UK Health Security Agency

Safer Radiotherapy

E-bulletin #12
January 2024

Welcome to the Safer Radiotherapy (RT) E-bulletin, which provides key messages and learning from radiotherapy error (RTE) reports and the national patient safety initiative.

Representatives from the UK Health Security Agency (UKHSA), the Royal College of Radiologists (RCR), the Society of Radiographers (SoR), Institute of Physics and Engineering in Medicine (IPEM), NHS England (NHSE) and a lay representative form the Patient Safety in Radiotherapy Steering Group (PSRT) to support the coordination of efforts to improve patient safety in RT across the UK. This work includes the collation, analysis, and dissemination of learning from RTE reports.

Anonymised RTE reports are currently submitted on a voluntary basis through the National Reporting and Learning System (NRLS) and Learn from Patient Safety Events service (LFPSE) of NHSE; the Once for Wales (OfW) Concerns Management System and directly to UKHSA, to promote learning and to minimise recurrence of these events. Each Safer RT E-bulletin accompanies the Triannual RTE Analysis & Learning Report, which summarises learning from RTE reports submitted for the preceding 4-month period. The report is designed to disseminate learning from RTE to professionals in the RT community to positively influence local practice and improve patient safety.

Please email **radiotherapy@ukhsa.gov.uk** for advice on incident learning from RTE and with any suggestions for the E-bulletin. Published three times a year, the next issue will be shared in May 2024. To subscribe to future editions please follow this link.

Thank you to all RTE reporters who facilitate this work.

PSRT, lay representative – update

We would like to extend our warmest wishes to Tony Murphy, lay representative of the PSRT, who has stepped down from the group.

Tony has ably represented the views of patients and the wider public on the PSRT for 12 years and has always been an active, enthusiastic and informed member of the group. Grounded and focussed, Tony has always challenged and inspired the group in its work to enhance patient safety in radiotherapy. His natural good temper has enabled him to engage and debate topics with group members in a positive and constructive manner. We wish Tony all the best in his future endeavours, he will be greatly missed.

Medical Exposures Group (MEG) Radiotherapy Team at UKHSA

The Radiotherapy team within MEG have recently welcomed two new members; Cristíona Logan and John Rodgers.

With increased capacity and resilience, the team look forward to working with the radiotherapy community on future patient safety projects.

Advancing Safer Radiotherapy (ASR) – update

Work continues on ASR with text drafted for all topics. The next phase of independent review has commenced. The independent review will be undertaken by three radiotherapy professionals.

Thank you to all those who are taking part in this work. It is hoped the document will be published early in 2024.

Radiotherapy Board

The Radiotherapy Board provides guidance, oversight and support for the continuing development of high quality radiotherapy services. Established in 2013 by RCR, the Society and College of Radiographers (SCoR) and IPEM, it has representation from across the four UK nations and from other organisations closely involved in radiotherapy services. The most recent work of the Radiotherapy Board has been published Summary Report 3 (October 2023).

LFPSE update

Lucie Mussett, Patient Safety Lead – Learn from patient safety events (LFPSE) service

The roll out of the LFPSE service, which replaces NRLS and eventually the Strategic Executive Information System (STEIS), is now well underway, with over 50% of NHS trusts submitting data to LFPSE – a list of transitioned providers is updated weekly and available here.

These providers have the option in LFPSE to submit radiotherapy error codes into a designated field, as well as in the free text.

Provider data will shortly become available to view through the new LFPSE Recorded Data Dashboard, due to launch in early 2024, which offers close to real-time, interactive views of the data, to support learning and safety improvement. In the meantime, a more basic view of the data is available through the Data Access App. From Q1 2024/25, we expect risk management software suppliers to start rolling out the next upgrade to the LFPSE taxonomy, which features many usability enhancements requested by users, as well improved capture of protected characteristics, and a module to support the adoption of the new Patient Safety Incident Response Framework. Guidance is available on recording serious incidents during the transition period on the FutureNHS platform.

If you have any feedback or suggestions on how LFPSE could be improved in future upgrades, please contact the LFPSE Helpdesk.

LFPSE podcast

The national NHS LFPSE service has provided podcasts to support organisations to transition and start recording patient safety events. These podcasts include steps to getting connected to LFPSE and Learning from transitioned providers.

HSSIB investigation report: Safety management systems

The Health Services Safety Investigation Board (HSSIB) have published an Investigation report on safety management systems (SMS)– an introduction for healthcare. A SMS is an approach to managing safety. The report explores the way SMSs are used and how the principles of an SMS could contribute to more effective safety management in healthcare.

Care Quality Commission (CQC) annual report published

The CQC has published the annual report on the enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017. Between April 2022 to March 2023 the CQC received 270 radiotherapy (RT) notifications. This is an increase since 2021/2022 when 182 RT notifications were received. Planning and verification imaging accounted for 54% of all RT notifications received.

The report includes key themes in RT along with recommended actions for employers, they include:

- The appropriate use of authorisation guidelines in Brachytherapy, further detail can also be seen in the May 2023 edition of the E-bulletin
- Employer's procedures, further guidance can also be found in the IR(ME)R: implications for clinical practice in radiotherapy
- SAUE threshold awareness, the SAUE guidance includes IR(ME)R notification codes, categories and criteria

Patient Related Incident Analysis (PRIA) update

Work continues to progress with the national incident reporting and learning system for clinical imaging, MRI and nuclear medicine. The refinement of the existing clinical imaging board user guidance and taxonomy coding is nearing completion and publication is expected for Spring 2024. This system will provide opportunities for clinical departments to share learning from clinical imaging incident data at a local, national and international level to maximise opportunities to improve patient safety.

National aggregate RTE data

To better support RT providers with trend comparison, the UKHSA has produced the second national annual aggregate RTE data. The national data includes:

- Data quality of aggregate RTE reports
- Number and classification level of RTE reports per provider
- Number and classification level of aggregate RTE reports per month
- Classification level of aggregate RTE reports
- Process subcodes of aggregate RTE reports
- Failed safety barriers of aggregate RTE reports
- Causative factors of aggregate RTE reports

The data for January to December 2023 is now available. If you are a RT provider, reporting to the national radiotherapy reporting and learning system and would like to receive this dataset, please email **RTEdata@ukhsa.gov.uk** with the following:

- Organisation name,
- How you propose to use the national aggregate RTE data.

Digital clinical safety training

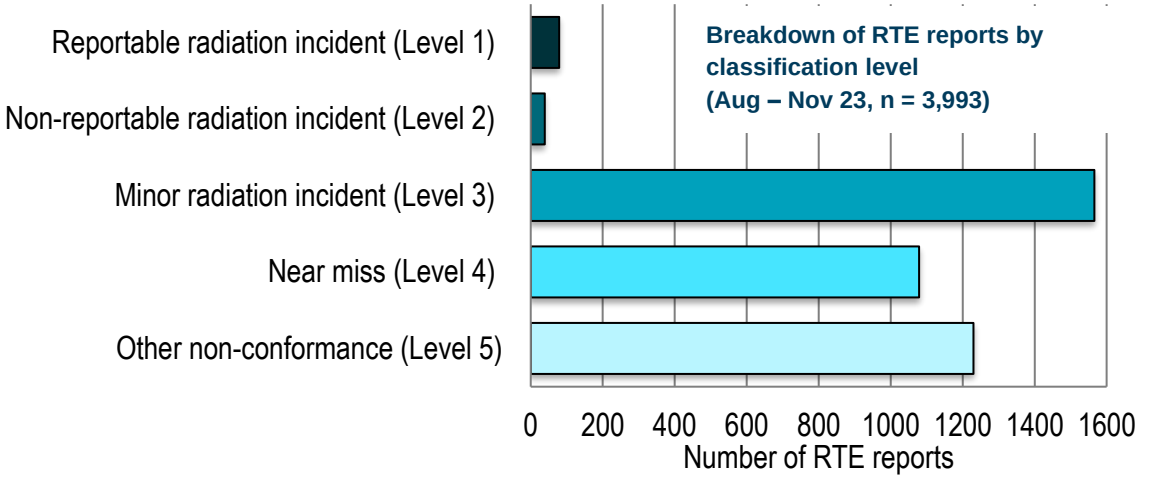
Digital clinical safety training is designed to provide training in the principles of safety, risk management and risk mitigation. The Intermediate digital clinical safety e-learning modules on e-learning for health have been relaunched. In response to user feedback, the clinical risk management module has been revised to improve understanding of the real-life application of digital clinical safety. To find out more about digital clinical safety, including courses available, visit Digital Clinical Safety training - NHS Digital.

RTE data analysis – August to November 2023

The full detailed data analysis is available here and includes data on primary process subcoding, failed safety barriers, methods of detection, causative factors, and the severity classification of the RTE. These taxonomies are described in the Development of Learning from RTE. A summary of findings is presented below.

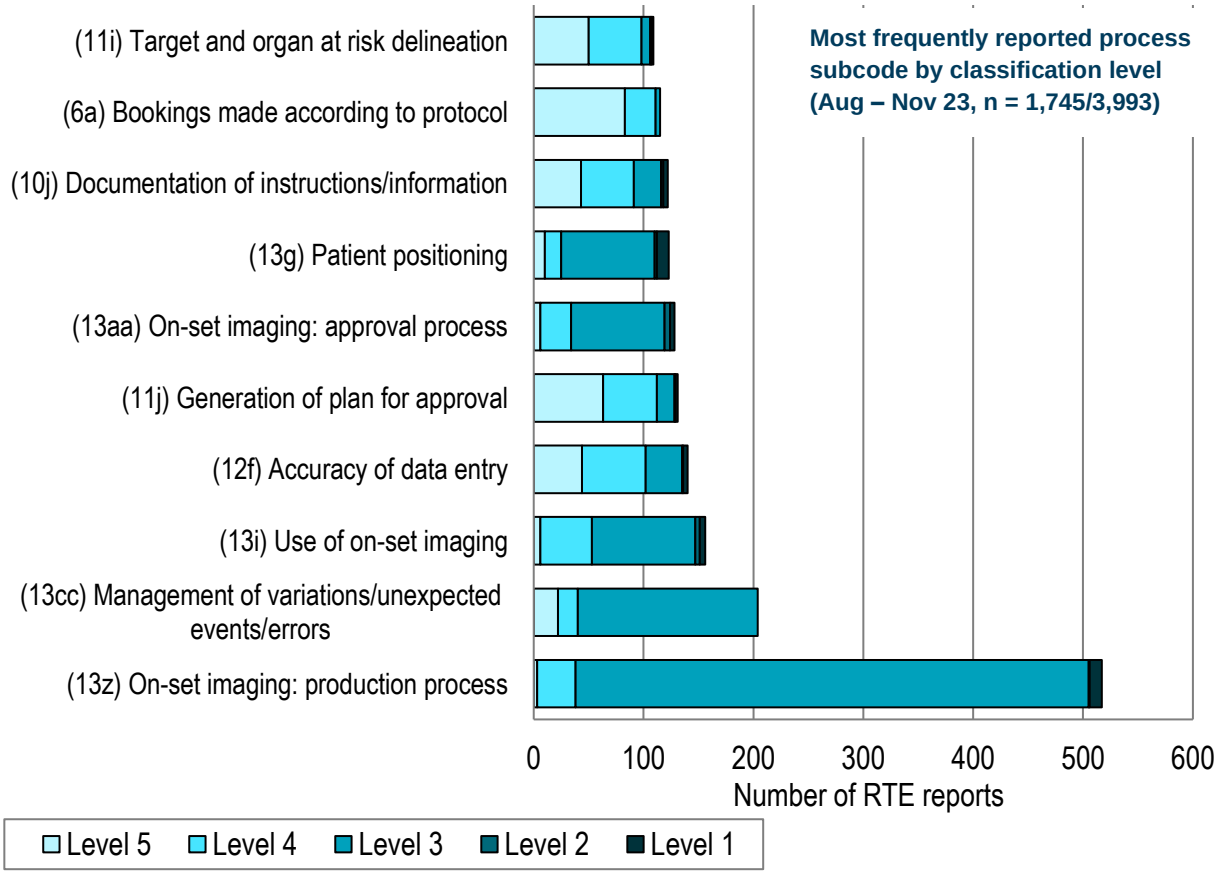
Classification (Level) of RTE

Of those 3,993 RTE reported, 3,875 reports (97.0%) were classified as minor radiation incidents, near misses or other non-conformances (Level 3 - 5). These had no significant effect on the planning or delivery of individual patient treatments or their outcome.



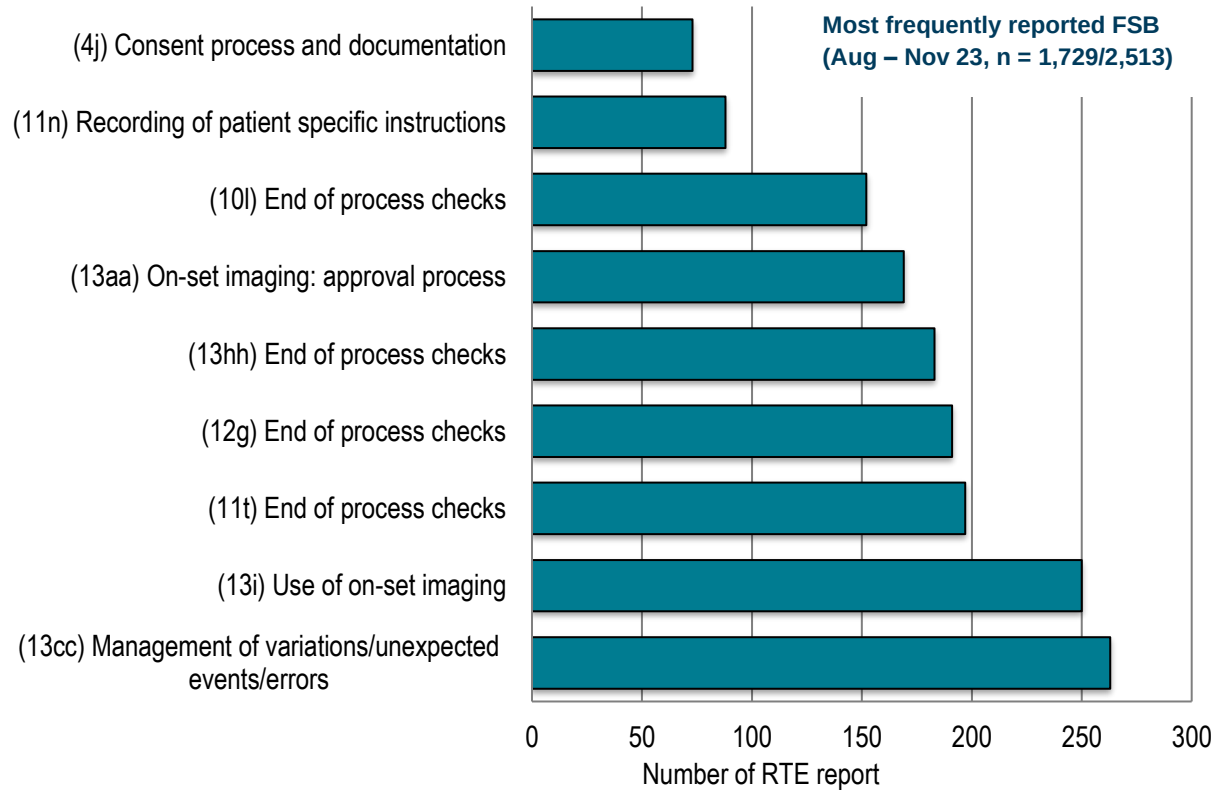
Primary process subcode

The most frequently reported points in the patient pathway where the RTE occurred are shown below. This is broken down by classification level. Consistent with the previous analysis 'on-set imaging: production process' was the most frequently reported process code (12.9%, n = 517/3,993).



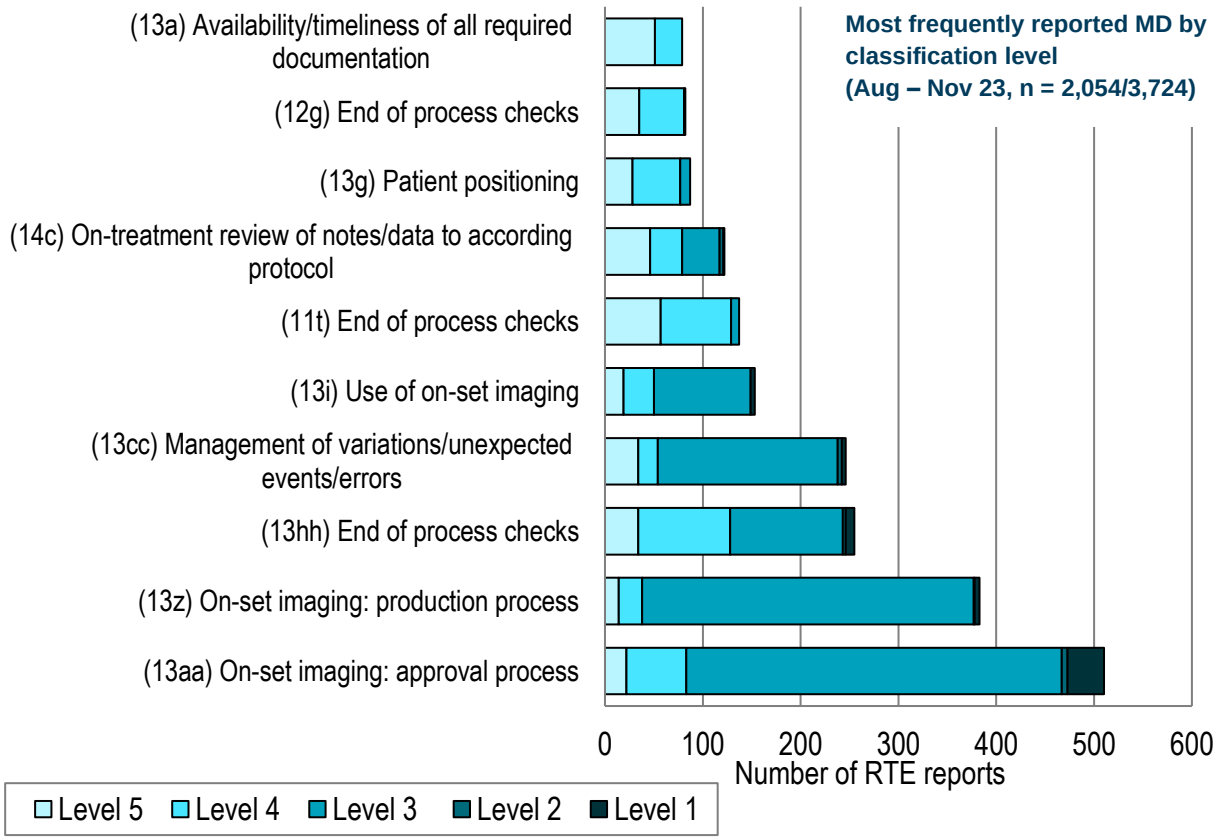
Failed safety barriers (FSB)

Multiple FSB can be attributed to each individual RTE. A total of 2,513 FSB were identified across all the RTE reported. The most frequently reported FSB can be seen below. Treatment unit process 'management of variations/ unexpected events/ errors' was the most frequently reported FSB (10.5%, n = 263).



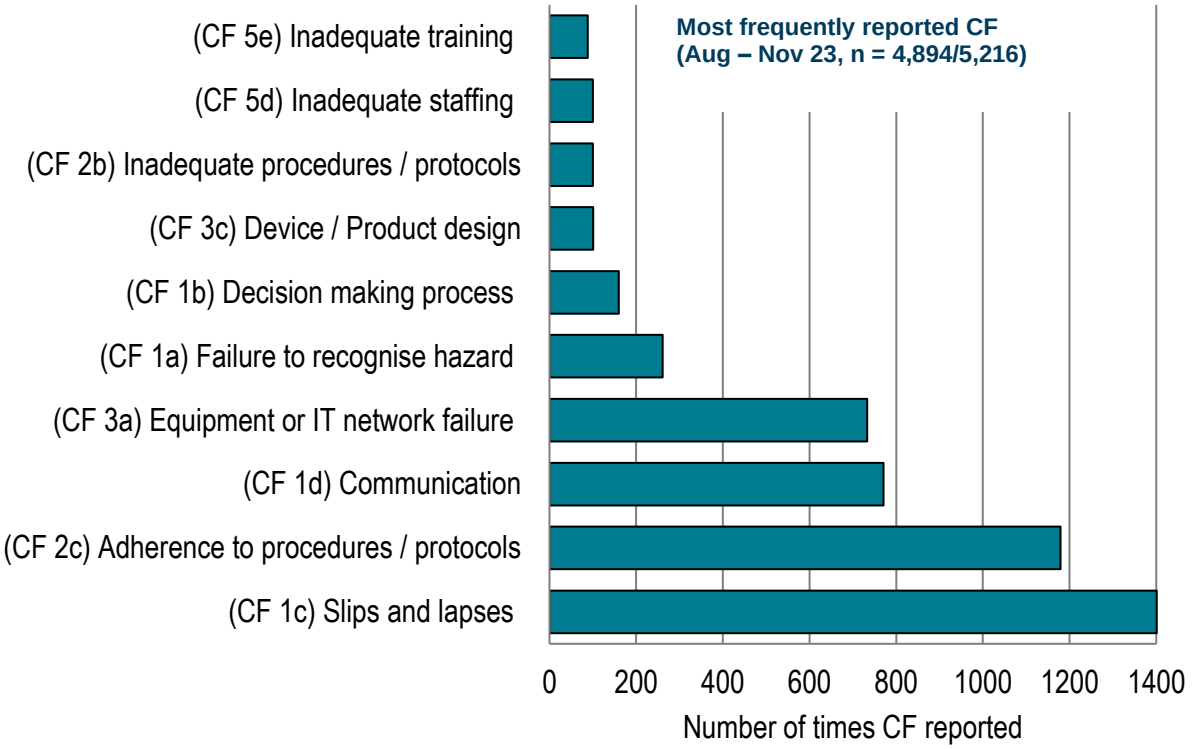
Method of detection (MD)

For this reporting period 3,724 reports included MD coding or data. The most frequently reported MD was 'on-set imaging: approval process' (13.7%, n = 510).



Contributory Factors

Each RTE can be assigned multiple CF codes. A total of 5,216 CF were reported in this period. The most frequently reported CF was individual ‘slips and lapses’ at 26.9% (n = 1,401).



Study of risk

IR(ME)R Regulation 8(2) requires employers to implement quality assurance programmes of radiotherapeutic practice which include a study of the risk of accidental or unintended exposures. Further information on study of risk can be found in national guidance (chapter 19).

In support of the IR(ME)R requirements for local providers to undertake a study of risk, a review of relevant RTE reports has been undertaken on the most frequently reported pathway process subcodes. These are intended to be used to inform local risk assessments. The published study of risk for the most frequently reported pathway subcodes for this reporting period are shown in the table below.

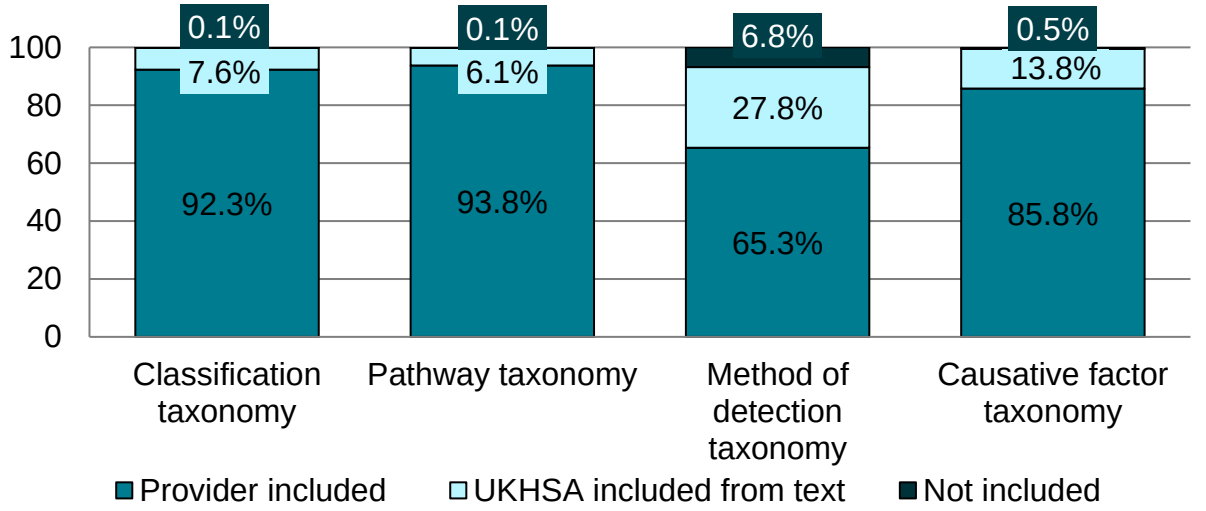
Most frequently reported Process subcode	Study of risk available in associated Safer Radiotherapy publication:
(13z) On-set imaging: production process	Triannual RTE analysis and learning report issue 32
(13cc) Management of variations, unexpected events or errors	Error and near miss reporting: the unseen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

Monitoring of RTE coding by RT providers

All providers are asked to apply a trigger code, classification, pathway (including failed safety barriers), method of detection and causative factor coding to their RTE reports to facilitate both local and national analysis. These should be included in the local incident learning system in the following format:

TSRT9/ Level 1/ 13k/ 13g/ 13hh/ MD13aa/ CF1c/ CF2c

The application of taxonomies by provider for RTE reported between August and November 2023 (n = 3,997) can be seen below.



There has been a decrease in the inclusion of all taxonomies across the reports for this reporting period. There were 4 reports which did not contain enough detailed information within the text to assign any taxonomies.

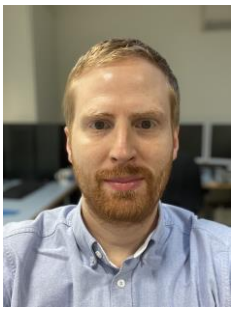
Thank you to all providers who report using the full RTE taxonomies. Further detail on the application of the taxonomies can be seen in the RT learning resources available on the Medical Exposures Group webpages.

If you have any further queries in regard to the assignment of the taxonomies, please email **radiotherapy@ukhsa.gov.uk.**

Safer Radiotherapy resources
Safer RT: triannual error analysis and learning reports contain analysis and learning from RTE reported voluntarily by UK RT providers and the relevant reporting authorities.
Safer RT: E-bulletins provide key messages from the national patient safety initiative
Safer RT: biennial error analysis and learning reports contain 2 years analysis and learning from RTE reported voluntarily by UK RT providers and the relevant reporting authorities.
A series of 15 minute RT learning resources developed to support RT healthcare professionals in learning from RTE are included on the Medical Exposures Group webpages
Towards Safer Radiotherapy contains the classification taxonomy for use when assigning a RTE severity level
Development of Learning from Radiotherapy Errors provides the pathway coding safety barrier, method of detection and causative factor taxonomies

Links to key publications
IR(ME)R: implications for clinical practice in radiotherapy
Guidance for compiling training records for clinical oncologists
IR(ME)R notification codes, categories and criteria

Guest editorial:



Failure Mode Effects Analysis in Routine Practice

Martyn Gilmore, Lead Consultant Clinical Scientist, Radiotherapy,
Carl Rowbottom, Director of Physics and Lead Scientist,
The Clatterbridge Cancer Centre NHS Foundation Trust

When assessing the risks associated with a technique, device or service, the Failure Mode Effects Analysis (FMEA) methodology (1), allows a proactive, systematic analysis of work activities. A FMEA employs a multi-disciplinary, team based approach to ensure all stakeholders involved in the process under review are represented. A process map is created, and a list identified of the ways in which a process can fail (failure modes). Each failure mode is characterised in terms of its type, the potential impact and causes, and the preventative measures/detection methods in place. Modes are then scored and stratified in terms of their potential severity, the likelihood of occurrence and how easily detected such a failure would be using a multiplicative score known as the Risk Priority Number (RPN).

Adopting the FMEA methodology allows development of a risk analysis with input from an interdisciplinary group with broad understanding of the topic. It identifies and classifies potential risks and allows prioritisation of which risks should be mitigated first.

However, some weaknesses and challenges are present in the FMEA approach. There can be significant variations in the resource requirements stated for FMEA and in the number of failure modes identified. Examples for Radiosurgery range from <100 to 400+ failure modes identified with resource requirements quoted up to 250+ hours (2). The RPN score must be used with caution (3) as the severity of a failure mode is often inversely proportion to likelihood and detectability. Reliance on RPN can bias towards relatively low severity, high frequency failure modes at the expense of more severe errors including those considered “never events”. It is important to be mindful of these caveats when developing a comprehensive risk assessment.

Our local FMEA approach, is discussed below:

<u>Assemble a team</u>

- Key to an effective FMEA is a genuine, mixed disciplinary team. Whilst it is often easier for an individual to carry out a risk assessment, and engagement of other professions can be challenging, failure to gather input from others may result in risk bias in the failure modes identified and their scores

<u>Identify the scope</u>

- From the literature, there are numerous examples of impressively large FMEA that, although undoubtedly comprehensive, are unmanageable beyond publication. A focussed scope is key to ensure a meaningful FMEA and any omissions should be made clear

<u>Map the process</u>

- The process map is important to ensure all required members of the team are identified and agree on a process. A clear map ensures failure modes can be identified for each step. The importance of this step can be missed in the rush to catalogue failure modes

Produce the FMEA matrix and agree scores

- This step benefits from a facilitator (4) leading discussion, producing some example failure modes to initiate dialogue, collating individual scores and noting variation between individuals. Scoring can either be done as a group or individually. To avoid bias when scoring individually, participants should be sent proposed failure modes without any prepopulated scores. Variation can be highlighted by the facilitator by looking at the range and/or standard deviation of individual scores returned.

Prioritise failure modes and actions, review at least annually

- It is important to avoid over-reliance on RPN for this stage and, with a suitably focussed FMEA, all failure modes should be reviewed for possible mitigations. The FMEA should be reviewed at least annually to ensure the risk analysis does not reflect "work as imagined" but still represents the process it was used to analyse

Experience and common issues

- Local work investigating FMEA for routine adoption (5) was carried out for an established, high volume, VMAT lung service and carried out with a MDT consisting of Physicists, Clinicians and Radiographers. A facilitator was used, establishing an initial framework for the MDT to follow. This approach allowed for a manageable resource commitment (30 hours total). Validation of the FMEA against locally reported incident data, however, showed the analysis failed to predict a number of incidents, namely those related to delays and communication issues. This was a result of an MDT focussed on technical and clinical issues that did not identify broader hazards. From our experience, validation against incident data, when available or during annual review, allows for refinement of the failure modes and a more effective and representative risk analysis.

Based on our initial experience (5), we have established FMEAs for a variety of services, equipment and techniques, as we've found FMEA a useful element of risk analysis within our broader institutional risk management framework. To maximise the impact of an FMEA care should be taken to avoid the development of narrowly focussed technical list of failure modes. Risks associated with patient experience, adequate resources or appropriately skilled staff should not be neglected. Regular review of established a FMEA must be carried to ensure the analysis remains representative and relevant.

References

1. Huq, M.S. et al. (2016). Application of risk analysis methods to radiation therapy quality management: Report of AAPM Task Group 100. *Med. Phys.*, 43(7), pp.4209–4262. [online]. Available from: http://dx.doi.org/10.1118/1.4947547.

2. Schuller BW, Burns A, Ceilley EA, et al. Failure mode and effects analysis: A community practice perspective. *J Appl Clin Med Phys*. 2017;(February):258-267. doi:10.1002/acm2.12190

3. Bowles J. An Assessment of RPN Prioritization in a Failure Modes Effects and Criticality Analysis. *Proc Annu Reliab Maintainab Symp*. Published online 2003. doi:10.17764/jiet.47.1.y576m26127157313

4. Ford EC, Smith K, Terezakis S, et al. A streamlined failure mode and effects analysis. *Med Phys*. 2014;41(6):61709

5. Gilmore, M.D.F., Rowbottom, C.G., 2021. Evaluation of failure modes and effect analysis for routine risk assessment of lung radiotherapy at a UK centre. Journal of Applied Clinical Medical Physics 22, 36–47. doi:10.1002/acm2.13238

Learning from good practice - Quality Improvement in Radiotherapy

Nathan Proudlove, Senior Lecturer, Alliance Manchester Business School; Director of the Leadership & Management component of the NHS Higher Specialist Scientist Training (HSST) Programme, and lead for its Quality Improvement module

'Quality' in healthcare is multifaceted. Some NHS organisations are adopting a Quadruple Aim, namely, improving health for the local community, best possible care for patients, value for money for taxpayers, and joy and pride in work for staff. Quality Improvement (QI) is a body of knowledge, tools and techniques that can be applied to any of these aims; in fact, whilst many might regard these four as involving trade-offs, the magic of QI is that it can lead to significant improvements in several, or even all, areas, simultaneously. For example, organising the processes involved in a care delivery system to better serve the patients (both in clinical and experience terms) can result in shorter waits, a cheaper system, and be more satisfying for staff.

In radiotherapy, we could think about how we organise processes, being sure to have a plan approved and ready for a first fraction appointment, removing duplication, automating steps including data entry or transfer, standardising and harmonising parallel pathways, investigating and reducing causes of plan rework, how and when to use AI tools, who is involved in authorisation and when this should be done, the potential for hypofractionation, reducing the length of very uncomfortable brachytherapy treatment day-sessions, and the scheduling and content of linac maintenance. All these are areas that HSST trainees have worked on with QI.

Outcomes include prompter appointment starts, releasing staff capacity, reducing errors, reducing patient and staff stress during appointments, and increasing treatment capacity. In short, we are aiming to use established QI techniques and the experience, insights, and intelligence of staff to increase the productivity of treatment processes, reduce staff 'niggles' and give patients a better experience. The HSST is one way in which the NHS is building QI capability, and I would encourage all radiotherapy departments to make the most of staff with this expertise and experience.

QI is a combination of systems thinking, management science and operations management, the latter including over a century of trial-and-learn evolution in organisations such as Toyota (associated with 'lean thinking'). The approach is rooted in practical data analysis, cause-and-effect thinking and incremental experimental testing. As such it should appeal to the constant exploration, discovery and prototyping mindset of the radiotherapy workforce.

I would encourage all radiotherapy staff to get involved. Short of the total immersion of HSST, a natural progression might be defining and recording metrics to understand how a pathway and its constituent parts work. Statistical process control (SPC) charts can be beneficial. Staff could get involved in digging into how work flows along a pathway; process mapping: identifying what is value vs 'waste' time or activity; building input-output causal logic (a driver diagram); then graduating to conducting a QI project to try to do address the area for improvement identified. QI projects may be guided by, for example, the Model for Improvement with Plan-Do-Study-Act cycles and ultimately, sharing your learning (for example BMJ Open Quality is useful for peer-reviewed QI case studies).

Dates for the diary	
BIR, Annual radiotherapy and oncology meeting	29 Feb – 1 March, London
ESTRO, 2024	3 – 7 May, Glasgow