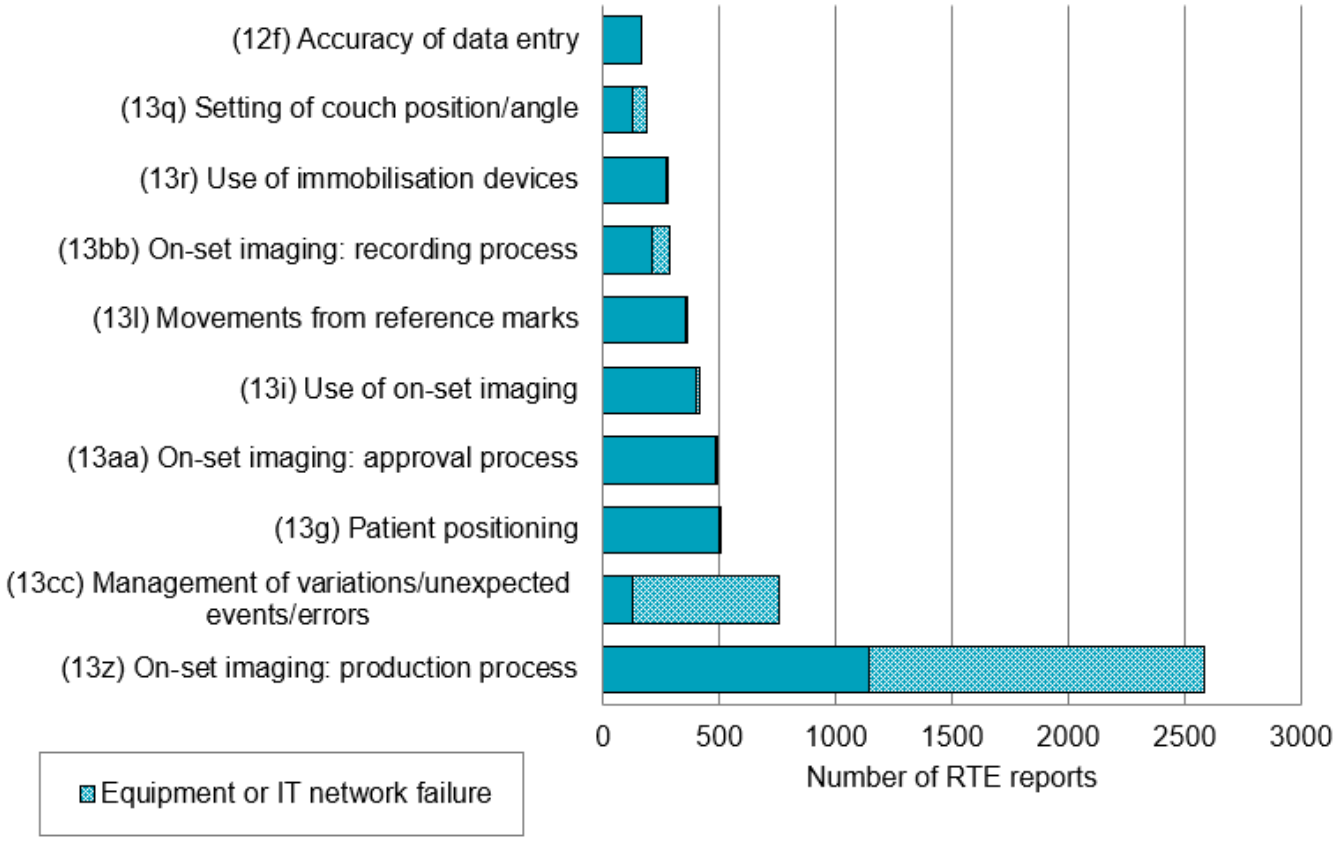
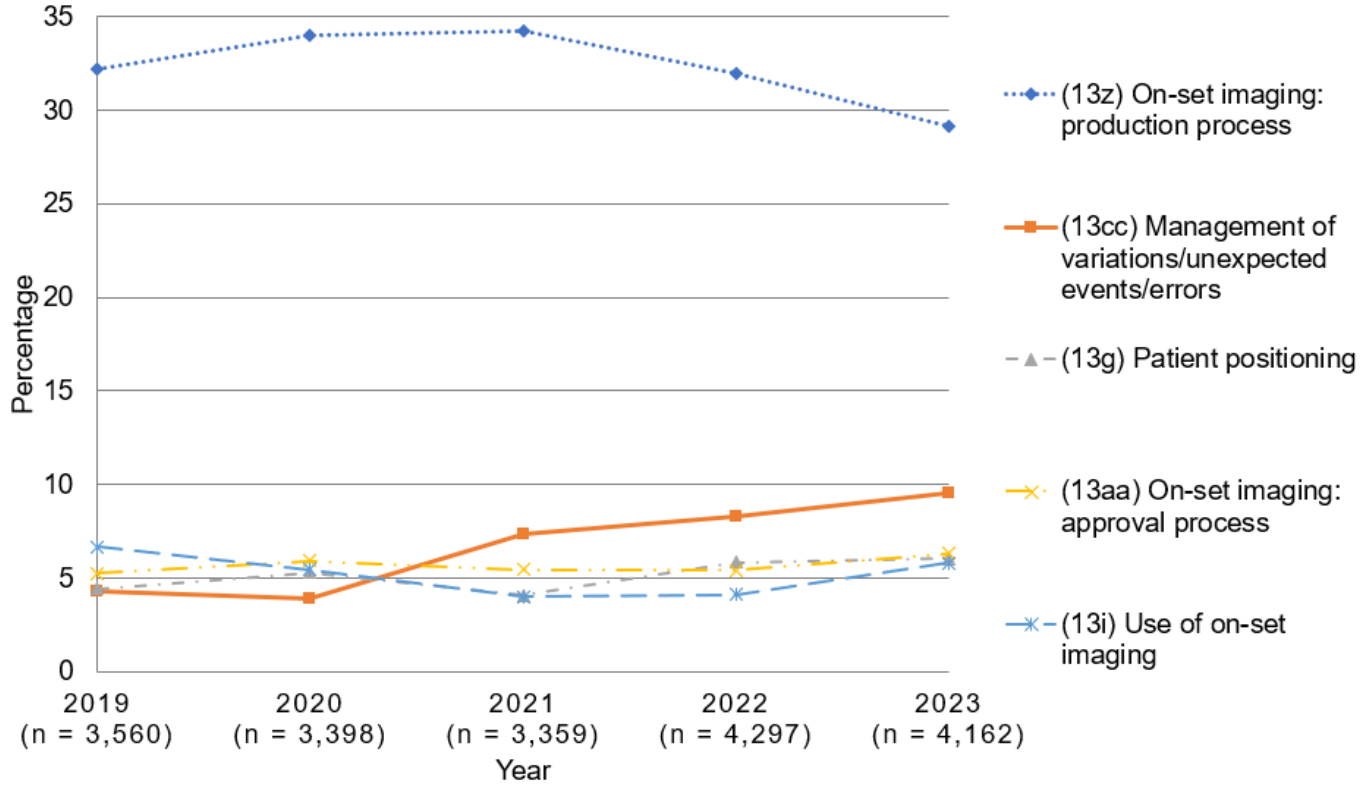


Figure 12 identifies trends by year across a 5-year period; 2019 to 2023. For the Level 3 RTE related to 'on-set imaging: production process', the rate has reduced from a peak of 34.2% during 2021 to 29.2% in 2023, but the overall trend for this decrease was not statistically significant (p = 0.25).

'Management of variations/unexpected events/errors' percentage has demonstrated a significant (p = 0.01) increase year on year since 2020 (3.9% in 2020 to 9.5% in 2023). The other most frequently reported pathway subcodes shown in Figure 12 demonstrated little significant change over the 5-year period.

Figure 12. Trends for most frequently reported Level 3 RTE by process subcode (January 2019 to December 2023)



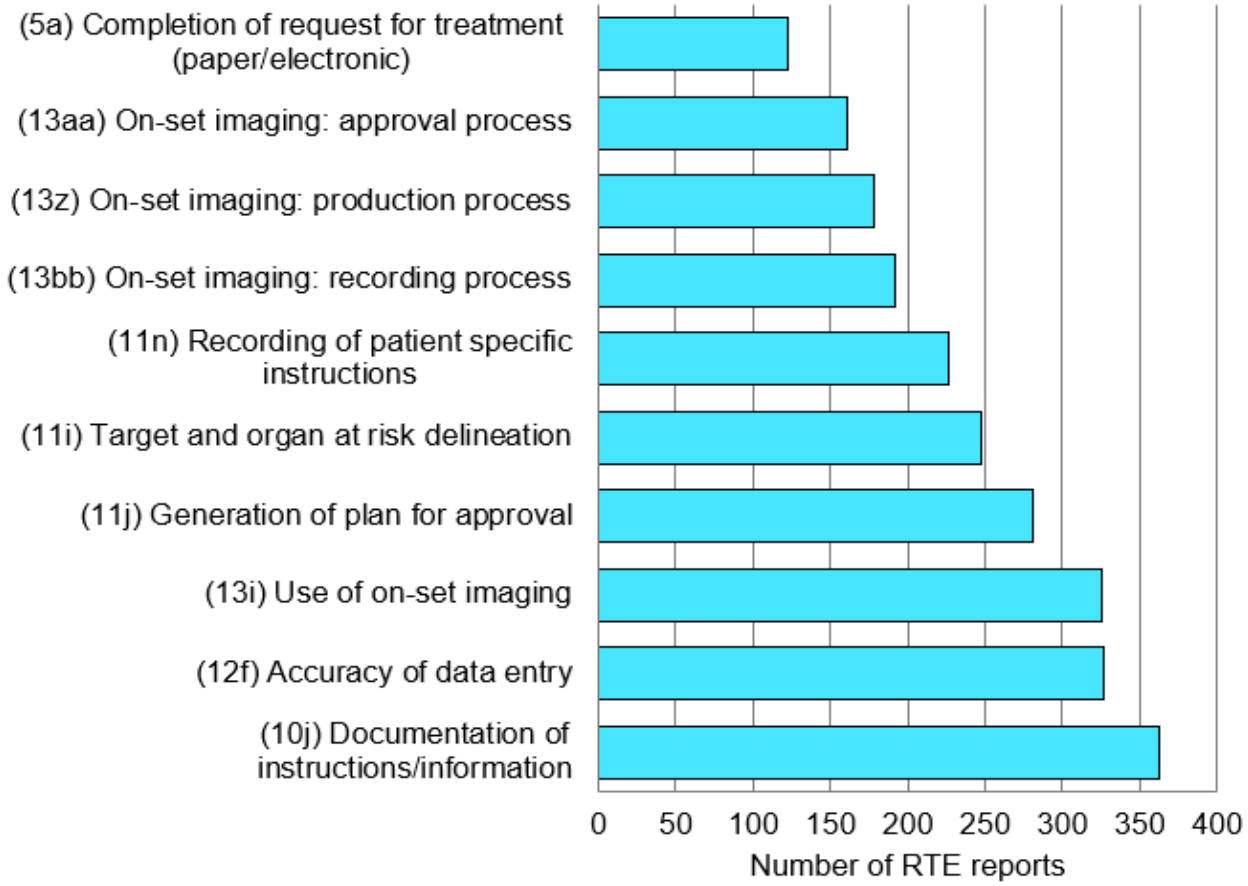
Near miss (Level 4) RTE

A ‘near miss’ is defined as a potential radiation incident that was detected and prevented before treatment delivery (9). There were 180 different subcodes associated with 5,726 Level 4 RTE. These were reported by 60 of the 61 providers. The most frequently reported RTE can be seen in Figure 13.

The most frequently reported subcode was ‘documentation of instructions/information’ making up 6.3% (n = 363) of all Level 4 reports. Examples of this type of RTE includes missing information within the documentation of patient positioning.

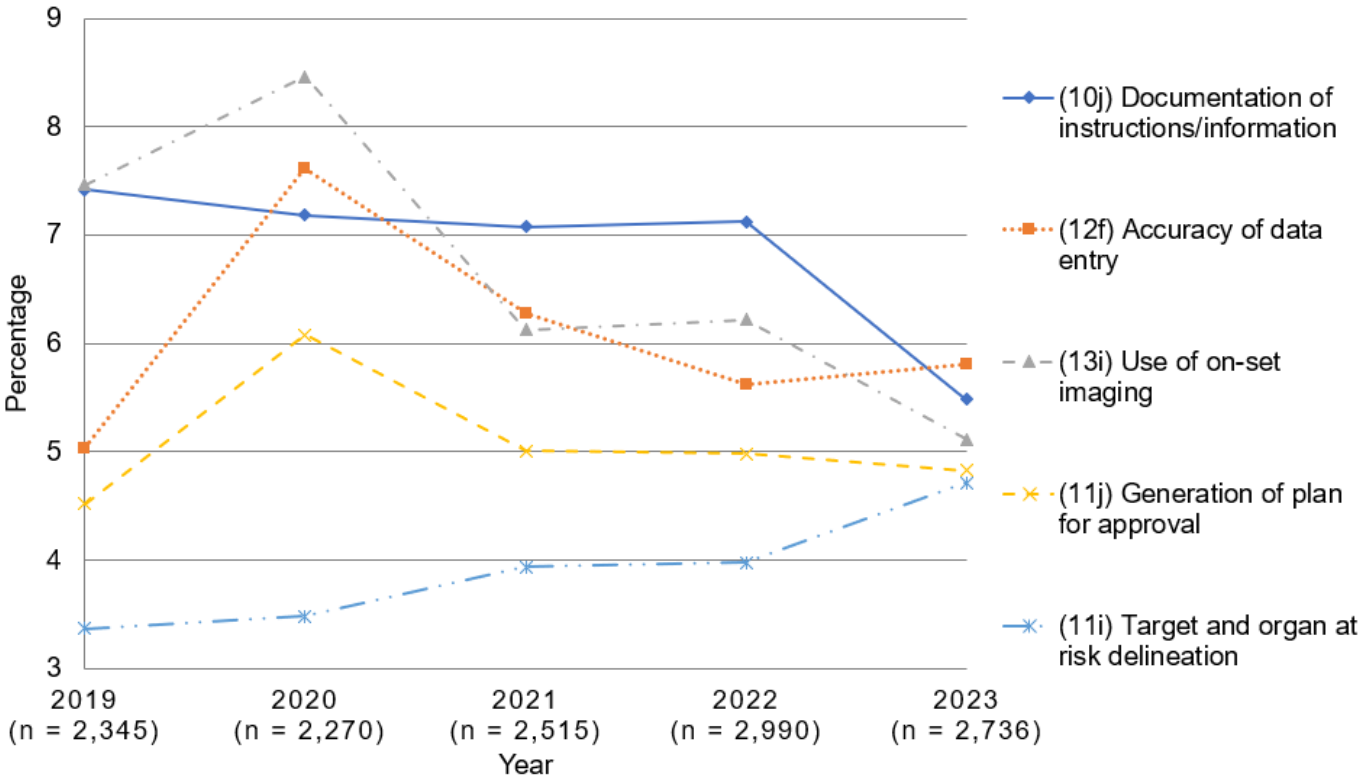
The second and third most frequently reported subcodes reflected similar proportions. ‘Accuracy of data entry made’ up 5.7% (n = 327). An example of this type of RTE includes incorrect imaging filter selected at data preparation but identified prior to image acquisition. ‘Use of on-set imaging’ contributed 5.7% (n = 326) of Level 4 reports. Examples of these types of RTE include where local protocol dictates that a weekly CBCT verification image is required to check potential changes in patient contour and internal anatomy, however a 2D KV is taken instead. The omission is identified afterwards and a CBCT is taken next fraction which confirms no issues.

Figure 13. Breakdown of most frequently reported Level 4 RTE by process subcode (n = 2,425 out of 5,726 subset of RTE)



As seen in Figure 14, process subcode ‘documentation of instructions/information’ was broadly stable between 2019 and 2022 (17.4% to 17.1%) but dropped steeply in 2023 (5.4%). ‘Accuracy of data entry’ has decreased from a peak of 7.6% in 2020 to 5.8% in 2023. There was an overall reduction of 2.4% in process subcode ‘use of on-set imaging’ between 2019 and 2023 (7.5% to 5.1%). None of these trends are considered statistically significant (p = 0.11, p = 0.91 and p = 0.07 respectively). In contrast ‘target and organ at risk delineation’ has experienced a significant (p = 0.01) rise in the 5-year period from 3.4% in 2019 to 4.7% in 2023.

Figure 14. Trends for most frequently reported Level 4 RTE by process subcode (January 2019 to December 2023)



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 (9).

There were 188 different subcodes associated with 7,384 Level 5 RTE reported. These were reported by 57 of the 61 providers that submitted data for analysis. The most frequently reported RTE are represented in Figure 15.

The most frequent process subcode reported was ‘bookings made according to protocol’ at 6.4% (n = 475). An example of this type of RTE include missing patient appointments or scheduling appointments for the incorrect fractionation during the booking process, and the error was identified and corrected as part of local checking processes prior to treatment. The second most common subcode was ‘communication of appointments to patient’ at 5.1% (n = 378). An example of this type of RTE include the failure to inform a patient of a change of appointment due to planning delays.

Figure 15. Breakdown of most frequently reported Level 5 RTE by process subcode (n = 3,049 out of 7,384 subset of RTE)

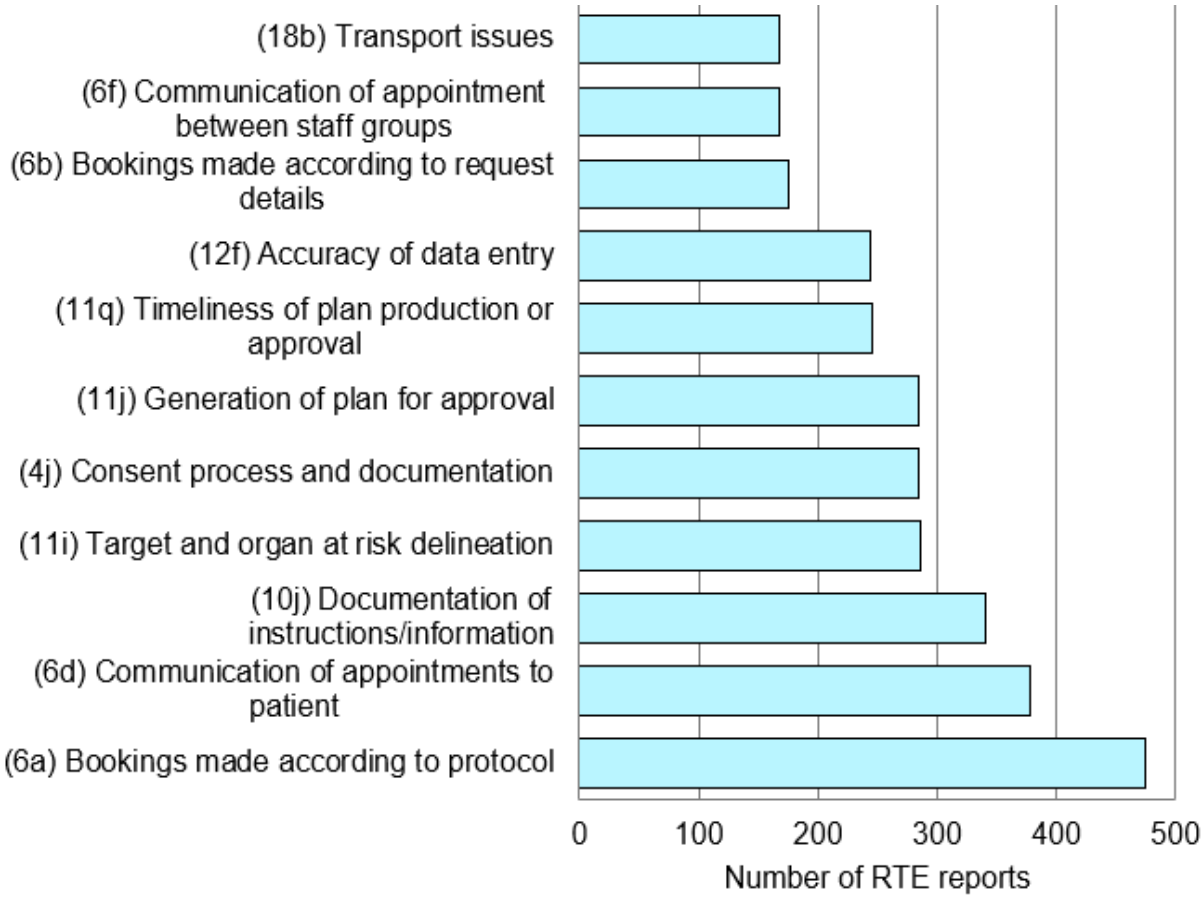
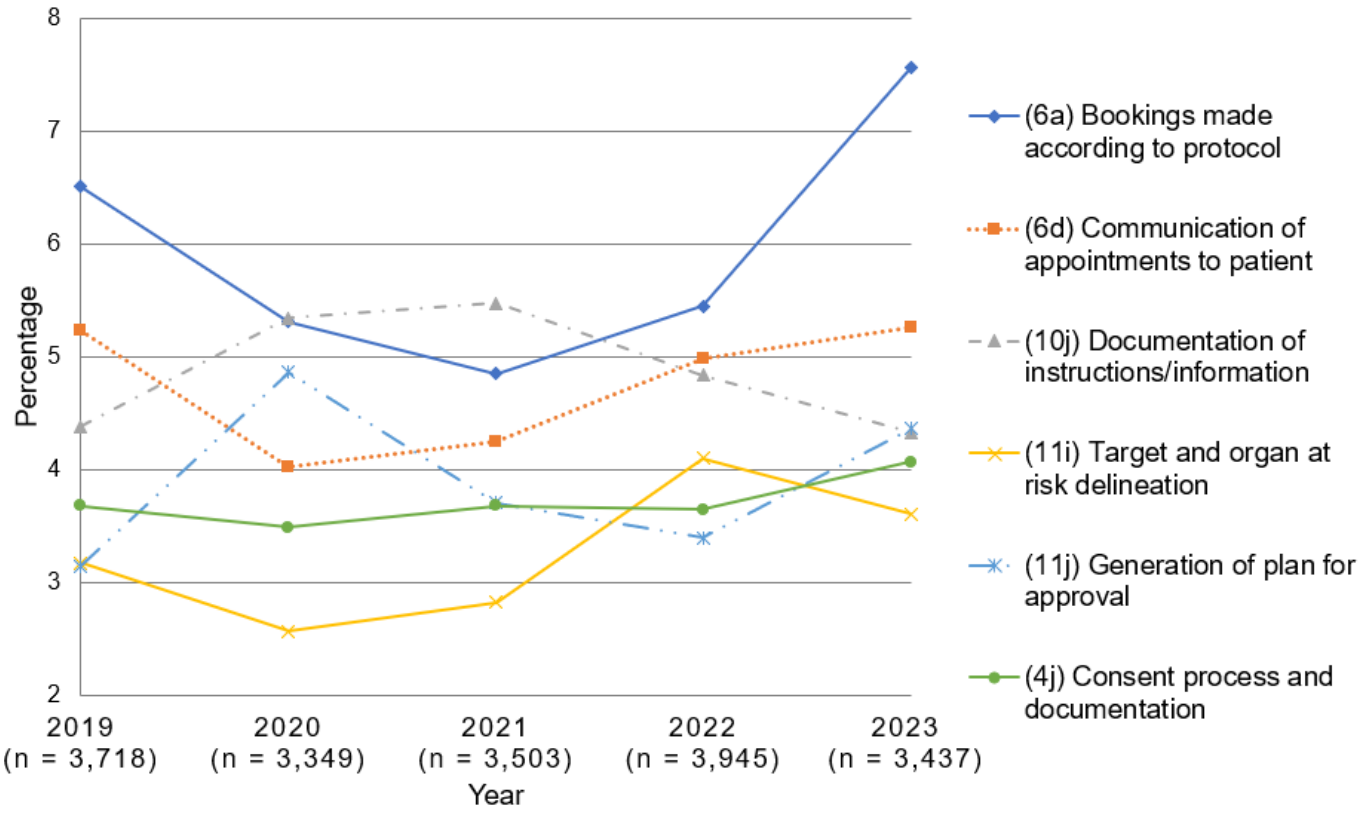


Figure 16 identifies trends by year across the preceding 5-year period. Having been broadly stable over 2020 to 2021 there has been a reduction in occurrence of Level 5 RTE associated with ‘documentation of instructions/information’ from 5.5% in 2021 to 4.3% in 2023. ‘Bookings made according to protocol’ decreased from 6.5% in 2019 to 4.9% in 2021 but subsequently increased in frequency to 7.6% in 2023. Reports associated with the process subcode ‘Communication of appointments to patients’ grew in proportion from 2.6% in 2020 to 5.3% in 2023. None of these process subcode showed a statistically significant either increasing or decreasing trend (p = 0.77, p = 0.60 and p = 0.65 respectively).

Figure 16. Trends for most frequently reported Level 5 RTE by process subcode (January 2019 to December 2023)



Failed safety barriers

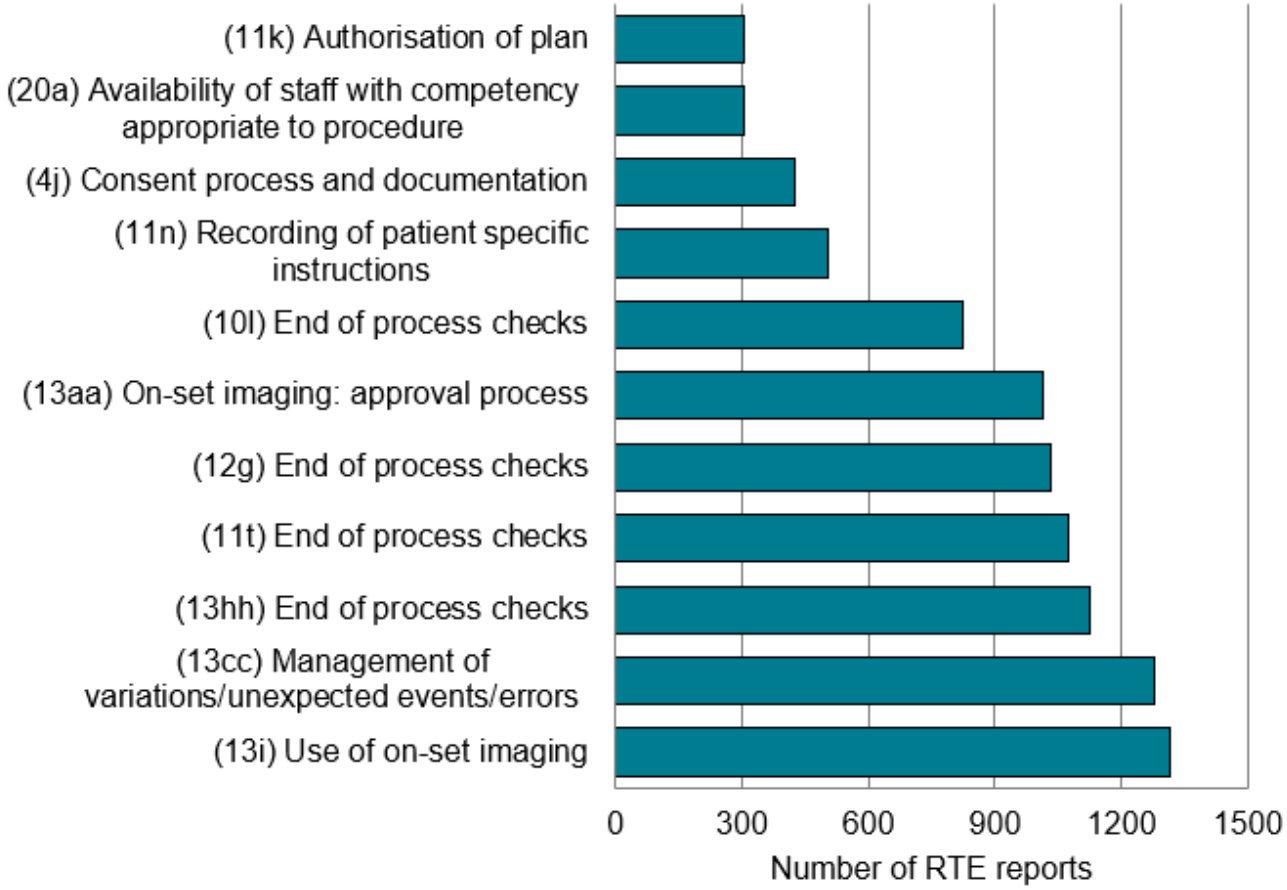
A safety barrier (SB) is a critical control point, detection method or defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow (16). UK RTE pathway taxonomy currently has 206 different process subcodes, which include 86 safety barriers (14). Safety barriers embedded in the pathway coding can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed safety barriers).

Multiple safety barrier codes can be attributed to each individual RTE. A total of 13,715 failed safety barriers were identified across the RTE reports. The most frequently reported failed safety barriers can be seen in Figure 17.

Treatment unit processes were attributed to 40.3% (n = 5,528) of all failed safety barriers. ‘Use of onset imaging’ was the most frequently reported (9.6%, n = 1,316). This pathway code relates to imaging according to local departmental protocols. An example is where departmental protocol may require the first 3 fractions to be imaged and subsequent offline assessment to determine any systematic set up error (SSE) needing correction. If the assessment is missed and the SSE left uncorrected this may lead to an increase in imaging throughout treatment.

'End of process checks’ occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised 30.0% (n = 4,128) of all failed safety barriers.

Figure 17. Breakdown of most frequently reported failed safety barriers (n = 9,204 out of 13,715 subset of RTE data)



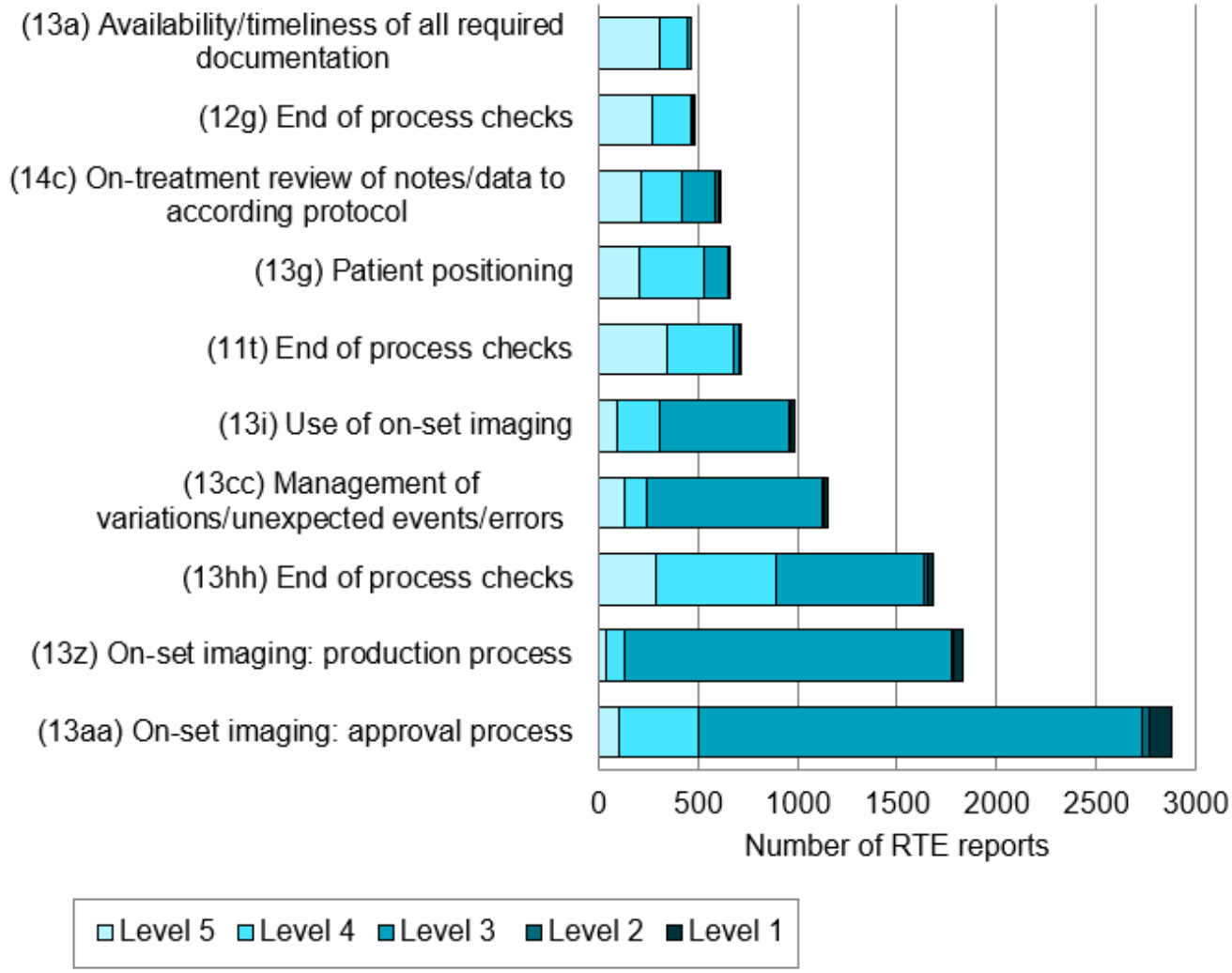
Method of detection

A method of detection is the process that identified an error and the entire RT pathway taxonomy within DoL (14) can be employed.

Method of detection coding was provided by 52 providers in 52.2% (n = 11,535) of reports. Following consistency checking, UKHSA coded a further 8,159 reports with method of detection taxonomy using information within the reporting text. This resulted in 89.1% of reports (n = 19,694) coded for analysis. This is a notable increase from the previous 2-year period when 49.2% (9,184 out of 18,861) reports contained a method of detection after consistency checking.

The most frequently reported methods of detection can be seen in Figure 18. The most frequently reported was ‘on-set imaging: approval process’ (14.6%, n = 2,880). This method of detection includes both online and offline verification processes and was most frequently reported with a primary process subcode ‘on-set imaging: production process’.

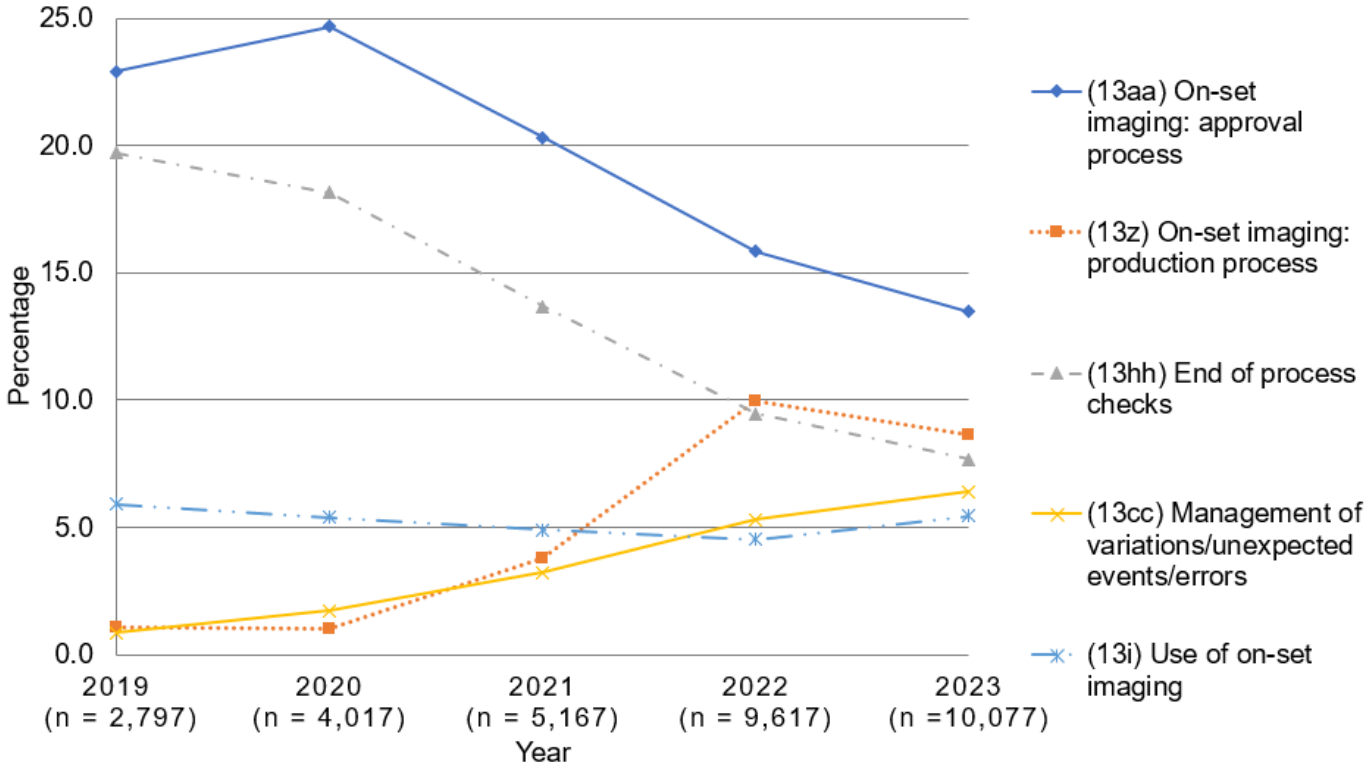
Figure 18. Breakdown of method of detection by Level (n = 11,436 out of 19,694 subset of RTE data)



Trend analysis of methods of detection demonstrates notable decreases in the proportion of both ‘onset imaging: approval process’, reducing from a peak of 24.7% in 2020 to 13.5% in 2023, and this decreasing trend was statistically significant (p = 0.02) (Figure 19).

Process subcode ‘on treatment: end of process checks’, demonstrated a statistically significant decrease (p = 0.02) from a peak of 19.7% in 2019 to 7.7% in 2023. Of the remaining top 5 methods of detection there were increases in ‘management of variations/unexpected events/errors’ from 0.9% in 2019 to 6.4% in 2023, whilst ‘on-set imaging: production process’ rose from 1.1% in 2019 to a peak of 10.0% in 2022 before settling to 8.6% in 2023. Both process subcode overall increasing trends were considered statistically significant (p = 0.001, p = 0.035 respectively).

Figure 19. Trends for most frequently reported methods of detection by process subcode (January 2019 to December 2023)



Contributory factors

Including contributory factors (CF) within a RTE taxonomy enables identification of system problems that could precipitate a range of different incidents (17).

Multiple contributory factors can be, and often should be, assigned to a single RTE. Of the 22,113 RTE reported 22,060 contained a primary contributory factor. Of these 5,720 contained additional contributory factors. Overall, there were a total of 28,996 contributory factor codes available for analysis. From the 61 providers, 57 applied contributory factor coding to their RTE reports.

Figure 20 shows the most frequently reported contributory factor codes. The most frequently reported contributory factor was ‘slips and lapses’ making up 28.4% (n = 8,241) of all contributory factor reported. A slip or lapse tends to occur during a learned, familiar task (commonly in highly trained procedures) of a repetitive nature and are often caused by distraction.

This was followed by ‘adherence to procedures/protocols’ (23.3%, n = 6,753). Adherence to procedures/protocols is where a locally defined process was not adhered to.

Figure 20. Breakdown of most frequently reported contributory factors (n = 27,310 out of 28,996 subset of data)

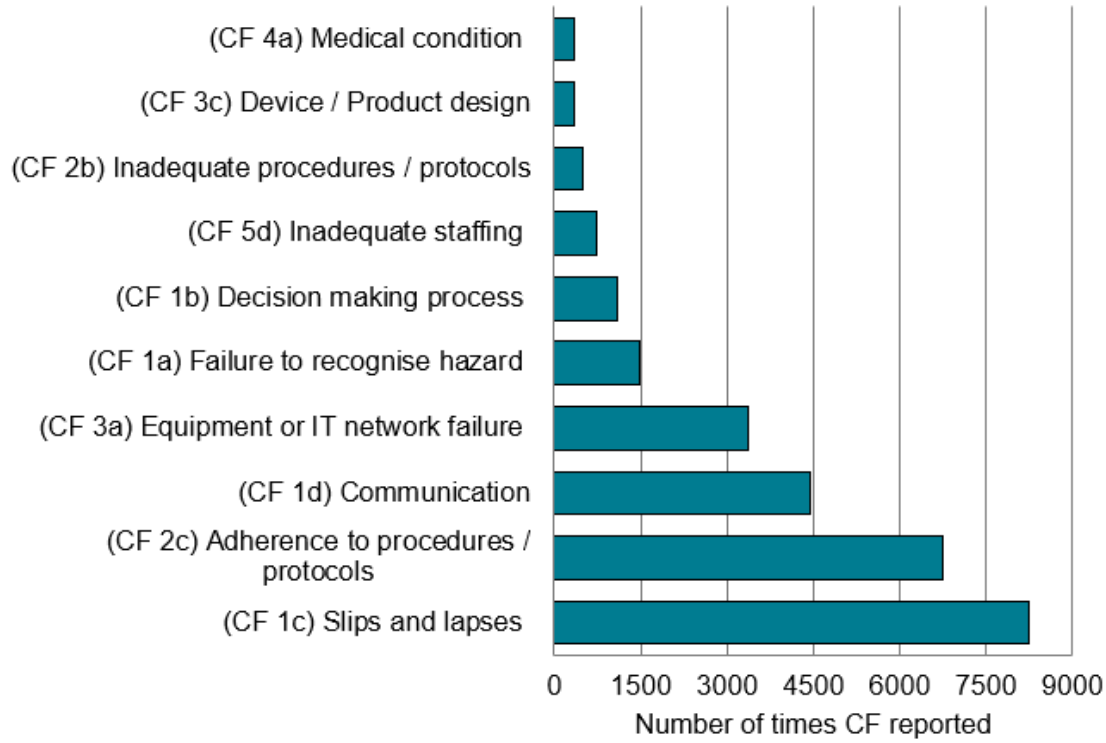
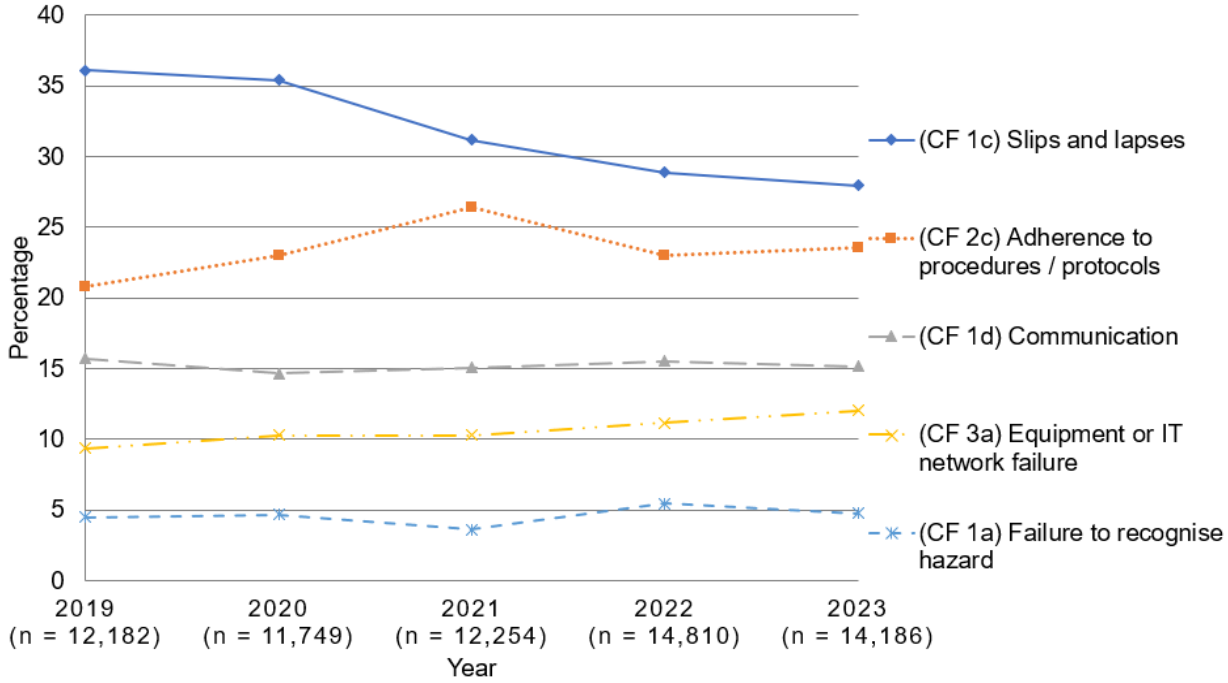


Figure 21 indicates the trends by year across the preceding 5-year period for the most frequently reported contributory factors are broadly consistent. The prevalence of the contributory factor 'slips and lapses' began to decline in 2019 (36.1%) to its current level in 2023 of 28.0% and this decreasing trend is considered statistically significant (p = 0.003). 'Equipment or IT network failure' had a statistically significant increase (p = 0.005) from 9.3% in 2019 to 12.0% in 2023.

Figure 21. Trends for most frequently reported contributory factors (January 2019 to December 2023)



Each of the 5 most frequently reported pathway subcodes were reviewed for the associated contributory factor codes. Table 4 shows that, of the 2,875 RTE reported with primary process subcode ‘on-set imaging: production process’, there were 3,355 contributory factors assigned. From these, the most frequently reported was ‘equipment of IT network failure’ making up 47.1% (n = 1,581) of all contributory factors for this process subcode. ‘Equipment or IT network failure’ was also the most frequently reported contributory factor for the second most frequent primary process subcode ‘management of variations/unexpected events/errors’ (62.8% n = 717 out of 1,141). The third most common primary process subcode ‘documentation of instructions/information’ had ‘communication’ as the most common contributory factor (33.6%, n = 421 out of 1,253).

Table 4. Most frequently reported primary process subcodes, other subcodes, contributory factors and methods of detection

Most frequently reported primary process subcode	Most frequently reported subsequent process subcodes [note 1]	Most frequent contributory factors	Most frequent methods of detection
(13z) On-set imaging: production process (n = 2,875)	(13hh) End of process checks, Treatment unit process (n = 119)	(CF 3a) Equipment or IT network failure (n = 1,581 out of 3,355)	(13z) On-set imaging: production process (n = 1,524)
(13cc) Management of variations, unexpected events or errors (n = 998)	(13z) On-set imaging: production process (n = 31)	(CF 3a) Equipment or IT network failure (n = 717 out of 1,141)	(13cc) Management of variations, unexpected events or errors (n = 716)
(10j) Documentation of instructions / information (n = 874)	(10l) End of process checks, pretreatment activities (n = 307)	(CF 1d) Communication (n = 421 out of 1,253)	(13g) Patient positioning (n = 223)
(13i) Use of on-set imaging (n = 834)	(13z) On-set imaging: production process (n = 97)	(CF 2c) Adherence to procedures / protocols (n = 443 out of 1,138)	(13hh) End of process checks (n = 198)
(13aa) On-set imaging: approval process (n = 756)	(13i) Use of on-set imaging (n = 35)	(CF 1c) Slips and lapses (n = 358 out of 1,037)	(13aa) On-set imaging: approval process (n = 401)

[Note 1]: Each RTE report can contain multiple pathway subcodes, others depicted in this table include all pathway process subcodes asigned to each RTE with the primary process subcode removed.

Brachytherapy RTE

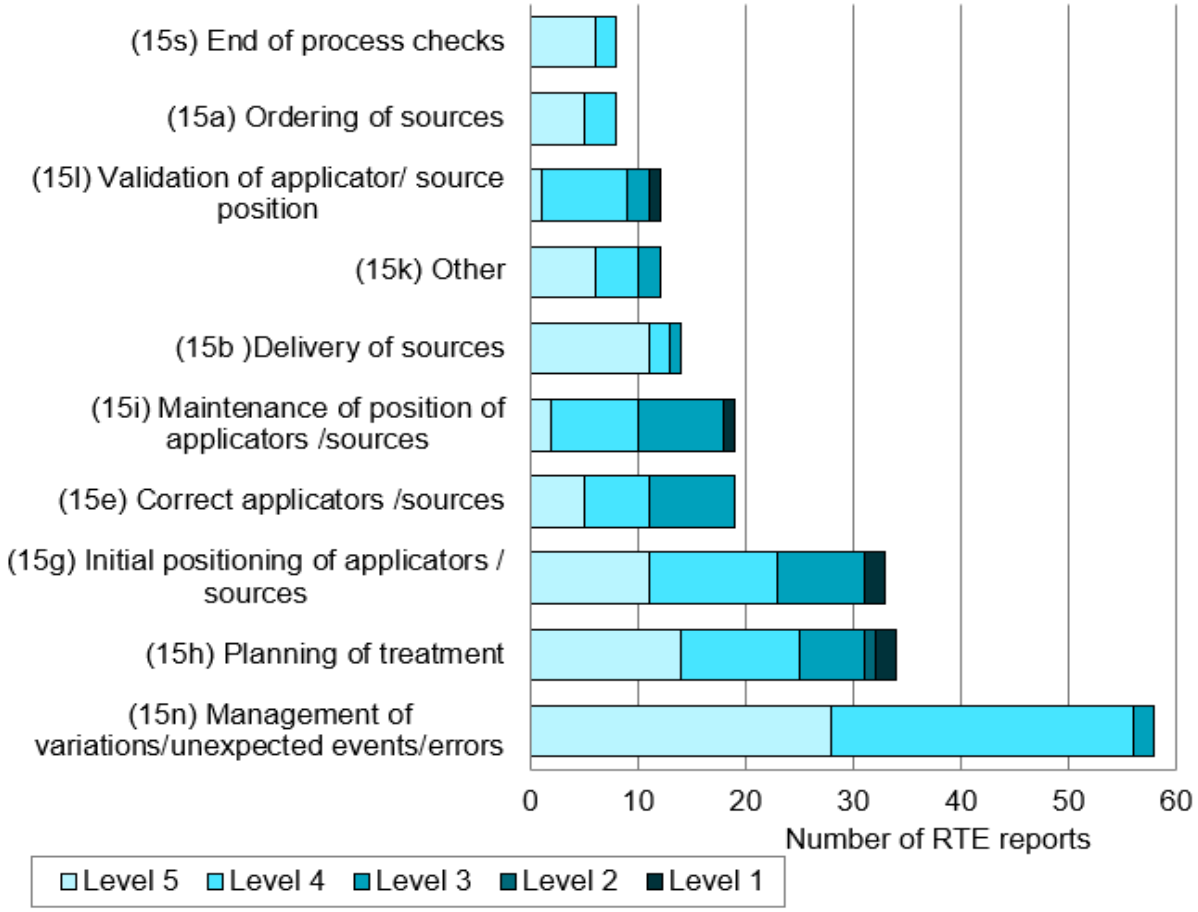
Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to a treatment area (18). The BRT RTE data was submitted from a total of 31 providers. This is an increase from the previous 2-year period when 21 providers reported. BRT make up less than 3% of all RT episodes (19), so it is expected the number of BRT RTE are comparatively low. Reports coded with BRT process subcodes (prefix 15) as the primary code account for 1.0% (n = 241) of RTE for this 2-year reporting period. This has increased notably since the previous 2-year reporting period from 0.6% (n = 104). As the number of BRT RTE reports is low this data should be interpreted with care. The increase in reporting of BRT RTE is positive and further growth should be encouraged. It allows the opportunity to facilitate learning as the nature of these events are often different to external beam due to the differences in their planning and delivery approaches and techniques and technologies employed.

There has been a minor increase in the numbers and proportion of Level 1 BRT RTE reported (2.5%, n = 6) since the previous 2-year reporting period when these Level 1 BRT RTE made up 1.9% (n = 2). The proportion of Level 1 reports for BRT (2.5%) for this reporting period contrasts with 1.6% for all RTE reports. This might be explained in part by the hypo-fractionated nature of BRT delivery (20), coupled with the manual aspect of the treatment processes and limited image guidance tools preceding treatment delivery.

A difference was also noted in the Level 3 RTE; with only 15.8% of the BRT RTE classified as Level 3 compared with 38.3% of all RTE. This difference in frequency of Level 3 RTE may be due to access to image guidance tools or adoption of non-ionising verification imaging within BRT for example, transrectal ultrasound imaging during permanent Iodine-125 seed prostate brachytherapy. This contrasts with the availability of ionising verification imaging within external beam RT. The percentage of other ‘non-conformances’ (Level 5) is also higher within the BRT RTE reports at 41.9% compared to 33.4% for all RTE reports. This may be in part be due to the higher number of defined processes external to the radiotherapy department, such as anaesthetics and in patient care.

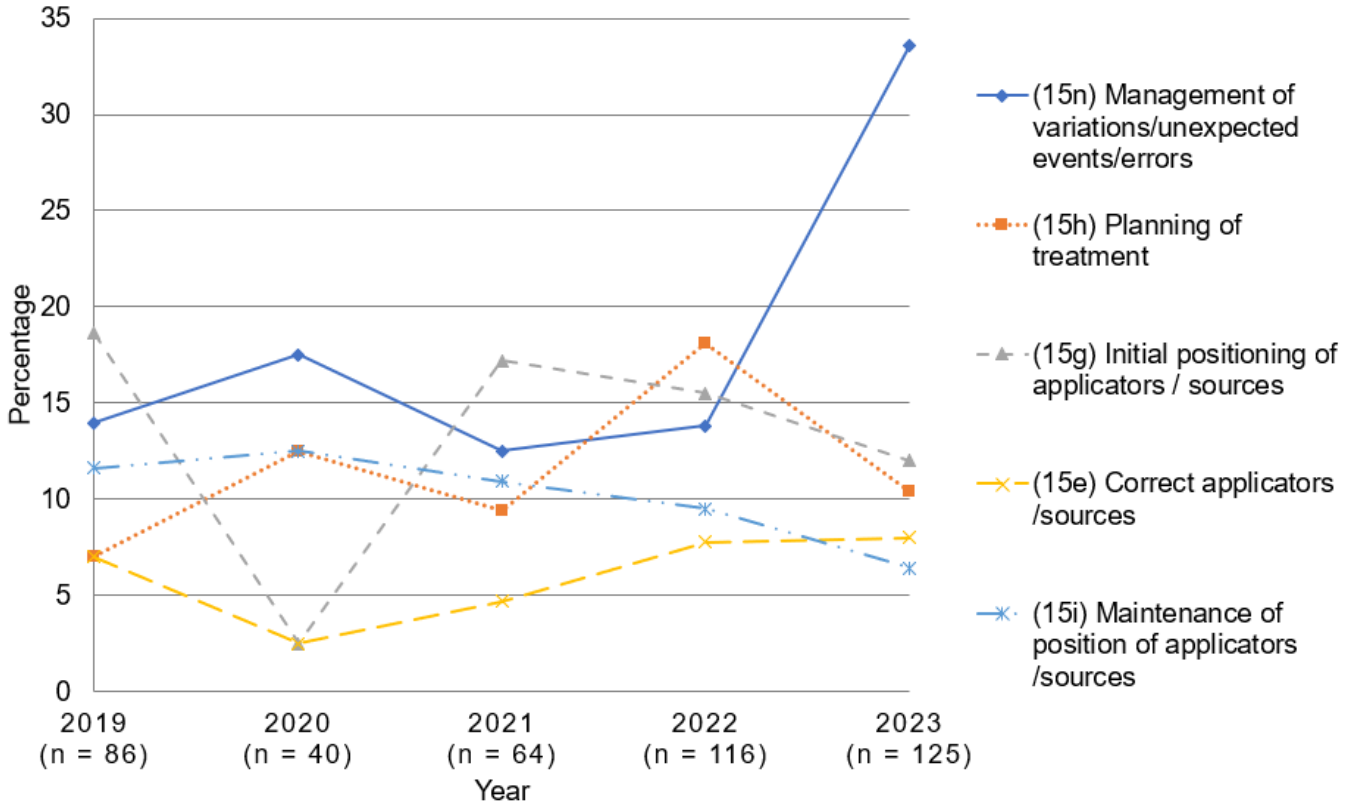
A breakdown of the BRT RTE can be seen in Figure 22. The most frequently reported BRT process subcode was ‘management of variations/unexpected events/errors’ making up 24.1% (n = 58) of all BRT. Within the reporting of this process subcode 70.7% (n=41) involved equipment or IT network failure. Examples of this type of RTE includes a breakdown of equipment, such as the loader for LDR brachytherapy, or cracks in the central tube for HDR vault kit. The proportion of reports comprised of this code has increased from the previous 2-year report (14.4%, n= 15), with the proportion of reports attributed to ‘equipment or IT network failure’ also increasing (40%, n = 6).

Figure 22. Breakdown of most frequently reported BRT RTE coded '15' by Level (n = 217 out of 241 subset of BRT RTE)



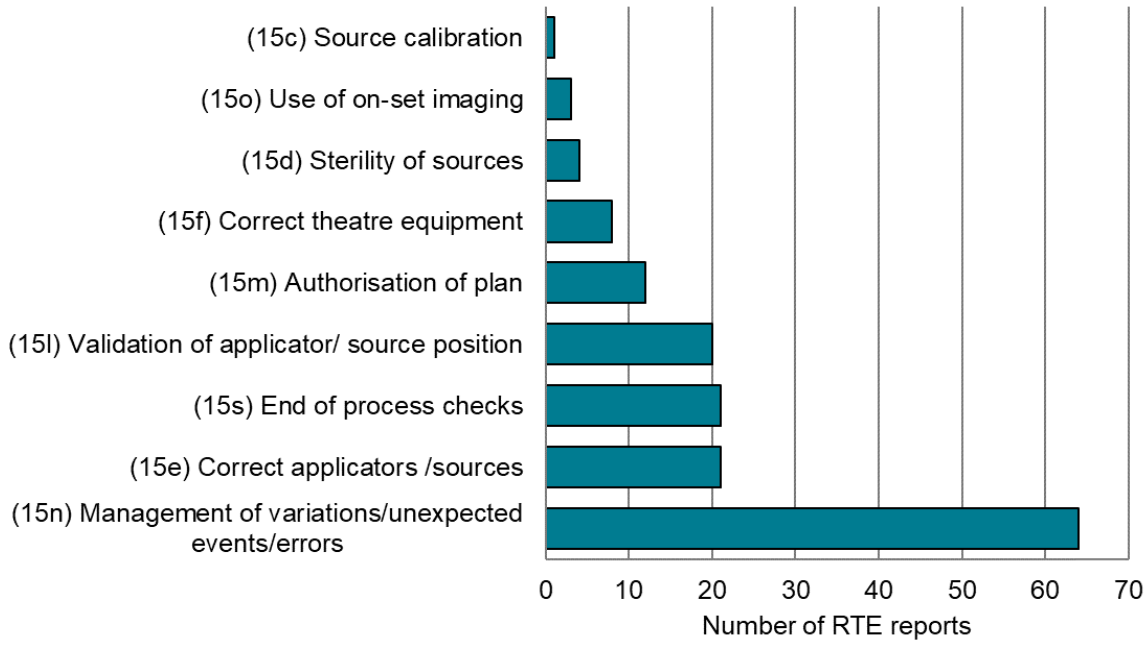
The trends by year across the preceding 5-year period of the most frequently reported BRT RTE can be seen in Figure 23. The most salient is a large increase in the proportion of 'management of variations/unexpected events/errors' between 2022 and 2023 (13.8% and 33.6% respectively), although the overall increasing trend was not statistically significant (p = 0.24). 'Maintenance of position of applicators /sources' has seen a gradual decline since 2020 from 12.5% to 6.4% in 2023.

Figure 23. Trends for most frequently reported BRT RTE by process subcode (January 2019 to December 2023)



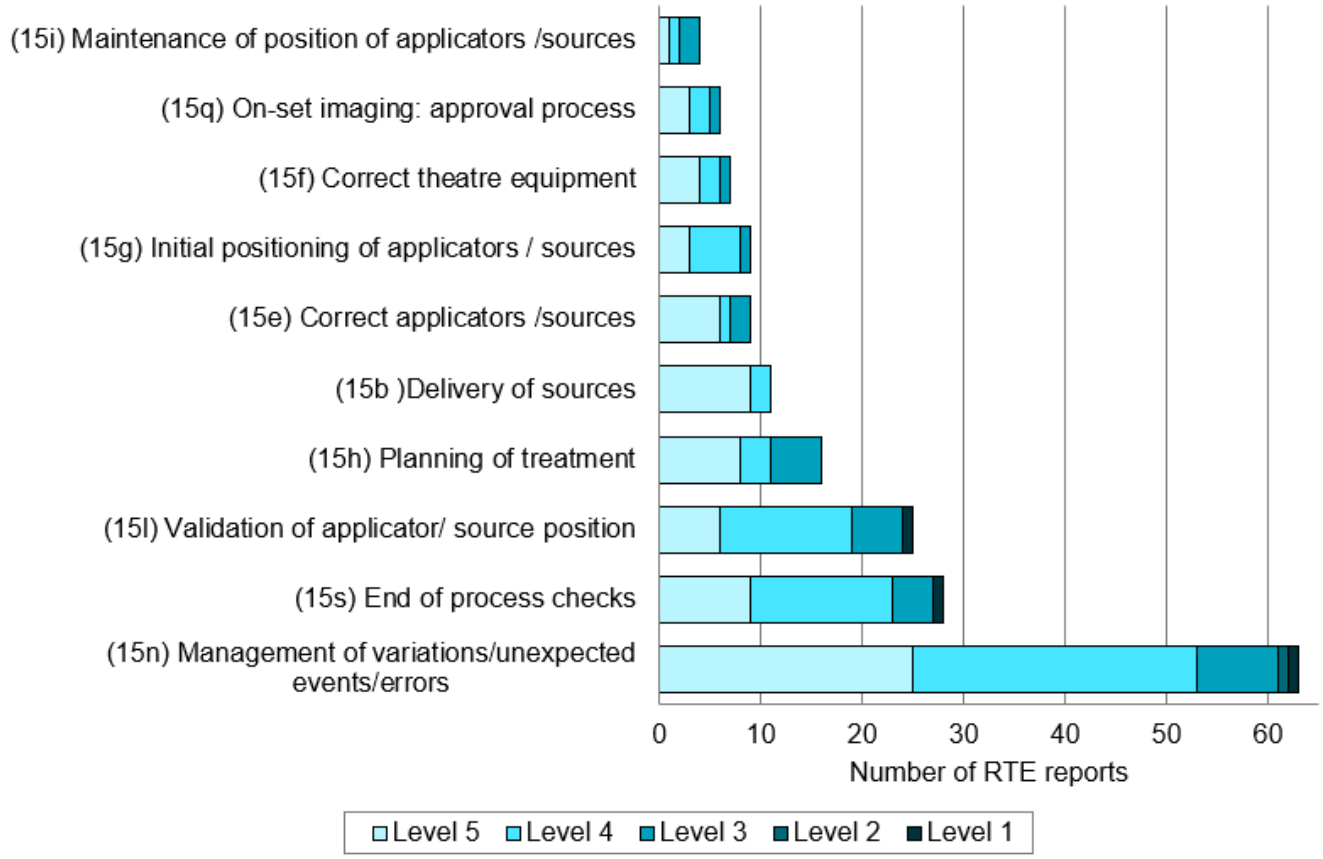
Multiple safety barrier codes can be attributed to each individual RTE. A total of 154 failed safety barriers were identified across reported BRT RTE. The most frequently reported failed safety barriers can be seen in Figure 24, the most frequent was ‘management of variations/unexpected events/errors’ making up 41.6% (n = 64) of all BRT failed safety barriers.

Figure 24. Breakdown of BRT failed safety barriers (n =154)



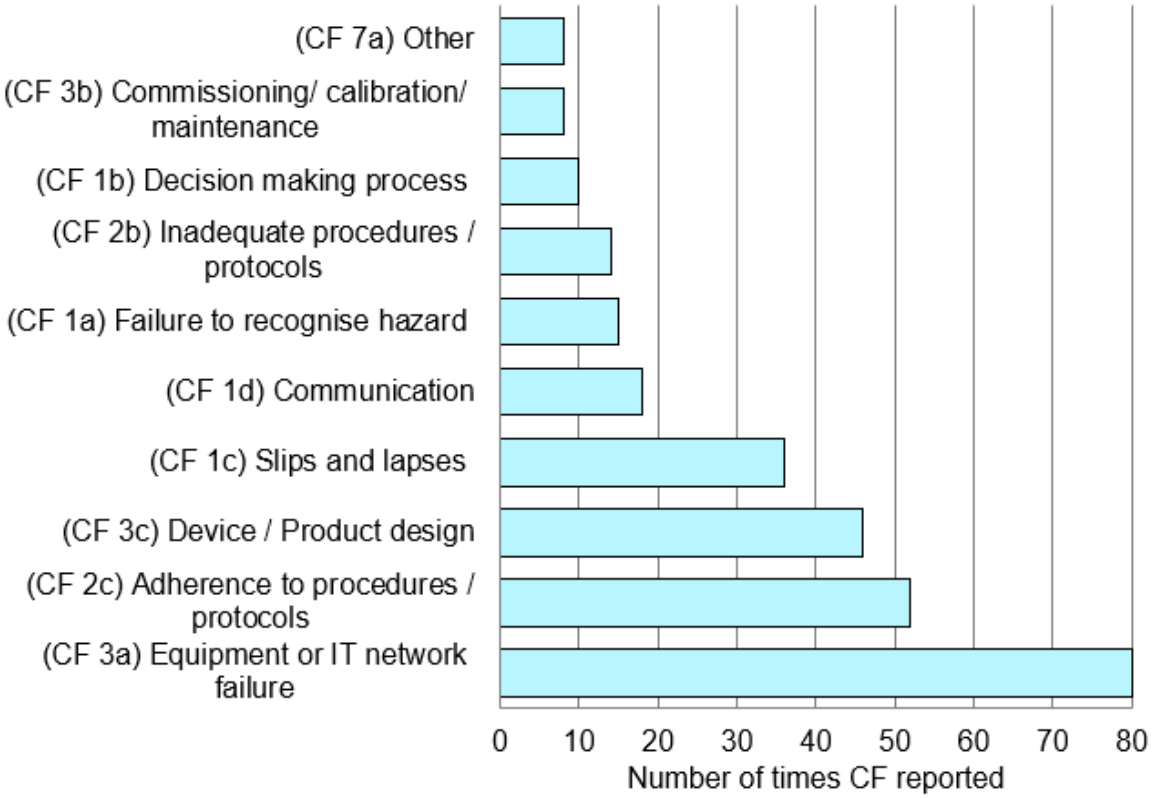
Of the 241 BRT reports, after consistency checking 90.0% (n = 217) contained a method of detection pathway subcode (Figure 25). This was a significant increase compared to the previous 2-year reporting period where only 20.2% (n = 21) contained a method of detection. The most frequently reported was 'Management of variations/unexpected events/errors' compromising 29.0% (n = 63) of all BRT methods of detection.

Figure 25. Breakdown of BRT method of detection by Level (n = 178/217 subset of BRT RTE)



Multiple contributory factors can be assigned to a single RTE. Across the 240 BRT RTE reported with contributory factors, 68 contained multiple contributory factors totalling 317 codes. Figure 26 shows the most frequently reported contributory factor codes. Unsurprisingly, given the predominance of pathway code 'management of variations/unexpected events/errors' the most frequently reported contributory factors for BRT were attributed to 'equipment or IT network failure' making up 27.9% (n = 80) of all BRT contributory factors reported. This was followed by 'adherence to procedures/protocols' (18.1%, n = 52). This contrasts to the findings in the total RTE dataset where the most frequently reported contributory factors was 'slips and lapses' making up 28.4.% of all contributory factors reported, whilst 'equipment or IT network failure' contributed 11.6%.

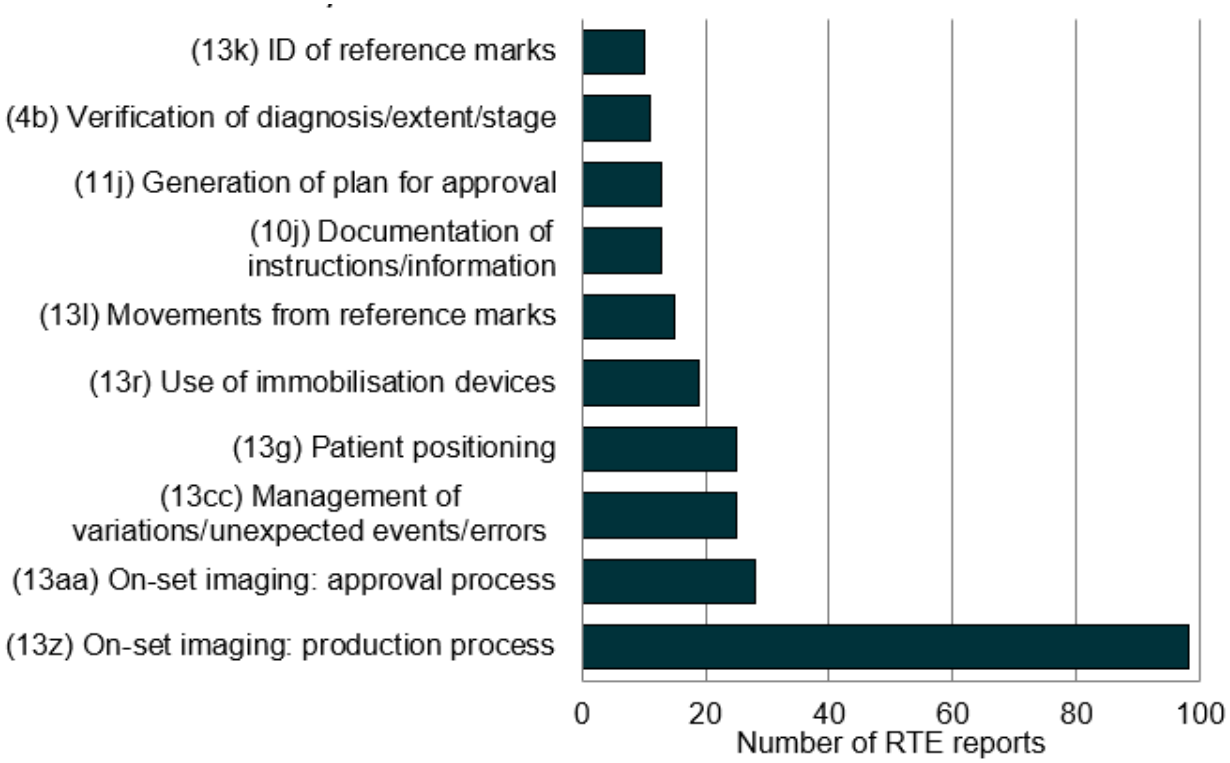
Figure 26. Breakdown of BRT RTE contributory factors (n = 287 out of 317 subset of BRT RTE)



Inspectorate RTE

The IR(ME)R (10 to 12) inspectorates for England, Northern Ireland, Scotland, and Wales shared a total of 406 anonymised synopses of closed reportable radiation incidents for analysis. This represents an increase of 63.1% from 249 in the previous 2-year reporting period. This would only partially be due to an increase in patient attendances over the reporting period.

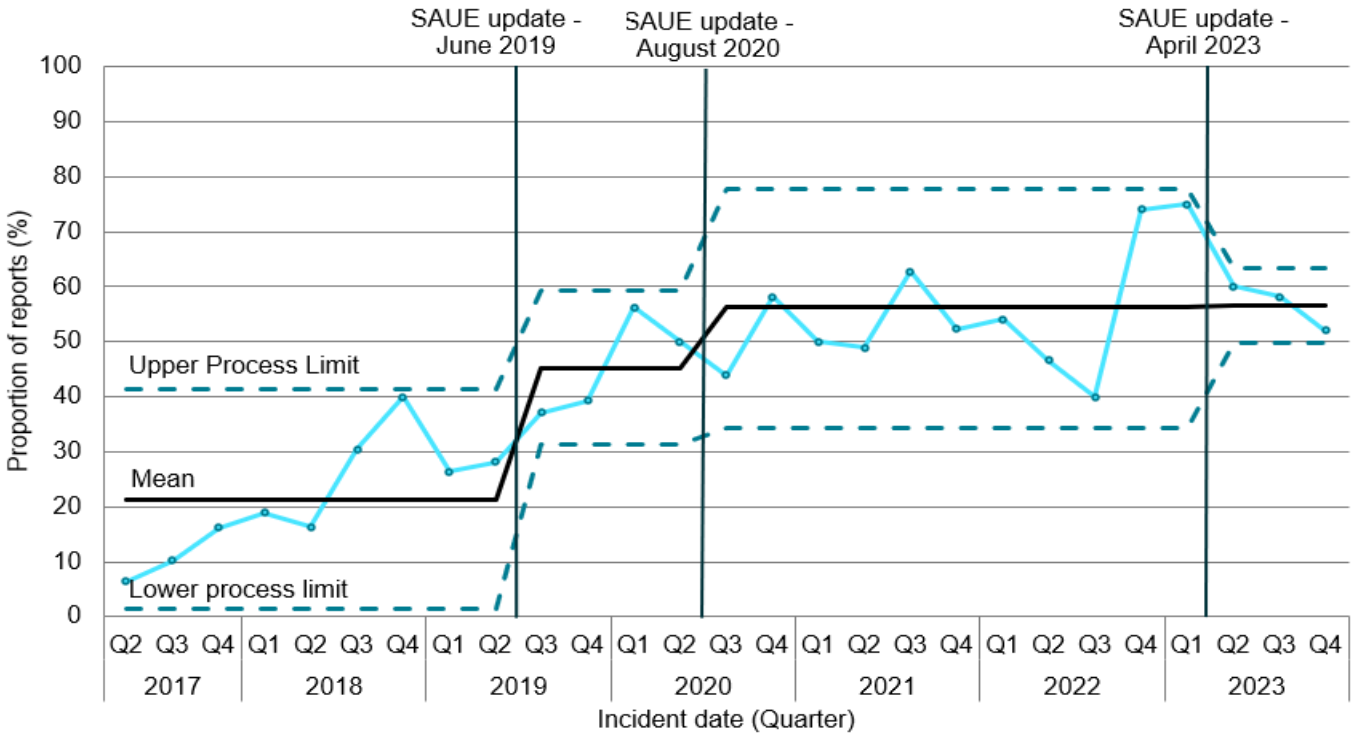
Figure 27. Breakdown of most frequent inspectorate notifications by process subcodes (n = 257 out of 406 subset of RTE)



Process subcode ‘on-set imaging: production process’ (24.2%, n = 98) has reduced proportionally from 30.9% (n = 77) since the previous 2-year report. Despite this decrease it remains the most frequently occurring subcode within the inspectorate data (Figure 27). This was followed by a trio of process subcodes with similar proportion ‘on-set imaging: approval process’ at 6.9% (n = 28), whilst both ‘patient positioning’ and ‘management of variations/unexpected events/errors’ contributed 6.2% (n = 25) of the inspectorate notifications.

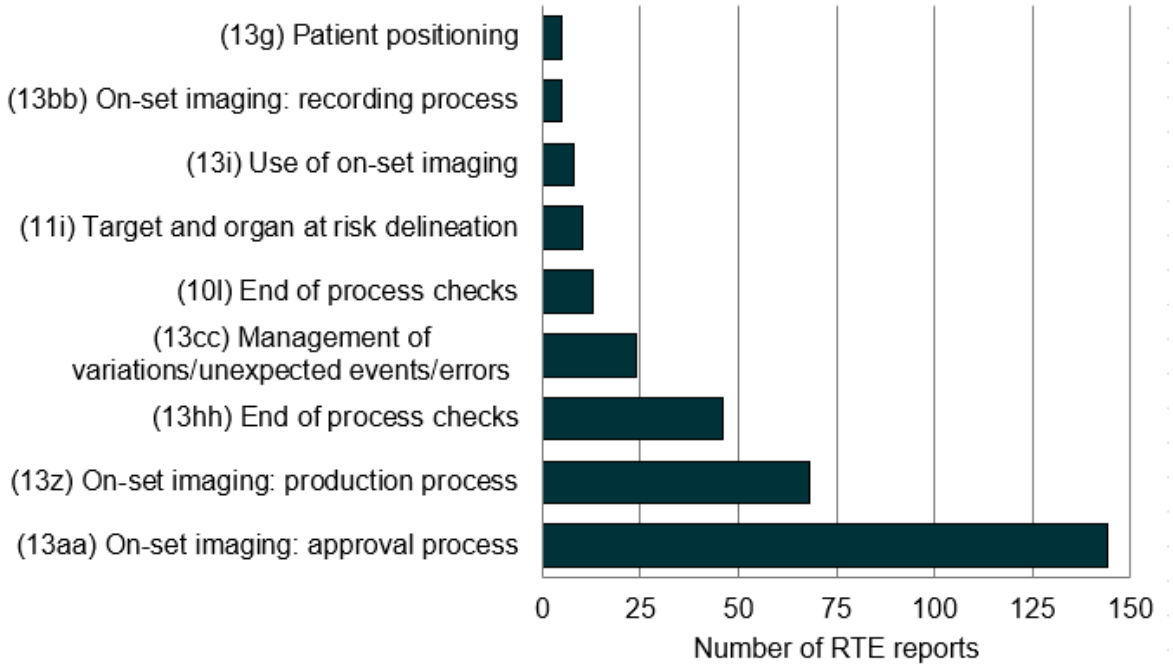
The inspectorates published SAUE guidance under IR(ME)R in June 2019 which was subsequently updated in August 2020, and April 2023 (21). The initial guidance included notification criteria for concomitant imaging and both updates sought to further define the reporting criteria. Figure 28 demonstrates a statistical process control chart (SPC). These allow the monitoring of data, in this case the proportion of radiotherapy verification image reports within inspectorate notifications, over time (22). Guidance updates to the notification system have been highlighted as vertical lines to allow the influence of their implementation to be monitored. SPCs contain a centre line that represents the mean value of the proportion of reports. Two dotted horizontal lines, called the upper and lower process limits are also plotted on the chart. These process limits are chosen so that if the process is in control, nearly all the sample points will fall between them. The chart shows that the proportion of radiotherapy verification imaging reporting numbers contributing to inspectorate notifications has gradually increased through time, although remaining within process limits. However, a consistent decrease in proportion has been noted since the updated SAUE guidance was published in April 2023 (21).

Figure 28. Proportion of radiotherapy verification image reports in inspectorate notifications from Quarter 2 2017 to Quarter 4 2023



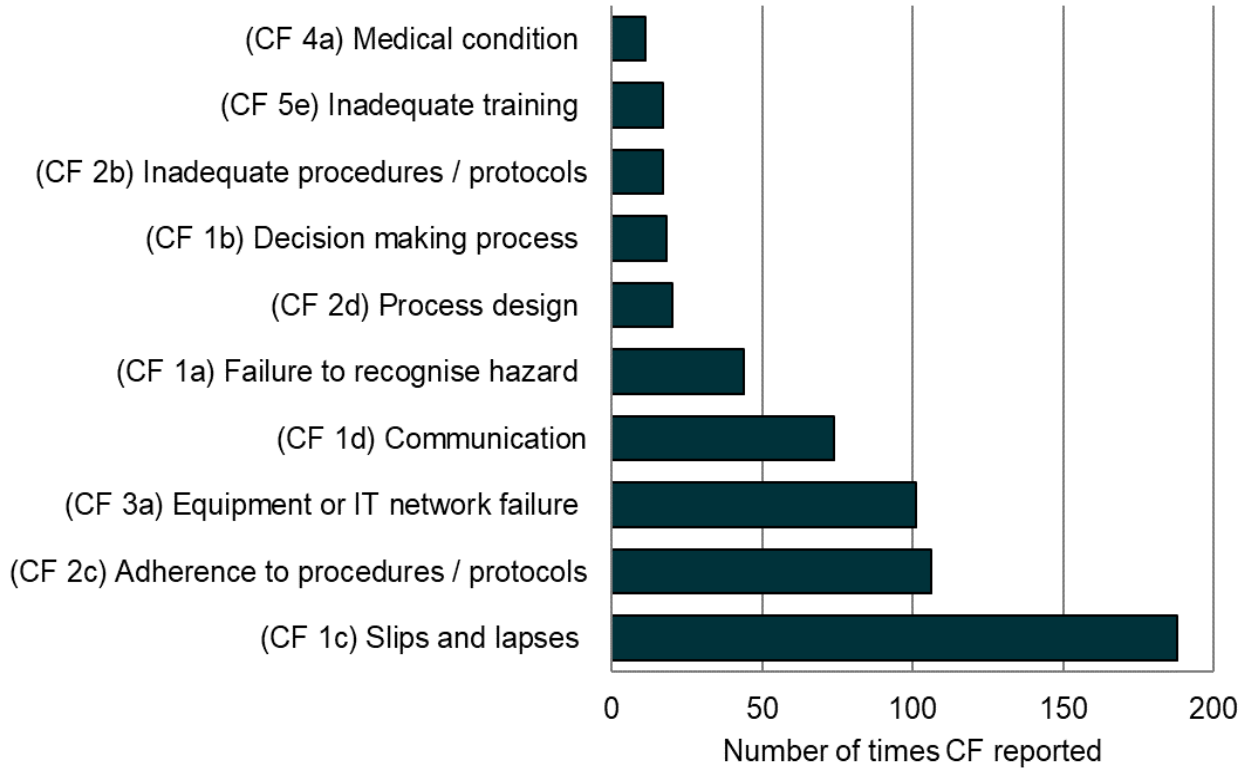
During the QA of the data, a method of detection was assigned to each report using the text descriptors shared. The most frequently reported methods of detection can be seen in Figure 29. 'On-set imaging: approval process' was the most frequently reported at 37.5% (n = 144).

Figure 29. Breakdown of most frequently reported inspectorate notifications by method of detection (n = 323 out of 406 subset of RTE)



There were 628 contributory factors assigned to the inspectorate reports. The most frequently reported contributory factors can be seen in Figure 30. The most frequently reported contributory factor was ‘slips and lapses’ (29.5%, n = 188) followed by ‘adherence to procedures/protocols’ (16.6%, n = 106).

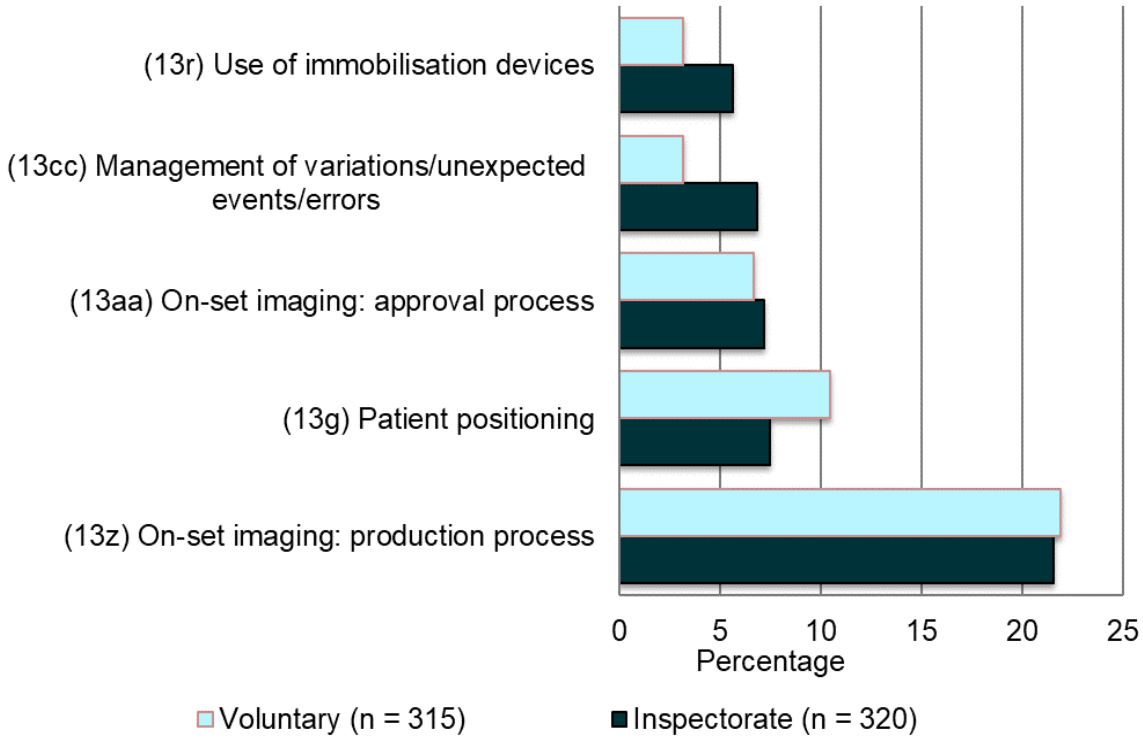
Figure 30. Breakdown of most frequently reported inspectorate notifications by contributory factor (n = 592 out of 638 subset of RTE)



Reporting numbers between voluntary and mandatory incident learning systems varied; a total of 350 Level 1 RTE were reported to the voluntary dataset within this 2-year period and 406 closed synopsis of reports were received from the inspectorates. A further review of the inspectorate data indicated a notable lag between the incident occurring and the date the report was received at UKHSA for analysis. This reflects the time taken to investigate and implement appropriate mitigations before closing the incident and sharing it for inclusion in the analysis. The lag varied between 714 and 34 days with an average of 174 days. Three outliers above 1,000 days were removed from these lag times. These reports described an extended lag due to identification of the error at time of patient follow up.

To better understand the likely impact of time lag on the variance in number of reports, a review of the incidents by date of occurrence (between January 2022 and December 2023) was carried out (Figure 31). The proportion of process subcode ‘on-set: production process’ was broadly similar between voluntary and mandatory reporting, there was a greater frequency of ‘management of variations/unexpected events/errors’ and ‘use of immobilisation devices’ in mandatory reporting, and fewer ‘patient positioning’ and ‘use of onset imaging’.

Figure 31. Comparison of most frequently reported process subcodes in inspectorate and Level 1 voluntary datasets (Incident date January 2022 to December 2023)



Discussion

Over the last 2 years, all UK NHS RT providers submitted RTE reports to the national voluntary incident learning system. In addition, reports were also received from independent RT providers during this review period. This reflects a strong community commitment to shared learning from incidents, a commitment supported by several drivers. Firstly, IR(ME)R (10 to 12, 23) requires the local recording of analyses of events involving or potentially involving accidental or unintended exposures and a study of the risk of these exposures as part of the local quality assurance programme. These local requirements facilitate participation in the national collection of RTE data. In addition, NHS England include the requirement to engage in national incident learning from RTE as part of the external beam service specification for providers based in England (24). Furthermore, recommendations of the Francis report (25) into failings at an NHS Foundation Trust included a requirement for openness, transparency, and candour throughout the NHS to support a culture of protecting patients and removing poor practice.

Increase in reporting numbers

For this 2-year reporting period, 22,113 RTE reports were received, an increase of 18.4% compared to the previous 2-year period when 18,681 were received. This exceeds the increase in radiotherapy visits over the period proportionally (19). This likely reflects an increase in the practice of reporting of incidents, although there is the potential that increased occurrence of radiotherapy errors within practice has contributed. In terms of radiotherapy safety, an increase in volume of reports is indicative of radiotherapy providers with open and transparent safety cultures and should be welcomed. Where reports are collated and meaningful analysis undertaken, shared, and used to inform practice, this reflects a progressive safety culture (2). It should be noted that, within the current reporting period, the annual number of RTEs reduced by over 800 reports from 2022 (n = 11,471) to 2023 (n = 10,642). It does appear that current reporting volumes are prone to variability, possibly due to changes in national reporting platforms in England.

The average number of RTE reported by providers increased from 316 per provider during the previous 2-year period to 363 for the current period (Figure 2). This overall increase in volume is tempered by the observation that the majority of providers (62.3% n = 38) submitted fewer reports than the average. There is some evidence to suggest that variations in reporting culture can occur, even between separate sites within a single radiotherapy provider (26). Therefore, it is likely that reporting culture varies across providers. This may explain some of the disparity in the number of reports submitted per provider.

There are several other potential explanations for the variation in reporting volume. Firstly, the number of reports per provider has not been normalised to account for differing levels of patient attendance, prescription or provider service specification. This means that those providers reporting fewer incidents may be smaller departments with proportionally less activity.

Secondly, incident learning systems are not always easily accessible, and this can affect ease of reporting. Organisations should support accessibility and usability of local systems to support timely reporting.

Thirdly, English organisations who previously reported to NRLS have transitioned, or are in the process of transitioning, to recording incidents via the new LFPSE platform which replaced NRLS at the end of June 2024. For some providers this has meant integrating new LFPSE compliant local risk management systems which may, temporarily, impact their capacity to report all incidents.

Finally, another possibility is that changes in activity and reporting levels may be linked. Organisations experiencing greater activity post-Covid may consequently have staff exposed to increasing work pressures and be more suspectable to burnout (27), consequently impacting on their personal wellbeing, a known risk factor for preventable medical incidents (28). Certainly, the causes are multifactorial and, ultimately, challenging to ascribe proper relevance to with any great certainty.

RTE data quality

The ongoing transition to LFPSE may also have contributed to a change in data report quality received by the national RTE database. In this current 2-year period 58.4% (n = 13,021) of reports were fully classified and coded by local RT providers (Figure 1). This is a marked reduction from the previous 2-year period (79.6% n = 14,940). From April 2022, a method of detection code was required for a report to be considered complete and this likely has affected the reduction the number of complete RTE received. The ongoing transition to LFPSE may also have contributed to a change in data report quality received by the national RTE database. There are many examples of providers who have successfully transitioned to the new platform within England and continue to submit a high volume of completed reports. Based on internal review, however, there has been an overall reduction in data quality when comparing providers submitting to NRLS in comparison to LFPSE. The Patient Safety in Radiotherapy Steering Group (PSRT) continue to liaise closely with NHS England and individual providers to ensure the opportunities offered by LFPSE for radiotherapy incident learning are fully maximised. The PSRT invites any providers who are experiencing any issues with national reporting to contact them for advice and assistance as UKHSA continue to work with LFPSE to refine the reporting process for RT providers.

There was an increase in the proportion of complete reports submitted by providers that required amended coding based on information provided within the report synopsis. The most revised pathway code was ‘use of on-set imaging’. Whilst the description of this code appears potentially broad, its use should be employed for occasions which are associated with issues relating to local imaging protocols. Three alternate pathway codes should be used for RTE involving on-set imaging production, approval and recording processes. The ‘use of on-set

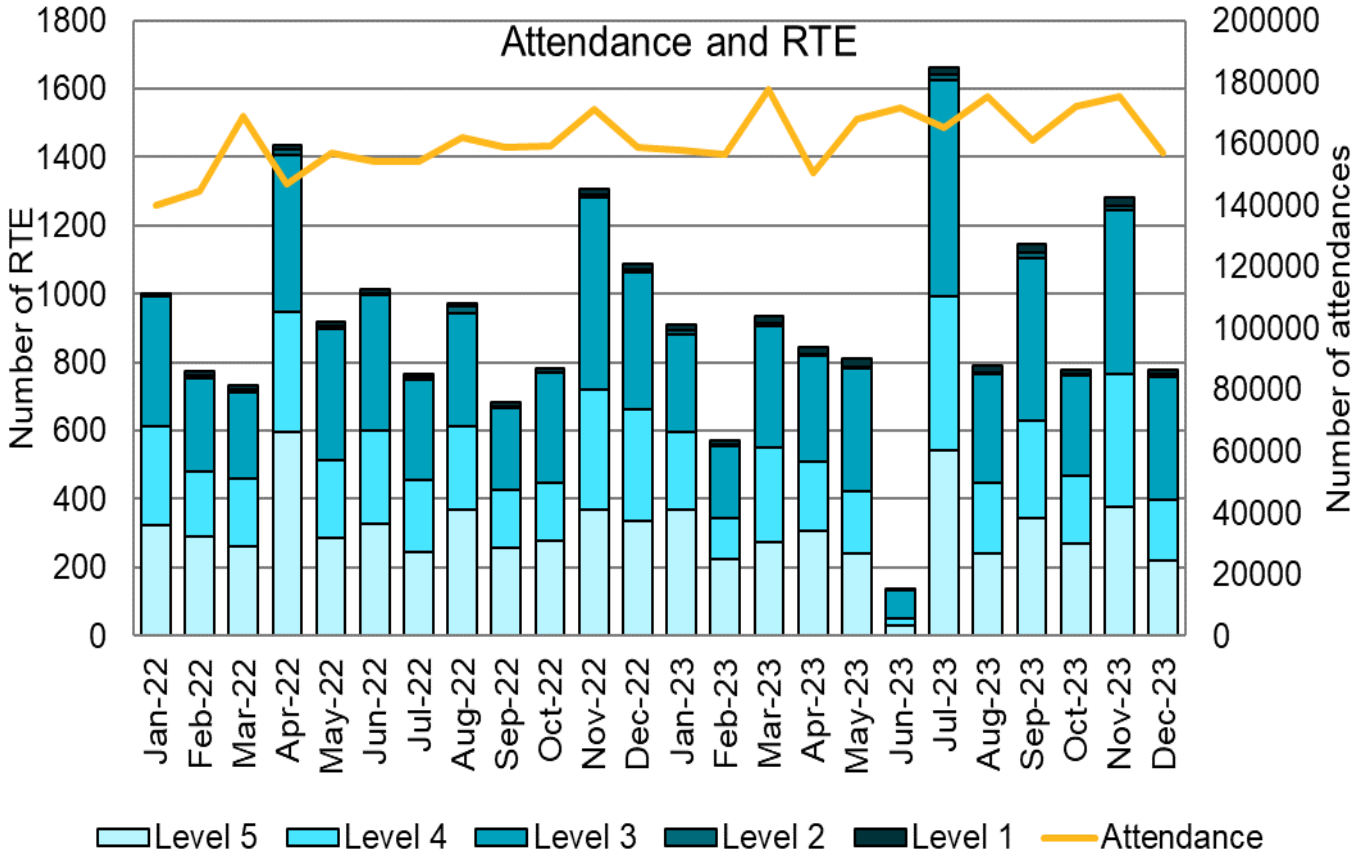
imaging' process code description is subject to review, within the broader 'Advancing Safer Radiotherapy' taxonomy appraisal.

A significant proportion of the amended codes were originally assigned one of the 'other' primary pathway subcodes, of which there are 16. Whilst there are likely to be occurrences where the use of these codes is appropriate, they are non-specific and generic in nature and reporters should consider the full range of pathway subcodes available for the relevant activity in question before selecting an 'other' pathway subcode.

RTE reports and attendance data

The national radiotherapy dataset estimated number of patient attendances in NHS providers across England, Scotland and Wales for this reporting period was 3,814,095 attendances (19). This required extrapolation, for the UK population to an estimated 3,861,707 attendances and 405,585 prescriptions. This represents an 11.5% increase in attendances and 11.7% increase in prescriptions compared to the previous 2-year reporting period when there were an estimated 363,220 prescriptions across 3,463,569 attendances.

Figure 32. Number of RTE reports submitted to the national voluntary reporting system by classification per month and attendance data



To establish a reported error rate, it was accepted that the great majority of RTE reported affected a single attendance within a single prescription. With this caveat applied, an estimated reported RTE rate of 5.7 per 1,000 attendances was calculated. This represents an increase

from a reported RTE rate of 5 per 1,000 attendances during the previous 2-year reporting period. It is worth noting the majority of these events were classified as minor radiation incidents (Level 3), near misses (Level 4) or other non-conformances (Level 5) which have no bearing on the treatment outcome for the patient. Using the same premise, an estimated reported RTE rate for Level 1 events was calculated as 0.9 per 1,000 prescriptions. This represents an increase from 0.5 Level 1 RTE reported per 1,000 prescriptions during the previous 2-year reporting period. Inevitably there is a lag between the date of incident occurrence and reporting to UKHSA which does affect interpretation, particularly June 2023 when NHSE reports were delayed by a month.

Provider reporting levels

All UK NHS radiotherapy providers have submitted RTE reports to the national voluntary incident learning system over this 2-year period. Additionally, independent RT providers are now also contributing nationally. Further welcome news is this reporting period experienced an increase in RTE volume of 18.4% compared to the previous 2-year period. This presents a positive and encouraging picture of both a mature and growing commitment to radiotherapy safety within the UK. Full and complete error reporting, regardless of severity, is fundamental within safe radiotherapy practice. By reporting minor errors and near miss events, organisations can put mechanisms in place to mitigate these types of incidents, and thus, proactively reduce the chance of those of greater magnitudes of severity and scale from occurring. Near miss events offer a valuable opportunity to address system malfunctions before incidents occur. One example during this reporting period is ‘target and organ at risk delineation’ that has experienced a gradual but significant rise. These types of RTE are usually detected before reaching the treatment unit, during the peer review process or planning checking procedures. However, if these RTE are not detected during these multiple checking processes they can significantly impact upon a patient’s treatment delivery.

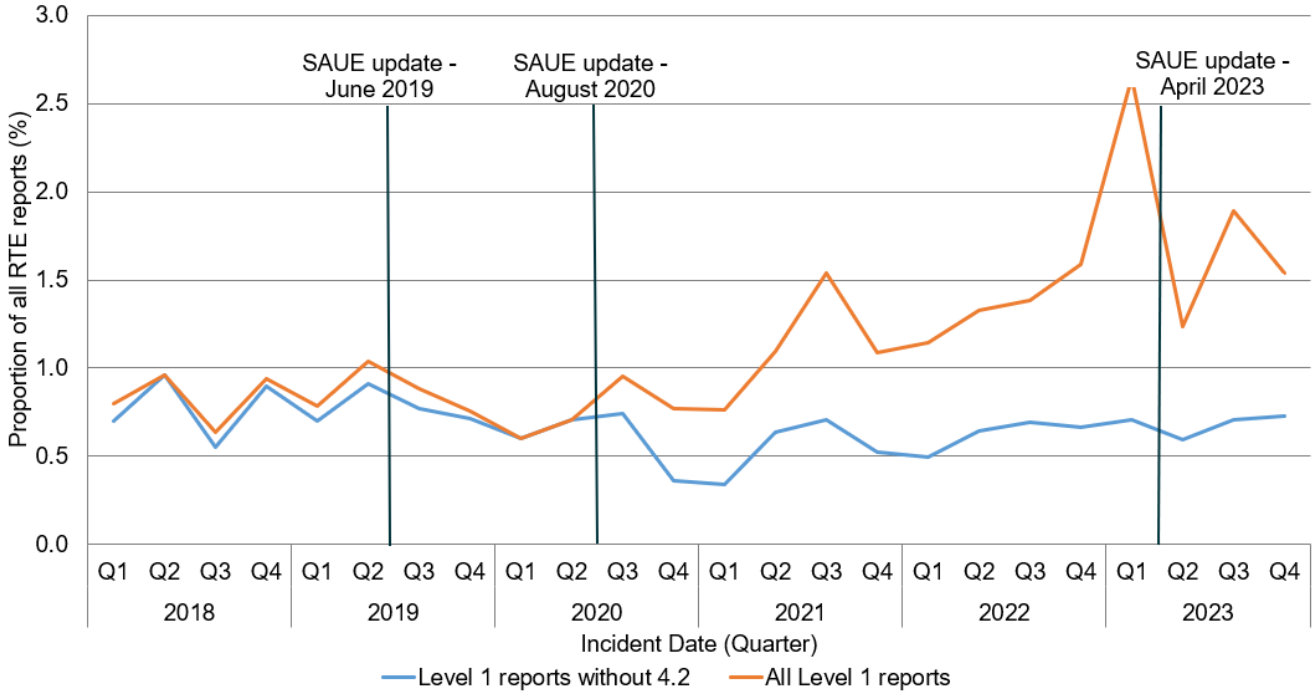
NHS England highlight that incidents within the English health care system have been reported with a frequency of 70.8% for those with no harm, 25.7% with a low level of harm, leaving 3.4% incidents classed as moderate to high levels of harm (29). The proportions in UK radiotherapy error reporting differs with a lower proportion of ‘no harm’ Level 4 and 5 incidents (59.3%) and a higher proportion of ‘low level harm’ Level 3 incidents (38.3%). This might be explained by a possibility that, that despite the growth in reporting numbers overall, all providers may not report low level radiotherapy errors. This is supported by the results of a recent survey, whose results are published in the September 2024 issue of ‘Safer Radiotherapy’, which indicated that whilst all respondents report Level 1 RTE to the national system, less than half stated they report all levels of RTE (n = 20 out of 46).

Level 1 data

The percentage of Level 1 incidents as a proportion of RTE as a whole has increased from 0.9% (n = 165) to 1.6% (n = 350) compared to the previous 2-year reporting period. There are a

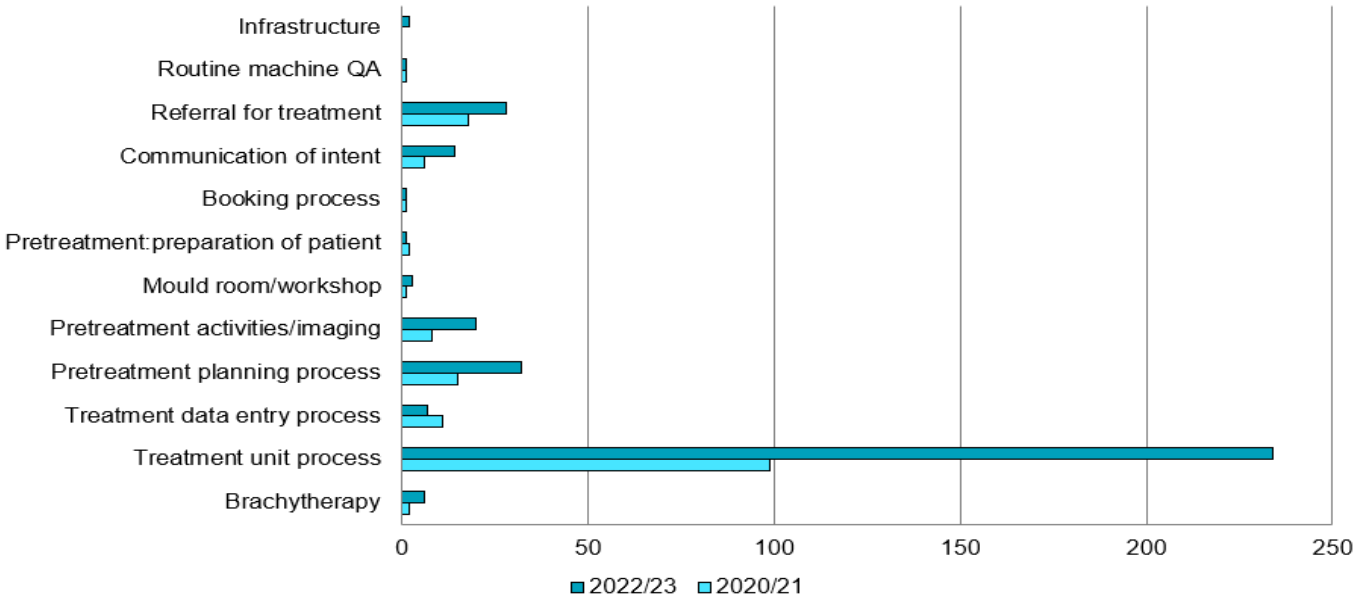
number of reasons for this increase. Firstly, as highlighted in figure 28, the proportion of radiotherapy verification imaging reporting numbers contributing to inspectorate notifications has gradually increased through time. This is mirrored in the national voluntary data. Figure 33 shows the proportion of Level 1 reports for all RTE received through time (in red). This has gradually increased. However, once those reports involving radiotherapy treatment verification images are removed, the proportion of remaining Level 1 RTE has remained consistent (in blue). This suggests that the increase of Level 1 incidents as a proportion of RTE as whole has been mainly driven by errors relating to onset radiotherapy treatment verification imaging. Whilst repeat radiotherapy treatment verification errors that reach a reportable level are occasions that providers must try to mitigate against, the dose involved is considerably less than that associated with therapeutic delivery and will generally not lead to injury. A decrease in proportion of radiotherapy treatment verification imaging for both inspectorate and voluntary reporting is noted since the April 2023 updated SAUE guidance was published (21).

Figure 33. Level 1 incidents as a proportion of all voluntary RTE received with, and without, radiotherapy treatment verification image reports, Quarter 1 2018 to Quarter 4 2023



A second factor relates to a greater breadth of reporting. Overall Level 1 reports with a greater spread of pathway codes were submitted – 66 pathway codes for the current review period (2022 to 2023) compared to 47 in the previous 2-year reporting period. As demonstrated in Figure 34, whilst reporting of Level 1s increased within treatment unit process activities, there were increases in many other areas of the treatment pathway, including referral for treatment communication of intent, pretreatment imaging and planning activities. This appears to indicate an increased awareness of the need to report Level 1 incidents throughout the entire radiotherapy pathway.

Figure 34. Comparison of Level 1 incidents between 2020 to 2021 and 2022 to 2023 reporting periods by activity code



Finally, a notable feature in Level 1 reporting was the increase of reports with a primary pathway code of 'patient positioning' from 3.6% (n = 6) in the previous 2-year reporting period to 10.9% (n = 38) in the current 2-year period. The most frequent method of detection for these errors is via onset verification imaging (47.4%, n = 18). 'Patient position' pathway coding can be used for incorrect or suboptimal patient set up that may lead to target and OAR coverage issues through rotations or large planar displacement errors. It includes other scenarios, such as errant limb positioning leading to unnecessary irradiation during treatment.

Level 2 data

Across the reporting period the number of Level 2 incidents has been low (0.9%, n=194). This is consistent with the previous reporting period. The low number of reports in this classification limit any meaningful thematic analysis and restrict learning opportunities. Future consideration might be given to a refinement of the definition of Level 2 incidents. This may provide greater granularity in the analysis and help identify imaging incidents and treatment incidents that fall below the reporting threshold but are considered potentially clinically significant with greater accuracy.

Level 5 data

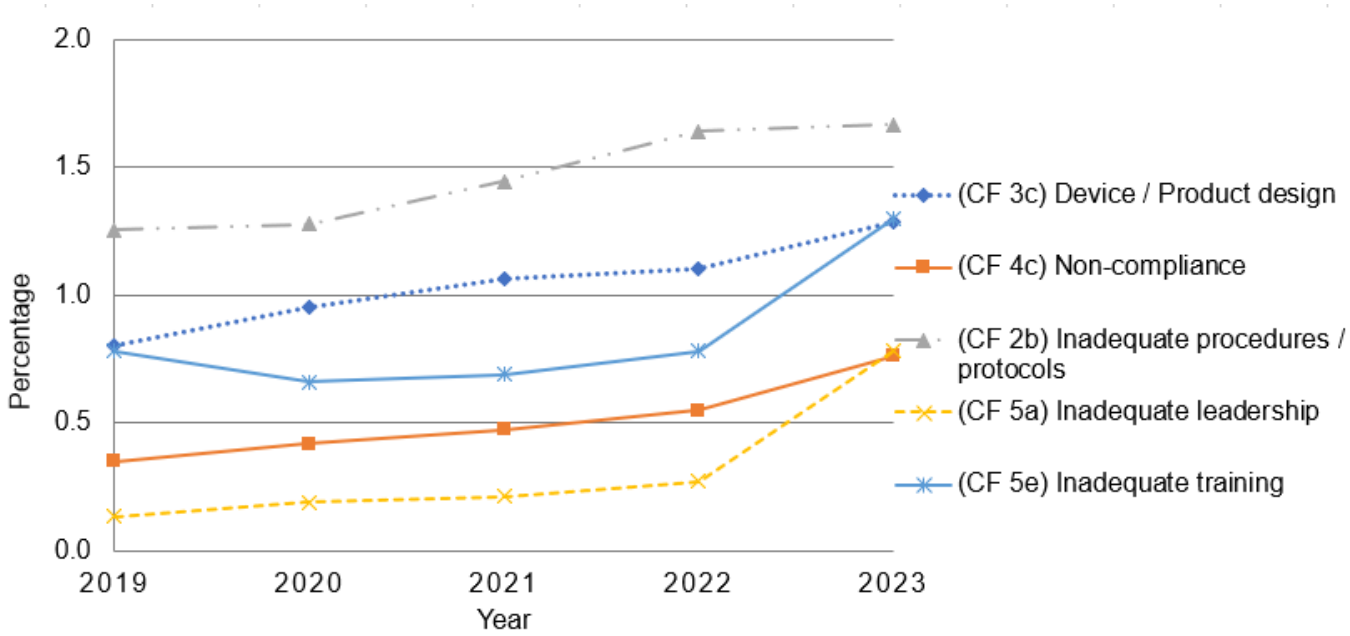
Within Level 5 RTE data, 'bookings made according to protocol' has increased in percentage from 4.9% in 2021 to 7.6% in 2023. The most common contributory factors associated with these types of reports is 'adherence to procedures/protocols' (57.5%, n = 273). Providers experiencing trends in these types of reports may benefit from reviewing current protocols to ensure they are achievable and reflective of current practice. Radiotherapy activity has increased by 11.5% over the current 2-year reporting period and consequently pressures on

(often non-clinical) booking teams have likely increased commensurably. Furthermore, the increase in complexity of treatment planning and delivery may create more intricate booking processes that require constant review to ensure staff are adequately trained and supported. Finally, consideration should be given to reviewing the accessibility and ease of use of quality management systems, to ensure bookings staff are able to access and interpret relevant procedures and protocols when required.

Contributory factors

The most frequently reported contributory factor was 'slips and lapses' (30.2%, n = 8,241), although it has gradually declined in proportion since 2019 (36.1%, n = 4,395). 'Adherence to procedures/protocols' represents the second most common reported contributory factor overall (24.7%, n = 6,753) and has remained broadly stable over the past 5-years. There have been increases in some less frequently used contributory factors over the past 5 years as demonstrated in figure 35. Some of these emerging contributory factors are more indicative of systems thinking and, possibly, suggesting a shift away from blaming human error towards an increasing focus on understanding underlying factors of how incidents happen.

Figure 35. Trends for selected reported contributory factors (January 2019 to December 2023)



When coding RTE reports, providers are encouraged to consider all possible contributory factors that may have influenced the error. Reporting all contributory factors, as well all process codes featured along the incident pathway is an important step in building a systems approach to RTE review. This also will support organisations in reducing employee perceptions of blame culture, where fault is attributed to an individual. If contributory factors are fully addressed, it can be expected that overall system safety is enhanced and not just individual weaknesses associated with a particular incident (16). Consideration and inclusion of all contributory factors is more in keeping with a systems approach to incident review and helps broaden the focus of

the investigation to consider latent failures and not just those events in the immediacy of the incident. This will be considered further as part of a refinement of the national taxonomies to ensure there is appropriate emphasis on the wider context of incidents.

Failed safety barriers

'End of process checks' from each part of the pathway collectively comprise 30.0% (n = 4,128) of all failed safety barriers. Most end of process checks are manual checks, and it is accepted that humans can err, and are not as effective as other preventative measures. Due to the prevalence of the 'end of process checks' as a failed safety barrier, the PSRT investigated the in-room, pre switch-on, and treatment completion checks to better understand these procedures within clinical services and to determine whether failed safety barriers positioned earlier in the pathway could be made more effective. Results of the review were published in 'Safer Radiotherapy eBulletin' number 8 (30).

As part of the review of the national taxonomies there is an opportunity to review the application of safety barriers in the pathway and to consider how to better use then to inform the national analysis.

On-set imaging

Some commonalities in themes can be seen across Level 1- 4 RTE reports. The most pertinent example is the prevalence of verification image associated RTE. Although 'on-set imaging: production process' has been discussed above, reports from all 4 on-set imaging pathway codes combined made up 22.6% (n = 5,006) of all RTE, broadly similar proportion to the previous 2-year reporting period when on-set imaging comprised 23.7% (n = 4,425) of all reports. On-set imaging is most predominant in Level 3 RTE, constituting 44.7% (n = 3,785) of all reports, however this represents a lower proportion, despite a greater volume, compared to the previous 2-year reporting period (48.5%, n = 3,277). On-set imaging also features heavily within Level 1 reporting with a 34.9% (n = 122) share. This has remained consistent with the previous 2-year reporting period when it represented a 35.2% (n = 58) proportion of Level 1 reports.

That on-set imaging features so prominently might be expected. Shortened fractionation regimes are more common and more likely to trigger the reporting thresholds set by the IR(ME)R inspectorates (10 to 12), whilst image guidance is ubiquitous within the radiotherapy treatment workflow. IGRT is an established cornerstone of modern radiotherapy delivery with imaging often taken prior to every treatment for many sites and techniques. Many recent developments, such as ultrahypofractionated treatment regimens, would be impossible without IGRT as a key driver. Effective IGRT ensures very high doses of radiotherapy are delivered accurately to target volumes, whilst avoiding organs at risk throughout the treatment course. In this regard, the high incidence of on-set imaging associated RTE reflects not only the high volume of imaging taking place but the complexity of modern image guidance. Current IGRT

workflows do lead to an increased dependence on skilled radiographer interpretation and decision-making during image acquisition and review. The consequence may be a high volume of on-set image related errors. The importance of clear, appropriate documentation and effective training mechanisms to support radiographers during IGRT cannot be overstated.

However, as mentioned above, there are many well documented benefits of on-set imaging to patient care, including evidence of improved clinical outcomes (31). Its role in reducing treatment delivery uncertainty provides a further benefit of acting in a safeguarding role in identifying many RTE which otherwise may have affected treatment delivery. This is highlighted by the most frequently reported error method of detection within voluntary and inspectorate data being 'on-set imaging: approval process', reinforcing the importance of imaging as a highly effective safety mechanism.

Equipment and IT network failure

The radiotherapy workflow, briefly summarised as localisation, planning and treatment, requires the use of a wide range of highly complex diagnostic, planning and therapeutic hardware and software. These tools generally perform with remarkable reliability and consistency. However, occasionally they do suffer from system dysfunction and failure. Equipment malfunction is most often reported from the treatment area and is featured most prominently in Level 3 reports.

The proportion of Level 3 reports comprised of 'on-set imaging: production process' reduced from the previous 2-year report (34.1% down to 30.6%). However, the most frequent contributory factor was 'equipment or IT network failure', increased from 42.2% to 51.8% (n = 1,193) indicating a notable contribution from imaging hardware and software faults.

Equipment malfunction is also a contributory factor associated with pathway code 'management of variations/unexpected events/errors'. Level 3 reporting of this pathway code has risen year on year (from 3.9% in 2020 to 9.5% in 2023), with a commensurate increase in the proportion of reports attributed to 'equipment or IT network failure' increasing from 74.1% (n= 280) in the previous 2-year report to 83.3% (n = 628) during the current review period.

Taken together, the equipment malfunction incidents associated with on-set imaging production process failures and treatment machine faults constitute a significant proportion of both Level 1 reports, and of RTE as a whole. Their continued prominence does represent an area for improvement, as there is currently little indication for a downward trend, whilst considerable workflow disruption is associated with these types of scenarios. However, this does present an opportunity. If issues attributed to equipment malfunction and IT failure were effectively addressed, then this would have a considerable impact on RTE reporting volume.

Guidance on reducing incidents associated with 'on-set imaging: production process' is included in case study 2 in issue 32 of 'Safer Radiotherapy' (32) and the 'good practice guidance' series (33), whilst pathway code 'management of variations/unexpected events/errors' was featured in 'Error and near miss reporting: The unseen pathway' (15). In trying to minimise errors linked

with equipment and IT failure it is expected that following commission and clinical acceptance of radiotherapy equipment and software, they are subject to regular and timely QA as per local procedures. Tasks, tolerance and action levels, as well as escalation routes should be clearly defined, and responsibilities allocated to appropriately trained and entitled staff.

When these events persist, it should be expected that:

- logged events are documented and monitored to identify root cause and trends so that action and escalation of these events can be taken as appropriate
- the manufacturer, the relevant agency (Medicines and Healthcare products Regulatory Agency, Northern Ireland Adverse Incident Centre and Health Facilities Scotland) and, where appropriate, the IR(ME)R inspectorates (10 to 12) are notified of the occurrence of these events
- providers are encouraged to investigate methods for predicting equipment failure and allow for proactive maintenance to limit the impact of unscheduled repairs on patient treatment (34 to 36)
- risk assessments are undertaken for ongoing use of the affected equipment. This may subsequently affect the decision of the practitioner (under IR(ME)R (10 to 12)) on the justification for additional imaging, and potential therapy dose due to failures of the equipment affecting the treatment prescription including concomitant imaging dose – the provider must consider the age profile of the relevant devices; assess alternative mitigations that could be implemented ensuring the risk and benefit to the patient is considered; to identify an appropriate threshold at which point there is consideration given to removing the device from clinical use

Error trends

On-set verification imaging is extremely valuable in identifying and correcting for errors, particularly those during patient set up, despite it contributing a significant volume of RTE. The overall proportion of RTE from onset imaging has appeared to be resistant to change. Whilst much has been done to improve patient safety in radiotherapy some error trends persist. The drivers for these trends can often be opaque, and are certainly multifactorial, but it is possible that the influence and scope of conventional national error learning methods may benefit from additional methods of analysis and dissemination. Those error trends that remain stubbornly prevalent may require new and novel approaches to mitigate and further drive safe radiotherapy. A more prospective, integral approach to safety that acknowledges the complex incident interplay between technical, individual, group, organisational, environmental and social factors may allow systematic, comprehensive analysis to better identify how work systems permit various modes of failure to occur within clinical workstreams.

The UK has successfully established a national reporting and learning system for radiotherapy which uses a nationally adopted, well defined, RTE coding taxonomy. This taxonomy can effectively characterise both where in radiotherapy pathways errors occur and what

circumstances are associated with the event. Allied to this taxonomy is a mature dataset of many tens of thousands of reports. This allows for identification of emerging trends that might not be immediately apparent within individual provider error reporting platforms. This remains highly pertinent in a healthcare field characterised by continually advancing practice facilitated by technological and technical innovation and improvement. The use of artificial intelligence (AI) and automation is already well established within many areas of radiotherapy (37) and its appropriate use is expected to enhance radiotherapy safety (38). Recently, the emergence of both MR- and CBCT-online adaptive RT has been enabled by AI and automation. This has allowed for many processes formerly carried out offline to be completed with the patient on the treatment couch. Whilst these techniques are characterised by numerous safety mechanisms there is possibility for new risks to arise within these workflows, some potentially severe (39). Because of this, transparency is critical and that providers continue to report all errors and near misses encountered when operating their online adaptive platforms. Online adaption data is starting to emerge on the national ILS but currently volumes are very limited and sometimes difficult to identify. The forthcoming refinement of the national taxonomies is expected to address issues with identification of specific modalities.

A second benefit of a mature UK national incident learning system is an opportunity to take a systems-based approach to incident learning which might identify safety gaps and areas of high risk and help formulate strategies to strengthen relevant systems. However, developing successful proactive systems-based approach is complex and is associated with multiple challenges. To be effective this will require a consensus building coordinated approach. Of fundamental importance is that providers submit reports with taxonomy coding that fully describes the entire error pathway, rather than simply where the error was detected or initially arose. Further information on both local and national principles and application of systems thinking quality improvement will be outlined within *Advancing Safer Radiotherapy* this year. This will be accompanied by a refinement of the national taxonomies to support this approach.

In addition, systems thinking advocates a shift from ‘Safety-I’ principles to identify the root cause of incidents, towards a ‘Safety-II’ paradigm where, instead of only looking at the few cases where things go wrong, the focus is on the many cases where things go right and attempting to understand how that happens (40). Highlighting and championing these successes may influence further improvements in different areas of practice. The PSRT will seek to address these aspects in the forthcoming ‘Advancing Safer Radiotherapy’.

Risk assessment and study of risk

Learning from RTE needs to be local, national, and international to optimise learning opportunities and mitigate against these types of events. Outputs from RTE analysis should be used to inform prospective risk assessments in thematic areas identified in the analysis as part of a study of the risk of accidental and unintended exposures (23, 41).

A study of risk, or a proactive risk assessment, is a process that helps organisations to understand the range of risks (both internal and external) that they face, their capacity to control those risks, the likelihood (probability) of the risk occurring and the potential impact thereof. This involves quantifying risks, using judgment, assessing, and balancing risks and benefits and weighing these against cost (41). A recognised risk assessment approach should be used and adapted as required with agreed timing for completion and review. Further guidance on the study of risk is available. Table 5 highlights the most frequently reported pathway subcodes and where the associated study of risk for these pathway subcodes can be found.

Table 5. Most frequently reported process subcodes and associated study of risk

Most frequently reported process subcode	Study of risk available in associated Safer Radiotherapy publication:
(13z) On-set imaging: production process	Triannual RTE analysis and learning report issue 32
(13cc) Management of variations, unexpected events or errors	Error and near miss reporting: the unseen pathway
(10j) Documentation of instructions/information	Triannual RTE analysis and learning report issue 33
(13i) Use of on-set imaging	E-bulletin number 5
(13aa) On-set imaging: approval process	E-bulletin number 5
(12f) Accuracy of data entry	Triannual RTE analysis and learning report issue 36
(11j) Generation of plan for approval	Triannual RTE analysis and learning report issue 38
(13g) Patient positioning	Triannual RTE analysis and learning report issue 39
(6a) Bookings made according to protocol	To be completed
(11i) Target and organ at risk delineation	Triannual RTE analysis and learning report issue 43

Supplementary learning resources have been made available to the RT community to support consistency in the local application of the existing taxonomies and the development of simple studies of risk of frequently reported RTE. This consists of a number of 20-minute presentations available on the UKHSA website for download, aimed at supporting professionals in the RT community. ‘Advancing Safer Radiotherapy’ will facilitate the review of taxonomies used for the coding of RTE to ensure they continue to reflect contemporary practice in RT and current thinking in patient safety in healthcare. This work focuses on learning retrospectively from RTE through incident analysis and use of RTE data to inform simple prospective risk assessments.

Molecular radiotherapy

Limited numbers of molecular radiotherapy RTE have been submitted to the national voluntary reporting platform and are included within this analysis. Later this year molecular radiotherapy RTE will be included within a separate national incident learning system. This will be managed by UKHSA to ensure incidents and near misses in clinical imaging, magnetic resonance imaging and nuclear medicine are monitored, analysed and learning shared to help mitigate such events. User guidance and application of the national taxonomy for incident learning in clinical imaging, MRI and nuclear medicine has been released for immediate adoption by providers, whilst the extraction of relevant incident data from existing systems such as LFPSE and OfW Concerns Management System will begin later in the year. Individual departments in Northern Ireland, Scotland and the independent sector will also have the opportunity to submit data directly to UKHSA.

Conclusion

Radiotherapy remains a very safe practice whose working community is acutely aware of their responsibility in maintaining a safe, secure environment where patients receive the best care possible. This is evidenced in the tens of thousands of radiotherapy exposures undertaken accurately and safely every day. However, on occasion things do go wrong and it is important that we learn from these events. Participation in the national voluntary incident learning system is indicative of an open and transparent safety culture (16, 17). This participation provides opportunities to learn from a greater pool of data and facilitates local comparison of events to the national picture to support a reduction in the magnitude and probability of RTE. Over the last 2 years, all providers have submitted RTE reports to the voluntary incident learning system reflecting a strong community commitment to shared learning from incidents. It is essential that this commitment, and further open reporting, is supported and encouraged by employers.

The volume of RTE reported increased by 18.4% compared to the previous 2-year period. Whilst the 11.5% increase in attendance between the 2-year periods can account for a proportion of the rise it does not account for the entirety. Furthermore, estimated reporting rates of 5.7 RTE per 1,000 attendances and 0.9 Level 1 RTE per 1,000 prescriptions for this reporting period represents notable increases from an estimated RTE rate of 5 per 1,000 attendances and 0.5 Level 1 RTE events per 1,000 prescriptions for the previous 2-year period. It is possible that providers commitment to patient safety is leading to a commensurate increase in reporting, a trend very much to be welcomed.

Another possibility is that changes in activity have impacted upon reporting levels. Providers may be experiencing staffing issues at a time when cancer incidence and referrals are rising (42, 43). This may lead to increasing work pressures for radiotherapy staff, making them more suspectable to burnout (27), increasing the likelihood of preventable incidents (28). Certainly, the causes are multifactorial and, ultimately, challenging to ascribe proper relevance to with any great certainty.

National radiotherapy error reporting in the UK is well established and provides a wealth of data. This data resource may possibly be utilised to proactively manage patient safety by accurately identifying emerging trends at national level and provide means for providers to intervene effectively to minimise their occurrence. To this end, the forthcoming guidance document ‘Advancing Safer Radiotherapy’ provides an opportunity to appraise the national approach to RTE data analysis and learning and consider the application of further systems-based patient safety incident responses.

Recommendations

Local provider recommendations:

1. All NHS UK providers should continue to use the national taxonomies, including classification, pathway subcodes, failed safety barriers, method of detection and contributory factors, to code all levels of RTE for local analysis, learning and practice.
2. Local employers should provide adequate resourcing to support the development and maintenance of effective patient safety systems and processes. Likewise, they should encourage national reporting of all classification Levels of RTE on a monthly basis to ensure timeliness of shared learning.
3. Equipment-related incidents should be reported to the relevant agency, manufacturer and UKHSA. If equipment faults persist a risk assessment should be undertaken for the ongoing use of the device.
4. Local learning should be compared with national data and used to inform local and regional practice.
5. Outputs from local RTE analysis should be used to inform prospective risk assessments as part of a study of the risk of accidental and unintended exposures.

National recommendations:

1. Learning from RTE should be used by the Patient Safety in Radiotherapy Steering Group (PSRT) and individual RT providers as part of a risk-based approach to allocating resources for improving patient safety in RT and to inform audit and research.
2. PSRT should engage the relevant agencies and vendors in developments to monitor and reduce the rate of RTE related to imaging equipment failure.
3. Following the review of safety barrier (SB) data analysis, the PSRT will provide updated guidance and refine future safer RT publications. Future trend analysis will not be limited to failed safety barriers but consider the multiple pathway codes detailed within RTE reports to reflect the multifaceted nature of a full systems analysis.
4. The taxonomies used for the coding of RTE were last updated in 2017, these should be reviewed by the PSRT to ensure they continue to reflect contemporary practice in RT.
5. Providers utilising molecular radiotherapy (MRT) or diagnostic MRI facilities are encouraged to use the National taxonomy for incident learning in clinical imaging, magnetic resonance imaging and nuclear medicine guidance. A mechanism to report these incidents nationally to UKHSA will become available later this year.
6. Working with stakeholders the PSRT will develop guidance for UK RT providers to support the advancement of safer RT through the adoption of contemporary thinking in the field.

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- Helen Best (UKHSA)
- Neil Burley (Society of Radiographer's Clinical Representative – Radiotherapy Quality Manager, University College London from 2024)
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