Public Health England

Protecting and improving the nation's health

Good practice in radiotherapy error and near miss reporting

On-set imaging

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Introduction

The fundamental role of reporting and learning systems is to enhance patient safety by learning from failures in the healthcare setting[1]. Radiotherapy errors and near misses (RTE) are submitted on a voluntary basis by NHS radiotherapy departments throughout the UK to the National Reporting and Learning System (NRLS) at NHS England and NHS Improvement, or directly to Public Health England (PHE). RTE are analysed by PHE using frequency trend analysis based on the classification from Towards Safer Radiotherapy (TSRT)[2] and the Development of Learning from Errors (DoL)[3] coding system. PHE in conjunction with the Patient Safety in Radiotherapy Steering Group publish learning from these events on a triannual basis[4] and summarised on a biennial basis[5], so their occurrence might be mitigated. The strength of the RTE analysis is based on the quantity and quality of the reports received. A good report will give anyone reviewing the report sufficient information to code and classify the RTE and provide additional data regarding efficacy of safety barriers, methods of detection, corrective steps and preventative actions.

Background

Image guided radiotherapy (IGRT) can be utilised at the treatment stage of the radiotherapy pathway as a tool to verify patient positioning. These images may be acquired using MV imaging, kV imaging, cone beam CT (CBCT) (kV or MV), ultrasound, Magnetic Resonance (MR) or other methods. The use of IGRT to aid patient set up and verify position has now become embedded within standard radiotherapy practice. Due to the frequency in using IGRT there has been a sustained increase in on-set imaging associated RTE. These will be discussed further within this document.

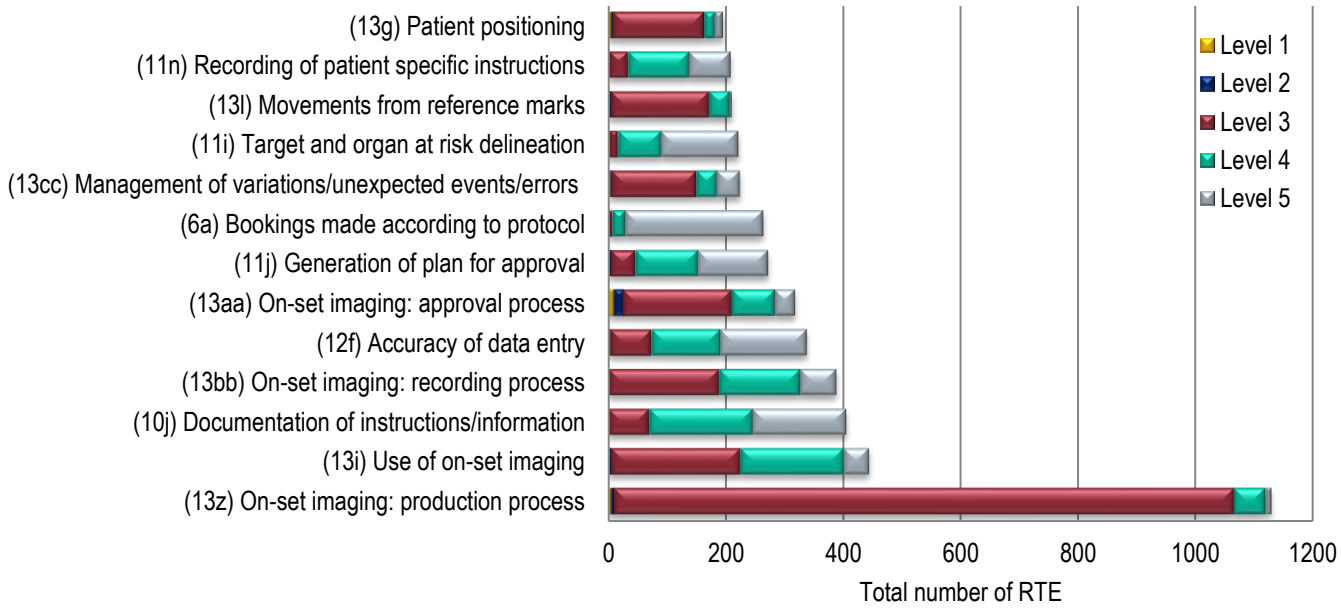
This document seeks to highlight the occurrence of on-set imaging associated RTE, describe the nature of these errors and provide suggestions on how to minimise the recurrence of these types of RTE. This document also provides guidance to improve the consistency of the application of on-set imaging RTE codes.

Breakdown of process codes

There were 9,613 RTE submitted for the reporting period December 2018 to November 2019. According to the radiotherapy dataset[6], the estimated number of attendances in NHS providers across England and Wales for this reporting period was 1,849,206. Across England and Wales 9,288 RTE were detected and reported by NHS providers, equating to 0.5% of all attendances for this reporting period.

The most frequently reported RTE process code for this reporting period was 13z On-set imaging: production process. Other treatment unit on-set imaging associated RTE were also featured in the most frequently reported RTE, these included 13i Use of on-set imaging, 13bb On-set imaging: recording process and 13aa on-set imaging approval process. The treatment unit on-set imaging associated RTE comprised 23.7% (n = 2,282) of the 9,613 RTE reported. This prevalence of image associated RTE can also be seen in previous RTE analysis[5].

Figure 1. Breakdown of most frequently reported RTE process codes by classification level, December 2018 to November 2019 (n = 4,628/9,613 subset of RTE)



The prevalence of on-set imaging associated RTE reflects the multiple tasks involved in achieving IGRT treatments and highlights areas at risk of error. This risk may be amplified due to the dynamic nature of online review and the rapid pace of development of new technology. However, the benefit IGRT brings to the patient is clear. The purpose of this document is to support the community in reducing these events.

On-set imaging coding application

Each report should contain sufficient information to classify, code and review the RTE. To be included in the first open text field are:

- trigger code/classification/coding
- anatomical site involved in the RTE
- prescribed fractionation
- if appropriate, dose administered or almost administered with an indication of the percentage error
- if appropriate, magnitude of the geographical misplacement
- random or systemic error
- a brief description of the circumstances surrounding the incident, which could include any significant contributory factors leading to the RTE, how the error was detected, implications for the patient and any corrective/preventative action taken

All providers are asked to apply a trigger code, classification, pathway coding, including failed safety barriers, where applicable effective safety barrier (detection method) and causative factors to their RTE reports to facilitate both local and national analysis, for example:

TSRT9/ Level 3/ 13z/ 13hh/ MD13aa/ CF1c/ CF2c Patient receiving 55Gy in 20# to right lung. Local protocol requires a weekly CBCT for verification purposes. On #8 the weekly CBCT was due. The patient was set up correctly and the CBCT was acquired. Unfortunately, during the review of the image, it was apparent that the incorrect filter had been utilised, this meant that the patient received a slightly higher CBCT dose than required. The anatomy filters could be used to review the image and a repeat CBCT was not required.

Consistency checking

Consistency checking is undertaken by PHE staff on the application of the TSRT[2] classification and the DoL[3] coding system by RT providers. During consistency checking the coding is reviewed for all RTE classified as reportable through to near miss (levels 1-4) and 10% of non-conformances (level 5) RTE are audited. Between December 2018 and November 2019 there were 9,613 RTE reported, 7,738 of those reported were deemed complete. A complete report contains the classification, pathway code and causative factor taxonomy. The other 1,875 were either incomplete reports where some of the required coding was absent (n = 1,808) or non RTE (n = 67). During consistency checking PHE staff amended 1,171 of the complete RTE reports, 825 of these required the primary pathway process code to be amended.

Of the 825 RTE process codes amended, 283 were originally coded using an on-set imaging treatment unit process code. Consistent application of the coding of on-set imaging associated RTE is key to informing local analysis and maximising learning from these events. This also ensures the learning can be shared more effectively at a national level.

On-set imaging associated RTE

Four process codes associated with on-set imaging within DoL[3] pathway coding

13i Use of on-set imaging (including imaging according to local protocol)

During consistency checking this code was amended in 109 RTE, 52 of these amendments were to another on-set imaging code, 13z On-set imaging: production process.

This pathway code should be used for RTE when imaging has not been conducted according to local protocol. This includes when an image has not been conducted when it is required, or when an image has been acquired when not needed, this can occur at any point during the patient's treatment.

13z On-set imaging: production process (including inappropriate exposure used, image not captured, incorrect CBCT filter used or left in for kV image, incorrect field localisation of exposure, unsuitable position of imaging panel)

During consistency checking this code was amended in 101 RTE, 39 of these amendments were to another on-set imaging code, 13i Use of on-set imaging.

This pathway code should be used for RTE when there has been the incorrect production of on-set imaging. This includes images being unusable due to overexposure, the incorrect field size exposed or an unsuitable positioning of the image panel, the incorrect exposure being used including the incorrect pre-sets, scan or image selected. This RTE is also associated with equipment malfunction; such errors should be reported locally and to the MHRA[7] and the relevant manufacturer.

13aa On-set imaging: approval process (including image review not completed, image review inaccurate, image matched to wrong reference image, incorrect prioritisation of structure matching)

During consistency checking this code was amended in 40 RTE, 18 of these amendments were to another on-set imaging code, 13bb On-set imaging: recording process.

This pathway code should be used for RTE when an error occurs at imaging approval. This includes when an image review is inaccurate, both online or offline, the image match has been conducted incorrectly, due to incorrect prioritisation of structure match, incorrect reference image match. This can also include the late approval of images

13bb On-set imaging: recording process (recording of result of image review not undertaken, resultant actions from image review not undertaken, documentation and application of systematic correction)

During consistency checking this code was amended in just 7 RTE, and the 7 amendments were to 7 different process codes.

This pathway code should be used for RTE which occur due to recording process issues. This includes when an image review has not been appropriately documented, or the actions from an image review have not been actioned. This includes the incorrect documentation of a systemic correction leading to further imaging exposures to correct.

Examples of on-set imaging associated RTE reports

The following are examples of RTE associated with treatment unit on-set imaging. These examples will include suggested coding and corrective and preventative actions (CAPA). CAPA can be used to reduce the risk of RTE occurring. Further examples of RTE can be seen in previous editions of Safer Radiotherapy[4] and the DoL[3] guidance document.

Example of RTE associated with 13i use of on-set imaging

TSRT9/ Level 4/ 13i/ 13hh/ MD14c/ CF1c/ CF2c Patient receiving radiotherapy for rectal tumour, 50.4Gy in 28# daily. Local imaging protocol stated daily kV imaging with one weekly CBCT. During the weekly check at #10 it was noted that no CBCT exposures had been given. All daily kV imaging was within the departmental tolerance. A CBCT was performed on #11 within tolerance and all future CBCT were appropriately scheduled.

CAPA for RTE associated with 13i use of on-set imaging:

- have in place anatomical site-specific imaging protocols that are tailored to the needs of that site and consider the factors affecting the accuracy of set-up, including site treated, immobilisation used and the patient's condition
- optimise the use of the oncology management system to build efficiencies in the scheduling of on-set imaging on the treatment pathway, ensure this includes review of how communication is achieved

Example of RTE associated with 13z on-set imaging: production process, human error

TSRT9/ Level 3/ 13z/ 13hh/ MD13aa/ CF1c First day treatment for breast patient, 40Gy, 15#. An online verification image was acquired, during image approval it was noted that the image panel was not in the correct position and the image did not give enough information to accurately verify the patient's position. The verification image had to be repeated resulting in the patient receiving an additional radiation exposure. The new position of the image panel was noted and acquired to ensure the next verification image was taken in the correct position.

Example of RTE associated with 13z on-set imaging: production process, machine malfunction

TSRT9/ Level 3/ 13z/ MD13i/ CF3a Right chest wall, 30Gy/ 10#. On #8 took a portal image of a field on breast which was out of tolerance. Following procedure, the couch was manually adjusted to the appropriate position to correct for the displacement. The image was retaken to verify the position, but the image did not capture. The patient received an unnecessary dose of 3MU.

Radiotherapy providers are encouraged to audit and report these events locally so appropriate and timely preventative measures might be implemented. In addition, the MHRA should be advised of all equipment failures.

CAPA for RTE associated with 13z on-set imaging: production process

- ensure adequate instructions are available on the clinical requirement of imaging
- ensure on-set imaging has been optimised
- capture image parameters on day 1 and action if further optimisation is required
- put in place contingency plans in case of equipment failure
- use end of process checks to ensure the correct imaging and factors are used before an exposure is initiated
- investigate repeat incidents, consider removal of equipment or technique from practice
- review equipment testing and QA processes to ensure imaging is included

Example of RTE associated with 13aa on-set imaging: approval process

TSRT9/ Level 1/ 13aa/ 13hh/ MD13aa/ CF1c/ CF2c Palliative spinal treatment (20Gy/5#), during 1st # on-set verification image completed and matched for spinal treatment. Due to image match digital move of 0.8cm superior completed (within threshold of departmental palliative imaging protocol), patient treated. During offline review it was recognised that the incorrect vertebrae was matched to, leading to a geographical miss. The verification image jaws were the same width and length as the treatment field indicating no distinguishable anatomy. All other #'s treated with wider view on verification image and patient treated correctly. A full investigation of this error was conducted, it was found that a geographical miss occurred, and a report was shared with the relevant IR(ME)R enforcement authority.

CAPA for RTE associated with 13aa on-set imaging: approval process:

- review the type of image taken and the quality of the verification image - consider the need for an MV, kV, 2D or 3D image
- ensure the verification image captures sufficient anatomy for accurate matching - consider the field of view
- ensure the locally available matching tools are utilised
- ensure the reference image is good quality with appropriate anatomy
- consider contouring appropriate anatomy structures for the purpose of the match such as carina or adjacent structures
- ensure staff are aware of site specific action levels
- reduce requirement for large moves by using appropriate immobilisation equipment, reference marks and couch digital parameter tolerances
- create an appropriate environment for image matching to take place with minimal distractions for staff
- audit couch moves and any authorised overrides to aid review of couch tolerances
- establish an MDT agreed image approval process using an appropriate skill mix

Example of RTE associated with 13bb on-set imaging: recording process

TSRT9/ Level 4/ 13bb/ 13hh/ MD14c/ CF1c/ CF2c A cervix cancer patient receiving 40Gy in 20#. At #4 a systematic move of 0.4cm superior was required due to the first 3# of imaging. The move was initiated, and treatment was completed. Local imaging protocol required an online verification image to confirm the systematic move. During weekly review of notes after #5 it was detected that the verification image had not been carried out. A verification image was scheduled for the following # which indicated the move was correct and the patient had been treated correctly.

CAPA for RTE associated with 13bb on-set imaging: recording process:

- use locally available systems such as oncology management systems (protocol drivers/prompts/messages) to ensure image approval is recorded and undertaken in a timely fashion
- review local protocols to ensure correction strategies are easily available to staff when required

CAPA for RTE associate with any on-see imaging process code:

- ensure staff are adequately trained, competent and appropriately entitled in the use of the technology (including reference image registration, image acquisition and review)
- ensure training records indicate competence to undertake tasks
- review image training and consider frequency of training
- allow time for the development of supporting documentation and workflow
- ensure procedures are robust, clearly identifying tasks and action levels, indicating how each exposure is justified, optimised and clinically evaluated
- apply consistent approach to nomenclature, image labelling and patient data ID
- review working practices for redundant processes, unnecessary transcription and repetition of data to improve process efficiency
- produce and follow a clearly defined implementation plan for the adoption of new technology and techniques
- audit staff compliance with written procedure and protocol
- monitor locally reported near miss and other non-conformance RTEs to identify further preventative action and enable learning
- design fail safes within the workflow to target areas identified from RTE analysis Share learning and good practice internally and externally

The report on 10 years of clinical site visits[8] indicated that the most common finding associated with the linac treatment area was on-set verification imaging. This included poor quality imaging and staff being unsure of local imaging tolerances. Good practice was seen when staff had access to departmental flow charts outlining imaging protocols. Further national guidance is available on image guided radiotherapy[9,10].

Conclusion

It is imperative that RT providers continue to report classified and coded RTE monthly to ensure timeliness of learning. Consistency checking highlights that the quality of the RTE reports continues to be high. Providers should consider all pathway coding when coding on-set imaging associated RTE.

The prevalence of on-set imaging associated RTE continues to be high. The risk of image associated RTE may be amplified due to the large number of imaging exposures, the dynamic nature of online review and the rapid pace of development of new technology. However, the benefit image guided radiotherapy brings to the patient is clear.

The imaging associated RTE should be reviewed at a local, network and national level to minimise the risk of re-occurrence. This review should include the adoption of corrective and preventative actions and encourage a culture of safety.

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