UK Health
Security
Agency

Safer radiotherapy

Biennial radiotherapy error data analysis and learning report

Report number 7: Full radiotherapy error data analysis January 2020 to December 2021

Contents

Executive summary

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 since its introduction in 2008.

This report is the seventh in a series of 2-year reports (2), providing an overview of Radiotherapy Error (RTE) data reported voluntarily to the National Reporting and Learning System (NRLS) and directly to UKHSA between January 2020 and December 2021 (n = 18,681). The report also contains aggregate data from January 2017 to December 2021 (n = 45,282) and compares data with that from the preceding 2-year period (n = 18,734). This report includes data received from each of the UK inspectorates for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (3 to 5) (n = 249)).

The analysis undertaken uses the taxonomies from ‘Towards Safer Radiotherapy (TSRT)’ (6) and the ‘Development of Learning from RTE (DoL)’ (7) thus facilitating comparisons of national RTE trends with both local and network or regional findings.

Of the 18,681 RTE reports reviewed, analysis of the severity of the reports showed 98.4% (n = 18,394) 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, 0.7% (n = 122) did not reach the notification threshold and only 0.9% (n = 165) were notifiable under IR(ME)R (3 to 5) to the inspectorates (Level 1). Of the Level 1 RTE reported, it is known most of them affected only one fraction of a course of treatment. This meant that corrective action could be taken over the remaining treatment fractions.

Extrapolating data from the Radiotherapy Dataset (RTDS) (8), an estimated 3,463,569 RT attendances and 363,220 RT prescriptions were delivered in the UK in this reporting period. An estimated reported RTE rate of 5 per 1,000 attendances was calculated. This was calculated as 0.5 per 1,000 prescriptions for reportable radiation incidents (Level 1). Please note this is a measure of number of errors reported as opposed to occurrence of errors.

Over the past 5 years there has been a decrease in the percentage of RTE associated with ‘accuracy of data entry’ and ‘on-set imaging: approval process’. The decrease in ‘accuracy of data entry’ may be due to further optimisation of the data pathway and the uptake in the use of IT to reduce the need for transcription. The decrease in ‘on-set imaging: approval process’ may be due to more competency-based imaging review protocols.

A notable trend within the Level 1 RTE includes a decrease in RTE associated with ‘on-set imaging: approval process’ from 11.9% in 2017 to 5.9% in 2021. Over the 2-year period, it was the second most frequently reported Level 1 RTE at 8.5% (n = 14) down from 8.9%, (n = 31) in the previous 2-year period (9), and the most frequently reported Level 2 reports at 16.4% (n = 20).

The reported trends in the Level 1 to 4 data differ from the Level 5 RTE reports where the most frequently occurring subcode was ‘documentation of instruction/information’ making up 5.4% (n = 371).

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 will only be 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, blame free reporting culture and where the clear aim of reporting is to learn and to improve patient safety (10, 11).

Learning from RTE continues to be an effective tool to learn from and mitigate RTE. It is important that learning continue to be shared locally, nationally and internationally to maximise opportunities to improve patient safety in RT. Use of RTE data to inform local prospective risk assessment is an additional effective tool to mitigate these events and optimises use of RTE data.

Participation in the national voluntary incident learning system (9, 12) is indicative of an open and transparent safety culture. This 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 5 years, all but one provider submitted RTE reports to the voluntary incident learning system. This reflects a strong community commitment to shared learning from incidents, which should be supported by the employer.

Local provider recommendations:

1. All NHS UK providers should continue to use the TSRT and DoL taxonomies, including the pathway subcodes, failed safety barriers (FSB), method of detection and causative factors, to code all levels of RTE for local analysis and to inform local learning and practice. The entire coding taxonomy should be considered before using the ‘other’ code within a taxonomy
2. Local employers should support adequate resourcing of effective incident learning systems to simplify the local reporting process and to encourage reporting of all classification levels of RTE on a monthly basis to ensure timeliness of shared learning.
3. Independent RT providers should submit RTE reports to the national voluntary reporting system.

4. Where imaging device faults persist, a risk assessment should be undertaken for the ongoing use of the device.
5. Local learning should be compared with the national picture and used to inform local and network level practice.
6. Outputs from local 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.

National recommendations:

7. 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.
8. PSRT should engage the MHRA and vendors in developments to reduce the rate of RTE related to imaging equipment failure.
9. PSRT should share key learning from the analysis related to on-set imaging RTE with the IR(ME)R inspectorates to inform future refinements to reporting criteria for significant and accidental unintended exposures.
10. Due to the prevalence of FSB at the end of process checks the PSRT should undertake work to better understand end of process check procedures and efficacy of safety barriers.
11. 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. A review of the pathway coding demonstrates that it does not lend itself well to molecular radiotherapy (MRT) errors and this should be addressed if MRT providers are to be encouraged to participate in incident learning.
12. 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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12. NHS Improvement. Report a patient safety incident

Introduction

Patient safety in radiotherapy (RT) has been defined as the absence of an unacceptable risk of harm when harm is excessive morbidity or sub-optimal tumour control (1). A strong safety culture is a cornerstone of patient safety and is essential in ensuring the risk of probability and magnitude of error are minimised. An incident learning system contributes to an effective safety culture (2).

The fundamental role of an incident learning system is to enhance patient safety by learning from failures of the healthcare system (3). It is known that most problems are not just a series of random, unconnected one-off events, they are provoked by weaknesses in systems and processes and often have common root causes which can be generalised and corrected. Although each event is unique, there are likely to be similarities in contributory factors and patterns in sources of risk that may go unnoticed if incidents are not reported and analysed. It is imperative errors and near misses are learned from and effective preventative measures are implemented (4).

To maintain or improve patient safety, errors must be prevented or minimised by reporting and analysis. All RT providers should have clear guidelines in their quality system on error management, and actions to be taken when errors occur. Experience has shown that as an organisation's reporting culture matures, staff become more likely to report radiotherapy error and near miss events (RTE). There is an emerging evidence base that organisations with a higher rate of reporting have a stronger safety culture (5). The value of near miss and error reporting and learning processes is well appreciated in the UK RT community with 100% of NHS RT providers having subscribed to a system of national voluntary reporting of RTE since 2008.

The 2006 (6) report of the Chief Medical Officer for England and 'Towards Safer Radiotherapy (TSRT)', published in 2008 (7), were seminal documents in the field of RT safety. Both contained practical recommendations for the RT community aimed at improving safety and reducing errors. These recommendations have been adopted by UK RT providers.

Background

In the context of this report, 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 and intraoperative therapies, brachytherapy and some molecular radiotherapy.

This report is the seventh in a series of 2-year reports (8), providing an overview of RTE data reported voluntarily between January 2020 and December 2021. The report also contains aggregate data from January 2017 to December 2021.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) (previously Public Health England) on RTE reported voluntarily by NHS RT providers and the relevant enforcing authorities for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (9 to 11). The analysis has been reviewed by the Patient Safety in Radiotherapy Steering Group (PSRT). This multidisciplinary group's membership includes a patient representative alongside representatives from the Institute of Physics and Engineering in Medicine (IPEM), Royal College of Radiologists (RCR), Society of Radiographers (SoR) and UKHSA. The PSRT are tasked with leading a collaborative programme of work to improve patient safety in RT. The PSRT recommends learning from this analysis and the triannual analyses (12). These publications facilitate the comparison of locally identified trends against the national picture.

TSRT (7) provides definitions for the terminology to be used in defining RT errors that include near misses (RTE) and proposed 2 taxonomies for use in describing RTE. The ‘classification of radiotherapy errors grid’ describes the severity of the error and the ‘radiotherapy pathway coding’ describes where in the RT pathway the error occurred. In 2016, the ‘Development of Learning from Radiotherapy Errors’ (DoL) (13), a guidance document supporting the enhancement of learning from RTE and their analysis, was published. It includes a refinement of the ‘radiotherapy pathway coding’ to include ‘safety barriers’ (SB) and a proposed ‘causative factor (CF) taxonomy’. The DoL document also contains definitions and examples on the application of the taxonomies. Following the adoption of safety barrier coding a further refinement was made to include methods of detection (MD). Coding of MD was introduced in 2018 (14) and refined in 2021 (15). These key publications have facilitated the national sharing of RTE.

The National Reporting and Learning System (NRLS) is an anonymised voluntary reporting system to collect and learn from patient safety incidents for England and Wales. The NRLS is managed by the Patient Safety Team who currently sit within NHS England (NHSE). UKHSA has a data sharing agreement with the NRLS and under this agreement RTE data is extracted from the NRLS and shared with UKHSA for analysis.

In November 2013, a mechanism for providers in Northern Ireland and Scotland to contribute to this voluntary reporting scheme was introduced. Data from across the UK, including data received from the relevant enforcing authorities for IR(ME)R (9 to 11) for the UK, was published in subsequent 2-year reports (8). The relevant enforcing authorities will be referred to as inspectorates here after.

The NRLS will be replaced by the new Learn from Patient Safety Events Service (LFPSE) which will receive data from across England (16). The Once for Wales Concerns Management System Programme has built a structured platform for capturing learning from incidents and concerns and achieving consistency across NHS Wales. The Datix Cymru System is the NHS Wales solution to collating National data from April 2022.

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 error occurrence, as such, this data requires interpreting with care.

Data for the reporting period January 2020 to December 2021 forms the focus for the analysis. Where possible, comparisons are drawn against the previous 2-year (17) reporting period and data for annual reporting periods going back over 5 years.

Obtaining the data

The data was obtained through 3 distinct routes: from the NRLS in England and Wales and directly from providers in Northern Ireland and Scotland. These 2 routes are described in detail below. In addition, anonymised synopsis of closed reportable radiation incidents was shared by the UK IR(ME)R (9 to 11) inspectorates with UKHSA for inclusion in the analysis.

National voluntary reporting system

There are 59 RT NHS providers across the UK, 53 of which are within England and Wales. Therefore, the vast majority of reports came through the NRLS (18) at NHSE, which collated reports for England and Wales. The NRLS operates a voluntary reporting system to collect and learn from patient safety incidents.

A patient safety incident (PSI) is defined as 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare' (18). PSIs are reported by NHS organisations in England and Wales through bulk upload via local trust risk management systems to the NRLS. Independent providers (IP) are also able to report to the NRLS using web-based forms, but none have done so to date. Both healthcare staff and the general public are encouraged to report any incidents directly through an open access form (19).

During the development of this work, a system was created to extract targeted data from the NRLS using a trigger code 'TSRT9'. This was proposed and described in 'Implementing Towards Safer Radiotherapy: guidance on reporting RTE effectively' (20). This code is searched for in the free text field rather than using search terms that were found to be less determinant.

A RTE is defined in TSRT as 'a non-conformance where there is an unintended divergence between a RT treatment delivered or a RT process followed and that defined as correct by local protocol' (7). PSIs that are not RTE, such as a report of a patient falling in a RT department, are not included in the RTE dataset. These are reviewed, analysed, and shared by NHSE.

A mechanism was developed to enable providers in Northern Ireland and Scotland to participate in this scheme in 2013. Once agreements for data sharing were achieved with health boards and hospital trusts, predefined criteria consistent with those employed for the NRLS data were shared with RT providers in Northern Ireland and Scotland for inclusion in reports.

Anonymised data has been accepted from providers as exports of local incident management systems as Microsoft® Office Excel spreadsheets for direct upload into the UKHSA RTE incident database to minimise the possibility of transcription error and to ensure the anonymity of the data.

Inspectorate data

There is a requirement for RT providers to notify the IR(ME)R (9 to 11) inspectorates of significant accidental or unintended exposures (SAUE) or 'reportable radiation incidents' (Level 1) as defined in TSRT (7). The UK inspectorates for IR(ME)R, Care Quality Commission, Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority shared anonymised closed synopses of reported significant accidental or unintended exposures (SAUE) for analysis. This data is analysed separately from the voluntary data to reduce replication of Level 1 reports within the data and presented in the results section of the report. As IR(ME)R applies to both NHS and IP RT providers, this data covered both sectors. As the majority of RT is delivered in NHS Trusts it is thought that the IP RTE data should make up a small proportion of the inspectorate data.

Data quality

All providers were asked to include a trigger code, classification (7), pathway coding, including failed safety barriers, causative factor, and methods of detection (13) in RTE reports to facilitate both local and national analysis.

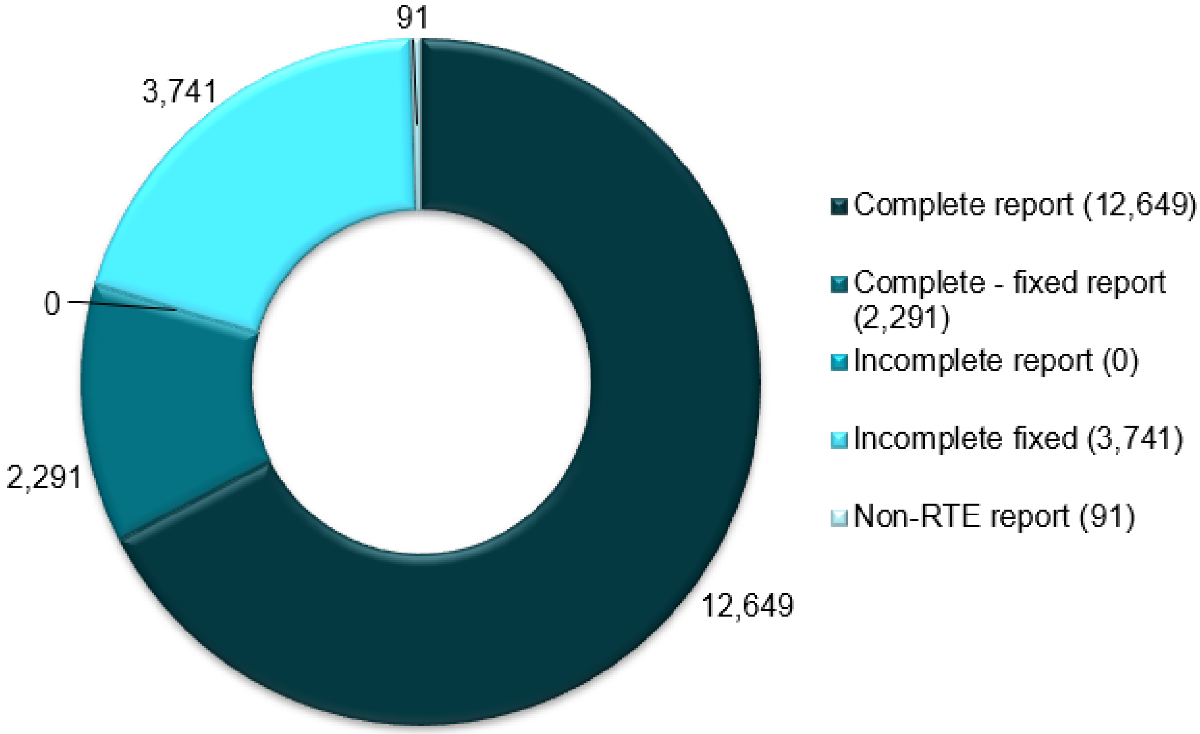
On receipt of the reports, UKHSA staff with clinical RT expertise performed consistency checking of the local application of the classification and coding. The coding was reviewed for all RTE classified as reportable through to near miss (Levels 1 to 4) and 10% of non-conformances (Level 5) RTE were audited. 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, pathway coding and causative factor taxonomies
- 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 defined as reports without the classification and coding being applied locally prior to submission

- 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 not RTEs as defined in TSRT (7)

Figure 1. Breakdown of report completeness (n = 18,772)



Of the 18,772 RTE reports received, 79.6% (n = 14,940) were classified and coded by local RT providers (Figure 1). Of these, 15.3% (n = 2,291) were amended (complete fixed). Of the complete fixed reports, 34.7% (n = 796) had the classification amended, 69.9% (n = 1,601) had the pathway subcode amended (see Table 2) and 11.0% (n = 252) had the causative factor amended.

The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (55.7%, n = 443), 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 2. ‘Use of on-set imaging’, made up 13.8% (n = 316) of all the 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 50.5% (n = 809) of all amended primary pathway subcodes were originally assigned one of the ‘other’ primary pathway subcodes.

Table 2. Amendments made to pathway process subcodes

Initial pathway subcode	Most frequently amended to
13i 'use of on-set imaging' (13.8%, n = 316)	13z 'on-set imaging: production process' (n = 150)
13jj treatment unit process 'other' (12.3%, n = 282)	13cc 'management of variations, unexpected events or errors' (n = 102)
13z 'on-set imaging: production process' (5.3%, n = 122)	13bb 'on-set imaging: recording process' (n = 26)
11v pretreatment planning process 'other' (4.5%, n = 103)	11j 'generation of plan for approval' (n = 40)
10n pretreatment activities 'other' (4.0%, n = 92)	10f 'production of images demonstrating correct detail' (n = 11)

The CF was amended in just 252 of the 2,291 complete fixed RTE, 41.3% (n = 104) of these were amended from CF7a 'other' and another code from the existing CF coding applied.

There were 14,940 RTE reported as complete (containing a classification, pathway coding and causative factor) only 39.4% (n = 5,887) of these contained a method of detection (MD) taxonomy, a further 3,297 contained sufficient text for UKHSA to assign an MD. All future RTE data quality analysis will include the method of detection taxonomy within the complete reports.

There were 3,741 incomplete reports received from 54 different providers. However, 45.1% (n = 1,686) of these incomplete reports were received from one provider. UKHSA are currently working with this provider to support the local application of RTE taxonomies. The 91 non-RTE reports (0.5%), were excluded from the analysis. These were largely slips, trips or falls that occurred within the RT setting. A total of 99.5% (n = 18,681) of the reports submitted were included in the analysis for this report.

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 system at either NRLS 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 798 days was found for individual RTE. There was an average lag time of 31 days and a mode of 21 days across providers.

A total of 69 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 at audit, at re-treat appointment, or report lost leading to a delay to reporting to local incident learning system.

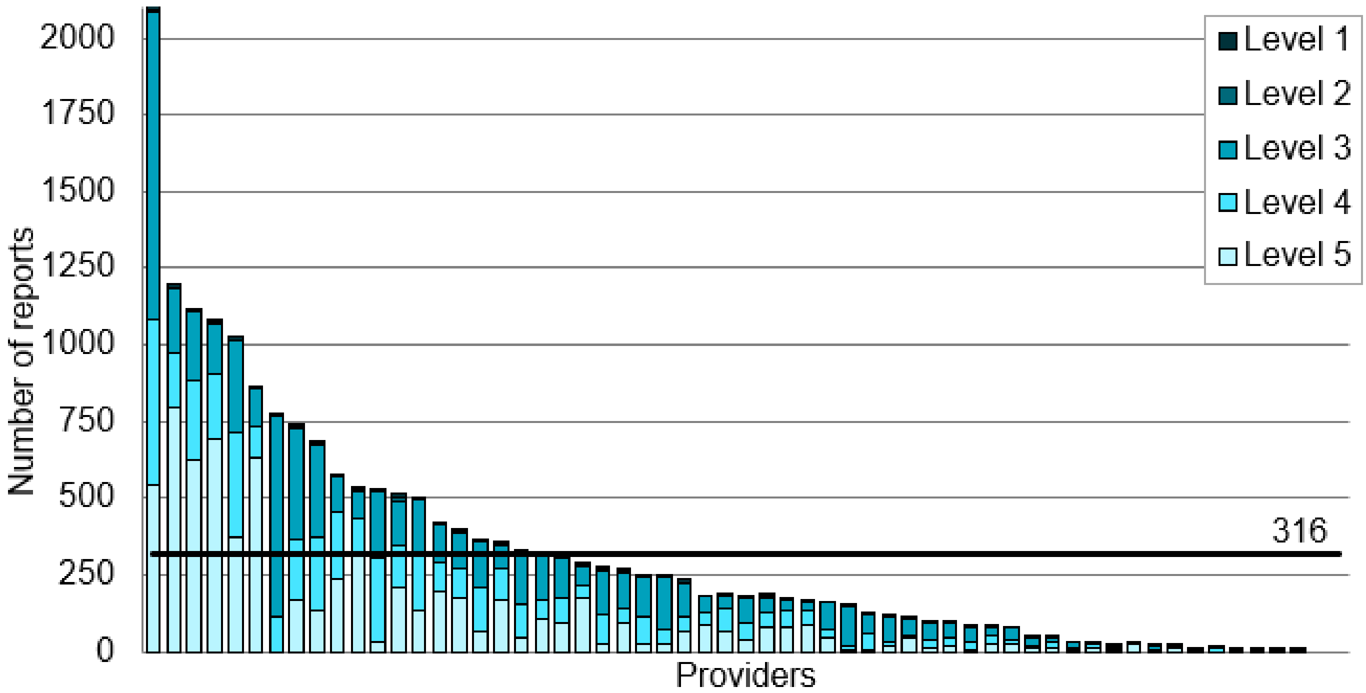
The average lag time of 31 days for submitting reports has decreased significantly from 51 days in the previous 2-year report (17). This may be in part due to the continued growth in use of electronic reporting systems and strengthened local processes for incident management (21).

Number of reports per provider

There are currently 59 NHS RT providers across the UK, this has reduced from 60 NHS providers due to provider merger. For this 2-year period, reports were received from the majority of NHS RT providers, 57 (96.6%). Over the last 5 years, all but one NHS provider submitted RTE reports to the voluntary incident learning system.

There is some variance in the number of reports submitted by provider as seen in Figure 2. This ranged from 3 to 2,111. Of note 64.4% (n = 38) providers reported less than the average of 316 RTE over the 2-year period.

Figure 2. Number of RTE reported by provider (n = 18,681)



Results

A total of 18,681 RTE reports were submitted to the voluntary reporting scheme between January 2020 and December 2021, with an average 778 reports received per month. The 18,681 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.

It is accepted that with any voluntary incident learning system there will be some subjectivity in reporting levels across providers. Figures presented in the report will only reflect those RTE submitted to the national system as opposed to the actual occurrence of RTE. Therefore, the data should be interpreted with care.

Between January 2017 and December 2021, UK NHS RT providers submitted 45,282 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 1. A total of 18,681 were reported between January 2020 and December 2021 and 18,734 were reported between January 2018 and December 2019 (17).

Table 1. Number of RTE reports submitted to the incident learning system by year

Year	2021	2020	2019	2018	2017
Number of reports	9,544	9,137	9,793	8,941	7,867

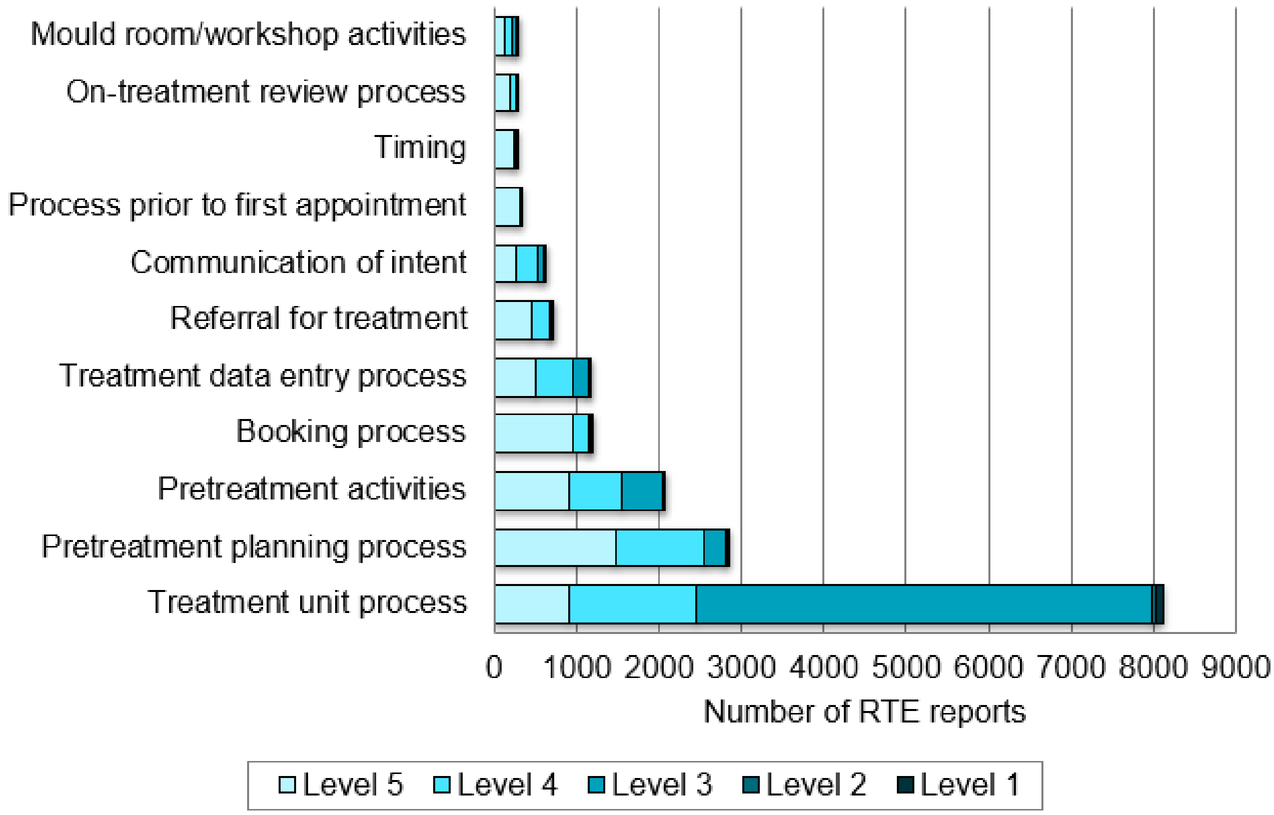
A z-test statistic has been used to compare 2 proportions (or rates) to see if they are the same. A linear regression analysis has been performed to estimate the slope for RTE classifications using yearly data and a t-test to determine whether the slope of the fitted trend model is significantly different 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 DoL (13) and TSRT (7) classification level so the main themes could be derived. RTE reports were spread across all 21 categories of process code and level. The RTE reports associated with ‘treatment unit process’ comprised 43.5% (n = 8,134) of the data and ‘pretreatment planning process’ 15.2% (n = 2,844) (Figure 3).

‘Treatment unit process’ process code reports were made up of ‘minor radiation incidents’ (Level 3) at 67.8% (n = 5,518), ‘near misses’ (Level 4) at 19.0% (n = 1,549) and ‘other non-conformance’ (Level 5) at 11.1% (n = 902). The remaining 2.0% (n = 165) of ‘treatment unit processes’ process code reports were ‘non-reportable radiation incidents’ (Level 2) and ‘reportable radiation incidents’ (Level 1).

Figure 3. Breakdown of RTE process code by Level (n = 17,888/18,681 subset of RTE)

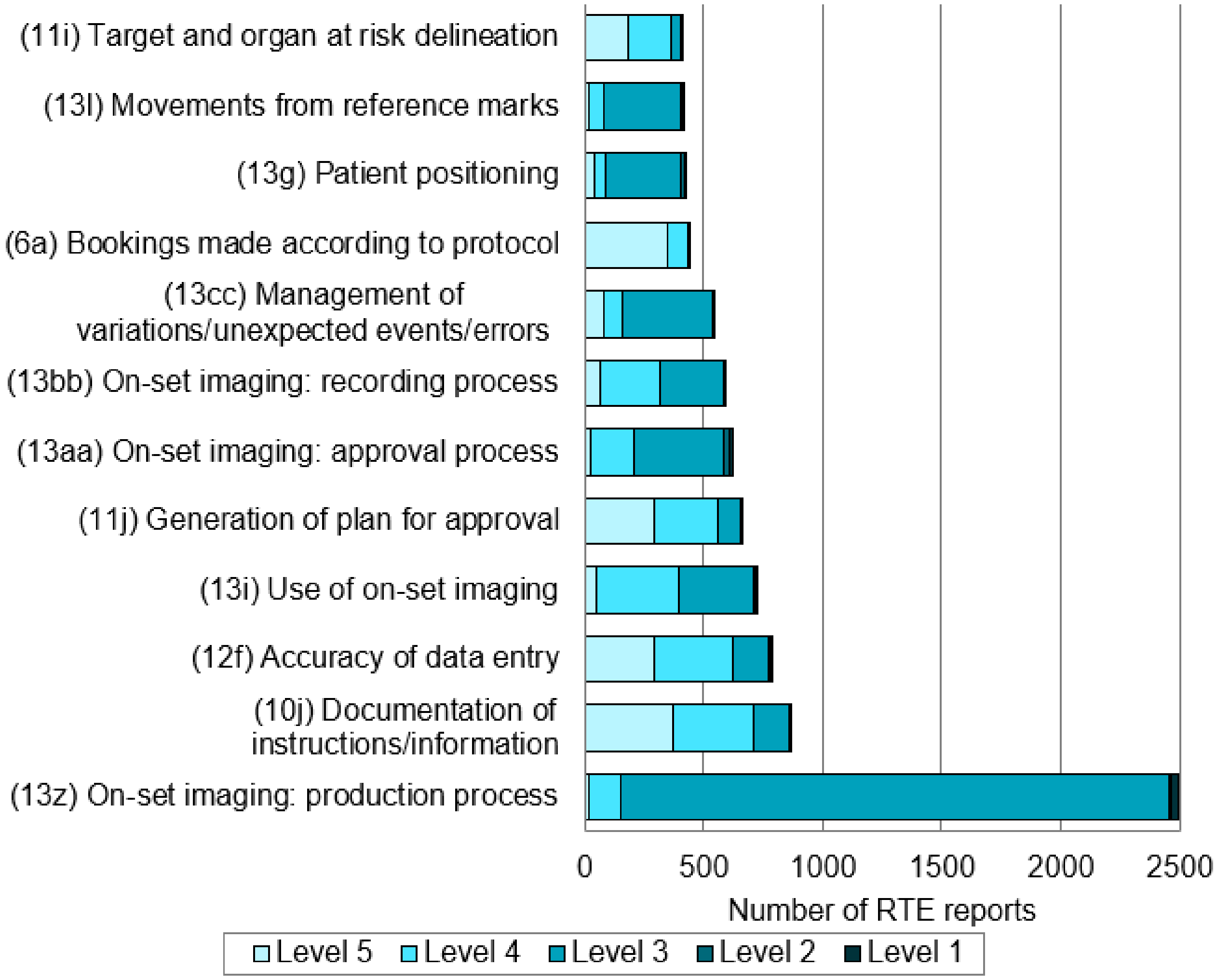


Breakdown of process subcodes

The most frequently reported process subcodes are presented in Figure 4 and broken down by level. The most frequently reported RTE reported was ‘on-set imaging: production process’ at 13.4% (n = 2,495). Of this subset, 92.4% (n = 2,305) reports were classified as minor radiation incidents (Level 3). The second most frequently reported RTE was ‘documentation of instructions or information’ at 4.6% (n = 861). Of these 82.7% (n = 712) were classified as Level 4 or 5 indicating that the majority of this type of RTE were detected before treatment occurred.

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 23.7% (n = 4,425) of all RTE reported.

Figure 4. Breakdown of most frequently reported RTE process subcodes by Level (n = 8,955/18,681 subset of RTE)



The most frequently reported RTE process code was treatment process (43.5%, n = 8,134), similar to the previous 2-year report (17) at 42.3% (n = 7,923). The treatment process represents the last opportunity to identify errors. Accurate treatment relies on the correct interpretation of the treatment plan and set-up details which need to be replicated at each fraction of treatment. This might explain the prevalence of RTE reported associated with ‘treatment unit processes’.

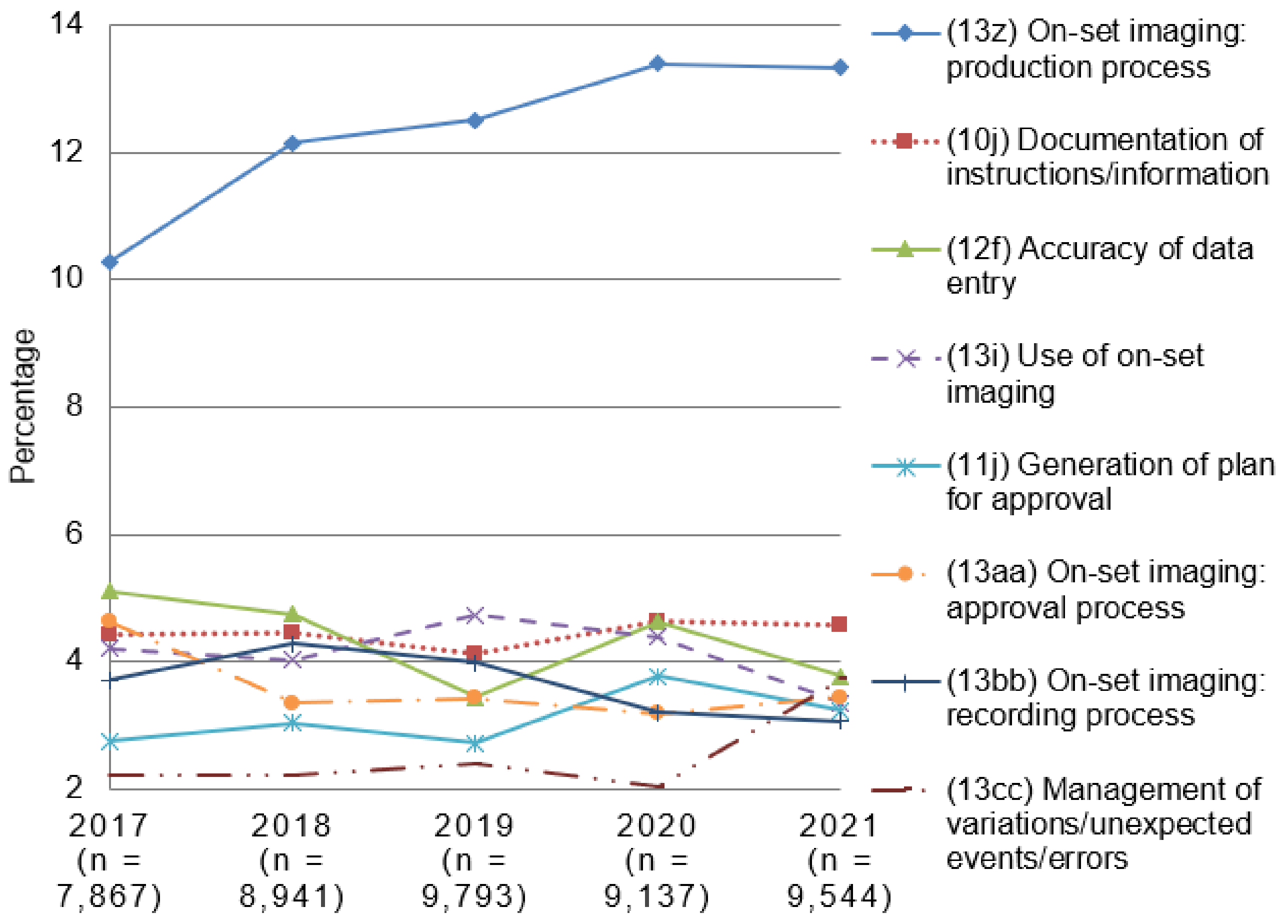
The 8 most frequently reported process subcodes were reviewed across the preceding 5-year period as shown in Figure 5. The subcode ‘on-set imaging: production process’ revealed a consistent increase in rate from 2017 to 2020 and remained stable in 2021. The evidence for this increasing trend was statistically significant (p = 0.03) with a small increase rate of 0.7% per year.

Since 2017 there has been an increase in percentage of RTE associated with ‘management of variations, unexpected events or errors’, with the biggest increase from 2020 from 2.0% to 3.7% in 2021, but the slope was not statistically significant over the 5-year period (p = 0.23). A separate UKHSA publication on ‘Safer Radiotherapy: the unseen pathway’ highlights an increase in RTE associated with the 'management of variations, unexpected events or errors' since 2009 (22). The unseen pathway relates to radiotherapy processes where the patient is not required to be present.

For other most frequently reported pathway subcodes, the trend was not statistically significant, although the slope of the trend line is positive for some and negative for others.

All but 2, 'patient positioning' and 'movements from reference marks', of the most frequently reported process subcodes were seen in the previous 2-year reporting period (17). As surface guided systems become available and implemented clinically it is hoped the number of these types of events will decrease again.

Figure 5. Trends for most frequently reported RTE by process subcode (January 2017 to December 2021)



Classification (Level) of RTE

Each of the 18,681 RTE reports was classified as 'other non-conformance' (Level 5), 'near miss' (Level 4), 'minor radiation incident' (Level 3), 'non-reportable radiation incident' (Level 2) or 'reportable radiation incident' (Level 1). A breakdown of these can be seen in Figure 6. Of the RTE reports, 98.4% (n = 18,394) were minor radiation, near miss or other non-conformances with little or no impact on patient outcome. Of the remaining 1.6% (n = 287) reports, only 0.9% (n = 165) were reportable under IR(ME)R (9 to 11) to the inspectorates.

Figure 6. Classification (Level) of RTE reports (n = 18,681)

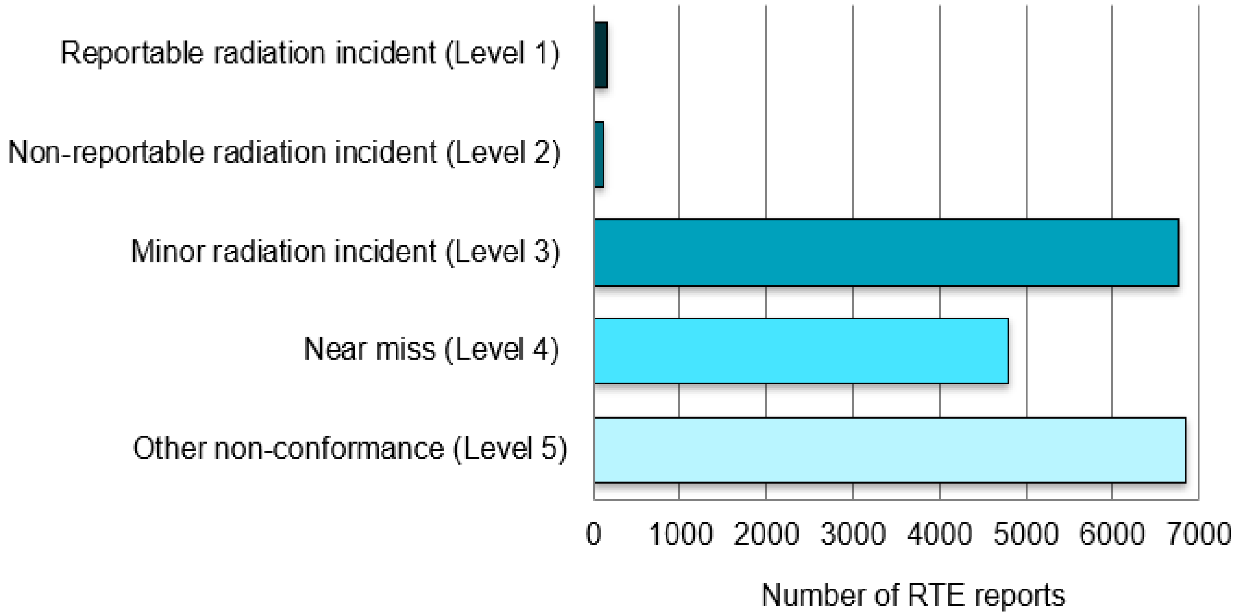
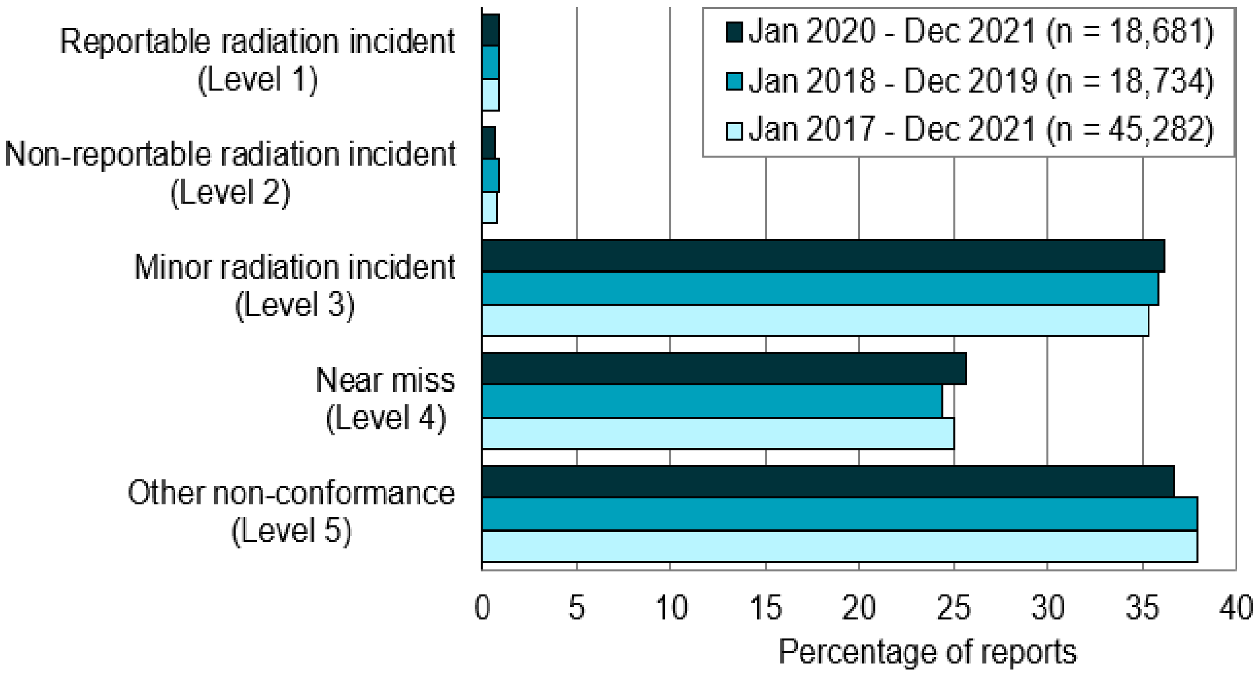


Figure 7 shows trends across the different classifications, similar for the previous 2-year reporting period (17) and 5 year period. The reportable radiation incidents made up 0.9% (n = 165) of all the RTE for this and the previous 2-year reporting period (17).

Figure 7. Classification (Level) as a percentage of RTE reports (January 2017 to December 2021)

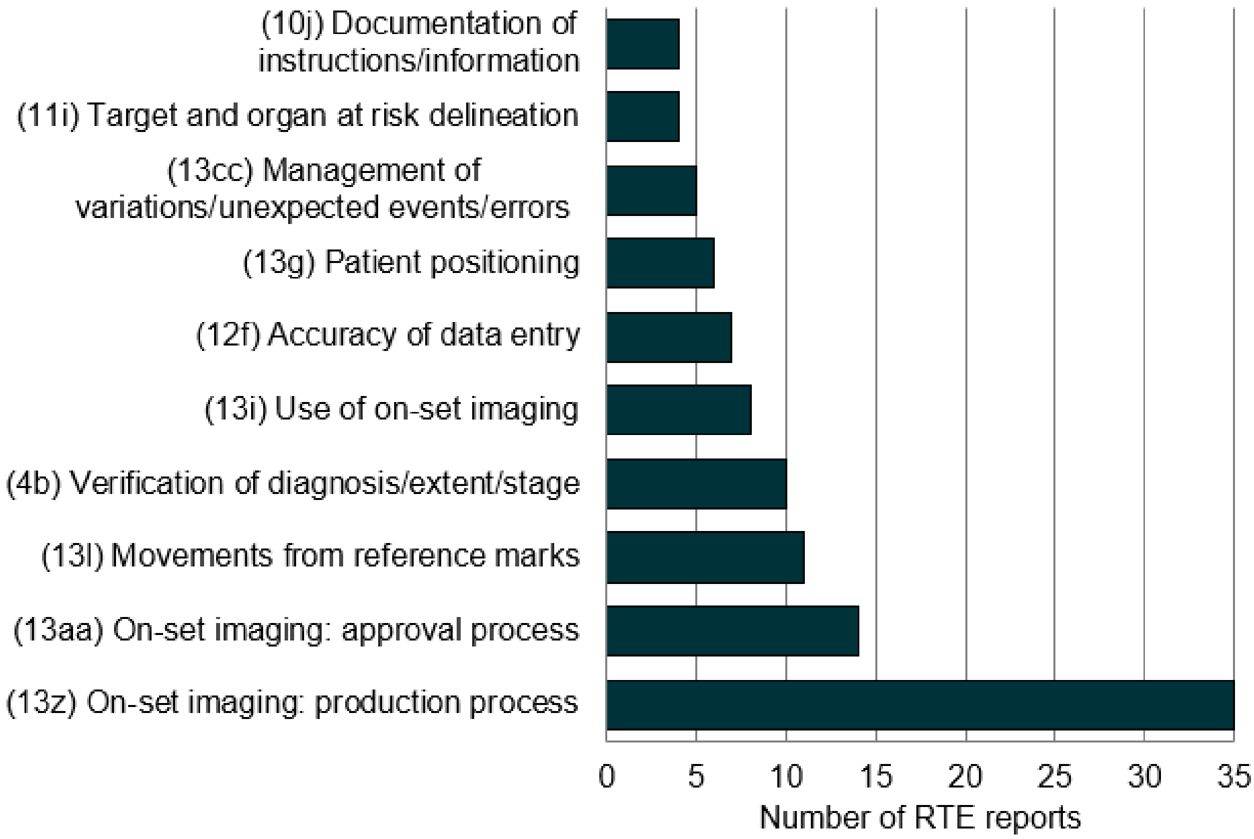


Reportable radiation incident (Level 1) RTE

Reportable radiation incidents, as defined in TSRT (7) fall into the category of reportable under IR(ME)R (9 to 11). These incidents will generally be significant, although they may be correctable within the course of treatment. The majority of these incident reports related to a single exposure. This meant that corrective action could be applied to the remaining treatment fractions, so the incident did not have a significant impact on the patient or the outcome of their treatment.

There were 47 different subcodes associated with the 165 Level 1 RTE (Figure 8). These were reported by 40 of the 57 providers that submitted data for analysis.

Figure 8. Breakdown of most frequently reported Level 1 RTE by process subcode (n = 104/165 subset of RTE)



The most frequently reported subcode was 'on-set imaging: production process' comprising 21.2% (n = 35) of all Level 1 reports. An example of this type of reportable RTE included when multiple repeat verification cone beam computed tomography (CBCT) were taken due to procedural failures such as not setting the panel in the correct position or utilising the incorrect filter, necessitating repeat exposures. Taking 3 or more images in one fraction due to procedural failure meets the current reporting threshold of the inspectorates. Of the 'on-set imaging: production process' associated reports 74.3% (n = 26) were due to equipment malfunction. An example of this type of RTE is when a verification CBCT is initiated and part way through the arc the machine malfunctions, the image is not suitable for verification and multiple additional verification images are required within one fraction.

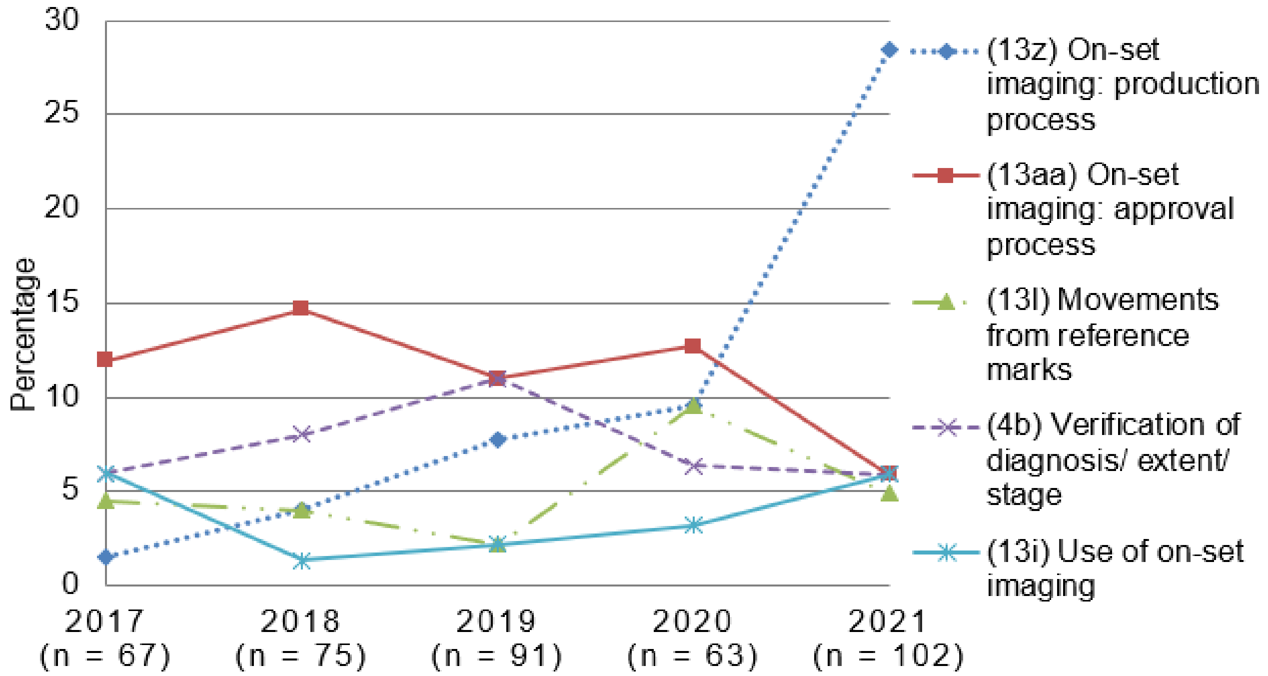
The second most frequently reported Level 1 RTE was associated with ‘on-set imaging: approval process’ at 8.5% (n = 14). Examples of this type of RTE included an incorrect online review resulting in a mismatch of vertebrae or soft tissue.

Of the 47 different process subcodes reported within the Level 1 RTE, 34 were present in the previous 2-year reporting period (17). These changes demonstrates the importance of ongoing cyclic monitoring of RTE.

Figure 9 identifies trends by year across the preceding 5-year period. A consistent increase from 2017 (1.5%) to 2020 (9.5%) and a spike in 2021 (28.4%) was observed for 'on-set imaging: production process’. This increase is of borderline statistical significance (p = 0.048) with a rate of 6% per year.

The lowest rate observed for ‘on-set imaging: approval process’, was in 2021 (6%). However, over the 5-year period the negative slope (indicating a decreasing trend) was not statistically significant (p = 0.21).

Figure 9. Trends for most frequently reported Level 1 RTE by process subcode (January 2017 to December 2021)

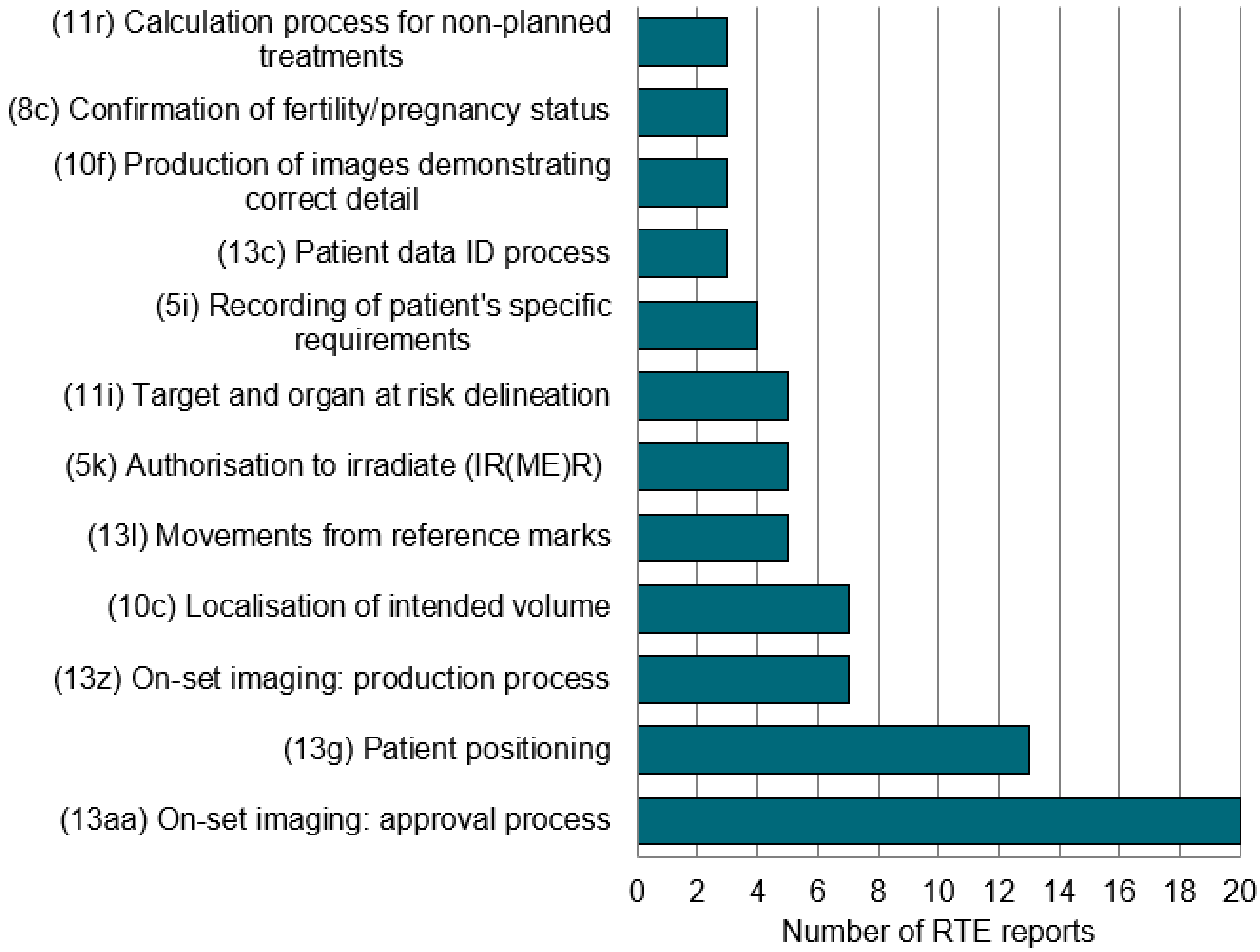


Non-reportable radiation incident (Level 2) RTE

A non-reportable radiation incident is defined as a radiation incident which is not reportable, but of potential clinical significance (7).

There were 48 different subcodes associated with Level 2 reports. The most frequently reported Level 2 RTE can be seen in Figure 10. These were reported by 36 of the 57 providers that submitted data for analysis.

Figure 10. Breakdown of most frequently reported Level 2 RTE by process subcode (n = 78/122 subset of RTE)



The most frequently reported Level 2 reports were associated with ‘on-set imaging: approval process’ at 16.4% (n = 20) of all Level 2 RTE. An example of RTE associated with ‘on-set imaging: approval process’ includes the mismatch of reference and verification imaging which did not lead to a total or partial geographical miss.

This was followed by ‘patient positioning’ at 10.7% (n = 13). An example of this type of RTE was when the patient was positioned incorrectly. This extended to the incorrect positioning of limbs, leading to a partial geographical miss but did not exceed the 2.5 times error margin (23). Of the

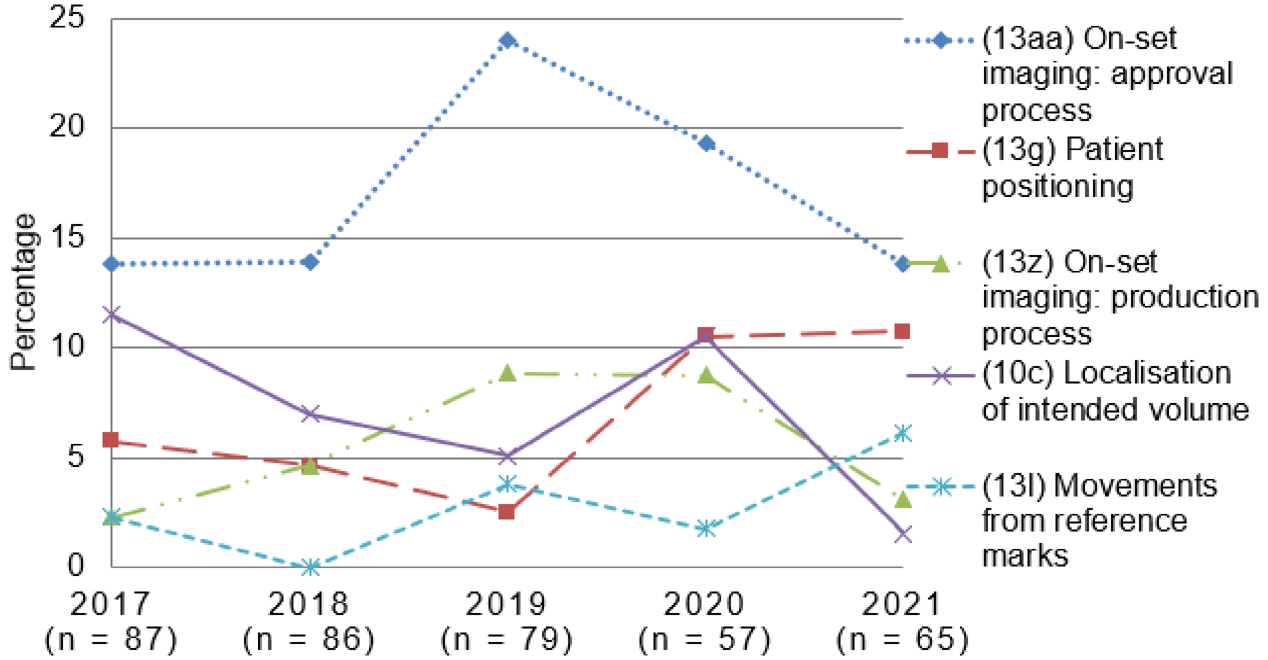
13 Level 2 RTE reported associated with 'patient positioning' 30.8% (n = 4) occurred for patients receiving RT for breast treatment.

Figure 11 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%) decreasing sharply in 2021 (13.8%). The slope was positive, but not statistically significant over the 5-year period (p = 0.77).

Level 2 RTE associated with 'localisation of intended volume' has decreased from 11.5% in 2017 to 1.5% in 2021, but the overall decreasing trend was not statistically significant (p = 0.25). This may be due to easier access to referral data, further optimisation of the electronic dataflow within RT planning departments, improvements in image optimisation and contouring tools.

For 'patient positioning' an increase was observed from 2019 to 2020 and remained stable in 2021, but the trend again was not statistically significant over a 5-year period (p = 0.20). For the other pathway most frequently reported Level 2 subcodes, there was no evidence of either an increasing or decreasing statistical trend with year.

Figure 11. Trends for most frequently reported Level 2 RTE by process subcode (January 2017 to December 2021)



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 (7).

There were 128 different subcodes associated with Level 3 reports. The most frequently reported RTE in this sub-group can be seen in Figure 12. These were reported by all 57 of the providers that submitted data for analysis. Of note, all of the most frequently reported Level 3 RTE occurred during the treatment unit process

'On-set imaging: production process' made up 34.1% (n = 2,305) of all Level 3 RTE. An example of this type of RTE included a repeated verification imaging due to use of the incorrect field size or equipment malfunction during image acquisition.

This was followed by 'on-set imaging: approval process' at 5.7% (n = 384). An example is when an online image is mismatched leading to a divergence from the planned treatment but not leading to a partial or geographical miss. 'Use of immobilisation devices' made up 3.7% (n = 247), examples of this included the incorrect setting of immobilisation devices such as breast board angles and wing board settings.

Figure 12. Breakdown of most frequently reported Level 3 RTE by process subcode (n = 4,951/6,757 subset of RTE)

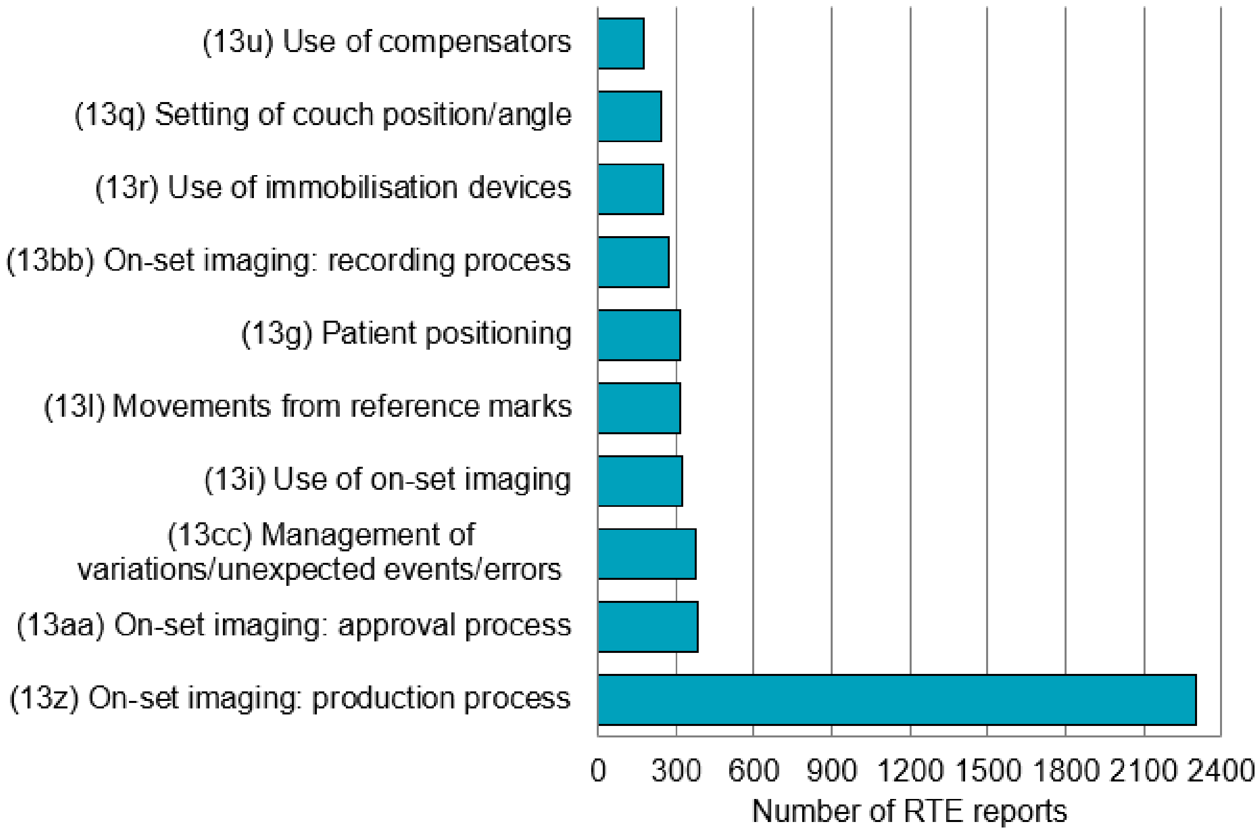
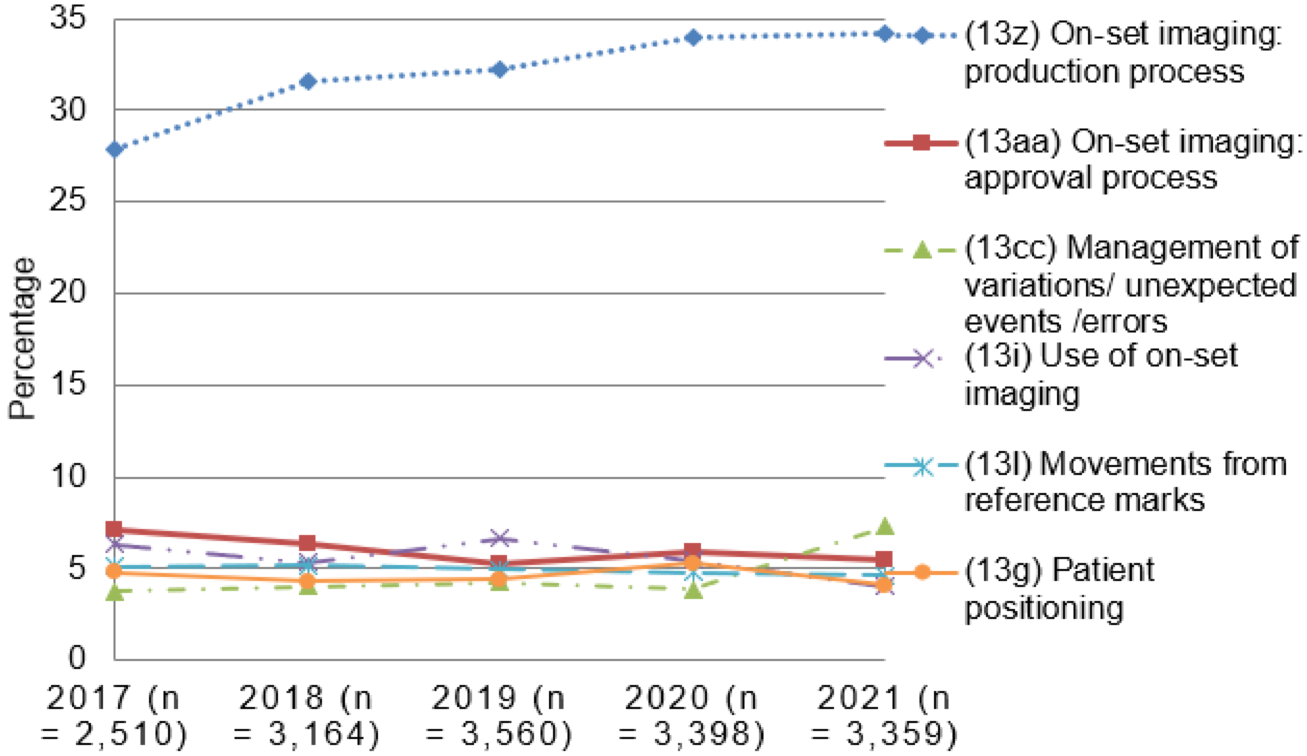


Figure 13 identifies trends by year across the preceding 5-year period. For the Level 3 RTE related to 'on-set imaging: production process', the rate increased with year (ranging from 27.9% to 34.2%). This increasing trend was statistically significant (p = 0.02) with a rate of 1.5% per year. This is an area of focus to reduce overall number of errors.

'On-set imaging: production process' made up 34.1% (n = 2,305) of all Level 3 RTE, an increase from 31.9% (n = 2,145) in the previous 2-year period (17). Of these RTE 51.7% (n = 1,193) were reported to be due to equipment malfunction.

Between 2017 to 2021 there was a decrease in percentage of RTE reported associated with 'movements from reference marks' (5.1% to 4.6%) which was statistically significant ($p = 0.01$) with a very small decreasing rate of 0.1% per year. For the other most frequently reported pathway subcodes shown in Figure 13, there was no statistical evidence for either increasing or decreasing trend with year.

Figure 13. Trends for most frequently reported Level 3 RTE by process subcode (January 2017 to December 2021)



Near miss (Level 4) RTE

A 'near miss' is defined as a potential radiation incident that was detected and prevented before treatment delivery (7).

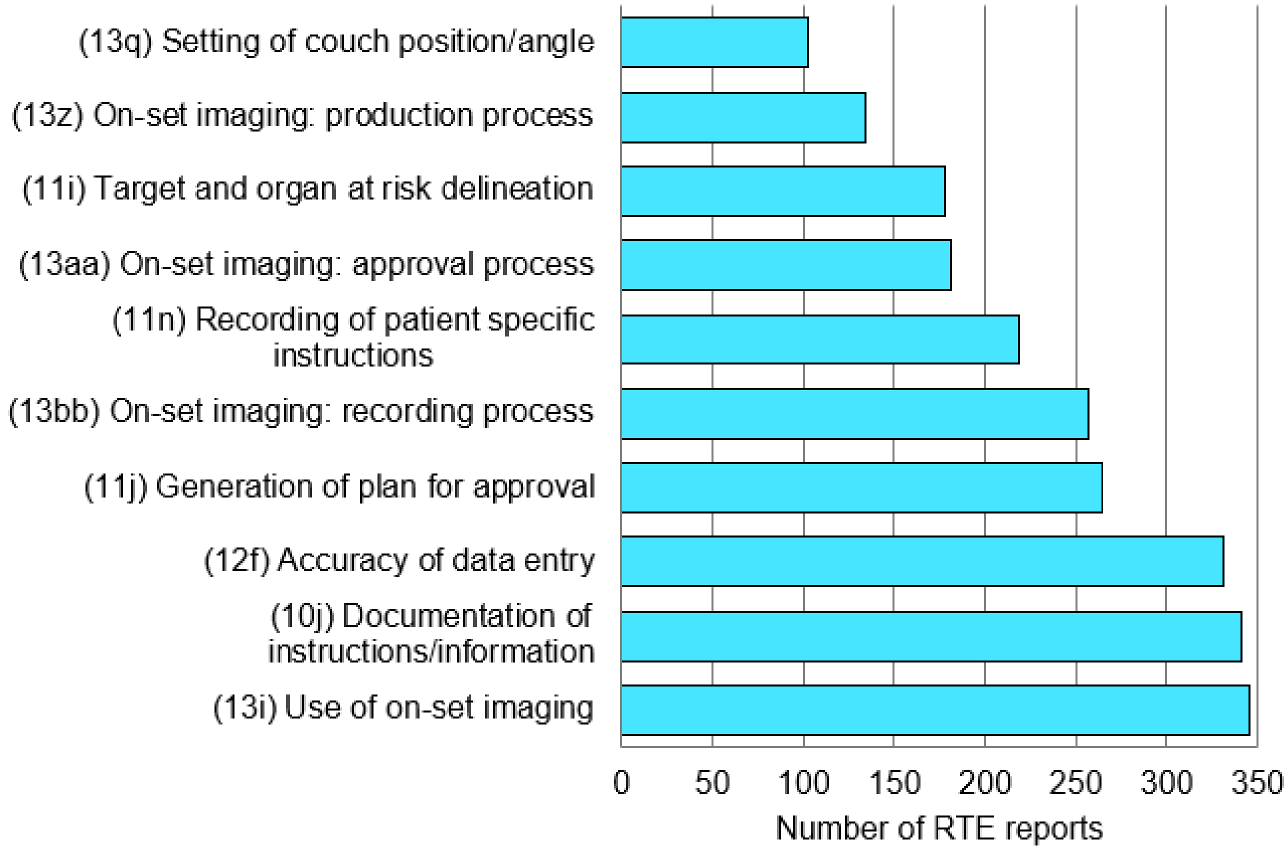
There were 175 different subcodes associated with the Level 4 RTE. The most frequently reported RTE can be seen in Figure 14. These were reported by 53 of the 57 providers.

The most frequently reported subcode was 'use of on-set imaging' making up 7.2% (n = 346) of all Level 4 reports. Examples of this type of RTE include when a verification image is required to confirm patient positioning but is not taken immediately before treatment. The error is identified after a few monitor units given and the treatment is interrupted and image taken confirming correct treatment placement prior to delivery of the remainder of the treatment.

This was closely followed by 'documentation of instructions or information', making up 7.1%

(n = 341) of all Level 4 RTE. Examples of this type of RTE includes missing information within the documentation of patient positioning. 'Recording of patient specific instructions' made up 4.6% (n = 219) of all Level 4 RTE, examples of these include when the movements from reference marks have been mis recorded during the planning process. This was not detected at end of process checks but during patient positioning on treatment.

Figure 14. Breakdown of most frequently reported Level 4 RTE by process subcode (n = 2,354/4,785 subset of RTE)

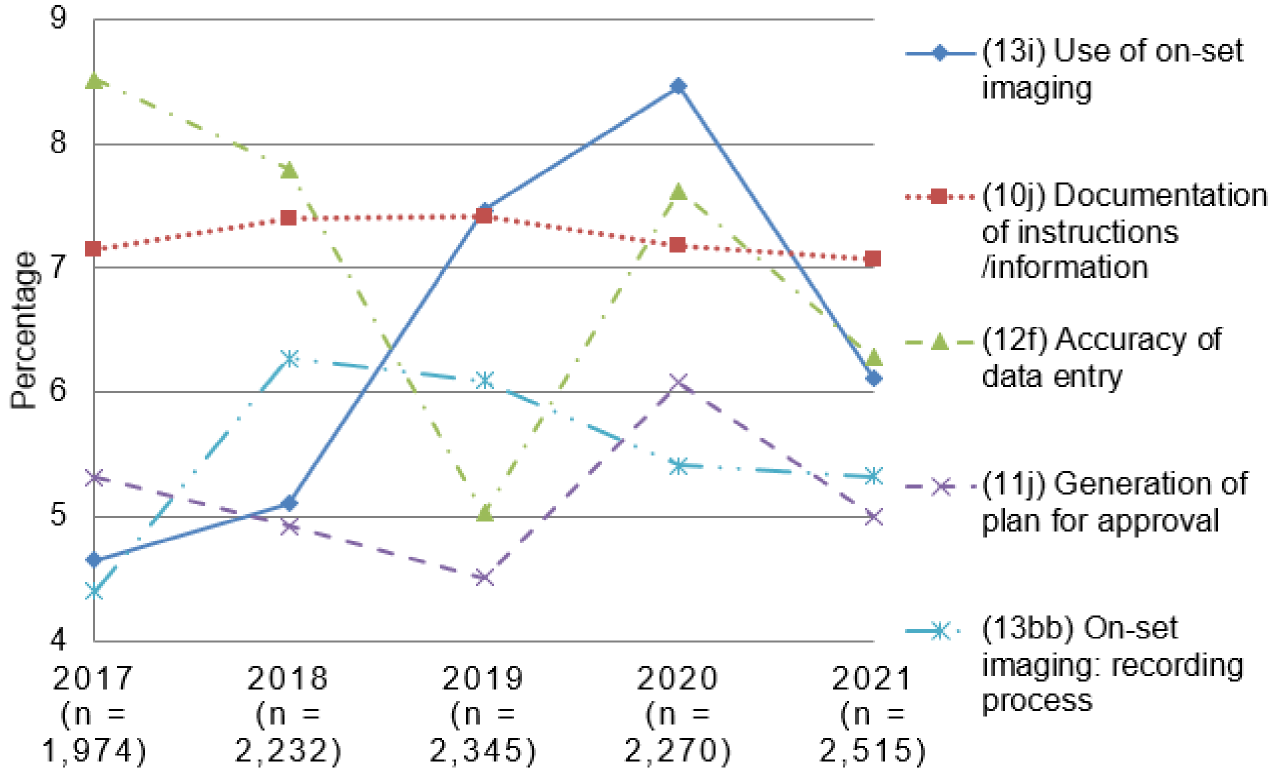


Between 2017 and 2020 there was an increase in percentage of Level 4 RTE for the process subcodes 'use of on-set imaging' (4.7% to 8.5%). This reduced to 6.1% in 2021, the slope was positive but not statistically significant over the 5-year period (p = 0.26). This is shown in Figure 15 which identifies trends by year across the preceding 5-year period.

'Accuracy of data entry' has decreased since 2017 by 2.2%. However, the trend was irregular across the preceding 5 years and not statistically significant (p = 0.36).

For the other most frequently reported Level 4 pathway subcodes shown in Figure 15 there was no statistically significant evidence of an either increasing or decreasing trends.

Figure 15. Trends for most frequently reported Level 4 RTE by process subcode (January 2017 to December 2021)



Other non-conformance (Level 5) RTE

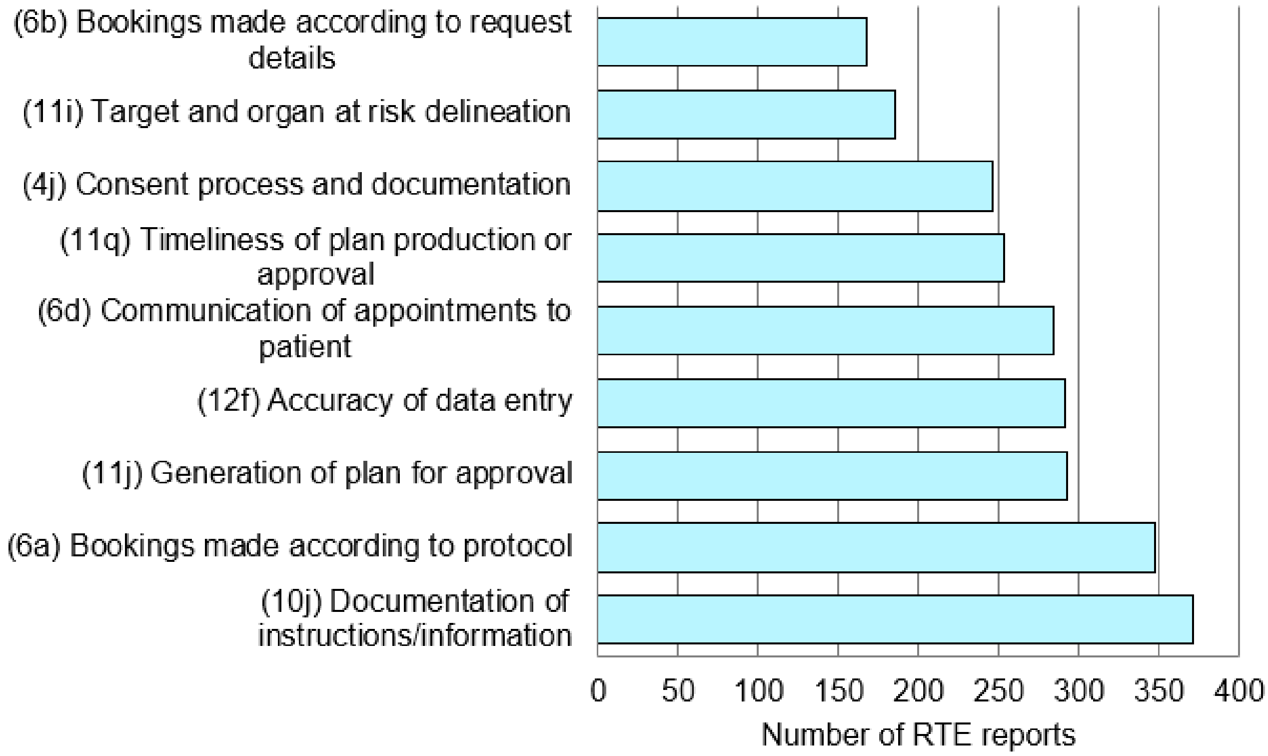
Other non-conformance is defined as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery (7).

There were 187 different subcodes associated with the Level 5 RTE reported. The most frequently reported RTE are represented in Figure 16. These were reported by 52 of the 57 providers that submitted data for analysis.

The most frequently occurring subcode was ‘documentation of instructions/ information’ making up 5.4% (n = 371) of all the Level 5 RTE. Examples of this type of RTE included the patient positioning instructions incorrectly documented during the CT process. This was detected during the end of process checks at CT before the documentation moved to planning.

This was followed by ‘bookings made according to protocol’ at 5.1% (n = 348). Examples of this type of RTE include missing patient appointments or booking appointments for the incorrect fractionation, whereby the error was identified and corrected as part of local checking processes prior to treatment.

Figure 16. Breakdown of most frequently reported Level 5 RTE by process subcode (n = 2,440/6,852 subset of RTE)



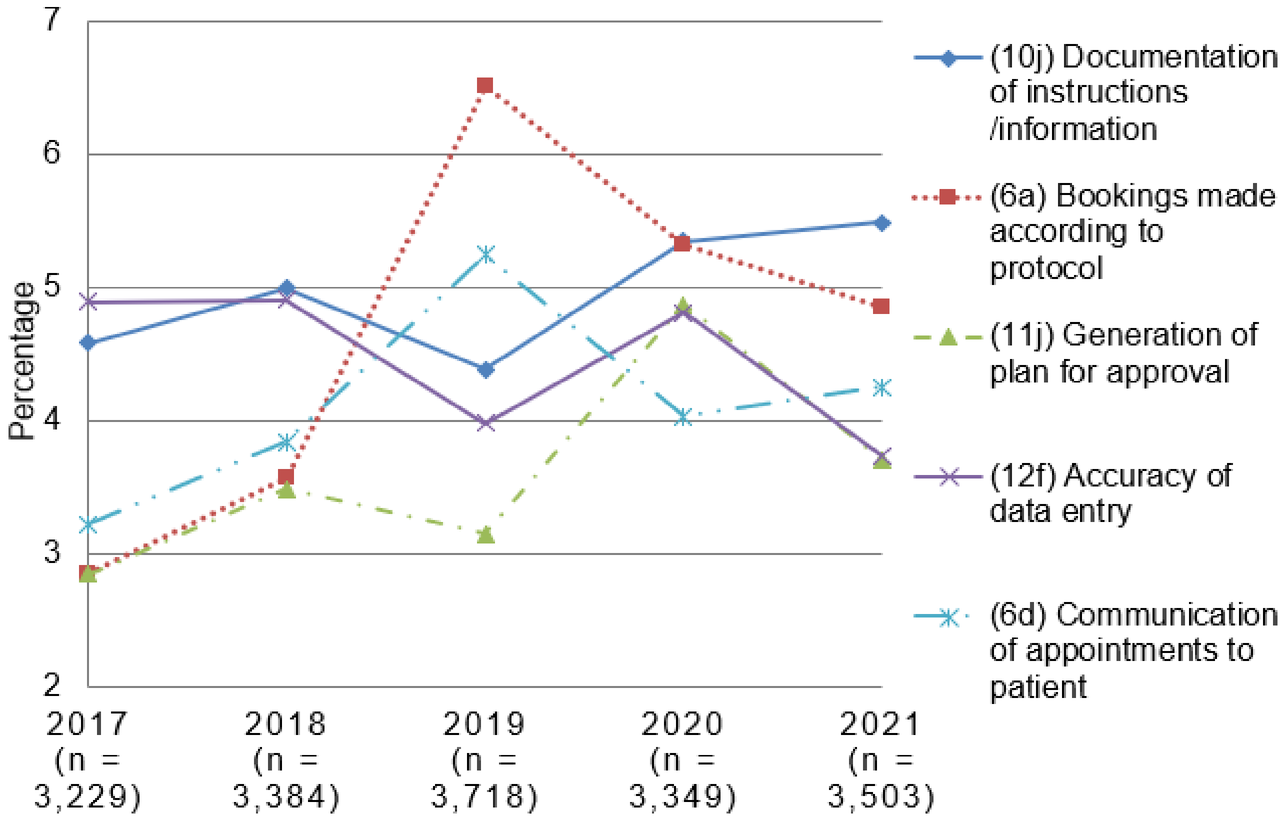
The most frequently occurring subcode was ‘documentation of instructions or information’ making up 5.4% (n = 371) of all the Level 5 RTE. Examples of this type of RTE included the patient positioning instructions being incorrectly documented during the CT process. This was detected during the end of process checks at CT before the documentation moved to planning.

This was followed by ‘bookings made according to protocol’ at 5.1% (n = 348). Examples of this type of RTE include missing patient appointments or booking appointments for the incorrect fractionation, whereby the error was identified and corrected as part of local checking processes prior to treatment .

Figure 17 identifies trends by year across the preceding years There was no significant increase in rate for Level 5 RTE associated with ‘documentation of instructions or information’ (p = 0.17). There has been a decrease in RTE reported associated with ‘accuracy of data entry’ since 2017 (4.9% to 3.7% in 2021 (p = 0.21)).

Of note ‘bookings made according to protocol’ has increased from 2.8% in 2017 to 4.9% in 2021 (p = 0.26). However, there was a peak in 2019 at 6.5%. Over the past 2 years this has started to decrease. For the other most frequently reported Level 5, no evidence of any trend was observed.

Figure 17. Trends for most frequently reported Level 5 RTE by process subcode (January 2017 to December 2021)



Failed safety barriers

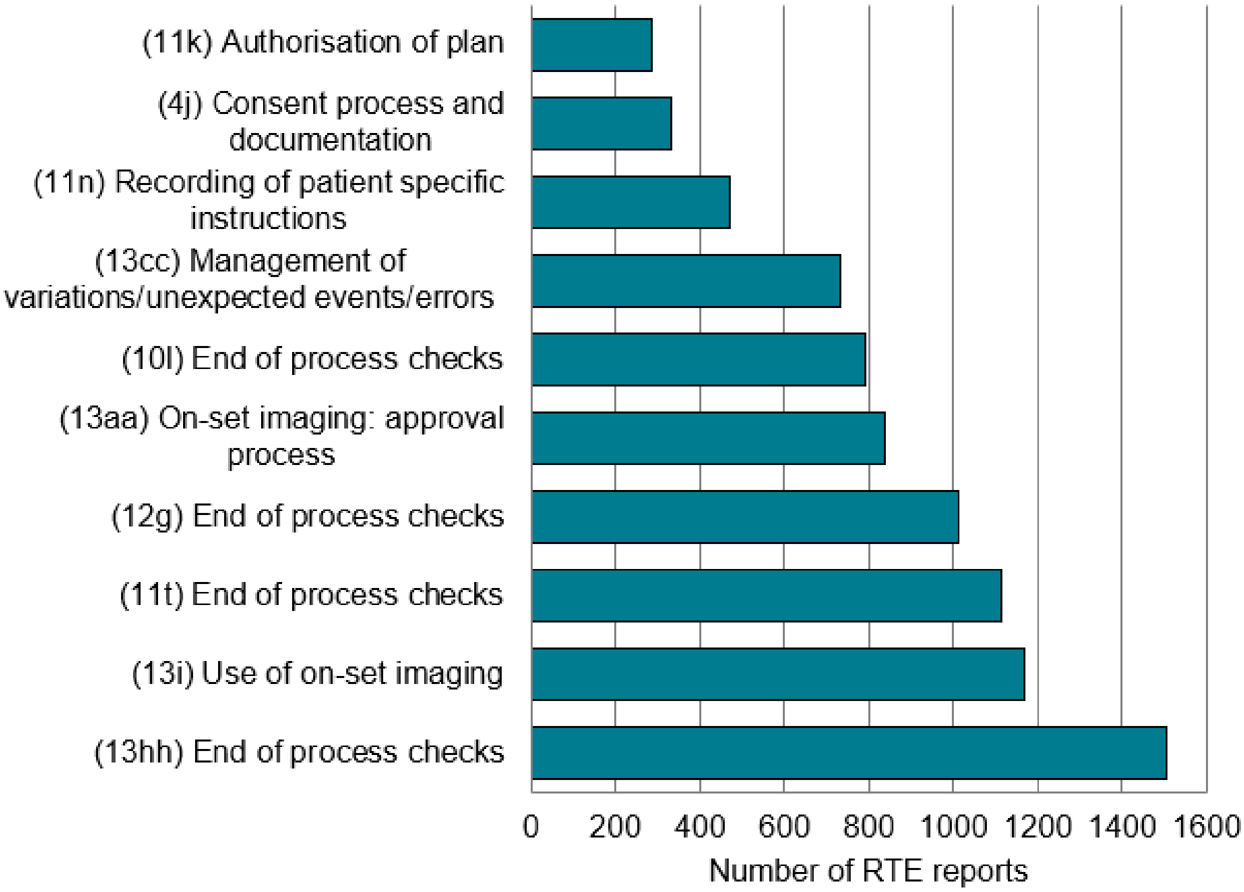
A safety barrier is a critical control point, detection method or defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow (24). The 'radiotherapy pathway coding' has 206 different process subcodes, including 86 SB (13). Safety 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 12,300 failed safety barriers (FSB) were identified across the RTE reports. The most frequently reported FSB can be seen in Figure 18.

Treatment unit processes were attributed to 39.9% (n = 4,909) of all FSB. Treatment unit processes 'end of process checks' was the most frequently reported FSB (12.3%, n = 1,507). An example is where an independent end of process check has either been omitted or carried out incorrectly.

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised of 36.8% (n = 4,523) of all FSB.

Figure 18. Breakdown of all failed safety barriers (n = 8,250/12,300 subset of data)

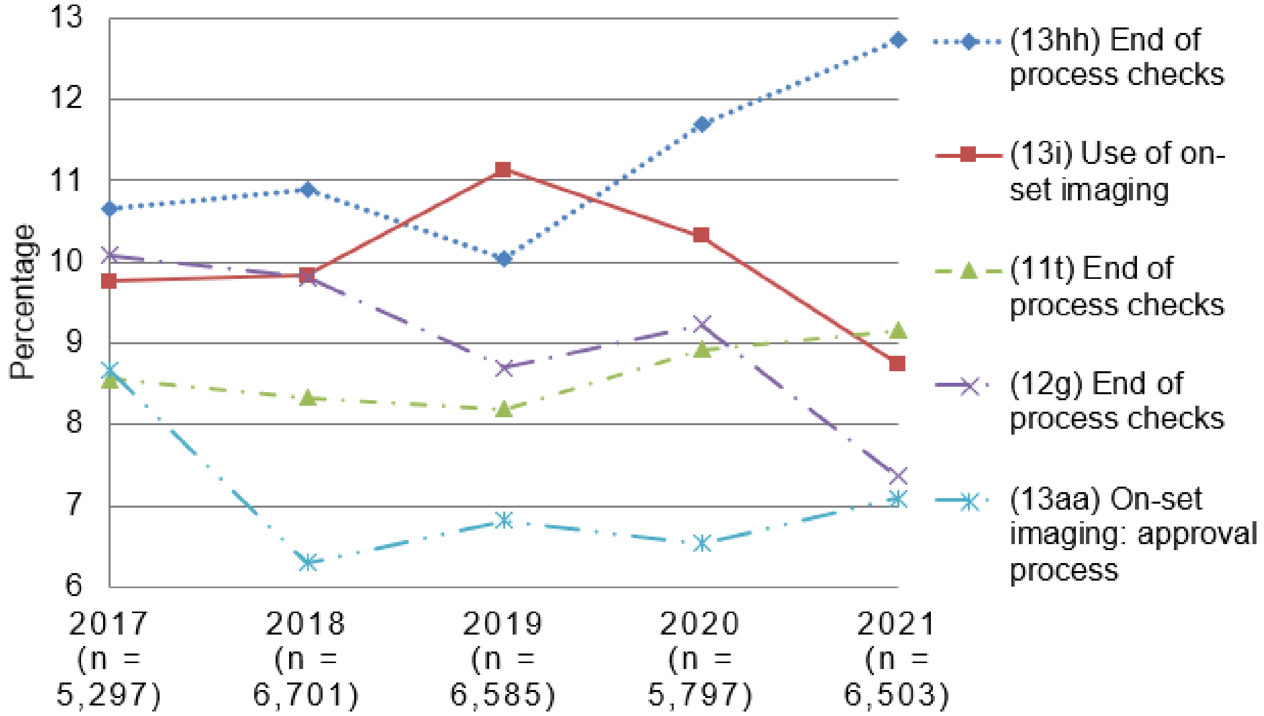


The trends by year across the preceding 5-year period of the most frequently reported FSB can be seen in Figure 19. There has been an increase in percentage of FSB reported associated with treatment unit process ‘end of process checks’ from 10.6% in 2017 to 12.7% in 2021, but the slope is not statistically significant (p = 0.14).

The FSB related to treatment data entry ‘end of process checks’ revealed a decreasing trend for the incidence rate and the regression analysis found a small decreasing trend of 0.6% per year for the period 2017 to 2021 which was borderline statistically significant (p = 0.046).

The estimated slopes for other FSB shows no evidence of any either increasing or decreasing trend.

Figure 19. Trends for most frequently reported failed safety barriers by process subcode (January 2017 to December 2021)



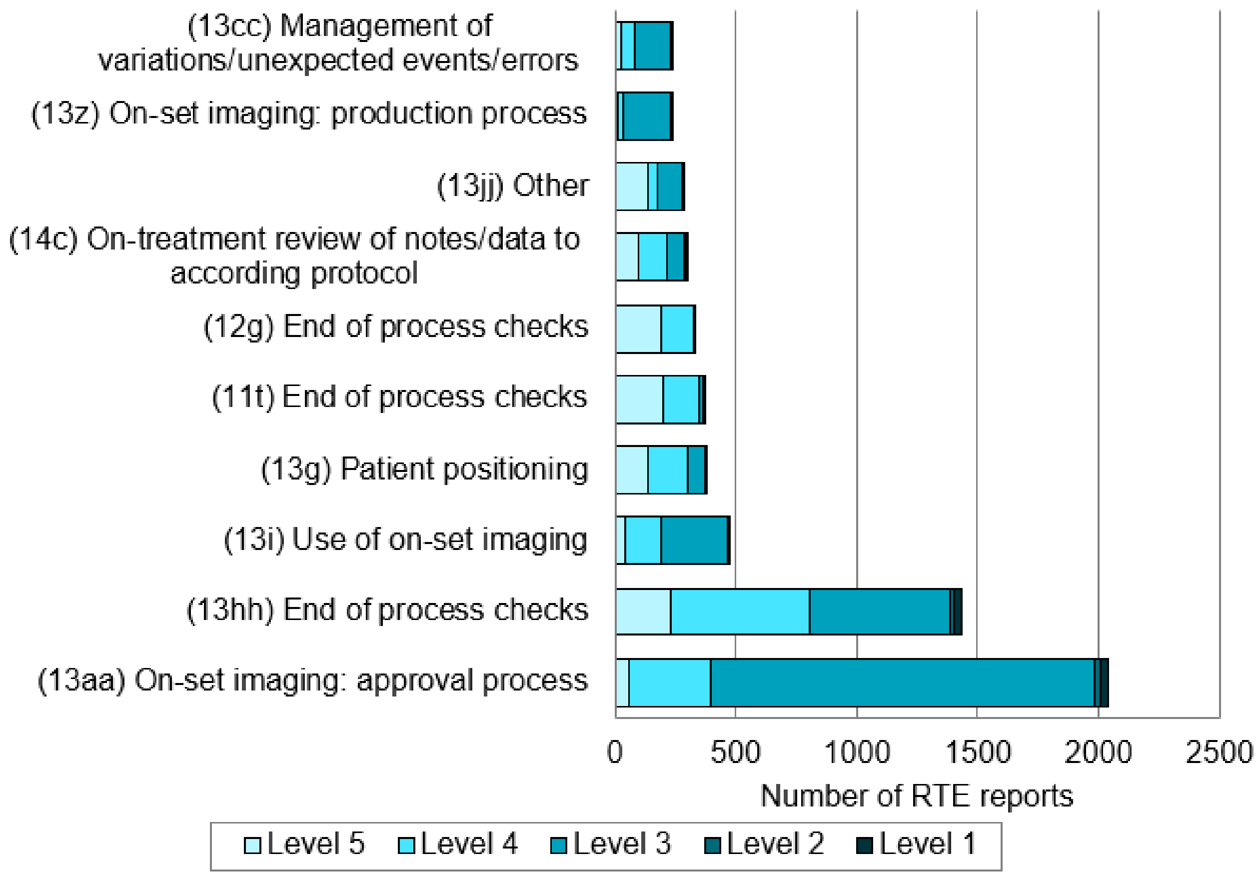
Method of detection

A method of detection (MD) is the process that identified the error and coding taken from the entire RT pathway taxonomy DoL (13).

From the 57 providers only 37 providers indicated MD in 32.8% (n = 6,140) of reports. Following consistency checking, UKHSA coded a further 3,044 reports with MD taxonomy, resulting in 9,184 of 18,681 reports for analysis.

The most frequently reported MD can be seen in Figure 20. The most frequently reported MD was ‘on-set imaging: approval process’ (22.2%, n = 2,041). This MD included both online and offline verification processes. This MD was most frequently reported with a primary process subcode ‘on-set imaging: production process’.

Figure 20. Breakdown of most frequently reported method of detection by Level (n = 6,728/9,184 subset of RTE data)



MD were introduced in 2018, since then the annual trend for the most frequently reported MD are similar. Modest decreases in percentage of the 5 most frequently reported MD were observed but the trends were not statistically significant. These included ‘on-set imaging: approval process’, ‘treatment: end of process checks’, ‘use of on-set imaging’, ‘patient positioning’ and ‘pretreatment: end of process checks’.

Causative factors

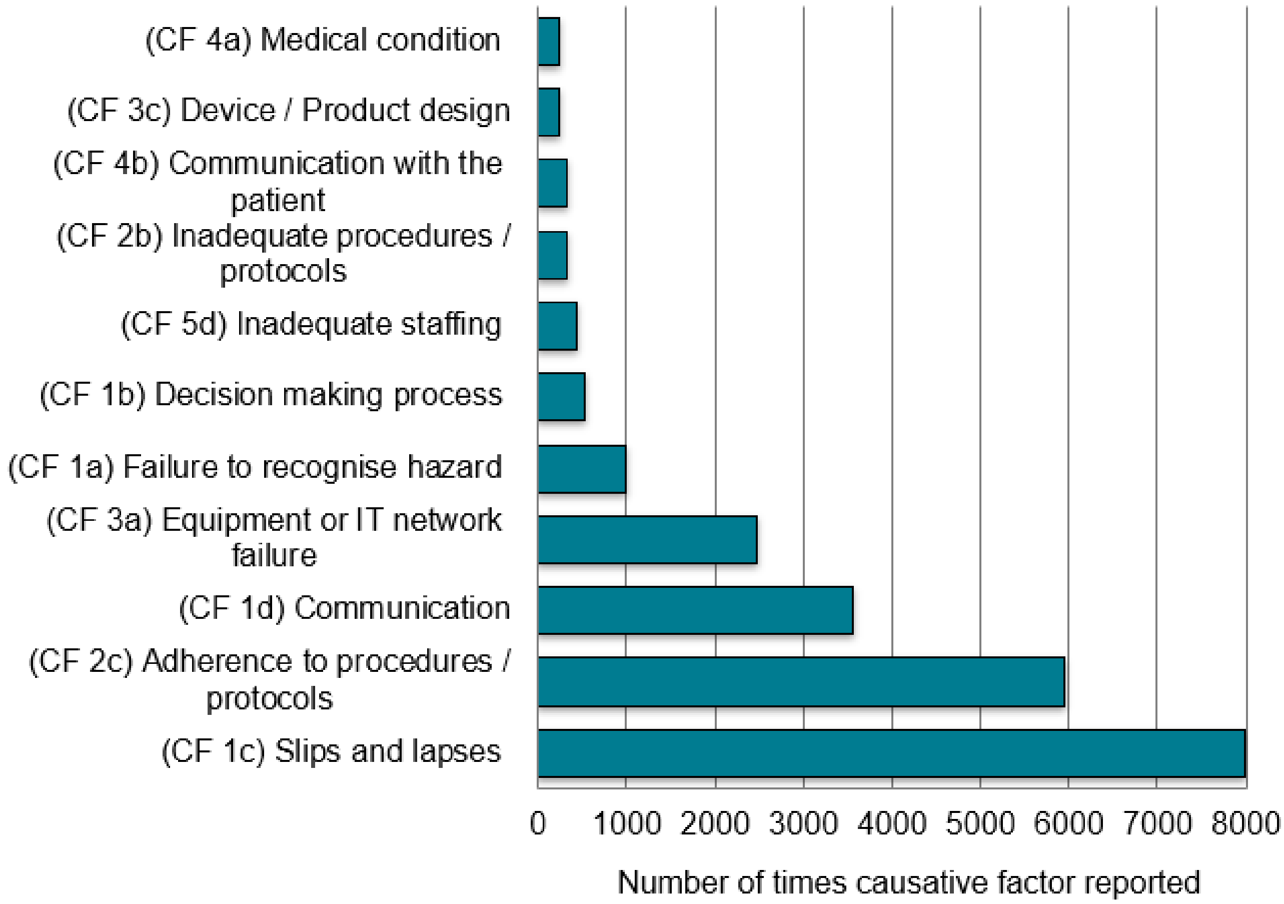
The use of a causative factor (CF) taxonomy enables identification of system problems that could precipitate a range of different incidents (25).

Multiple CF can be assigned to a single RTE. Of the 18,681 RTE reported 4,630 contained multiple CF totalling 24,003 CF codes. From the 57 providers 50 applied CF coding to their RTE reports.

Figure 21 shows the most frequently reported CF codes. The most frequently reported CF was ‘slips and lapses’ making up 33.3% (n = 7,982) of all CF reported. A slip or lapse is any actions that are well learned and practiced, proceeding without much conscious involvement, this can include completing movements from reference marks in the incorrect direction.

This was followed by ‘adherence to procedures/protocols’ (24.8%, n = 5,946). Adherence to procedures/ protocols is where the locally defined process was not adhered to.

Figure 21. Breakdown of most frequently reported causative factors (n = 23,049/24,003 subset of data)



The trends by year across the preceding 5-year period for the most frequently reported CF are similar. The highest percentage change was seen in the CF ‘adherence to procedures or protocols’ which has increased from 21.5% in 2017 to 26.4% in 2021 with no statistical significance (p = 0.10).

The prevalence of the CF ‘slips and lapses’ began to decline in 2019 at the same time the CF ‘adherence to procedures or protocols’ began to increase.

Each of the 5 most frequently reported pathway subcodes were reviewed for the associated CF codes. Table 3 shows from the 2,495 RTE reported with primary process subcode ‘on-set imaging: production process’ there were 2,981 CF assigned, from these CF the most frequently reported CF was ‘equipment of IT network failure’ making up 42.2% of all CF for this process subcode. The other 4 most frequently reported process subcodes had ‘slips and lapses’ as the most frequently reported CF.

Table 3. Most frequently reported primary pathway subcode by CF

Primary pathway process subcode (number of reports)	Number of CF reported by pathway subcode	Most frequently reported CF by pathway subcode
(13z) On-set imaging: production process (n = 2,495)	2,981	(CF 3a) Equipment or IT network failure (42.1%, n = 1,257)
		(CF 1c) Slips and lapses (30.7%, n = 916)
		(CF 2c) Adherence to procedures or protocols (14.0%, n = 418)
(10j) Documentation of instructions or information (n = 861)	1,197	(CF 1c) Slips and lapses (39.8%, n = 477)
		(CF 1d) Communication (36.8%, n = 441)
		(CF 2c) Adherence to procedures or protocols (17.9% n = 214)
(12f) Accuracy of data entry (n = 784)	1,072	(CF 1c) Slips and lapses (44.3%, n = 475)
		(CF 2c) Adherence to procedures or protocols (29.9%, n = 321)
		(CF 1d) Communication (16.2%, n = 174)
(13i) Use of on-set imaging (n = 722)	994	(CF 1c) Slips and lapses (41.6%, n = 414)
		(CF 2c) Adherence to procedures or protocols (39.2%, n =390)
		(CF 1d) Communication (6.3%, n = 63)
(11j) Generation of plan for approval (n = 654)	864	(CF 1c) Slips and lapses (45.0%, n = 389)
		(CF 2c) Adherence to procedures or protocols (24.5%, n = 212)
		(CF 1d) Communication (14.6%, n = 126)

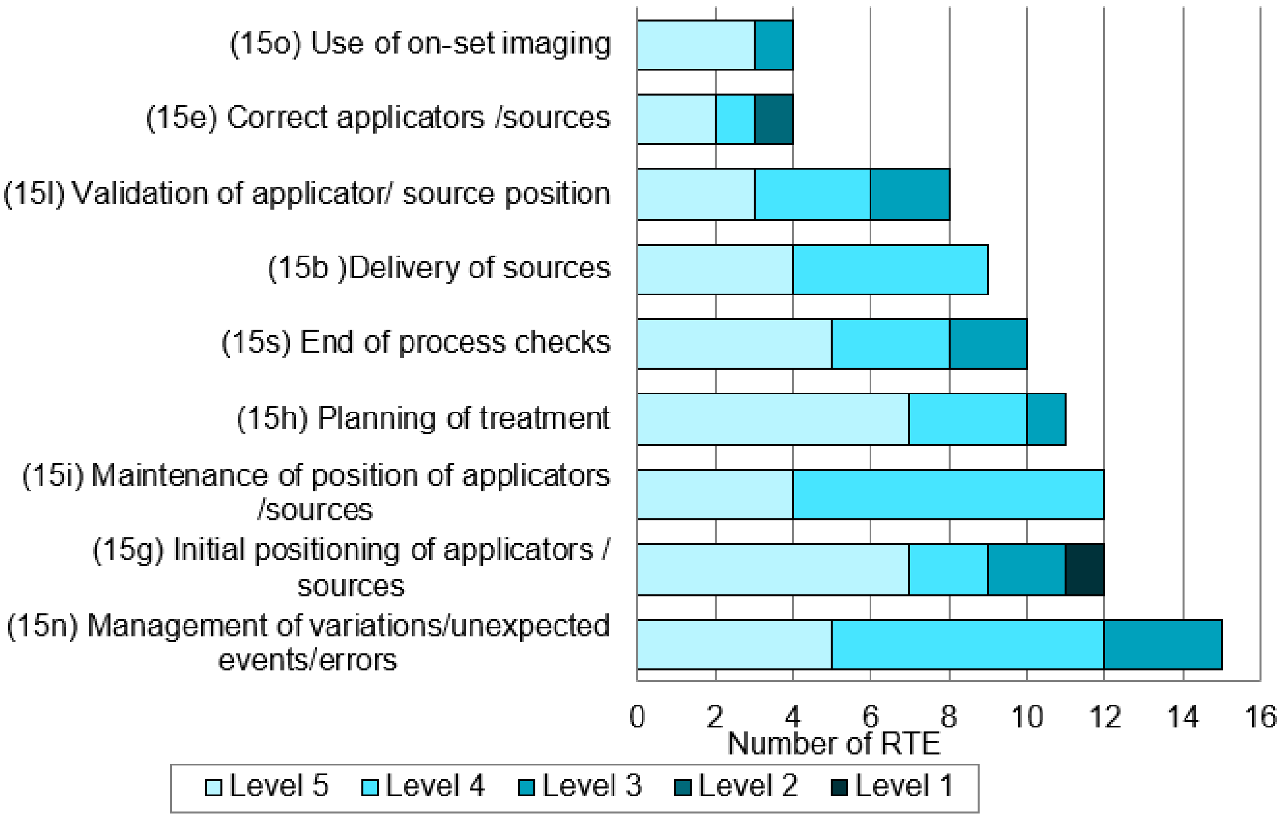
Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to a treatment area (26). The BRT RTE data was submitted from a total of 21 providers. BRT make up less than 3% of all RT episodes (27), so it is expected the number of BRT RTE would be low. Reports coded with BRT process subcodes (prefix 15) as the primary code account for 0.6% (n = 104) of RTE for this 2-year reporting period. This has reduced since the previous 2-year reporting period (17) from 0.8% (n = 159). As the number of BRT RTE reports is low this data should be interpreted with care. This reduction is reflected in the pause of some brachytherapy services during the response of the coronavirus (COVID-19) pandemic. Reporting of BRT RTE is to be encouraged to facilitate learning as the nature of these events are likely to be different to external beam due to the differences in their planning and delivery approaches and techniques and technologies employed.

There has been a decrease in the percentage of Level 1 BRT RTE reported since the previous 2-year reporting period (17) when these Level 1 BRT RTE made up 3.1%. The percentage of BRT (Level 1) for this reporting period was 1.9% compared with 0.9% for all RTE reports. This might be explained in part by the hypo-fractionated nature of BRT delivery (28). External beam delivery tend to have longer fractionation regimes which provide more opportunity for correction.

A difference was also noted in the Level 3 RTE; only 11.5% of the BRT RTE were classified as Level 3 compared with 36.2% of all RTE. This difference in Level 3 RTE may be due to the possible differences in the uptake of IGRT between BRT and external beam RT. The percentage of other ‘non-conformances’ (Level 5) is also higher within the BRT RTE reports at 48.1% compared to 36.7% for all RTE reports. This may be in part due to the higher number of other professionals involved in treatment such as anaesthetics and nursing.

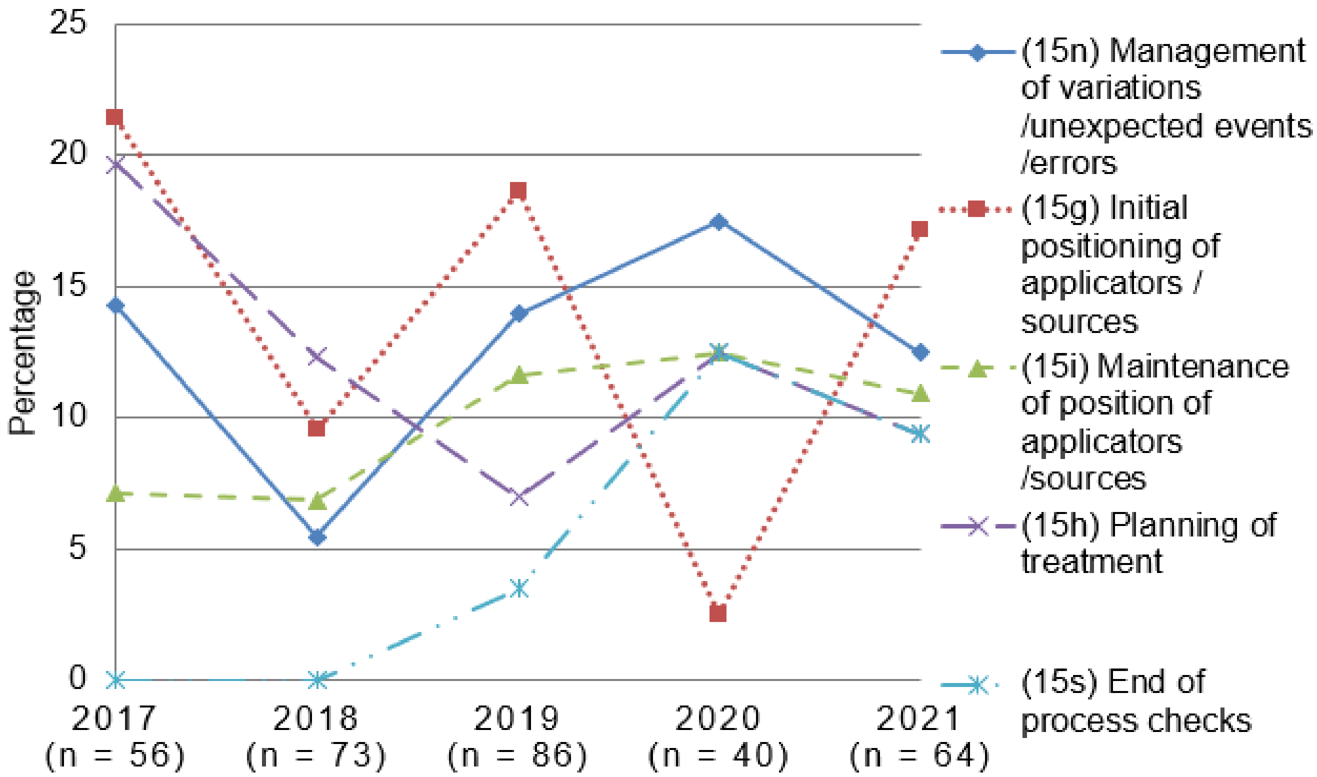
Figure 22. Breakdown of brachytherapy RTE (with prefix subcode 15) by Level (n = 94/104 subset of data)



A breakdown of the BRT RTE can be seen in Figure 22. The most frequently reported BRT process subcode was ‘management of variations or unexpected events or errors’ making up 14.4% (n = 15) of all BRT. Examples of this type of RTE includes a breakdown of equipment, such as the loader for LDR brachytherapy, or cracks in central tube for HDR vault kit.

The trends by year across the preceding 5-year period of the most frequently reported BRT RTE can be seen in Figure 23. There have been a number of changes within the most frequently reported BRT. ‘Planning of treatment’ has reduced in percentage from 19.6% of all BRT reported in 2017 to 9.4% in 2021, but this decreasing trend was not statistically significant (p = 0.21). An increase in the percentage of reported BRT associated with 'end of process checks' has been seen. Reports associated with this subcode have increased from 0% in 2017 and 2018 to 9.4% in 2021. This increase is borderline, statistically significant (p = 0.05) with the rate of 3% per year.

Figure 23. Trends for most frequently reported brachytherapy RTE (prefix subcode 15) (January 2017 to December 2021)

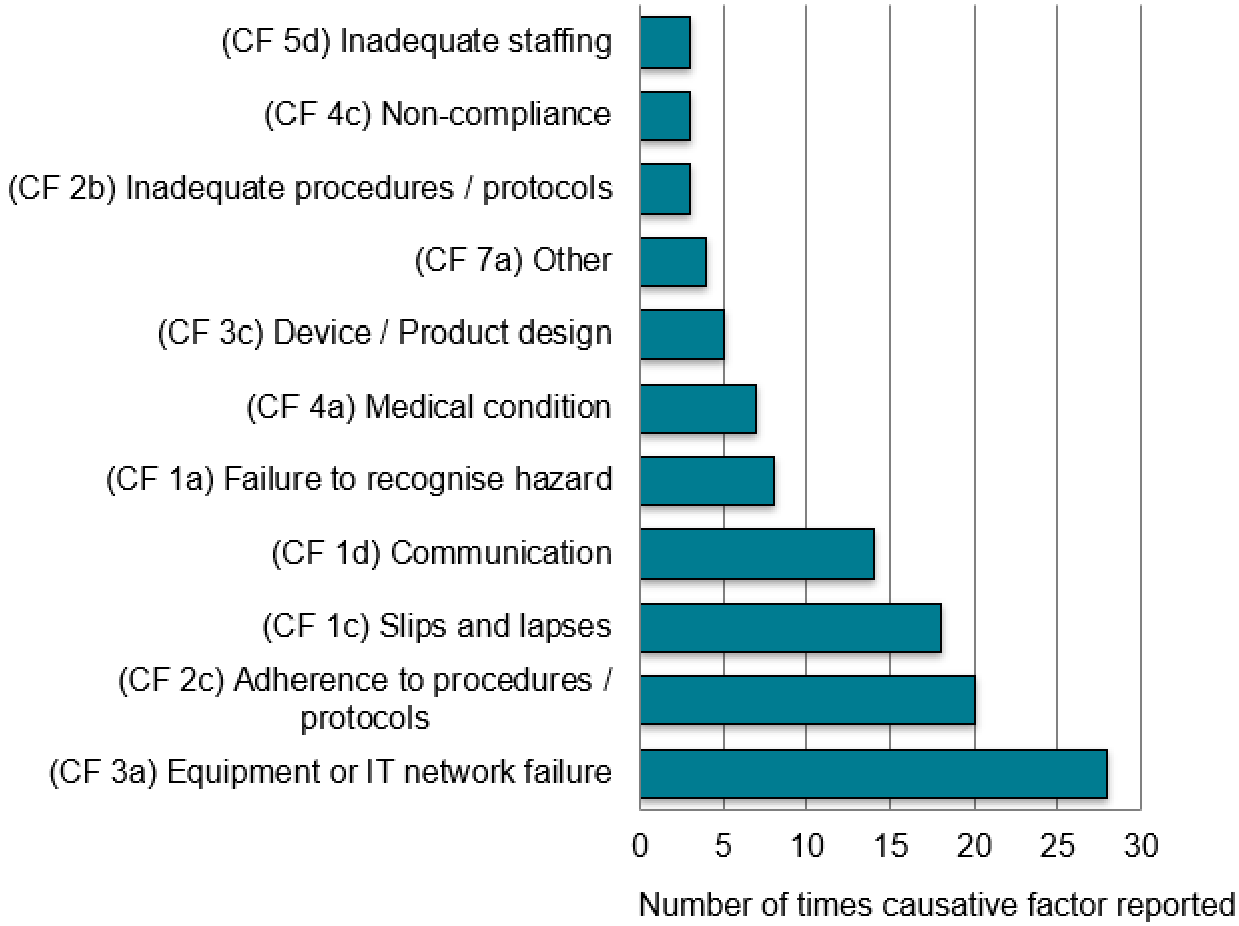


Multiple safety barrier codes can be attributed to each individual RTE. A total of 79 failed safety barriers (FSB) were identified across the BRT RTE reported. The most frequently reported FSB was 'management of variations/unexpected events/ errors' making up 32.9% (n = 26) of all the BRT FSB.

Of the 104 BRT 20.2% (n = 21) contained a MD pathway subcode. The most frequently reported BRT MD was 'end of process checks' making up 52.4% (n = 11) of all of the BRT MD. This was also the most frequently reported BRT MD in the previous 2-year reporting period (17) at 37.5% (n = 9).

Multiple causative factors (CF) can be assigned to a single RTE, across the 104 BRT RTE reported 16 contained multiple CF totalling 120 CF codes. Figure 24 shows the most frequently reported CF codes. The most frequently reported CF for BRT was 'equipment or IT network failure' making up (n = 28) of all BRT CF reported. This was followed by 'adherence to procedures/protocols' (16.7%, n = 20). This is different to the findings in the total RTE dataset where the most frequently reported CF was 'slips and lapses' making up 33.3% (n = 7,982) of all CF reported. 'Equipment or IT network failure' makes up 10.3% (n = 2,471) of all CF within the RTE dataset.

Figure 24. Breakdown of most frequently reported brachytherapy RTE causative factors (n = 113/120)



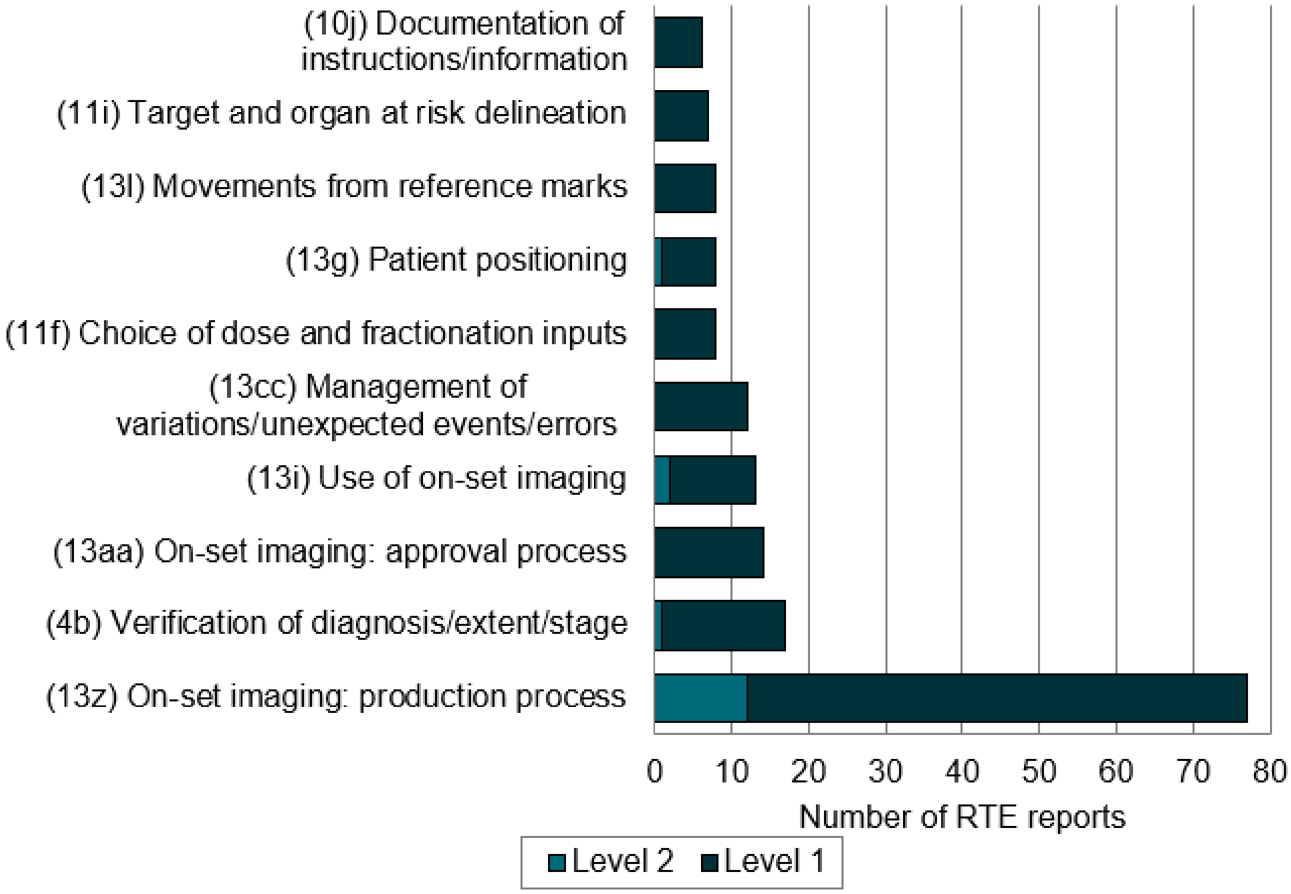
Inspectorate RTE

The IR(ME)R (9 to 11) inspectorates for England, Northern Ireland, Scotland, and Wales shared a total of 249 anonymised synopses of closed reportable radiation incidents for analysis. This had decreased from 300 in the previous 2-year reporting period (17). This decrease may in part be due to the reduction in patient attendances over the reporting period.

On review of the inspectorate data, it became clear there was some variation in the locally applied classification of incidents and that a number of voluntary notifications were made to the inspectorates. To separate these data, 8.8% (n = 22) of the reported incidents might be coded as Level 2. These are represented as Level 2 RTE in Figure 25. The inspectorates published guidance in June 2019, updated in August 2020 (23) which includes guideline factors for concomitant imaging. The updated guidance sought to clarify the reporting criteria.

The most frequently occurring subcode within the inspectorate data was ‘on-set imaging: production process’ (30.9%, n = 77). This has increased significantly (p = 0.03) from 11.3% (n = 34) since the previous 2-year report (17). This is also a prevalent process subcode within the Level 1, 2 and 3 RTE within the voluntary data for this time period. This was followed by 'verification of diagnosis/ extent/ stage' at 6.8% (n = 17) and 'on-set imaging: approval process' at 5.6% (n = 14).

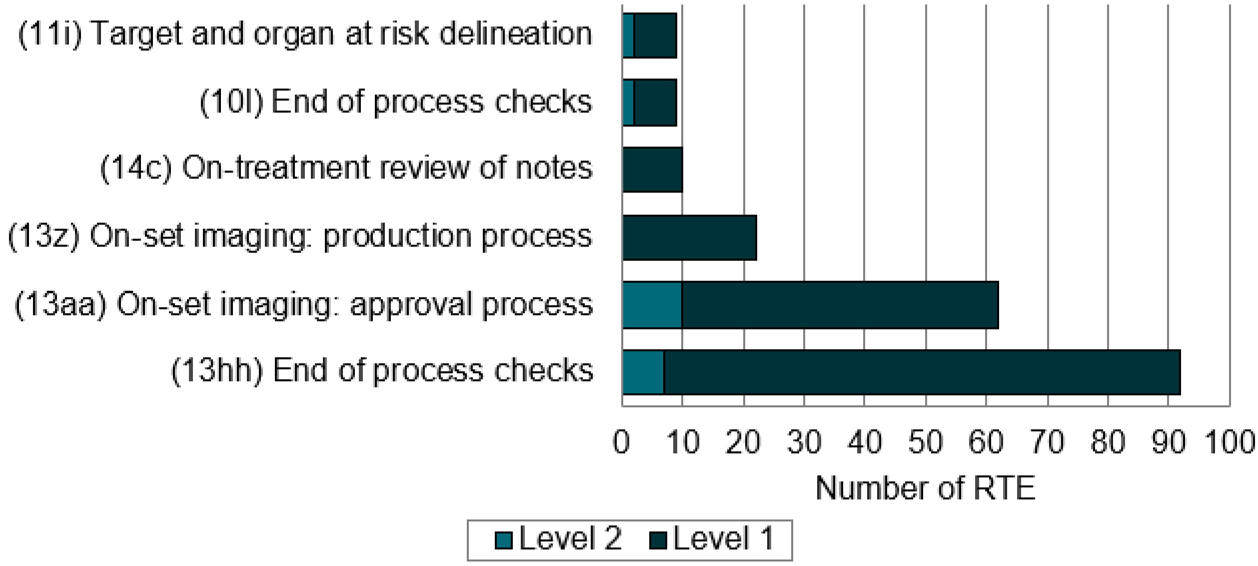
Figure 25. Breakdown of most frequent inspectorate notifications by process subcode (January 2020 to December 2021, n = 170/ 249 subset of RTE)



A total of 507 pathway subcodes were assigned in the inspectorate data. These included 264 failed safety barriers (FSB). The most frequently reported FSB was treatment unit process 'end of process checks' at 26.1% (n = 69).

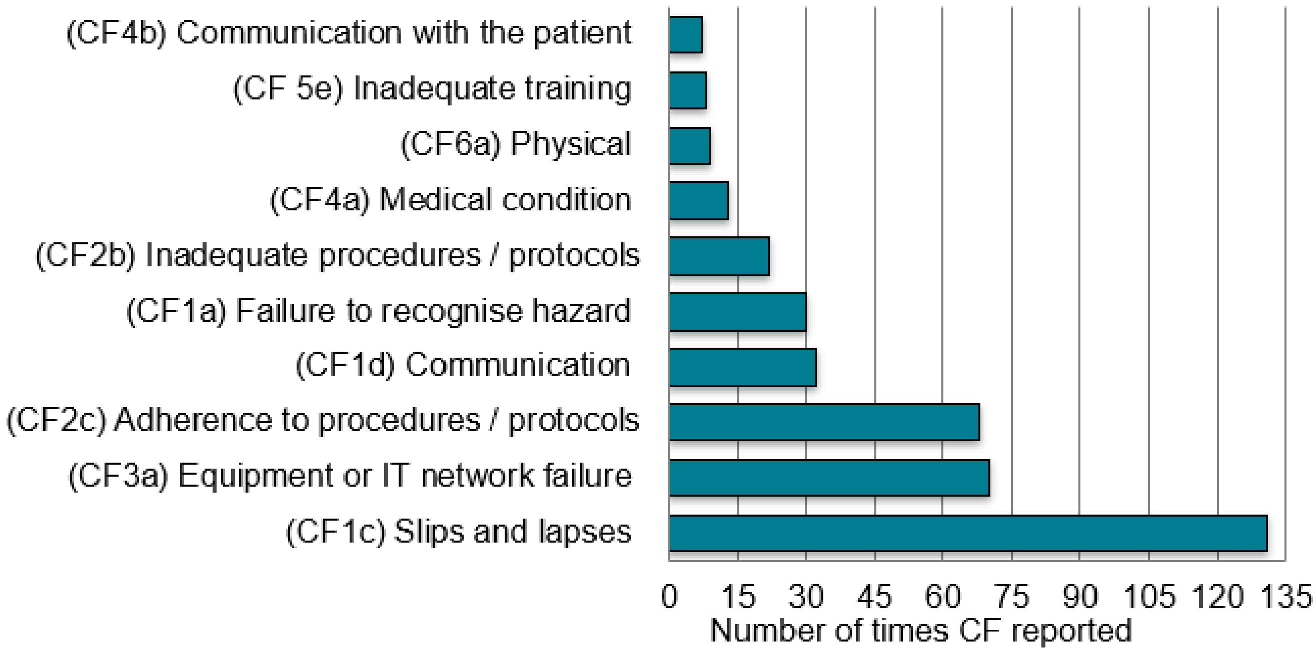
During the QA of the data, a MD was assigned to each report using the text descriptors shared. The most frequently reported MD can be seen in Figure 26. This indicates the treatment unit process 'end of process checks' was the most frequently reported MD at 36.9% (n = 92).

Figure 26. Breakdown of method of detection by Level for inspectorate notifications (n = 204/249 subset of RTE data)



There were 421 causative factors (CF) assigned to the inspectorate reports. The most frequently reported CF can be seen in Figure 27. The most frequently reported CF was 'slips and lapses' (31.1%, n = 131) followed by 'equipment or IT network failure' (16.6%, n = 70).

Figure 27. Breakdown of most frequent inspectorate notifications by all causative factors (January 2020 to December 2021, n = 390/ 421 subset of RTE)

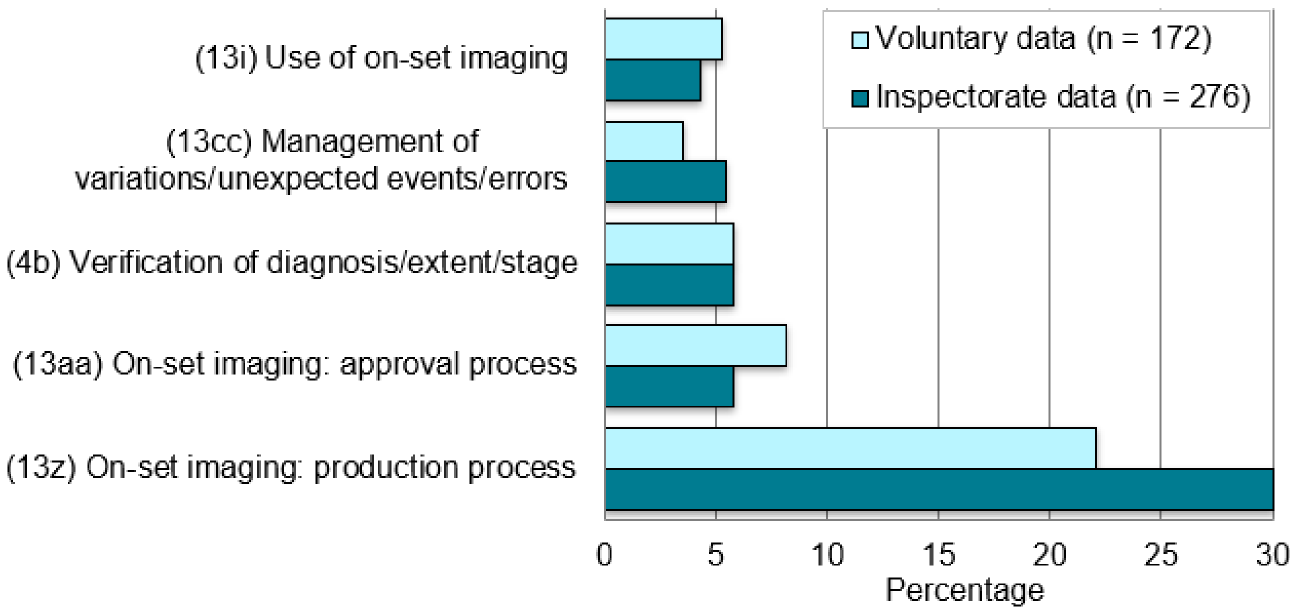


A variance in reporting numbers was noted between the voluntary and mandatory incident learning systems. A total of 165 Level 1 RTE were reported to the voluntary dataset and 249 reports to the inspectorates. A total of 40 providers submitted Level 1 RTE to the voluntary scheme. The number of providers that reported to the inspectorates was not shared as part of this data. Independent RT providers report to the inspectorates but not to the voluntary scheme, which in part accounts for the disparity in report numbers. Furthermore, there is a natural difference in the time lag of reporting, between those reports that come directly to UKHSA and those that come via the inspectorates.

A further review of the inspectorate data indicated a notable lag between the incident occurring and the date the report 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 497 and 16 days with an average of 166 days. One outlier of 1,617 days was removed from these lag times. The report 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 2020 and December 2021) was carried out (Figure 28). Although there are differences in the percentage of reports the most frequently reported process subcode within both the voluntary Level 1 RTE and the inspectorate data was 'on-set imaging: production process'.

Figure 28. Comparison of most frequently reported process subcode in inspectorate and Level 1 voluntary datasets (Incident date January 2020 to December 2021)



Discussion

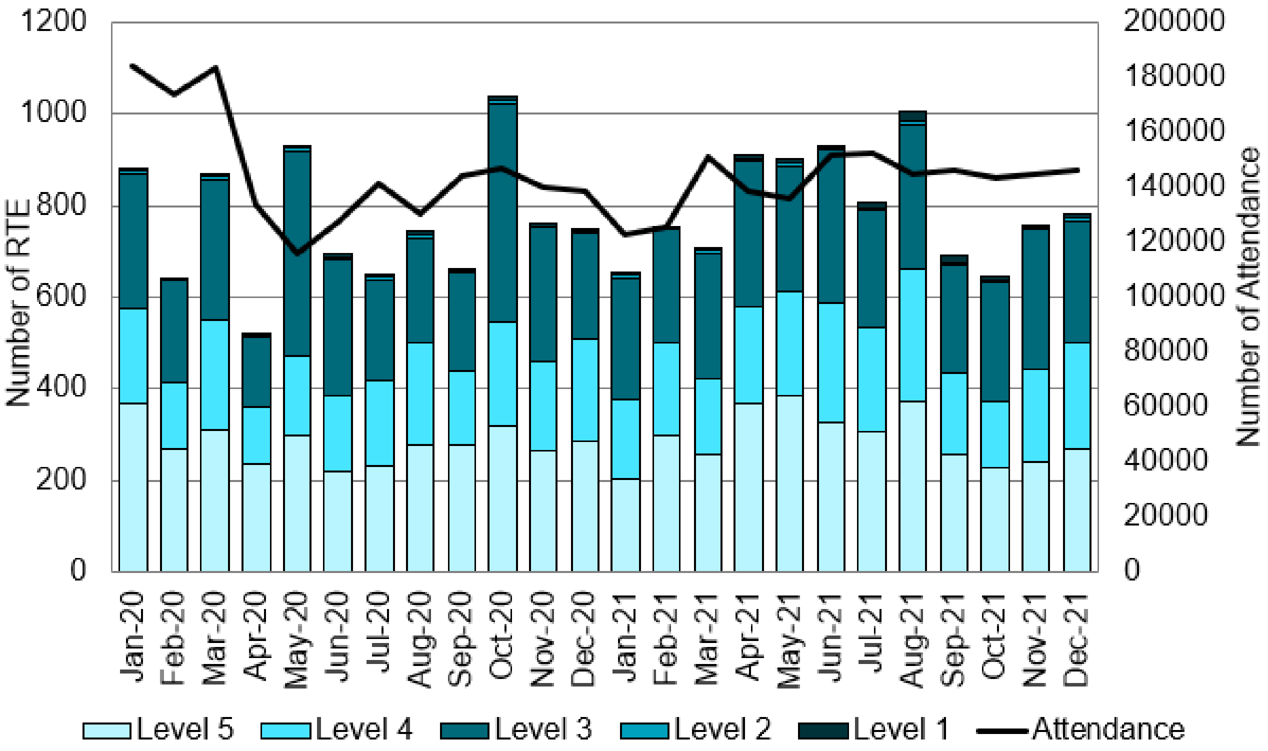
Over the last 5 years, all but one UK NHS RT provider submitted RTE reports to the voluntary incident learning system. This reflects a strong community commitment to shared learning from incidents supported by a number of drivers. IR(ME)R (9 to 11, 29) requires the local recording of analyses of events involving or potentially involving accidental or unintended exposure 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 (30) for providers based in England. Furthermore, recommendations of the Francis report (31) 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.

There is some variance in the number of reports submitted by provider. This variation in reporting rate is also seen in other incident reporting systems (32) and there are several potential explanations for this disparity. The number of reports per provider has not been normalised to account for the variation in number of patient attendances or prescriptions or provider service specification. Reporting culture varies across providers. Incident learning systems are not always easily accessible locally impacting on the ease of reporting. Additional resource may be required to support a full incident learning system. A local requirement to use more than one reporting system may disincentivise reporting. The national survey on reporting culture published in the January 2022 issue of Safer Radiotherapy (21) indicated all providers did not report all levels of RTE to the national system, with Level 1 and 2 RTE most likely to be reported. Those providers with requirements to use more than one incident learning system were less likely to submit all classification levels of RTE, leading to lower reporting numbers. Those providers reporting higher numbers of RTE represent providers with mature reporting cultures and systems and should be encouraged to continue reporting.

For this reporting period 18,772 RTE reports were received, similar to the previous 2-year (17) period when 18,853 were received. Annual number of reported RTE over the last 3 years (2021 (n = 9,544), 2020 (n=9,137) and 2019 (n=9,793) seems to have started to plateau. However, it should be noted there has been a notable variation in the number of patient attendances and prescriptions delivered across providers over this 2-year period.

The Radiotherapy Dataset (27) estimated number of patient attendances in NHS providers across England and Wales for this reporting period was 3,281,303 attendances. This data was extrapolated for the UK population to an estimated 3,463,569 attendances and 363,220 prescriptions. This is a decrease since the previous 2-year reporting period (17) when there were an estimated 415,786 prescriptions (12.6% decrease) across 4,441,536 attendances (26.1% decrease). It can be seen in Figure 29 that there was a sharp decline in attendances in early 2020. This decrease is likely due to the response to the COVID-19 pandemic with reported delays in diagnosis and referrals, treatment deferrals and the national adoption of shortened fractionations for some disease (33, 34).

Figure 29. 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 the clear majority of RTE reported affected a single attendance as part of a prescription. With this caveat an estimated reported RTE rate of 5 per 1,000 attendances were calculated. 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), thus not affecting the treatment outcome for the patient. Using the same premise an estimated report RTE rate for Level 1 events was calculated as 0.5 per 1,000 prescriptions.

This is an increase from 4 RTE reported per 1,000 attendances and 0.4 Level 1 RTE reported per 1,000 prescriptions from the previous 2-year reporting period (17). The percentage as a proportion of Level 1 RTE was very similar for the previous 2-year reporting period (17). Of the Level 1 RTE reported through the voluntary system and the IR(ME)R (9 to 11) inspectorates, 21.2% and 30.9% respectively were associated with ‘on-set imaging: production process’, contributing to the overall increase in Level 1 RTE. This is discussed further below. Further consideration might be given to the potential for a refinement to reporting criteria for significant and accidental unintended exposures as it relates to on-set imaging processes.

A small number of more significant incidents and a much greater number of less significant incidents are consistent with findings in the literature (35). It is known that for every Level 1 incident that occurs, many less severe incidents are also seen. Heinrich illustrated this point in 1931 (35). It may be seen in the data as the severity of an incident decreases, the probability of its occurrence increases. Heinrich postulated that for every 1 severe accident there would be 30 minor accidents and 300 near misses. Figures 7 and 29 indicate the classification levels of the voluntary RTE data. Although there is a notable higher proportion of Level 3-5 RTE within the voluntary data, the ratios aren't as marked as Heinrich postulated. This might be explained by the fact that all providers do not report all levels of RTE.

The definition of a Level 1 (reportable radiation incident) and Level 2 (non-reportable radiation incident) (7) relies on how incidents reportable under IR(ME)R (9 to 11) are categorised. In 2017/18 IR(ME)R was updated with a broader categorisation of radiation incidents deemed reportable. This was followed by guidance from the IR(ME)R inspectorates in 2019 and 2020 (23) on criteria and thresholds for reporting. This recategorisation of reportable incidents has rendered the Level 2 classification less useful in grouping incident data by severity. A review of the current use of the classification levels might usefully assess how best to address this.

Some commonality in themes can be seen across Level 1-4 RTE reports. This is exemplified by the prevalence of imaging associated RTE across these levels. On-set imaging associated RTE combined made up 23.7% (n = 4,425) of all RTE. A significant proportion of Level 3 RTE were related to on-set imaging, (48.5%, n = 3,277). This is similar (48.7%, n = 3,278) to the previous 2-year reporting period (17).

Focusing on RTE associated with on-set imaging, a notable trend within the Level 1 RTE includes a decrease in RTE associated with 'on-set imaging: approval process' from 11.9% in 2017 to 5.9% in 2021. It was the second most frequently reported Level 1 RTE at 8.5% (n = 14) and the most frequently reported Level 2 reports at 16.4% (n = 20), down from 8.9%, (n = 31) in the previous 2-year reporting period (17). The highest rate in the Level 2 data was observed in 2019 (24.1%) decreasing sharply in 2021 (13.8%).

The incidence of 'on-set imaging: approval process' associated RTE reflects the increase in automation during set-up and the focusing of decision-making processes during on-set imaging resulting in more imaging related errors. This is reflected in the volume of data and image interpretation required as part of imaging processes. This risk may be amplified due to the dynamic nature of online review and the rapid pace of development of new technologies. This equates to more on-set imaging-based errors. However, the many benefits on-set imaging brings to the patient are clear (36). The reduction in reported 'on-set imaging: approval process' between reporting periods may be linked to user familiarity with local processes and software systems in addition to improved and more streamlined software systems for the analysis and management of verification images.

The most frequently reported MD was 'on-set imaging: approval process' demonstrating the efficacy of imaging in identifying some types of RTE. This MD included both online and offline verification processes. Within the inspectorate data (Figure 26), on-set imaging approval process was the second most frequently reported MD, reinforcing the importance of imaging as a safety tool.

'On-set imaging: production process' made up 13.4% (n = 2,495) of all RTE reports for this 2-year reporting period marking a statistically significant increase (p = 0.001) from 12.3%, (n =

2,310) since the previous 2-year (17) report. It contributed to 12.5% (n = 2,347) of Level 1, 2 and 3 RTE. The increase in Level 1 RTE reports associated with ‘on-set imaging: production process’ may be due in part to the national adoption of shortened fractionations (33, 34). The shortened fractionation regimes are more likely to trigger the reporting thresholds set by the IR(ME)R (9 to 11) inspectorates. It was the most frequently reported subcode in this reporting period. Of the 35 Level 1 RTE reported associated with ‘on-set imaging: production process’, 74.3% (n = 26) were reported to be due to equipment malfunction.

‘On-set imaging: production process’ made up 34.1% (n = 2,305) of all Level 3 RTE, an increase from 31.9% (n = 2,145) in the previous 2-year period (17). Of these RTE 51.7% (n = 1,193) were reported to be due to equipment malfunction. For the Level 3 RTE related to ‘on-set imaging: production process’, the rate increased with year (ranging from 27.9% to 34.2%). This increasing trend was statistically significant ($p = 0.02$) with a rate of 1.5% per year.

Table 3 indicates that from the 2,495 RTE reported with primary process subcode ‘on-set imaging: production process’ there were 2,981 CF assigned, from these CF the most frequently reported CF was ‘equipment or IT network failure’ making up 42.2% of all CF for this process subcode. If the most frequently occurring equipment malfunction issues associated with on-set imaging: production process failures are addressed, the numbers of Level 3 RTE associated with this type of RTE could be significantly reduced by 1,193.

Guidance on reducing this type of event is included in case study 2 in issue 32 of Safer Radiotherapy (37) and the good practice guidance series (38). In trying to minimise the frequency of imaging equipment failure it is expected that following commission and clinical acceptance of the imaging devices, they are subject to regular and timely QA as per local procedures with tasks, tolerance and action levels and escalation routes clearly defined and responsibilities allocated to appropriately trained and entitled staff.

When these events persist, it might be expected that:

- logged events are monitored to identify root cause and trends so that action and escalation of these events can be taken as appropriate
- the manufacturer, MHRA (39) or the IR(ME)R inspectorates (23) are notified of the recurrence of these events
- a risk assessment is undertaken for ongoing use of the affected imaging. This might reflect the view of the practitioner (under IR(ME)R) on the potential for additional imaging dose due to these failures of the equipment as part of the treatment prescription and usual imaging dose; consider the age profile of the relevant imaging devices; assess alternative mitigations that could be implemented ensuring the broad risk and benefit to the patient is considered; to consider an appropriate threshold at which point there is consideration given to removing the device from clinical use

The reported onset imaging related RTE in the Level 1 to 4 data differ from the Level 5 RTE reports. This might be expected as Level 5 RTE are detected and corrected as part of routine quality management system checks, thus stopping these RTE from propagating through the pathway. The most frequently reported Level 5 pathway subcode was 'documentation of instructions or information' making up 43.0% (n = 371) of all the Level 5 RTE reported. This was the second most frequently reported process subcode overall at 4.6% (n = 861). This only appeared in the 10 most frequently reported process sub-codes for Levels 1, 4 and 5 RTE.

Of note 'bookings made according to protocol' has increased in percentage from 2.8% in 2017 to 4.9% in 2021 in Level 5 RTE. There was a peak in percentage of reports in 2019 at 6.5%, over the past 2 years this has now started to reduce. This may in part be due to the rapid uptake of IT systems to optimise data flow during the COVID-19 pandemic. This demonstrates the learning opportunities derived through analysis and sharing of Level 5 RTE.

It is known there are risks inherent in the planning and delivery of RT. Therefore, a number of safety barriers (SB) are built into the patient pathway to identify and stop RTE propagating across the pathway and affecting the patient (13). Analysis of failed safety barriers (FSB) gives an understanding of where resources might be focused to be most beneficial in mitigating RTE.

Treatment unit processes 'end of process checks' was the most frequently reported FSB (12.3%, n = 1,507). 'End of process checks' from each part of the pathway collectively comprised 36.8% (n = 4,523) of all FSB. Most end of process checks are manual human checks and it is accepted that humans are not as effective as other preventative measures. Due to the prevalence of the 'end of process checks' as a FSB, further work will be undertaken to better understand these procedures within clinical services and to see if FSB positioned earlier in the pathway could be made more effective. Consideration should be given by all RT providers to reviewing the effectiveness and timing of end of process checks ensuring they are fit for purpose, contain minimum criteria for checking and processes are automated where appropriate.

The benefit of the use of causative factor (CF) taxonomy is that it enables identification of system problems that could precipitate a range of different incidents. Within the previous 2-year reporting period (17) not all RTE contained a CF, nor contained enough detail to assign one. Within this report all RTE contained the CF taxonomy or enough detail for UKHSA to assign one, this demonstrates a growth in the uptake of the CF taxonomy

The most frequently reported CF was 'slips and lapses' (33.3%, n = 7,982) and 'adherence to procedures/protocols' (24.8%, n = 5,946). The prevalence of the CF 'slips and lapses' began to decline in 2019 at the same time the CF 'adherence to procedures and protocols' began to increase. This is particularly of note when considering the importance of adherence to local procedures and protocols in demonstrating due diligence in clinical care.

Consideration should be given to reviewing the accessibility and ease of use of quality management systems (QMS) to ensure staff can access relevant procedures and protocols when required. This might extend to the location of the QMS and access rights to electronic

QMS. Also, active engagement and inclusion of staff in review of procedures is key to ensuring they are fit for purpose.

In reviewing the volume of reported CF with a primary root cause of 'slips and lapses', consideration was given to the wider use of the taxonomy and the use of contributory factors. In keeping with a systems approach to RTE review, UKHSA will report on the totality of contributory factors to identify casual trends in RTE. It is hoped this will support a further move away from a blame culture where fault is attributed to an individual. If the CF are addressed, it can be expected that overall system safety is enhanced and not just a weakness associated with a particular incident (25).

During this reporting period a total of 15 molecular RT (MRT) errors were submitted to the voluntary system from a single provider. A review of the pathway coding demonstrates that it does not lend itself well to MRT errors and this should be addressed if MRT providers are to be encouraged to participate in the RT incident learning system. The Clinical Imaging Board has tasked UKHSA to coordinate a feasibility study for a bespoke diagnostic imaging, interventional radiology and nuclear medicine imaging incident learning system. As part of this work consideration has been given to inclusion of MRT errors within that dataset. This would mean nuclear medicine providers would submit data to a single system, making participation in this work easier for them.

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 (4, 29).

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 (4). A recognised risk assessment approach should be used and adapted as required with agreed timing for completion and review. Further guidance on study of risk is available (29).

Table 3 highlights the most frequently reported pathway subcodes and where the associated study of risk for these pathway subcodes can be found. Only one of the top 10 most frequently reported subcodes has not had a study of risk published, this will be included in January 2023 edition of 'Safer Radiotherapy'.

Table 3. Most frequently reported process subcodes and associated study of risk

Process subcodes	Study of risk available
(13z) On-set imaging: production process	Safer Radiotherapy: triannual RTE analysis and learning report issue 32 (37)
(10j) Documentation of instructions/information	Safer Radiotherapy: triannual RTE analysis and learning report issue 33 (40)
(12f) Accuracy of data entry	Safer Radiotherapy: triannual RTE analysis and learning report issue 36 (41)
(13i) Use of on-set imaging	Safer Radiotherapy: E-bulletin #5 (42)
(11j) Generation of plan for approval	Safer Radiotherapy: triannual RTE analysis and learning report issue 38 (43)
(13aa) On-set imaging: approval process	Safer Radiotherapy: E-bulletin #5 (42)
(13bb) On-set imaging: recording process	Safer Radiotherapy: E-bulletin #4 (44)
(13cc) Management of variations, unexpected events or errors	Safer Radiotherapy error and near miss reporting: the unseen pathway (22)
(6a) Bookings made according to protocol	Safer Radiotherapy: triannual RTE analysis and learning report, issue 39 (due in January 2023)

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 comprises of a number of 20-minute presentations available on the UKHSA webpages for download, aimed at supporting professionals in the RT community.

The taxonomies used for the coding of RTE were last updated in 2017, consideration might be given to their review to ensure they continue to reflect contemporary practice in RT and current thinking in patient safety in healthcare. As part of this consideration might be given to:

- use of the Level 2 classification
- focus of the causative factor taxonomy to reflect contributory factors
- use of the 'other' coding within taxonomies
- review of pathway sub-coding to ensure it continues to reflect contemporary practice
- inclusion of a modality coding to describe the type of exposure undertaken

This work focuses on learning retrospectively from RTE through incident analysis and use of RTE data to inform simple prospective risk assessments. Consideration might be given to using the data in additional ways to improve patient safety in RT. This will be considered as part of the guidance document 'Advancing Safer Radiotherapy', in 2023 by the PSRT.

Since the publication of 'Towards Safer Radiotherapy', its recommendations on how to improve patient safety in radiotherapy have been adopted locally and nationally and continue to be relevant to clinical practice today.

There have been significant developments in patient safety approaches over the last decade relevant to improving patient safety in radiotherapy. Traditional patient safety models in healthcare focus on learning from incident and near miss events (Safety I Principles). Much of the work of the PSRT to date has focused on improving patient safety in radiotherapy through adoption of Safety 1 Principles which often focus on the individual. Latterly academics have developed safety thinking to include Safety II Principles. Safety II thinking includes a systems approach and a focus on learning from where things have gone well.

Whilst much has been done to improve patient safety in radiotherapy some error trends persist. It is time to consider new approaches to address these. In addition, when the opportunity for error is weighed against the reported occurrence of error, relative numbers of errors are low. This would suggest that there are many more opportunities to learn from where things have gone to plan as opposed to where they have gone wrong. The PSRT will seek to address this in the forthcoming publication 'Advancing Safer Radiotherapy'.

Reporting of RTE will only be 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, blame free reporting culture and where the clear aim of reporting is to learn and to improve patient safety (29, 45). High reporting numbers of RTE is indicative of an awareness of safety issues among healthcare professionals and a well-established reporting culture. Employers should support adequate resourcing of effective incident learning systems to simplify the local reporting process and to encourage reporting of all classification levels of RTE.

Conclusion

Learning from RTE continues to be an effective tool to learn from and mitigate RTE. It is important that learning continues to be shared locally, nationally and internationally to maximise opportunities to improve patient safety in RT. Use of RTE data to inform local prospective risk assessment is an additional effective tool to mitigate these events and optimises use of RTE data.

Participation in the national voluntary incident learning system (17, 18) is indicative of an open and transparent safety culture. This 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 5 years, all but one provider submitted RTE reports to the voluntary incident learning system. This reflects a strong community commitment to shared learning from incidents, which should be supported by the employer.

Since the voluntary incident learning system was introduced in 2008, the number of RTE reported has stabilised for the first time. An estimated reported RTE rate of 5 per 1,000 attendances was calculated for this reporting period and an estimated reported RTE rate for Level 1 events was calculated as 0.5 per 1,000 prescriptions. This indicated a slight increase from an estimated 4 per 1,000 attendances and RTE rate for Level 1 events calculated as 0.4 per 1,000 prescriptions for the previous reporting period. These increases might be explained by the wide adoption of hypofractionation regimes and the adoption of more streamlined reporting processes and software to facilitate submission of RTE. This is reflected in the average lag time of reporting at 31 days. The increase in Level 1 RTE reflects the increase in on-set imaging related RTE triggered by the change in the criteria for reporting to the IR(ME)R (9 to 11) inspectorates.

On-set imaging associated RTE made up a significant proportion of all reported RTE. This reflects the volume of these types of exposures undertaken and the associated decision-making processes on the pathway and is the last point on the pathway prior to initiating treatment exposures. The most frequently reported subcode was ‘on-set imaging: production process’, just over half of these were reported to be due to equipment malfunction. Equipment failure reports should be reported to local engineers, the manufacturers and the MHRA. Further work is required to address these types of events nationally.

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. Changes in trends over time demonstrate the importance of ongoing cyclic monitoring of RTE.

Recommendations

Local provider recommendations:

1. All NHS UK providers should continue to use the TSRT and DoL taxonomies, including the pathway subcodes, failed safety barriers, method of detection and causative factors, to code all levels of RTE for local analysis and to inform local learning and practice. The entire coding taxonomy should be considered before using the ‘other’ code within a taxonomy.
2. Local employers should support adequate resourcing of effective incident learning systems to simplify the local reporting process and to encourage reporting of all classification levels of RTE on a monthly basis to ensure timeliness of shared learning.
3. Independent RT providers should submit RTE reports to the national voluntary reporting system.
4. Where imaging device faults persist, a risk assessment should be undertaken for the ongoing use of the device.
5. Local learning should be compared with the national picture and used to inform local and network level practice.
6. Outputs from local 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.

National recommendations:

7. 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
8. PSRT should engage the MHRA and vendors in developments to reduce the rate of RTE related to imaging equipment failure
9. PSRT should share important learning from the analysis related to on-set imaging RTE with the IR(ME)R inspectorates to inform future refinements to reporting criteria for significant and accidental unintended exposures
10. Due to the prevalence of FSB at the end of process checks the PSRT should undertake work to better understand end of process check procedures and efficacy of safety barriers
11. 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. A review of the pathway coding demonstrates that it does not lend itself well to MRT errors and this should be addressed if MRT providers are to be encouraged to participate in incident learning.
12. 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.

Acknowledgements and PSRT Steering Group membership

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- National Reporting and Learning System (NRLS) at NHS England and Improvement
- Inspectorates for IR(ME)R across the UK:
    - Care Quality Commission (CQC) in England
    - Healthcare Improvement Scotland (HIS) in Scotland
    - Healthcare Inspectorate Wales (HIW) in Wales
    - Regulation and Quality Improvement Authority (RQIA) in Northern Ireland
- Nezahat Hunter (Medical Statistician, UKHSA)
- Radiotherapy data set for attendance and prescription numbers – this work uses data that has been provided by patients and collected by the NHS as part of their care and support; the data is collated, maintained and quality assured by the National Disease Registration Service, which is part of NHS Digital

PSRT steering group membership

- Julia Abernethy (Patient Safety Team, NHS England and Improvement until 2021)
- Helen Best (UKHSA and PSRT secretariat)
- Martin Duxbury (Society of Radiographer’s Clinical Representative: Deputy Head of Radiotherapy, St James Institute of Oncology, Leeds)
- Úna Findlay (UKHSA and Group Chair)
- Spencer Goodman (Society of Radiographers: Professional Officer from 2021)
- Petra Jankowska (Royal College of Radiologists: Consultant Clinical Oncologist, Taunton and Somerset Foundation Trust and Quality and Safety Lead at RCR)
- Chris Mainey (Patient Safety Team, NHS England and Improvement from 2021)
- Maria Murray (Society of Radiographers: Professional Officer for Scotland and UK Radiation Protection Lead until 2021)
- Tony Murphy (Lay Representative)
- Carl Rowbottom (Institute of Physics and Engineering in Medicine: Head of Physics, The Clatterbridge Cancer Centre NHS Foundation Trust)
- Kim Stonell (UKHSA and PSRT secretariat)

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UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

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