WK Health Security Agency

E-bulletin #11 September 2023

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 promulgation 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. Safer RT 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 suggestions for the E-bulletin. Published three times a year, the next issue will be shared in January 2024. To subscribe to future editions please follow this link.

Thank you to all RTE reporters who facilitate this work.

Advancing Safer Radiotherapy (ASR) – update

Work to develop guidance for UK radiotherapy stakeholders to support the advancement of safer radiotherapy through the adoption of contemporary thinking in the patient safety field is progressing. Each of the topics for inclusion have been drafted. Once agreed by sub-groups, these will be independently reviewed by three radiotherapy professional. The final guidance will then be reviewed by the PSRT.

Many thanks to all those who are taking this work forward. Further updates on this work will be shared in future E-bulletins.

Guidance for compiling training records for clinical oncologists

The Radiotherapy Board have published guidance for compiling training records for clinical oncologists. This contains advice on the training records required by clinical oncologists to support their roles as operators and practitioners under the lonising Radiation (Medical Exposure) Regulations.

The Appendix contains an example of a clinical oncologist training record which can be adapted to reflect local practice and individual's scope of practice. The guidance has been produced by the RCR, IPEM, SoR and UKHSA and reviewed by the UK IR(ME)R inspectorates.

National aggregate RTE data

To better support RT providers with incident trend comparison, the UKHSA have produced national aggregate RTE data as described in Safer Radiotherapy. The data for January to December 2022 is now available. If you are a RT provider, reporting to the national radiotherapy incident 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

LFPSE data received

The national NHS Learn from Patient Safety Events service (LFPSE) service was launched in 2021. All NRLS users are in the process of transistioning to LFPSE. RTE data from RT providers continues to be received and included in the Safer RT analysis. LFPSE will replace the NRLS in Autumn 2023.

All providers are encouraged to ensure the RTE taxonomies are included within the first open text field of their RTE reports prior to upload to the NRLS and LFPSE.

National radiotherapy patient survey

The NHS **recommendations** include that "service providers employ surveys to engage with patients, with an aim to ensure high standards and an ethos of personcentred care". Surveys such as the National Cancer Patient Experience Survey (NCPES) ; and the Adult in-patient survey, have been pivotal in improving services based on patient experiences and feedback. The NCPES and Adult in-patient service surveys both provide valuable information, although have limitations from a radiotherapy perspective. The NCPES is light touch in its approach to individual specialities within cancer care as there are only 2 questions relating to RT. Similarly, the majority of radiotherapy is delivered on an outpatient basis.

In 2012, a RT specific survey was undertaken by the National Radiotherapy Implementation Group (NRIG). The results from this survey provided a greater understanding about patient experiences and addressed a gap in our knowledge of patients' experience of receiving RT. Despite a recommendation that the '*survey is repeated at regular intervals*' the 2012 version is the first and only national RT survey.

The NW (RODN), in 2021, conducted a regional Radiotherapy Patient Experience Survey. 653 patients responded and their experience has informed areas for focus and improvement.

The NW RODN have been working with colleagues from the North of England RODN, East of England RODN, and Birmingham City University to develop a National Radiotherapy Patient Experience Survey. This survey contains 42 questions dedicated to the experience of RT. Ethical approval was granted from Birmingham City University in early 2023 for the survey. Support has also been secured from the Society of Radiographers and the National Radiotherapy Service Manager's group.

This National RT patient experience survey will be only the second time such a survey has been undertaken for RT in England following on from the 2012 survey (https://doi.org/10.1016/j.radi.2014.03.013) and will facilitate comparison between centres of similar size and configuration.

Danny Hutton, Northwest (NW) Radiotherapy Operational Delivery Network (RTODN)

Patient Safety Day 2023, 'Engaging the patients for patient safety'

The World Health Organisation (WHO) World patient safety day was on the 17th September 2023. The theme was 'engaging patients for patient safety' and international colour was orange. The tagline for the day was 'Elevate the voice of the patients'. This reflects the patient's active involvement in their own care and policy formation and to be represented in healthcare governance structures.

The objectives of this year's patient safety day were:

- 1. Raise global awareness of the need for active engagement of patients and their families and caregivers in all settings and at all levels of health care to improve patient safety.
- 2. Engage policymakers, health care leaders, health and care workers, patients' organisations, civil society and other stakeholders in efforts to engage patients and families in the policies and practices for safe health care.
- 3. Empower patients and families to be actively involved in their own health care and in the improvement of safety of health care.
- 4. Advocate urgent action on patient and family engagement, aligned with the Global Patient Safety Action Plan 2021–2030, to be taken by all partner

Patient engagement in international guidance:

One of the objectives of the WHO Global Patient Safety Action Plan is to engage and empower patients and families. Patients view the entire treatment pathway and are uniquely positioned to have a full holistic view. The views and perspectives of the patient should be harnessed to make patients into a frequent partner in improving patient safety.

Patient engagement in national guidance:

The NHS Framework for involving the patients in patient safety sets out how organisations should involve patients in patient safety. The guidance contains both how to involve patients in their own safety and how patient safety partners should be involved in organisational safety.

RT guidance on patient engagement

'Patient engagement in safety' is one of the topics which will be included in the upcoming Advancing Safer Radiotherapy guidance. If you would like to share any examples of patient engagement in patient safety, please email: radiotherapy@ukhsa.gov.uk

Patient experience of engagement

The following experience has been shared by one patient who stated that listening and including patients in their own safety is vital to patient engagement:

"A second tumour was not identified during initial imaging, this led to additional operations. Had the tumour been correctly identified in the initial imaging I would not have needed so many additional operations. I asked if I could talk through what had happened with the radiologists involved in my care. They listened to my concerns, and they explained the circumstances that had led to the second tumour being missed. Not only was it reassuring to just feel heard, I felt reassured that the radiologist had also learnt something important from my case that would change how they scanned future patients. I feel because my voice was listened to, the chance that other patients will experience a missed second breast tumour (and potentially additional unnecessary surgical interventions) will be significantly reduced."

Thank you to Heidi Probst, Sheffield Hallam University and Rachel Harris, Society of Radiographers for their input into this text.

NHS England letter following verdict on trial of Lucy Letby

Following the outcome of the trial of Lucy Letby, NHS England issued a letter asking leaders and boards to ensure:

- All staff have easy access to information on how to speak up.
- Relevant departments, such as Human Resources, and Freedom to Speak Up Guardians are aware of the national Speaking Up Support Scheme and actively refer individuals to the scheme.
- Approaches or mechanisms are put in place to support those members of staff who may have cultural barriers to speaking up or who are in lower paid roles and may be less confident to do so, and also those who work unsociable hours and may not always be aware of or have access to the policy or processes supporting speaking up. Methods for communicating with staff to build healthy and supporting cultures where everyone feels safe to speak up should also be put in place.
- Boards seek assurance that staff can speak up with confidence and whistleblowers are treated well.
- Boards are regularly reporting, reviewing and acting upon available data.

The letter also reminds organisations of their obligations under the Fit and Proper Person requirements and makes reference to medical examiners and the Patient Safety Incident Response Framework, as well as listening to the concerns of patients, families and staff.

RCR Implementing peer review in your service

Following on from the launch of the RCR updated Radiotherapy target volume definition and peer review guidance last year, the RCR is now launching a Peer Review Implementation Group to help providers move towards embedding these guidelines in their service. An online webinar is available.

MHRA publish change programme and supporting roadmap

Information for manufacturers, healthcare organisations and professionals, researchers, and patients & public on Software as a Medical Device (SaMD), including Artificial Intelligence as a Medical Device (AlaMD).

The MHRA announced plans for an extensive Change Programme and supporting **Roadmap** to drive regulatory changes including key reforms across the software as a medical device lifecycle, from qualification and classification, to requirements that apply both pre and post-market. This programme also considers the challenges and opportunities posed by AlaMD, ensuring that these devices are appropriately evidenced, as well as address wider issues of transparency of AI (both explainability and interpretability), and adaptivity (retraining of AI models).

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, aggregate data reports and good catches. The most recent good catches include a dosimetry great catch.

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

BIR Survey on the radiotherapy Linac Engineer workforce

Firstly, a huge word of thanks – to all who kindly contributed to our 2021 online national survey of the Radiotherapy Dosimetrist workforce in the UK; devised by a small working party from the BIR's Radiotherapy and Oncology SIG. Over 200 dosimetrists responded and the results, if you haven't already seen them, were published in the British Journal of Radiology in 2022.

Many different aspects were revealed from the survey, which are being used as a resource for regular CPD Webinars from the BIR. But also, we hope, all across the Dosimetrist workforce can make use of the peer-reviewed published evidence – the first of its kind in the UK; not least for supporting professional groups (such as IPEM) and furthering the discussions in solving the 'mixed-economy' of statutory registration which exists within this important section of the Radiotherapy workforce – particularly in terms of CPD; something required for our whole workforce to 'practice safely and effectively'. Not least also in enabling the whole workforce to respond flexibly and optimise capacity when the Radiotherapy clinical service is under pressure.

As mentioned in a previous E-bulletin, in light of the richness of the data obtained from the dosimetrists, we are now undertaking another national survey – this time with Linac Engineers; a group for which there is even less published data and evidence. It will examine demographics; recruitment, training and working experiences; current working patterns, skills and practices and their CPD opportunities and career aspirations, etc.

The link to the survey is being circulated through professional groups, Radiotherapy discipline contact lists, Manufacturers, the Medical Physics mail base, the link for the survey can be found here Please feel free to circulate as widely as possible amongst your own networks – so that we can get as big a response as possible; to hear clearly the voice of this vital part of our Radiotherapy workforce.

Many thanks for all your responses previously and your help with this work in the future – and for all you do for the benefit of our patients.

Mike, The Revd Canon Dr Mike Kirby

HCPC update standards of proficiency

The HCPC standards of proficiency were updated on 1st September 2023. The changes are profession specific; these reflect the developments in practice within each profession. Further information on the new standards can be seen here.

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

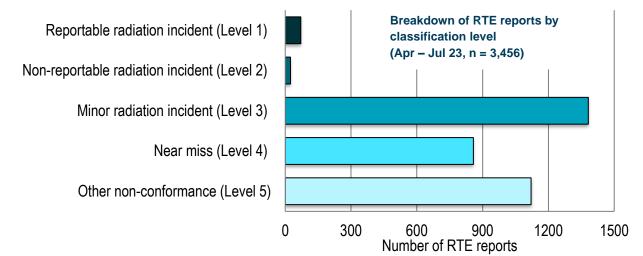
Development of Learning from Radiotherapy Errors provides the pathway coding safety barrier, method of detection and causative factor taxonomies

RTE data analysis – April to July 2023

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.

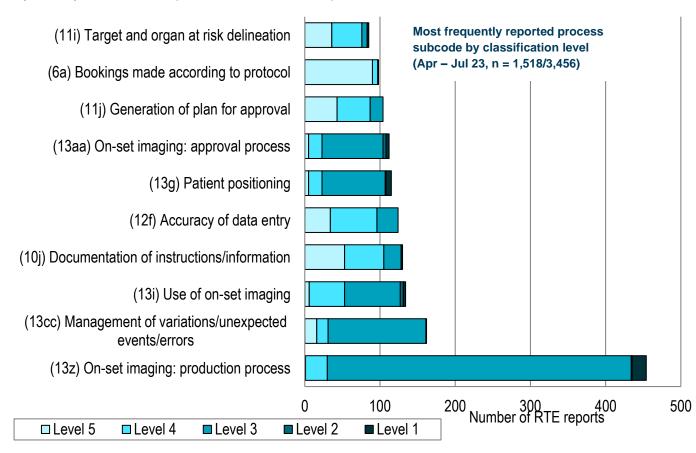
Classification (Level) of RTE

Of those 3,456 RTE reported, 3,361 reports (97.2%) 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.



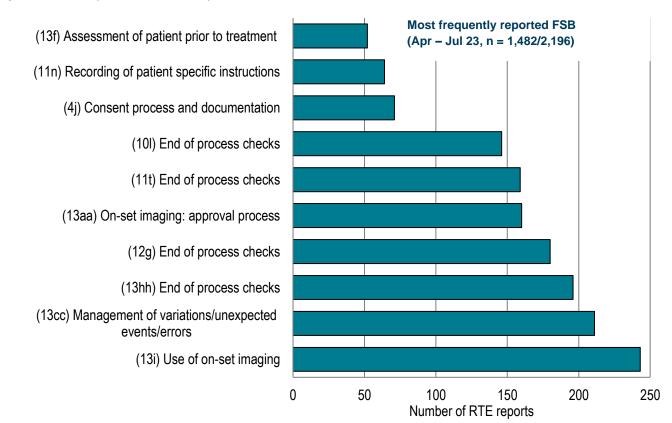
Primary process subcode

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 (13.1%, n = 454/3,456).



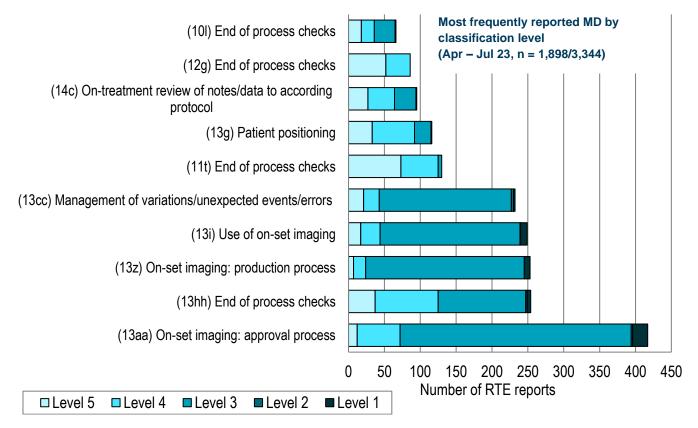
Failed safety barriers (FSB)

Multiple FSB can be attributed to each individual RTE. A total of 2,196 FSB were identified across all the RTE reported. The most frequently reported FSB can be seen below. Treatment unit process 'use of on-set imaging' was the most frequently reported FSB (11.1%, n = 243).



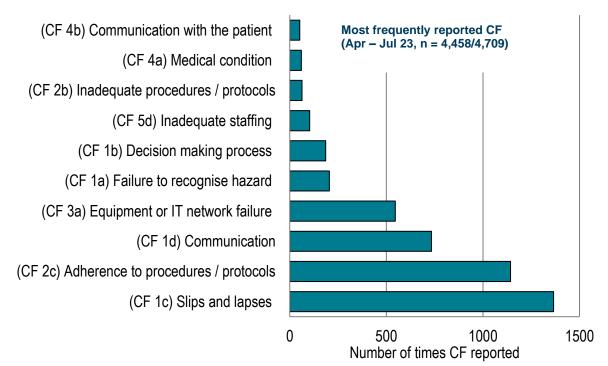
Method of detection (MD)

For this reporting period 3,344 reports included MD coding or data. The most frequently reported MD was 'on-set imaging: approval process' (12.5%, n = 417).



Contributory Factors

Each RTE can be assigned multiple CF codes. A total of 4,709 CF were reported in this period. The most frequently reported CF was individual 'slips and lapses' at 29.0% (n = 1,366).

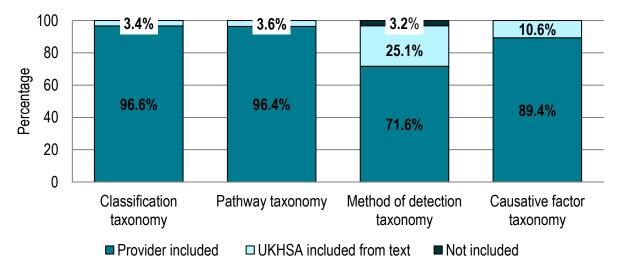


Monitoring of RTE coding by RT providers

All providers are asked to apply a trigger code, classification, pathway coding (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 first open text field of 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 April and July 2023 (n = 3,456) can be seen below.

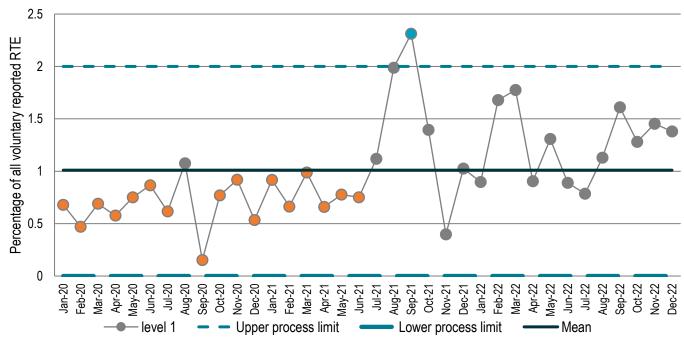


There has been an increase in the inclusion of MD from 64.0% to 71.6% and an increase in CF from 87.3% to 89.4%. Thanks to all those that apply the coding locally and include it in submissions to UKHSA.

Standard statistical process control tool (SPC)

The **Safer Radiotherapy** publications include trend analysis of the national data to facilitate a comparison of locally identified trends against the national picture. One tool which can be used to review trends over time is a **standard statistical process control tool** (SPC). This can show statistically relevant quality improvement, outliers and potential future trends and may be helpful in better understanding RTE data locally.

The SPC chart below shows the reportable radiation incident (Level 1) data as a percentage of all RTE reported each month between January 2020 and December 2022. This data should be interpreted with care as the numbers are very low and the data is submitted on a voluntary basis so may not be complete.



- The SPC chart has three reference lines; upper and lower process limits (dotted lines) and mean (solid line) to enable an appreciation of data variation. 99% of data points are expected to fall within the process limits.
- If a single point falls outside the upper or lower process limit it indicates something unexpected has happened and is highlighted. In this example, a single point (Sept 21), falls above the upper process limit. The point falling above the upper process limit occurred after a bulk report upload from three providers covering a year period. This explains the anomaly. Of note, a review of these RTE reports revealed the majority of these reports related to repeat on-set imaging.
- If six or more consecutive points are above or below the mean line this represents a trend that should not result from natural variation in the system. In this example, multiple consecutive points (orange points) within 2020 and 2021 were below the 1.01% mean line, the increase following these points is thought to be due to changes in inspectorate reporting criteria for accidental and unintended exposures.
- If six or more consecutive points are increasing or decreasing this is a sign that something unusual is happening in the system. This is irrespective of where the run starts or stops in relation to the mean line. This is not seen here.

SPC are widely used across the NHS and allow analysis of data over time. Further information on SPC can be found **here**.

Thank you to Paula Steele, HCA Healthcare UK for their input into this text. **Guest editorial:**

Radiotherapy alignment tattoos with Indian tattoo Ink: Time for challenge and change?

Sairanne Wickers, Consultant Therapeutic Radiographer (breast cancer), UCLH NHS Foundation Trust **sairanne.wickers@nhs.net**

With input from Heidi Probst, Sheffield Hallam University, Naman Julka-Anderson, Macmillan Cancer Support and Rachel Harris, Society of Radiographers

Image gifted with consent by UCLH patient undergoing radiotherapy. Image not to be used without permission of the author.



Radiotherapy (RT) utilises a mixture of technology and multidisciplinary working to deliver patient centred care. This area of healthcare continuously advances in the use of technology and the development of new techniques. Although each treatment is unique to the individual patient, there are standard requirements for good patient set up to ensure accuracy of treatment, these include:

- Effective communication with the patient
- Patient comfort and compliance
- Use of effective immobilisation devices
- Clear and accurate set up information
- Use of standard nomenclature
- Clear reference marks (e.g., alignment tattoos)
- Appropriate reference images (e.g., photographs, surface templates, skin rendered imaging)
- Treatment verification on-set image acquisition and correction

The majority of RT departments apply skin marks to support patient set up and reproducibility. These skin marks are used as a reference point to which beams are localised for each treatment fraction. Technology such as Surface-guided RT has provided some opportunity to consider RT without skin-marking but cannot provide a solution for all patients.

Radiotherapy tattoos:

The most common method of skin-marking is with permanent dark-ink tattoos, applied with a lancing needle, usually between 3 and 6, dark green/blue/black in colour, and approximately 2mm in diameter. They are defunct of purpose after the treatment course has completed, typically 1-2 months after application. They can be difficult to localise on brown and black skin and can remain highly visible on white skin. RT tattoos are associated with a negative impact on body image due to their permanent visibility and unnatural colour. They may increase in size in the years following treatment, sometimes up to 5 mm in diameter.

Patients are asked/expected to provide their consent for RT tattoos, but alternatives are not routinely offered. We must therefore ask ourselves whether this is informed consent. Suggestions of less accurate treatment, the risk of needing to replan and incur a delay if alternatives such as pen marks are lost, are often communicated to those patients not wanting tattoos, which commonly results in reluctant consent.

If a patient has a natural skin mark or mole at the location of a proposed tattoo, this can often be considered a frustration and move the reference position to an area of skin that will not confuse the tattoo visibility – why? Other tools are available such as

photographs and templates to facilitate using a natural skin mark as the reference mark, meaning one less permanent unnatural tattoo for the patient, this may make a difference to the impact on body image.

Tattoos can be difficult to localise on brown and black skin. The picture above shows the poor contrast between tattoo and skin colour. Localising the tattoos commonly requires at least 2 radiographers to closely scrutinise and confirm the tattoo location with the aid of a torch on the exposed patient. Transparent dressings are placed over pen marks which highlight the difficult-to-see tattoo position, to preserve them throughout the treatment course. These interventions can have a negative impact on the dignity of our patients.

Patient experience:

Although small, the permanent tattoos do have a negative impact on the quality-of-life for many following RT. Some patients have stated that 'the tattoos bothered them more than their mastectomy scar'. They matter to patients, and therefore they should matter to us. Tattoos can directly impact patients' choice of clothing, particularly due to the unnatural colour and feeling self-conscious about them, continuing to bother them in a negative way in the months and years following treatment. A common theme is that they serve as a constant reminder of the cancer diagnosis and treatment. One patient stated they "didn't want to be tattooed but felt they could not refuse as they didn't want to be labelled as a difficult patient. They didn't have the confidence to say no."

Challenging the current standards:

The NEAT (Non- permanent alignment tattoos for breast cancer radiotherapy) trial aims to evaluate to accuracy of using non-permanent ink for patient alignment marks during RT.

The Support4All project (S4A) has tested the feasibility of using a specially designed bra for RT positioning for women diagnosed with breast cancer (following conservative surgery). The randomised feasibility trial tested using a single lower midline permanent tattoo with the remaining set up marks placed on the S4A bra. The lower mid-line tattoo was positioned closer to the xiphisternum to avoid visibility when wearing normal clothes. Reproducibility using this single lower tattoo and the marks on the S4A bra was clinically acceptable but further testing across a larger sample is needed.

Natural skin marks could be used in place of a tattoo. A pen mark and transparent dressing could be considered for some anterior mark (often the most visible and troubling to people post-treatment). This could also be considered for single fraction and short-course radiotherapy, do these patients need a permanent mark when they are having their radiotherapy on the day of, or a few days after planning when the pre-treatment alignment pen marks are still clearly visible?

The first step in driving and implementing change is to challenge practice. Alternatives are worthy of acknowledgement, conversation, and consideration.

Dates for the diary	
RCR, Annual conference 2023	12-13 October, Birmingham
BIR, Annual congress 2023	2-3 November, London