Public Health England

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Safer Radiotherapy

e-Bulletin #5
September 2021

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

In 2010, PHE brought together representatives from The Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR), Institute of Physics and Engineering in Medicine (IPEM), NHS England & Improvement (NHSEI) and a lay representative to form a steering group to support the coordination of efforts to improve patient safety in RT across the UK. This work includes the collation, analysis and promulgation of learning from RTE reports.

Anonymised RTE reports are currently submitted on a voluntary basis through the National Reporting and Learning System (NRLS) of NHSEI or directly to PHE, to promote learning and to minimise recurrence of these events. Providers reporting through the NRLS will note the new Learning from Patient Safety Events (LFPSE), further information can be seen within this e-bulletin. Safer RT accompanies the **Triannual RTE Analysis & Learning Report**, designed to disseminate learning from RTE to professionals in the RT community to positively influence local practice and improve patient safety.

Published three times a year, the next issue will be shared in January 2022. All previous e-bulletins can be found **here**. To subscribe to future editions of the e-bulletin please follow this **link**. Please email **radiotherapy@phe.gov.uk** for advice on reporting and learning from RTE and with comments or inclusions in the e-bulletin.

Thank you to all RTE reporters who facilitate this work.

UKHSA update

The Medical Exposures Group at PHE will be transitioning to the UK Health Security Agency (UKHSA) from the 1st October. Further details can be found **here.** Look out for our new UKHSA branding in the future editions of Safer RT publications. Existing contact details will continue to work for some time. Updated contact and webpage details will be shared once available.

Medical Exposures Group (MEG) Webpage

MEG has developed webpages which introduce the work of the group and describe how the group contributes to improving patient safety in medical exposures. Information on the services provided is also included. This relates to the provision of advice on the clinical implementation of IR(ME)R and tailored clinical site visits, designed to support clinical departments to build safer systems of work. The Radiotherapy Patient Safety Initiative and work of the PSRT are also described. Additional content will be added to the pages over the coming weeks. Further information can be seen **here**.

Short RTE reporting survey

A short RTE reporting survey has been launched by the PSRT. This has been emailed to the UK Radiotherapy Service Managers. The purpose of this survey aims to identify trends in national reporting and understand what type of local reporting systems are in place in RT centres across the UK. Results will be used to inform the work of the PSRT and published in the next e-Bulletin. The closing date for this survey is the 8th October. We would be very grateful for all responses.

Independent provider RTE report submissions

Independent providers can submit RTE reports to the Learn from Patient Safety Events (LFPSE), previously the National Reporting and Learning System (NRLS). Further information can be found **here**. If you are unable to report through this route and would like to contribute to the national analysis please contact the RT team at **radiotherapy@phe.gov.uk** for information on how you can do this via PHE.

New NHS Learn from Patient Safety Events (LFPSE) service

The project previously known by the working title of the Patient Safety Incident Management System (PSIMS) has now been launched, with a new name, the Learn from Patient Safety Events (LFPSE) system. The new system will replace the current National Reporting and Learning System (NRLS) and the Strategic Executive Information System (StEIS).
Organisations will be able to connect to LFPSE in one of two ways:

- Organisations NOT currently reporting to the NRLS via a Local Risk Management System (LRMS), should register now for an account and begin to use the online **Learn from patient safety events service** to record safety events immediately.
- Other organisations with an LRMS, typically trusts, will need to upgrade their LRMS to be LFPSE compliant. Once organisations have upgraded to an LFPSE compliant LRMS, they will be able start uploading safety events to LFPSE. All organisations with an LRMS should continue to upload to the NRLS until their system has been upgraded and they have confirmation from the LFPSE team they are connected to LFPSE.

A list of LFPSE compliant local risk management system suppliers is available **here.** PHE will continue to receive TSRT9 data for inclusion in the national RTE reporting, analysis and learning system.

National Patient Safety Alerts (NatPSAs)

NatPSAs are official notices, giving instructions to NHS bodies to take action to prevent incidents which might cause serious harm or death. The alerts set out clear and effective system-wide actions that providers must take on critical patient safety issues. PHE, the MHRA and the Patient Safety Team at NHSEI are currently accredited to issue NatPSAs. Further detail can be found **here**.

IAEA Radiation safety culture trait talks

An animated video by Isabel Ho (Quality Superintendent HCA Healthcare, London) and Geri Briggs (Patient Safety Manager, Patient Safety Oxford) won the first place in the trait Continuous Learning in the IAEA competition Towards a Strong Radiation Safety Culture in Medicine. You can access the video **here** which is embedded in the **traits talks handbook**.

On target 2: updated guidance for image-guided radiotherapy

The **Radiotherapy Board** has published **On Target 2**. This guidance is intended to support the continued application of image guided radiotherapy (IGRT), and the implementation of 4D adaptive radiotherapy (ART). The guidance makes recommendations on evidence-based practice for IGRT. It also provides guidelines on how individual centres may implement and optimise local imaging processes.

Study of risk of on-set imaging associated RTE

In support of safe IGRT processes and the IR(ME)R requirement for local providers to undertake a study of risk of accidental and unintended exposures, a review of relevant RTE reports submitted (May 2020 to April 2021) as part of the national analysis was undertaken. This was used to inform a study of risk for all on-set imaging processes. It is intended these risk matrices might be used to inform local risk assessments. These include:

- use of on-set imaging (available below)
- on-set imaging approval process (available below)
- on-set imaging production process (included in **e-bulletin #4**)
- on-set imaging recording process (included in **e-bulletin #4**)

Area of Risk	**Initial Risk**			**Following mitigation**		
(13i) Use of on-set imaging	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Verification image taken when not required across entire treatment course	3	1	3	2	1	2
Verification image taken when not required for single fraction	2	2	4	2	1	2
Verification image not taken when required	2	3	6	2	1	2
(13aa) On-set imaging: approval process						
On-set image match completed to incorrect vertebrae leads to geographical miss	4	1	4	4	1	4
On-set image match to incorrect soft tissue	3	1	3	3	1	3
Image matched to wrong reference image	3	2	6	3	1	3
On-set image match incorrect leading to slight deviation in treatment, not geographical miss	2	3	6	2	2	4
Offline image match not completed before next treatment fraction	2	2	4	2	1	2

Corrective actions of these pathway codes found within the reports include:

- Have image protocol accessible at treatment area
- Include imaging schedule checks at pre-treatment checking process
- Ensure appropriate anatomy is available for matching
- Ensure quality of reference image is fit for purpose
- Consider immobilisation and patient position to reduce moves

Mitigations from On-target 2 include:

- Protocols should be reviewed regularly with the most recent evidence obtained in the literature
- National site-specific recommendations for protocols are available
- Each department should decide on a clear method for IGRT which will depend on the available equipment
- When using fiducial markers, the size and material of the markers should be compatible with the imaging procedure
- The online registration and correction process should, where possible, be performed by radiographers involved in the actual patient set up.

Thematic review of CQC RT IR(ME)R inspections

The CQC continue to carry out IR(ME)R inspections and aim to inspect each English RT centre every three years. CQC has shared the following thematic review of recent **IR(ME)R** enforcements:

Reg 6 (5) b – establish quality assurance programmes for written procedures and written protocols:

- Reference to out of date regulations (IR(ME)R 2000, MGTI, MARS etc)
- Spelling mistakes (please spell IR(ME)R correctly)
- Documents not reviewed in accordance with QA cycle specified by the employer
- Documents not reflective of practice
- Version history and review date incorrect
- No process for document quality review

Reg 17 – Training:

- Training records or procedures not available
- No protocol/procedures that detail how competency is achieved & maintained

Action points were also shared these included:

- No study of risk being available
- Poor thematic review of non-notifiable events
- Equipment inventory does not contain specified information

Do you share your good practice as highlighted within your reports and areas of improvement? Do you share your IR(ME)R reports, action points and experience with your ODN? Further information on the enforcement action summaries is **available**.

Radiotherapy Board guidance on **IR(ME)R implications for clinical practice** is available to support local compliance with IR(ME)R. The **Development of Learning from RTE** contains nationally agreed taxonomies for use when reviewing RTE to aid local analysis and facilitate learning from accidental or unintended exposures.

Single operator practice in radiotherapy

A strong safety culture is at the heart of patient safety in radiotherapy practice. This is particularly important during preparation and initiation of radiotherapy exposures (Switching On), as this is the last opportunity in the pathway to identify and mitigate potential errors.

In trying to reduce the probability and magnitude of accidental and unintended exposures (IR(ME)R Schedule 2 (k)), an appropriate staff skill mix must be available where RT exposures are carried out. A **TSRT** recommendation states ‘‘*checks and verification should be performed independently by entitled operators working to clear protocols, which make explicit the individual’s responsibilities and accountability*’’ (Recommendation 7,Pg 45). The wording and recommendation within TSRT outline that operators (plural) should be involved in the set up and treatment of patients.

It is also important to have more than one operator available at time of switch on and beam delivery to deal with supporting tasks, manage the local environment and respond to any unexpected events.

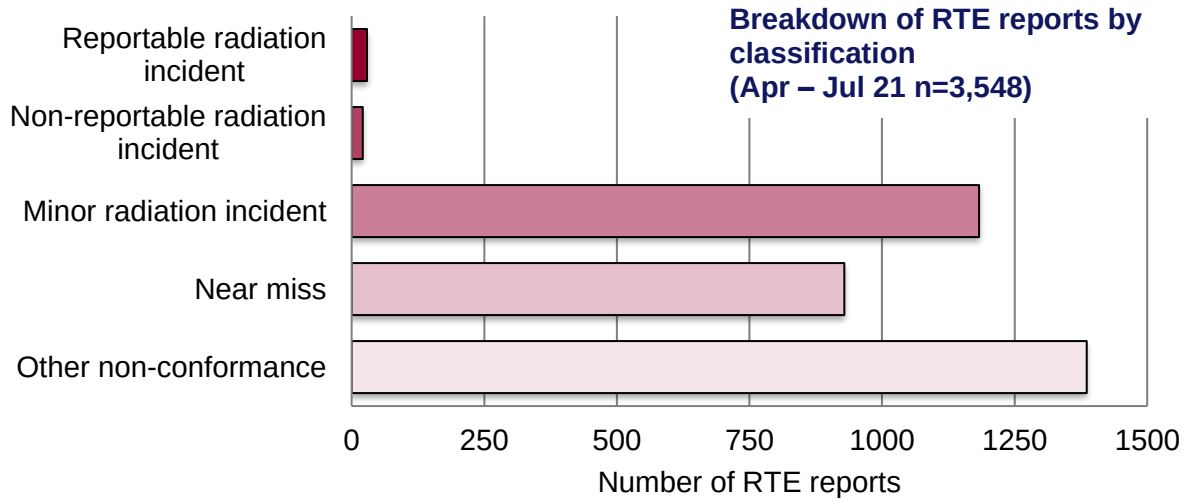
The PSRT recommend that at least two appropriately trained and entitled operators should always be available during set-up, verification and initiation of radiotherapy exposures. Individual operator responsibilities must be defined in local procedures.

RTE Data analysis: April to July 2021

The full detailed data analysis is available **here** and includes data on primary process subcoding, 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.

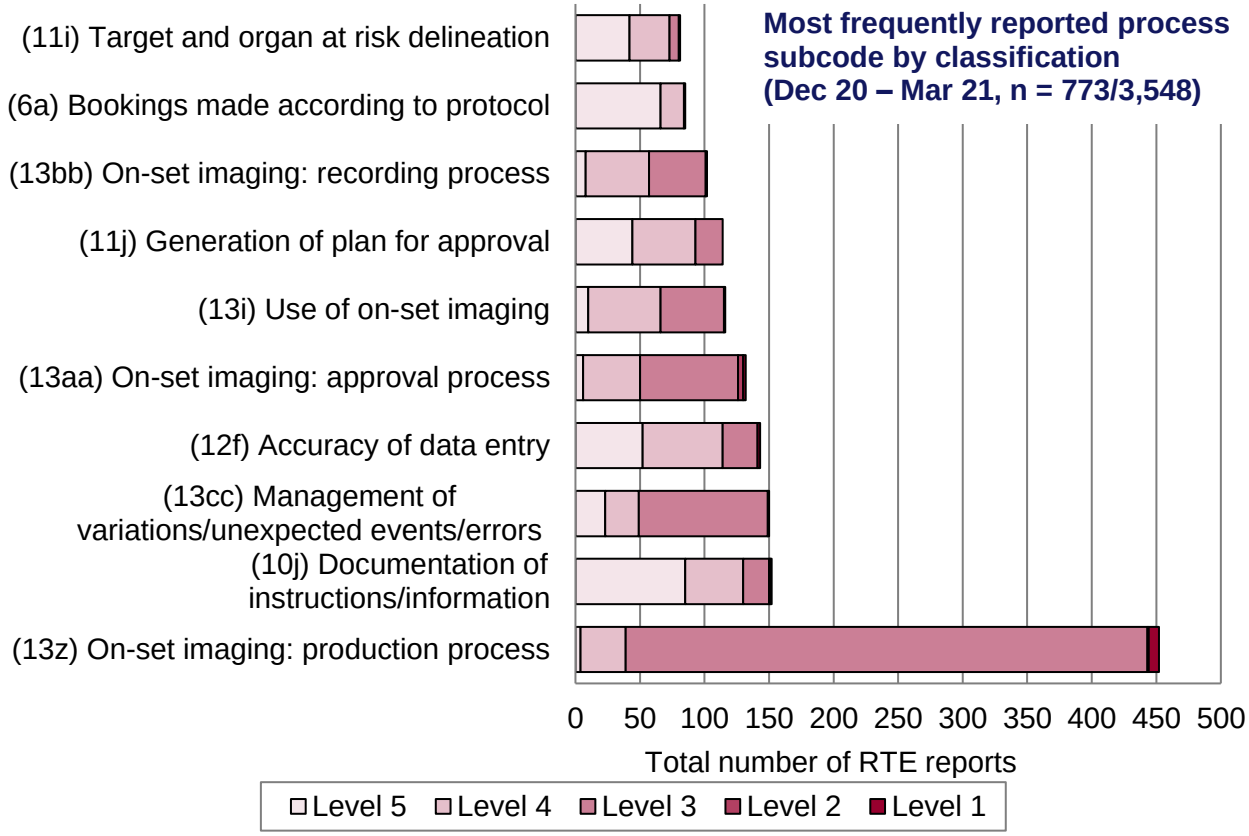
Classification of RTE

Of those 3,548 RTE reported, 3,498 reports (98.6%) were classified as minor radiation incidents, near misses or other non-conformances. These would have no significant effect on the planning or delivery of individual patient treatments.



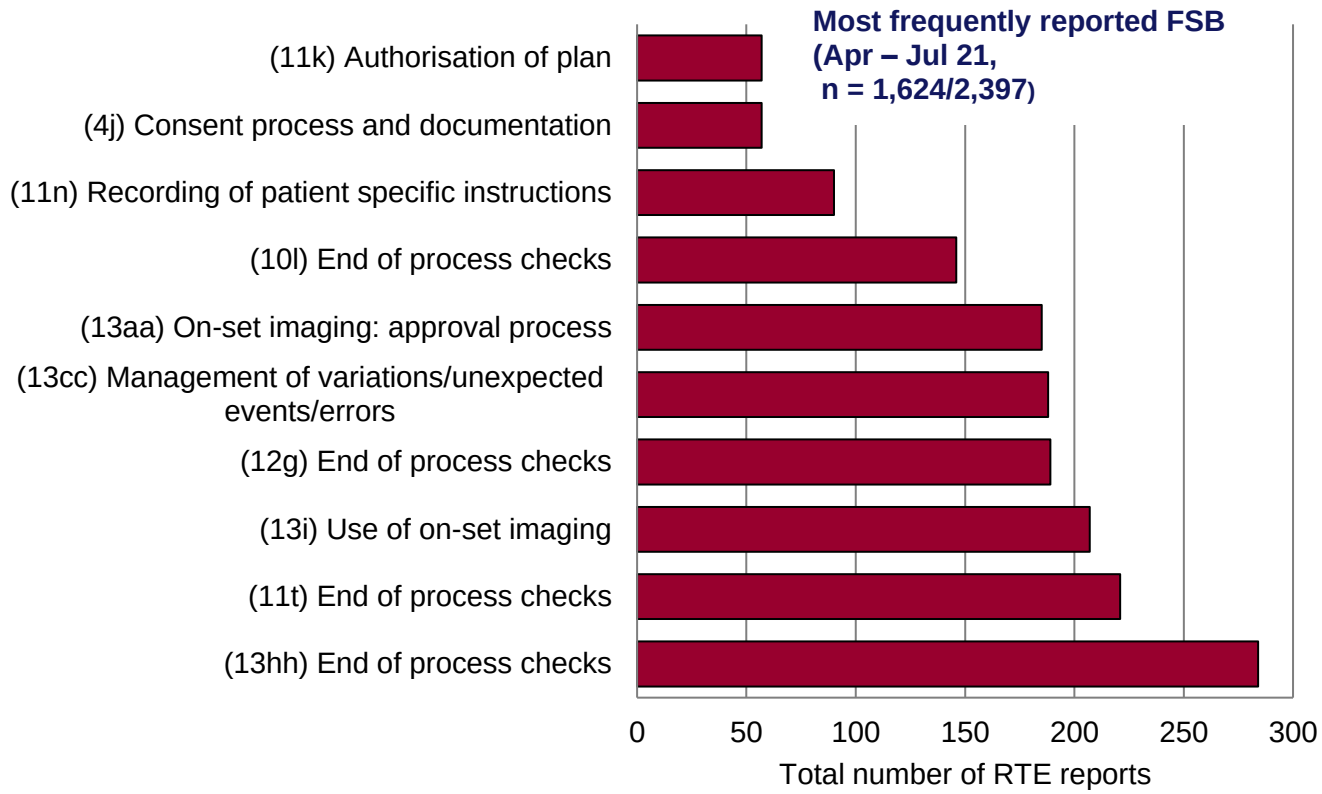
Primary process subcode

The most frequently reported points in the patient pathway where the RTE occurred are shown below. Consistent with the previous analysis 'on-set imaging: production process' was the most frequently occurring process code (12.7%, n = 452).



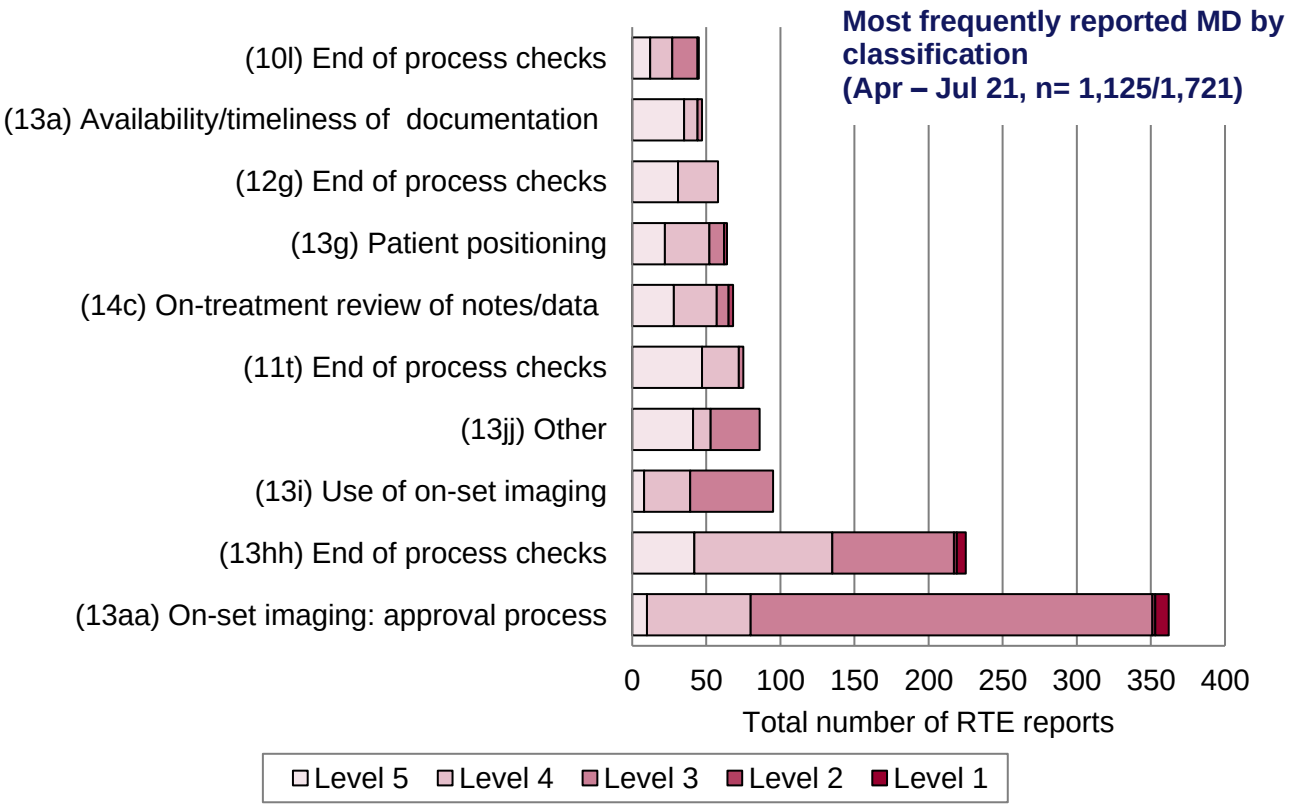
Failed Safety barriers (FSB)

A total of 2,397 FSB were identified across all the RTE reported. The most frequently reported FSB can be seen below. Treatment unit process 'end of process checks' was the most frequently reported FSB (11.8%, n = 284).



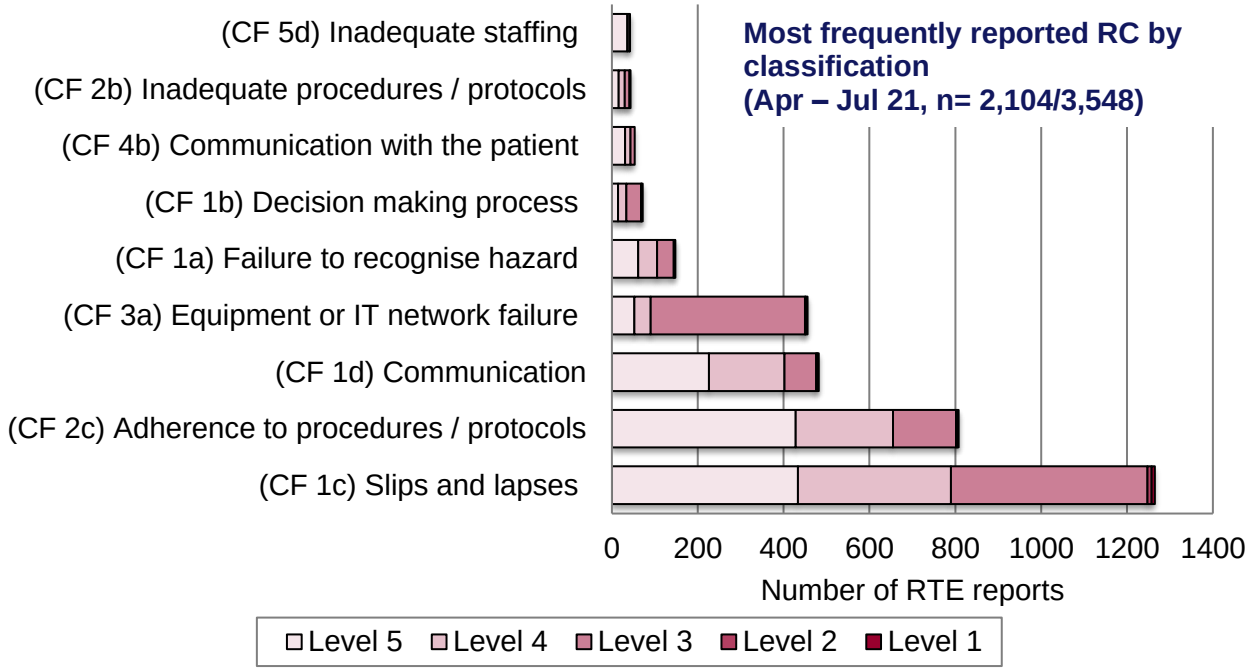
Method of detection (MD)

For this reporting period 1,721 reports contained MD. The most frequently reported MD was 'on-set imaging: approval process' (21.0%, n = 362).



Causative Factors

The primary causative factor is the root cause (RC) and the subsequent factors are contributory factors (CF) associated with an RTE. The most frequently reported RC was individual 'slips and lapses' (35.7%, n = 1,265). CF were indicated across 887 reports. Of these 128 contained multiple factors leading to 1,033 CF. The most frequently reported CF was 'adherence to procedures/protocols' (37.6%, n = 388).



Quality of reporting – Causative factor (CF) taxonomy.

We are grateful to reporters for their efforts in including the national taxonomies in RTE reports submitted for national analysis. To enable automatic upload of reports at PHE and reduce the risk of transcription errors we ask reporters to code reports in the following format:

TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c.

The pathway taxonomy contains causative factor codes 1c and 2c and each of these require the CF before them to indicate they are CF and not pathway codes. Please email **radiotherapy@phe.gov.uk** for any further guidance on coding of RTE.

Top tips for paperlite/ paperless working in RT update

The Radiotherapy Board guidance, Top tips for implementing paperlite/ paperless working in radiotherapy has been updated and is available **here.**

Links to international patient safety resources

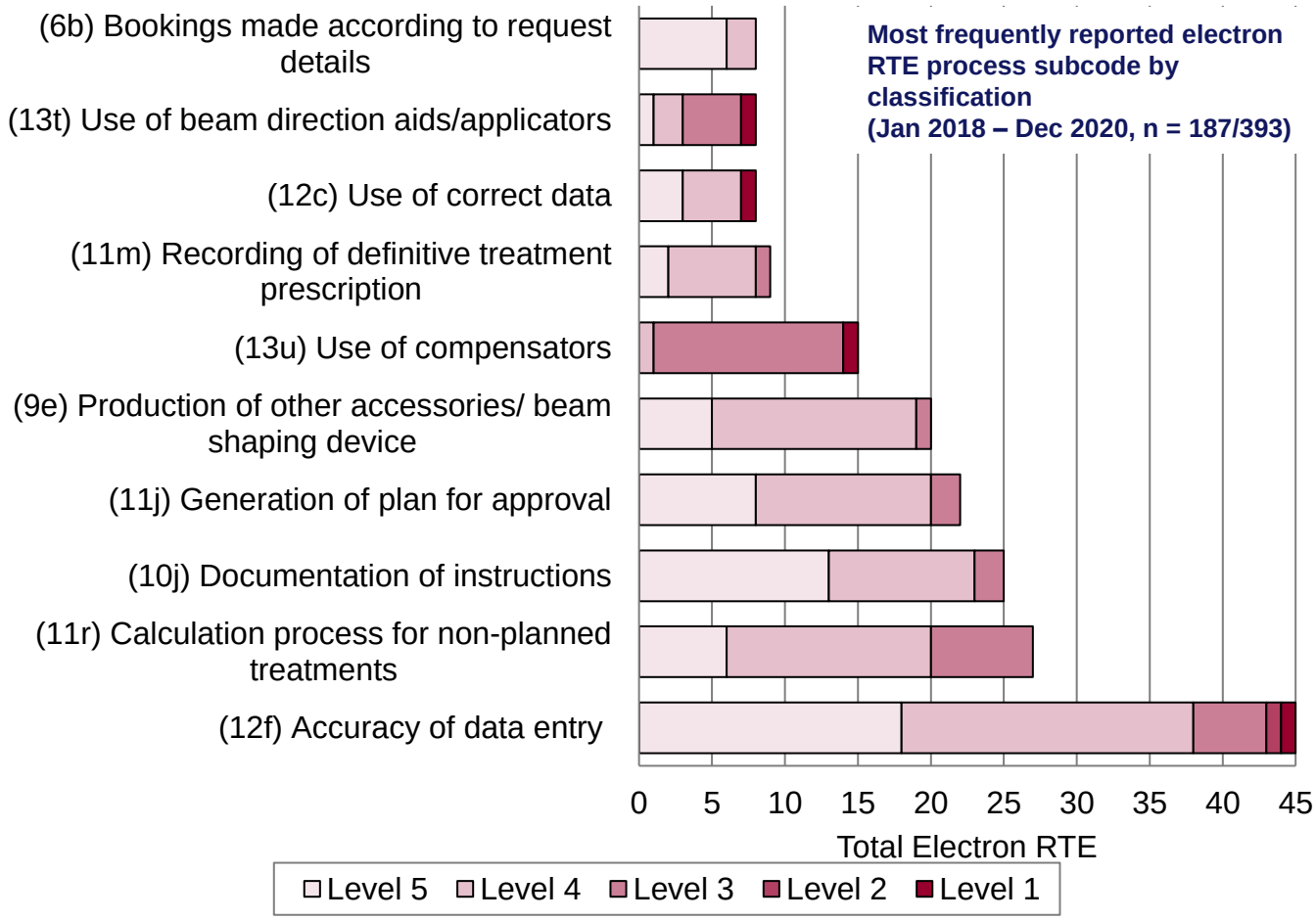
IAEA **SAFRON,** the latest **publication** includes examples of incident reports and the effective use of timeout

ASTRO and AAPM **RO-ILS,** publish Case Studies, these stand-alone case studies summarise an event and provide learning and feedback. RO-ILS also publish themed reports including COVID – 19 disruptions to process and peer review.

Autorité De Sûreté Nucléaire (French Nuclear Safety Authority) **Publications for Professionals** contain patient safety messages and experience feedback

Electron associated RTE

Following a request from a radiotherapy provider for electron associated RTE analysis, a search of the PHE RTE database was performed. Electrons are usually used for superficial treatments and make up a small proportion of radiotherapy treatments across the UK. The search covered the incident date range 1st January 2018 to 31st December 2020. The search terms for electron associated RTE included: electron, stand-off, cut-out, TSE, total skin electron. It should be noted that modality of treatment is not currently a core data item when reporting RTE. Therefore, the results should be interpreted with care.



From a total of 27,871 reports, a total of 393 reports (1.4%) were identified as being electron associated RTE. Findings from the analysis include the following:

- A total of 2.3% (n = 9) of the RTE were coded as level 1 or 2 incidents, this is slightly higher than the 1.6% (n = 451) from the entire database for the same time period. This difference may be due to electron treatments being a less frequently used technique.
- Within the entire database for this time period 36.3% (n = 10,123) RTE were level 3, and 24.6% (n = 6845) were level 4. A difference can be seen within the electron data where 19.6% (n = 77) were level 3 and 38.7% (n = 152) were level 4. This difference may be due to the difference in utilisation of on-set imaging for electron treatments when compared to photon treatments.
- The most frequently reported RTE associated with electrons were coded as accuracy of data entry (11.5%, n = 45) followed by calculation process for non-

planned treatments (6.8%, n = 27). This may be due to the potential for manual input leading to transcription errors.

- A total of 731 pathway codes were assigned to the 393 reports. Of these 308 were designated as failed safety barriers (FSB). 150 of which were 'end of process checks'.
- End of process checks at treatment was the most frequently reported effective safety barrier or method of detection. (Only available for subset of data, 31.0%, n=122).
- The most frequently reported root cause of the electron associated RTE was slips and lapses (48.1%, n = 189), followed by communication (17.3%, n = 68) and adherence to procedures / protocols (11.5%, n = 45).

Typical examples of electron associated RTE included:

a. Incorrect entry of data during preparation
b. Incorrect manual calculation carried out for electron treatment leading to incorrect MU recorded
c. Incorrect patient position or immobilisation documented at pretreatment
d. Incorrect applicator code entered at treatment planning
e. Bolus slipped or moved during treatment

A case study including a study of risk has been completed for electron RTE associated with the calculation process for non-planned treatments. This can be found in **issue 34 of the triannual analysis**.
It is hoped that this analysis of electron associated RTE will allow local providers to review their electron RTE with the national analysis. This could then lead to a review of local RTE which may highlight areas where end of process checks can mitigate less frequently utilised techniques.

AXREM publish radiotherapy manifesto

The association for healthcare technology providers for imaging, radiotherapy and care (**AXREM**) have published an industry **manifesto** for radiotherapy 'improving patient outcomes'. The document outlines the health and economic benefits of radiotherapy and some of the current issues that have magnified since the start of the pandemic.

Workforce reports

The RCR UK **workforce census report** 2020 is now available. This report indicates that the consultant oncology workforce grew by 3% per year over the past five years, however 55% of CO consultant vacancies remained unfilled in 2020 and the picture across the UK varies significantly. Also, the report states that over half of all cancer service leaders reported that workforce shortages have negatively impacted the quality of patient care.

A radiotherapy workforce survey is planned for late 2021 by **IPEM.** The CoR **radiotherapy radiographic workforce UK census** 2020 is now available. This report compares the results with similar surveys carried out annually from 2012 to 2019. The current vacancy rate for therapeutic radiographers is 7.6%. Similar to the RCR survey there are variations across the UK

Guest Editorial

Time to use national consent forms for radiotherapy

Dr Emma Kenney-Herbert, National radiotherapy consent forms, RCR Clinical Fellow.
Clinical Oncology Registrar, Mount Vernon Cancer Centre

As with all medical and surgical procedures, it is a requirement to take informed consent for radiotherapy. There is unique complexity to the consent process for radiotherapy as there are both significant acute risks associated with treatment and late toxicities which may present years after treatment. Written consent is an essential part of the treatment process as it addresses the IR(ME)R requirement of communicating the benefits and risks of an exposure (Schedule 2 (i)(1).

A survey of RT providers across the UK revealed that 54% had developed a site-specific consent form for prostate radiotherapy. However, no two of these were the same (2). Most surprising was the variability in which long term side effects were mentioned. With encouragement from clinicians and radiographers and following the GMC guidelines on decision making and consent (3), the RCR has developed a suite of national standard consent forms. I was appointed as a clinical fellow to lead this project.

The forms were developed in two phases, firstly a consent form template was developed. This was adapted from consent form 1. The most notable differences were that the side effects were separated into early/short term and late/long-term as well as being separated into expected, common, less common and rare. There was also a section for specific risks to individual patients from their treatment which supports patient individualisation. This is consistent with the Montgomery judgement which held that inclusion of risks material to a specific patient was required (4). This form was reviewed and amended in focus groups with: Clinical Oncologists, radiographers, risk communication academics, nurse clinicians, patients and lawyers. A national steering group was set up to oversee the publication of consent forms. This steering group comprised of the consent project leads, legal representative, patient representative, nurse clinician, radiographer, lead clinician from each tumour group, expert consultant from each tumour group.

The site-specific side-effects were collated from clinical trials, trials protocols, personal experience, consultant experience and other consent forms. Populated forms were reviewed amended and approved by a panel of experts in that particular tumour site, selected from groups such as the UK Breast Group. They were then reviewed by a patient group prior to final approval in the steering group. Initial pilot of the forms was successful and the forms met with approval of patients and clinicians.

The first panel of consent forms has now been released on the **RCR website** and will come under review for update over the next few months.

This project has only been possible due to the enormous support the RCR has received from nearly 100 individuals. These include clinicians both consultants and registrars, radiographers, lay people, patients, lawyers, risk communication academics and nurse clinicians who have all generously given their time for free. Although every treatment is patient-specific, using the national standard consent form for each radiotherapy site designed by experts, reviewed by patients and approved

by lawyers will put us in a stronger position both ethically and legally. I hope cancer centres across the UK will move towards using these forms which will perhaps spare litigation and most importantly support patients making informed decisions at a difficult time.

A lay perspective from Tony Murphy, member of the PSRT

Dr Kenney-Herbert and the Team should be praised for the degree of ***patient and public involvement*** in the process. As one of those involved in the consultation, I noted the various stages in the development, this included the amendments to the generic structure, treatment intent section, the categorisation of side effects by severity and frequency by each cancer site.

Nationally approved consent forms take out major areas of variability. True informed consent is so important, ethically and practically, so the RCR initiative must be congratulated in addressing the variation in radiotherapy consent forms. For patients and those close to them, there should be less confusion and upset, complaints and litigation. Well done all those involved!

1. Ionising Radiation (Medical Exposure) Regulations, Implications for clinical practice in radiotherapy
2. Kenney-Herbert E, Mylonas M, Todd J, Tipples K. Consent consensus: time for a national site-specific consent form for radiotherapy? Clin Oncol (R Coll Radiol) 2021; 33(1):1-4
3. General Medical Council. Guidance on professional standards and ethics for doctors. Decision making and consent. Manchester: General Medical Council, 2020.
4. Montgomery (Appellant) v Lanarkshire Health Board (respondent) (Scotland) 2015) UKSC11

Study of risk: consent process and documentation

In support of safe consent processes and the IR(ME)R requirement for local providers to undertake a study of risk of accidental and unintended exposures a review of relevant RTE reports submitted (May 2020 to April 2021) as part of the national analysis was undertaken. This was used to inform a study of risk for all on-set imaging processes. Below an example of a study of risk for consent process and documentation is shared to inform local risk assessments.

Area of Risk	**Initial Risk**			**Following mitigation**		
(4j) Consent process and documentation	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Consent form was not completed and signed by consultant prior to CT scan	1	3	3	1	2	2
Consent form was not completed and signed by consultant prior to treatment	1	2	2	1	1	1
Consent form was not signed by patient prior to CT scan	1	3	3	1	2	2
Consent form was not signed by patient prior to treatment	1	2	2	1	1	1
Consent form was not available prior to CT scan	1	3	3	1	2	2
Consent form was not available prior to treatment	1	2	2	1	1	1

Corrective actions of these pathway codes found within the reports include:

- Have mandatory fields on consent form

- If paper-based scan consent form to OMS when completed to ensure available across pathway
- Include consent form in pretreatment checks

Mitigations from RCR national standard site-specific RT consent forms:

- The best ethical and legal practice is to ensure valid written, signed consent is sought before starting treatment
- Utilise national consent forms to avoid confusion when practitioners move between centres
- When consent is taken before treatment the patient should be asked to confirm consent before the start of treatment

Dates for the diary	
IPEM, MPE update 2021	6 October, Virtual
RCR, Learning live 21	4-22 October, Virtual
IPEM, MR safety update 2021	2 November, Virtual
BIR, Annual congress 2021	4 November, Virtual
IPEM, Margins, how low can you go?	24 November, Virtual

Learning from good practice – The ‘red chair’

The royal Marsden Radiotherapy Team, The Royal Marsden NHS Foundation Trust

Radiotherapy is delivered in a complex, challenging and changing environment. There can be a number of different healthcare professionals within the control room area, and this can lead to distractions.

We have introduced a number of measures to reduce distractions and allow the operators to focus and concentrate on delivering accurate treatment in the safest manner possible. These measures include the ‘red chair’. The initial idea for the red chair came from discussion with other departments within the hospital. We learnt that nurses wore a red tabard when ‘drawing up’ (checking the dose) of controlled drugs for patients. This aimed to avoid staff distractions and process interruptions.

The operators responsible for an exposure sit in red chairs. This highlights to all other staff that these individuals are not to be interrupted.

Do you have any **learning from good practice** that you would like to share? Please email **radiotherapy@phe.gov.uk** with your ideas for inclusion in future editions of a Safer Radiotherapy e-bulletin.