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Advancing safer radiotherapy

Guidance for radiotherapy providers on improving patient safety

Contents

Foreword

I feel very honoured as a patient and Chair of the Patient Advisory Group at the Society and College of Radiographers (SCoR) to be invited to write the foreword to this important document. We continue to see major progress in technology, and the way medical practice and procedures are managed. The patient voice is increasingly at the core of healthcare change. It is 17 years since Towards Safer Radiotherapy was published. During this time, it is reassuring to note that the radiotherapy community has improved and consolidated patient safety through the implementation of the learning and recommendations highlighted within Towards Safer Radiotherapy. An example of the community's commitment to safety is the success of the national radiotherapy event learning system, which receives and monitors voluntary reports from all NHS radiotherapy providers across the UK, as well as the independent sector.

The Radiotherapy Dataset demonstrates that overall, radiotherapy offers a safe and effective service, with almost 2 million radiotherapy patient attendances recorded in 2023 across the UK. Analysis undertaken by the UK Health Security Agency (UKHSA) demonstrates the likelihood of a clinically significant event occurring remains very low. However, it should be mentioned that a number of cases over the last 2 decades have demonstrated the potential risk of harm to the patient, if a significant event occurs within radiotherapy.

Although some technological advances may appear to offer enhanced safety actions, the efficacy of any new technology will be dependent upon the considered way in which it is implemented. As techniques, technologies and working practices within radiotherapy evolve, the opportunity for new types of event may arise from several, interacting components of complex radiotherapy planning and treatment processes.

To advance safety in radiotherapy it seems fundamental that we must progress from focussing on human error to designing safer systems that provide consistent, accurate treatment delivery. We must work with patients, carers and the families of our service users to learn from what works, not just what does not.

This document has been curated on behalf of the radiotherapy community and is a statement of a collective intent to improve patient safety by recognising that to advance, we must improve the way we learn, and actively engage with all patients.

Philip F Plant
Chair of the Patient Advisory Group
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Executive summary and key recommendations

Background

Towards Safer Radiotherapy (TSRT), published in 2008, is widely accepted as the cornerstone document for improving patient safety in radiotherapy (1). Many of the 37 recommendations have been adopted by the community and continue to form the basis for the strong and effective safety culture present within radiotherapy today.

The 2024 biennial radiotherapy error data analysis and learning report (2) estimated a nationally voluntary reported radiotherapy events (RTE) rate of 5.7 per 1,000 attendances during a 2-year period (January 2022 to December 2023). However, the RTE rate for reportable radiation incidents was estimated at 0.9 per 1,000 prescriptions, for the same period, with less than 0.5% of RTE reported affecting the delivery of radiotherapy.

Despite this positive analysis, some patient safety events persist. As techniques, technologies and working practices continue to evolve, the opportunity for RTE may increase. These can arise from several, interacting components of complex radiotherapy planning and treatment processes.

Advancing Safer Radiotherapy has been developed by the multi-disciplinary radiotherapy community to promote a greater focus on the patient as an active and valued participant in safety; reflect contemporary approaches to patient safety, including proactive risk management and system-based approaches to RTE analysis; and to build on the TSRT recommendations.

Key recommendations

1. Radiotherapy providers should establish and maintain a positive safety culture in which key safety culture traits are embedded and individuals are encouraged to speak up.
2. Patients should be seen as equal partners in safety; engaged in local processes at all levels within organisations and with representation of local population demographics.
3. An accessible and diverse range of patient communication systems should be in place, with processes for timely adaption to individual or situational needs.
4. Healthcare professionals should actively assess patient comfort and facilitate supported coping strategies throughout the patients' radiotherapy journey.
5. Tumour-site-specific radiotherapy protocols for patient review should detail the nature and frequency of monitoring and assessment before, during and after

radiotherapy. Early and late radiotherapy adverse effects should be audited both locally and nationally to inform practice.

6. The national radiotherapy consent forms (3) should be adopted nationally.
7. National tumour-site specific outcome data for radiotherapy adverse effects, training and resources should be developed and validated by key stakeholders. A new UK reporting system for recording, collating and analysing patient radiotherapy late adverse clinical effects is proposed.
8. Safety management system frameworks should be built into existing quality management systems and organisational quality governance structures.
9. Risk should be managed proactively, learning from where things have gone right, not simply reacting when things have gone wrong.
10. To facilitate thematic analysis of radiotherapy events (RTE) and timely learning at a local and national level, it is recommended:
    a. Local event learning systems (ELS) are appropriately supported and resourced
    b. Staff are supported by appropriate RTE training, documentation and communication frameworks
    c. All classification levels of RTE are reported locally and nationally with the full national patient safety RTE taxonomy applied (4)
    d. Radiotherapy ELS and continual quality improvement initiatives are utilised to examine work as done and identify areas for improvement
    e. Learning from RTE analysis is shared locally and regionally.
11. The wider context of the system should be considered when reviewing RTE to ensure all contributory factors are identified and addressed. For each area for improvement identified a safety action should be applied and periodically reviewed to assess efficacy.
12. RTE investigation teams should adopt an interdisciplinary approach. The team should include individuals with clinical expertise as well as individuals who are trained and competent to carry out an effective systems-focused investigation.

References

1. The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. ‘Towards Safer Radiotherapy 2008’
2. UKHSA. ‘Safer radiotherapy: biennial report’
3. The Royal College of Radiologists. ‘National radiotherapy consent forms’
4. UKHSA. ‘Safer radiotherapy: national radiotherapy patient safety event taxonomy’

Introduction

The purpose of this document is, twofold. The first 4 chapters seek to enable a deeper understanding of state-of-the-art safety tools and practices in a rapidly developing technological environment and to offer guidance on their practical application and implications for radiotherapy professionals and patients.

Secondly, the final 3 chapters advocate for the positioning of the patient front and centre in radiotherapy safety. They consider the merits of patient engagement in all areas of practice and encourage health professionals to critically reflect on how they can influence the future shape of radiotherapy services for the benefit of patients. Whilst a narrative arc runs through the entire document and there is considerable value in reading from start to finish. Each chapter is designed as a standalone and can be perused in isolation by a reader interested in a specific chapter's subject.

This guidance has been developed by the multi-disciplinary radiotherapy community to advance the learning and recommendations laid out within Towards Safer Radiotherapy (TSRT) (1), promote active patient engagement in safety and reflect contemporary approaches to patient safety.

The radiotherapy error terminology defined in TSRT and subsequent Safer Radiotherapy publications, has been revised and consolidated in line with current patient safety thinking (2). Table 1 includes a summary of updated terminology and corresponding acronyms. These are reflected in the National patient safety radiotherapy event taxonomy (2), which combines all taxonomies and updates in a single document.

Table 1. Updated terminology

Previous terminology	Updated terminology	Acronym
Radiotherapy error	Radiotherapy event	RTE
Near miss (a subset of radiotherapy errors)	Good catch (a subset of radiotherapy events)	
Causative factor	Contributory factor	CF

Since the publication of TSRT in 2008, there has been much work to improve patient safety in radiotherapy (3 to 5). The 37 recommendations included have been widely adopted by the community and form the basis for the strong and effective safety culture present within radiotherapy today.

Radiotherapy event learning systems (ELS) and bespoke quality management systems have become commonplace, with a national radiotherapy ELS implemented in 2010. A positive patient safety culture coupled with technological improvements have provided the opportunity

for mitigations to both counter and detect RTE. Although the number of significant events has been estimated to account for less than 0.5% of all RTE reported nationally (3), the frequency and composition of UK RTE reporting has remained stubbornly consistent for several years. The reason for this may be that the influence of traditional safety approaches has plateaued.

Technology and treatment models continue to evolve and advance, with a shift from traditional radiotherapy practice towards more adaptive, individualised methodology. This inevitably introduces an associated increase in innovations and complexity during treatment planning, quality assurance (QA), and delivery. Allied to this, a new generation of health care professionals are now participating within the radiotherapy community. The community is working within a fast-changing and challenging environment that is influenced by external socio-economic factors. This requires more effective, timely output from increasingly finite resources at a time when demand is projected to increase significantly.

In such circumstances complacency is not an option. This publication provides an opportunity to place a greater focus on the patient, as an active, valued participant in safety. Secondly, it develops the TSRT recommendations, to reflect contemporary approaches to patient safety, including proactive risk management and system-based approaches to RTE analysis. The complex incident interplay between technical, individual, group, organisational and social factors should be implicitly acknowledged and comprehensively analysed to identify potential modes of failure within clinical workstreams. Thirdly, it affirms the belief that enhancing radiotherapy practice and patient care should take place within an environment where its leaders nurture a strong safety culture.

Chapter 1. Safety culture

The health, safety and wellbeing of patients and employees are a priority in radiotherapy, so developing a mature safety culture is fundamental to practice. This chapter aims to explore various aspects of safety culture: what is required to implement one and, most importantly, what is required to make it successful and sustainable. Creating a culture of safety can be challenging; organisations may need to instil behavioural change through policy growth, but also through the empowerment of staff to allow them to prioritise the safety of their patients and colleagues.

1.1 Definition of safety culture

Safety culture is a shared set of attitudes, beliefs and values that influence how work is done, rather than how it should be done. Safety culture and patient safety are interlinked. Where one is present the other will prosper.

NHS England (6) explain that patient safety is “maximising the things that go right and minimising the things that go wrong”. They describe how patient safety is not an absolute concept and has no single measure or defined endpoint. Rather it is a continual process of review and improvement that can be enhanced by new innovations and research.

The International Atomic Energy Agency (IAEA) (7) defines safety culture as “the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance”. In addition, NHS England (8) emphasise that a positive safety culture includes “collaboration… continuous learning and improvement of safety risks, supportive, psychologically safe teamwork, and enabling and empowering speaking up by all”.

1.2 Creating a safety culture

A positive safety culture does not seek to blame or accuse individuals, thereby negating the fear of disclosing concerns or incidents. Positive reporting where events are discussed openly and honestly should be encouraged and any staff involved should be treated fairly as part of a just culture. No individual should be subject to, or fear, sanction due to making a mistake.

In a just culture, investigators try to understand why events occur within the context of the complex interactions between human behaviour and radiotherapy systems (9). The focus is to promote all opportunities for learning from event reporting, including review of systems and processes to identify areas for improvement. In addition, managers are expected to treat staff involved in any patient safety event in a consistent, constructive, and fair way. This supports staff to be open and encourages reporting of safety issues. Individuals should feel safe when

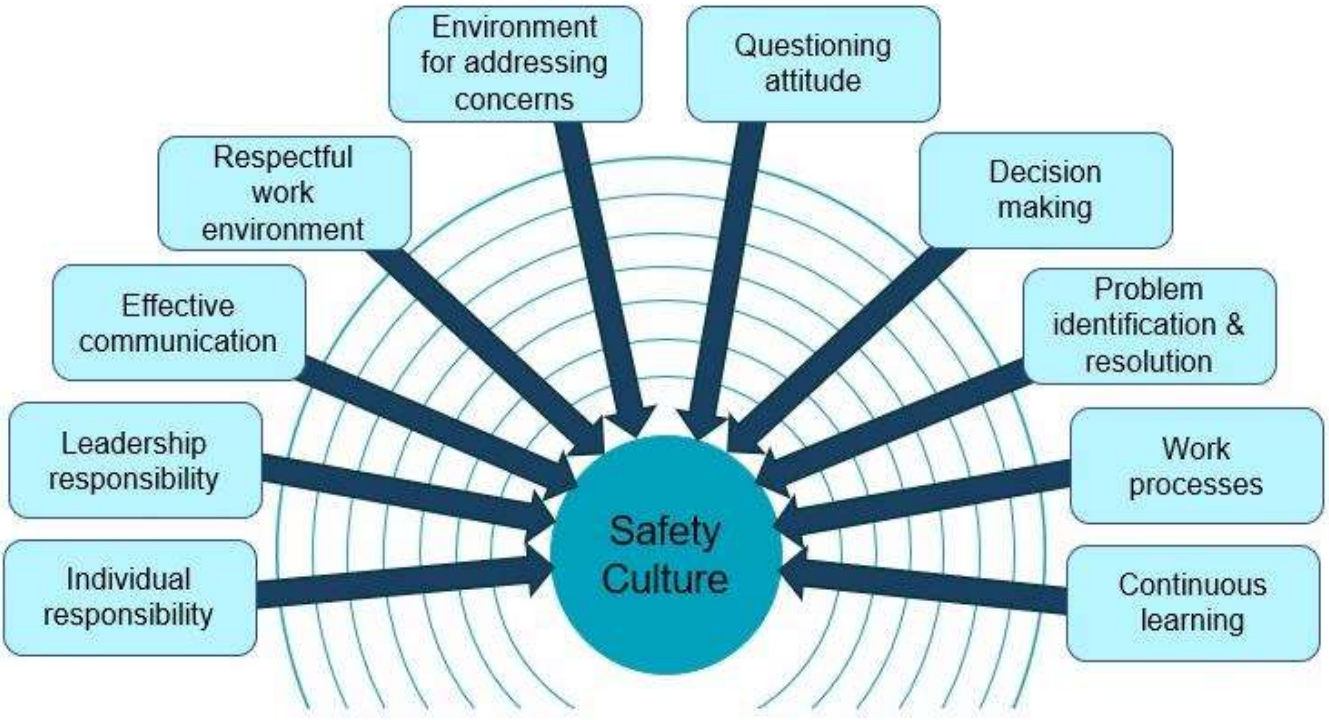
voicing concerns about safety and have the freedom to discuss their own actions, or the actions of others, regarding actual or potential adverse events.

A just culture does not absolve staff from accountability on rare occasions where events are caused by risky or reckless actions. However, the consequences should be proportionate with accountability and learning from the event carefully balanced.

1.3 Key traits in radiotherapy safety culture

How people and organisations act is important in establishing a good safety culture, and so the way individuals and providers behave is essential to minimise the risk of patient harm and ensure practices are safe. The IAEA and World Health Organization (WHO) both outline 10 key traits that are evident when a strong safety culture is embedded in an organisation (10 to 11). These are seen in Figure 1.1 and discussed below.

Figure 1.1. Key safety culture traits



1.3.1 Individual responsibility

All individuals should take ownership for their work performance and behaviour and have a strong sense of accountability for their actions. Individuals should encourage each other to adhere to high standards, foster open communication and promote teamwork. Individuals need to be aware of shared goals, including elements of safe working and understand their personal responsibility in raising safety issues. Whilst many safety mechanisms, such as automation and independent checking, have been implemented along radiotherapy workflows, they will only perform as intended if individuals are clear about their roles (12 to 13). In radiotherapy

individuals are accountable for ensuring they have appropriate registrations as required for the role, work within their scope of practice and are adequately trained and competent.

1.3.2 Leadership responsibility

NHS England (8) acknowledge that effective leadership is a fundamental part of patient safety culture. Northouse (14) summarises leadership as ‘a process whereby an individual influences a group of individuals to achieve a common goal’. Everyone can demonstrate positive leadership irrespective of their position within an organisation. However, management teams should guide and motivate others, empowering employees by providing the skills and training needed to communicate, explain, and perform effectively. To build psychological safety in radiotherapy, leaders should be fair and inclusive, and create a compassionate environment where others feel listened to, valued, respected, and supported. Leaders can demonstrate openness and inclusivity, asking for feedback on how they can improve (15). Compassionate leadership drives a culture, and the culture drives safety.

1.3.3 Effective communication

Effective communication, with consistent dialogue and openness, is fundamental in establishing and maintaining a safety culture (16). Transparent communications that reinforce the principles of safe practice encourage individuals to understand the expected behaviours and actions necessary to provide safe care. Leaders should encourage the free flow of safety information, listen to and act on concerns. Regular staff meetings, ‘open door’ policies and listening events are helpful in supporting open communication. If confidentiality is requested, then it should be assured. Potential or perceived barriers to open communication should be addressed.

1.3.4 Respectful work environment

A respectful workplace culture is where everyone feels valued, respected, and encouraged to contribute to the organisation’s success. Level of employee trust in management is positively related to employee job performance and engagement in safety behaviours (17 to 18). Open communication, fairness, and management accountability are mechanisms that managers can employ to build trust and respect. It is important to be civil. Successful teamwork and collaboration requires respect for all individuals’ opinions and differing views.

1.3.5 Environment for addressing concerns

A safety conscious work environment encourages staff to raise concerns without fear of retaliation, intimidation, harassment, or discrimination (17). Concerns should ideally be communicated with the line manager in the first instance, where appropriate. However, speaking up can be done locally or nationally to a dedicated guardian. Issues can be raised with external bodies if required. Individuals should never be prevented from speaking up and any negative connotations associated with raising issues should be addressed.

1.3.6 Questioning attitude

Individuals should continuously assess their own performance and remain vigilant for inconsistencies or abnormalities within procedures and activities which might result in error or inappropriate action. Anticipating what has the potential to go wrong reflects a questioning attitude within a positive safety culture and should be encouraged. A climate of respect, trust and openness in which people can raise concerns and suggestions without fear of reprisal fosters psychological safety. Psychological safety at work involves teams having a shared understanding about productive disagreement and speaking candidly, free exchange of ideas and feeling safe about reporting mistakes (18). Additionally, leaders should be committed to continuously interrogate their operational systems to ensure they understand what is happening within work processes and the associated risks.

1.3.7 Decision making

Decisions regarding patient and employee safety should utilise a systematic approach where risk assessment is incorporated as standard. Leaders should acknowledge potential conflict between safety and operational pressures. Leaders should seek input from different work groups within their workplace or externally as appropriate when making decisions which may influence work processes and safety. It is important that decisions are justified and communicated transparently, and that responsibility is well defined. Decision making should be collaborative so that everybody (individual staff, teams, patients, service users, families, and carers) can contribute to achieving high quality, safe care.

1.3.8 Problem identification and resolution

Providers who accurately identify and evaluate safety concerns, and take appropriate, timely corrective action to address emerging problems engender confidence and trust within their workforce (19). A provider with a positive safety culture has a robust system that monitors events, anticipates issues, reviews change effectiveness, and tracks local as well as national thematic trends. Radiotherapy event learning systems are explored further in Chapter 3. This learning is used to improve processes and to mitigate the risk of events occurring. Quality improvement projects are essential to drive practice advancements and identify areas requiring improvement.

1.3.9 Work processes

Effective work processes include well-designed workflows that provide clear assignment of responsibilities to leaders, teams, and individuals, as well as required coordination across different disciplines. Work activities should always be developed and prioritised to include the identification and management of risk, whilst being coordinated and communicated effectively. Policies and procedures should incorporate appropriate risk insights and be effectively planned, executed, verified, documented and audited.

1.3.10 Continuous learning

An environment that supports continuous learning is one that encourages an employee to ask questions, demonstrates appreciation for raising differing views, allows time for understanding, and encourages communication and collaboration. Providers must be committed to learning from their mistakes. They should continually evaluate their service and look for opportunities for improvement, ensuring that learning is shared and performance is benchmarked. Providers should embrace the importance of training, actively supporting the provision of opportunities for staff to develop professionally.

In learning cultures, people accept that they have limits in understanding and gaps in knowledge and apply curiosity and openness to innovative practice. Evidence shows that in a learning culture, providers innovate more and make fewer mistakes (18, 20).

Recommendation

Providers should establish and maintain a positive safety culture in which key traits are embedded and individuals are encouraged to speak up.

1.4 How to monitor safety culture

Monitoring safety culture can be challenging (6). However, the continual assessment of a safety culture is an important tool to monitor progress and facilitate improvement. Safety culture may be assessed quantitatively or qualitatively.

Quantitative indicators may include the number of completed audits or the number of staff who have completed the relevant safety culture and event learning system training. Radiotherapy event reporting numbers are not recommended as a single measure of safety culture, as these will be reliant on reporting culture and system access.

Qualitative assessment tools may include staff engagement and culture surveys. These may assess how engaged employees are and their alignment with the department's goals, thus making safety culture more tangible. The World Health Organization (WHO) have provided an in-depth summary of appropriate tools and indicators which may be used to measure and assess safety culture (11).

1.5 Summary

This chapter has explored definitions for safety culture, what this looks like in practice and how it can be monitored and developed. It outlines the responsibilities of workers, leaders, and organisations in contributing to, and nurturing safety cultures. Fundamentally, all organisations should strive to achieve an effective and sustainable safety culture with the full engagement of the leadership team, workforce, and stakeholders.

Chapter 2. Advancing safety practice in radiotherapy

Radiotherapy services are complex dynamic systems (21). Ensuring safe delivery of radiotherapy processes is essential but becomes more challenging with increasing system complexity and change.

Providers need to be continuously alert to the possibility of error and sensitive to changes in the environment that may result in an unexpected outcome. This allows providers to anticipate and mitigate the compounding consequence of small problems by targeting minor adjustments in the system (22).

Traditional patient safety models in healthcare focused on learning from incidents. This approach often focuses on the individual involved in the last interaction prior to an incident, with little or no consideration of the latent influences on the incident (for example, equipment, task, environment and the organisation).

In this chapter, systems thinking, key principles, and challenges in safety learning as they apply to radiotherapy will be explored.

2.1 Relationship between quality, safety and governance

Safety and quality are interlinked and many of the recommendations and tools developed in the context of safety could be applied equally to improving clinical outcome (clinical effectiveness) and quality improvement (QI) (23). Therefore, it is important that providers have safety arrangements clearly described in their quality management systems.

Radiotherapy processes are highly standardised through the adoption of certified Quality Management Systems (QMS). This has led to high levels of reliability being achieved in radiotherapy.

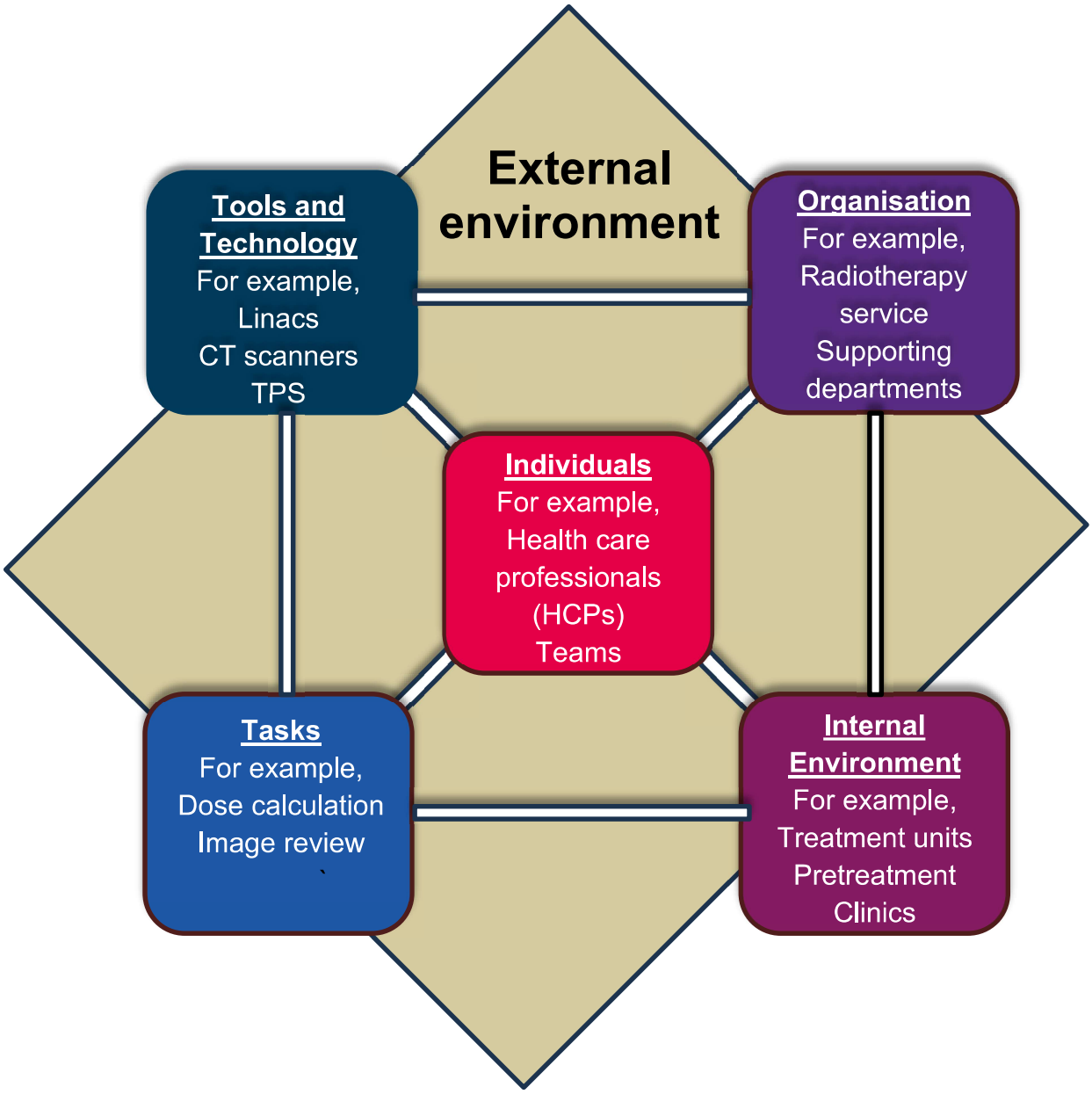
Governance refers to the structure of an organisation, how it is run and how it holds itself to account to ensure regulatory standards are delivered in order to protect patients and staff and ensure continual quality improvement (24). Effective governance requires a combination of leadership and accountability, structure and processes, data and intelligence (25).

To advance safety practice in radiotherapy, a common understanding of quality, safety and governance and local arrangements among multidisciplinary team (MDT) members working in radiotherapy is required.

2.2 Systems approach to safety

Safety is an essential characteristic of radiotherapy services or systems. It includes the reliability of, and the interaction between, system elements. The elements of a system or their interactions can directly and indirectly contribute to patient safety events. Although individuals are often involved in the last interaction prior to an event, actions and behaviour are the product of influences from the whole system (26) and should be considered as part of any response.

Figure 2.1. Work system as described by the Systems Engineering Initiative for Patient Safety (SEIPS) framework



Text version of Figure 2.1 Work system as described by the Systems Engineering Initiative for Patient Safety (SEIPS) framework

This graphic outlines the work description as described by the SEIPS framework. SEIPS considers the interactions between all elements of the work system. These include:

1. Tools and technology: for example, Linacs, CT scanners, TPS, OMS.
2. Organisation: for example, radiotherapy service, supporting departments, hospital.
3. Individuals: for example, health care professionals (HCPs), teams, patients.
4. Tasks: for example, dose calculation and image review.
5. Internal environment: for example, treatment units, pretreatment, clinics.
6. External environment.

Systems thinking is about relationships, integration and interdependent interactions between the elements that make up the system. Risks arises within these relationships (17). Therefore, it is important to explore typical interactions between the elements of the system.

One approach to adoption of systems thinking is the Systems Engineering Initiative for Patient Safety (SEIPS) (27 to 28). The interactions between elements of the work system, processes and the planned outcome for the patient, staff member or organisation are considered in Figure 2.1. This approach ensures all contributory factors are identified and used to inform actions required to reduce risk and potential for harm.

Recommendation

The wider context of the system should be considered when reviewing radiotherapy events (RTE) to ensure all contributory factors are identified and addressed appropriately.

2.3 Safety management system (SMS)

The development of safety management systems (SMS) to ensure a methodical and systematic approach to risk management is another step to advance safety practice in radiotherapy. An SMS is a proactive and integrated approach to managing safety (29), which can be built into existing QMS and organisational quality governance structures.

QMS have already established many of the processes that the SMS requires, such as management review and internal audit. The difference between the 2 systems is how the tools and techniques are used, for example, the QMS focuses on process improvement to reduce variation and the SMS focuses on safety performance. The unique and shared characteristics of QMS and SMS are summarised in Table 2.1.

Table 2.1. Characteristics of a QMS and SMS

QMS	SMS	Shared
Quality assurance	Safety assurance	Change management
Quality control	Hazard identification and risk control	System or process approach
Quality culture	Safety culture	Data driven or evidence based

QMS	SMS	Shared
Compliance to a standard	Acceptable level of safety performance	Focus on continual improvement
Prescriptive	Performance-based	Learn from feedback of day-to-day work
Standards and specifications	Organizational and human factors	Requires leadership commitment

An SMS sets out the organisational structures and accountabilities necessary for effective governance whilst facilitating continual improvement. It supports effective monitoring and communicating of safety information across a service, which enables the management team to change actions as required. There are 4 recognised areas associated with SMS frameworks as shown in Figure 2.2.

Figure 2.2. The 4 areas of a safety management system (SMS)

Text version of Figure 2.2. The 4 areas of a safety management system (SMS)

This graphic illustrates 4 recognised areas associated with SMS frameworks. These are:

1. Safety policy: establishes an organisation's commitment to improve safety and outlines responsibilities.

2. Safety risk management: the identification, assessment and mitigation of hazards and risks.
3. Safety assurance: the monitoring and measuring of safety performance.
4. Safety promotion: actions to support a positive safety culture within the workforce.

Recommendation

Radiotherapy providers should ensure safety management system frameworks, to include safety policy, safety risk management, safety assurance and safety promotion are built into QMS and organisational quality governance structures.

2.4 Safety actions

Safety actions in radiotherapy can be described as safeguards, safety barriers, preventative and corrective actions:

1. Safeguards are actions that support and underpin the availability and performance of safety actions but don't meet the standards of robustness or specificity to be relied on as a safety action. Safeguards should have clear ownership, be traceable to some requirement, process or activity in the wider organisation and be auditable (30). Examples include local implementation of legislation or recommendations from professional guidance.
2. Safety barriers are defences or functions deliberately inserted into the pathway to prevent, mitigate, or contain incidents (2, 21). These are considered to be over and beyond core tasks undertaken as part of the planning and delivery of radiotherapy treatment.
3. Preventive actions aim to avert the occurrence of patient safety events.
4. Corrective actions aim to prevent patient safety event recurrence.

It is recognised that system-orientated safety actions are more effective than human-orientated actions. However, they are more difficult to achieve and often require input from stakeholders outside the local system. These are represented in Figure 2.3.

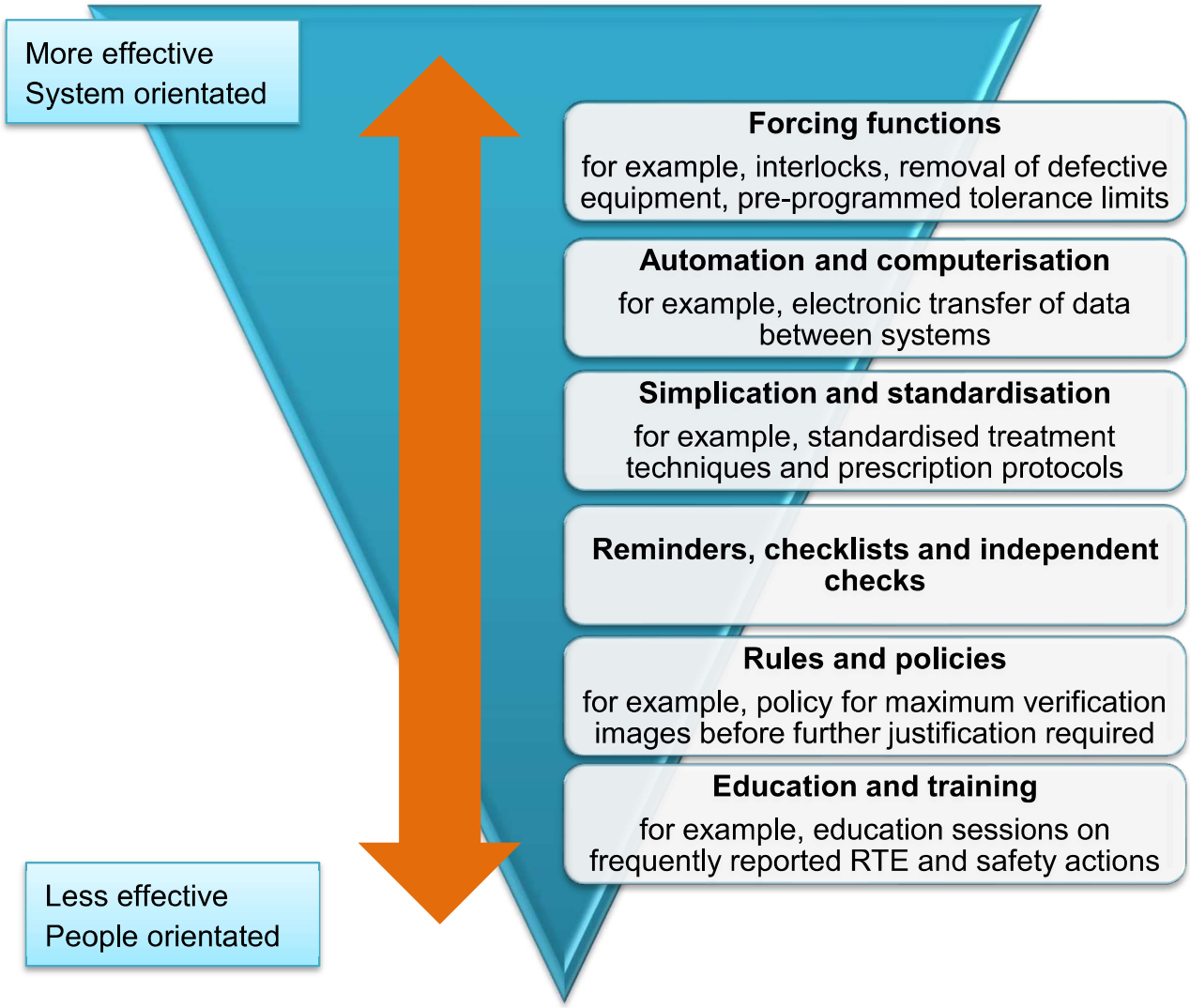
In selecting an appropriate safety action, the Health Services Safety Investigation Body recommends a blended approach (31). It suggests applying different levels of safety actions so that both people and system focused actions are included. Safety actions should be applied against each area for improvement identified as part of an RTE response (32). In addressing failed or absent safety barriers it is worth considering the efficacy of the planned safety action to be introduced.

The quality of a safety action depends on its impact, sustainability, effectiveness and the governance processes in place (32). Safety actions should be periodically reviewed to assess their efficacy and amended or removed if redundant. They should be reassessed when introducing new processes, techniques and technologies, in response to significant events or emerging themes and as part of continual quality improvement cycles.

Recommendation

Safety actions should be applied against each area for improvement identified as part of an RTE response. Both people and system focused actions should be considered. These should be periodically reviewed to assess their efficacy or presence and amended, created or removed if redundant.

Figure 2.3. Hierarchy of effectiveness of safety actions (33)



Text version of Figure 2.3. Hierarchy of effectiveness of safety actions

Certain types of risk mitigation strategies are known to be more effective than others. This graphic lists 6 of them, moving from most to least effective.

1. Forcing functions: for example, interlocks, removal of defective equipment, pre-programmed tolerance limits.
2. Automation and computerisation: for example, electronic transfer of data between systems.

3. Simplification and standardisation: for example, standardised treatment techniques and prescription protocols.
4. Reminders, checklists and independent checks.
5. Rules and policies: for example, policy for maximum verification images before further justification required.
6. Education and training: for example, education sessions on frequently reported RTE and safety actions.

2.5 Opportunities to advance safety practice

2.5.1 Document management system

In safety critical complex organisations such as radiotherapy services we need documented procedures to guide practice. It is imperative that access to the QMS is available where workers are operating. The QMS should be appropriately resourced to maintain pace with practice. In the absence of these basic requirements the QMS will be limited in efficacy.

Quality management certification is a snapshot of a system in time but cannot account for practices that adapt around new technology, particularly if the technology is revised and amended in response to practical experience (17). Therefore, quality assessment needs to be used to drive regular review and continual quality improvement, assessing if appropriate processes are in place to facilitate the safe implementation and evaluation of new or evolving services or techniques.

2.5.2 Risk management

Individuals should remain vigilant to the risk of error. Ongoing consideration should be given to the evaluation and mitigation of risk to prevent harm to patients. Radiotherapy providers should horizon scan and be prepared for future risks or emergency situations. These should be considered as part of:

- business continuity plans which consider how an entire or part of a pathway might fail
- workforce planning in accordance with professional guidance, and reflective of patient safety requirements
- capital equipment replacement planning in conjunction with the multi-professional team and commissioners

Procedures and processes should be in place to affect continual review and improvement in patient safety. Due consideration should be given to the introduction of new techniques and technologies as part of this process. Opportunities should also be taken to learn from ‘better practice’ where things have gone right, not simply reacting when things have gone wrong. Subsequent learning is used to inform improvements and mitigate the risk of recurrence.

Recommendation

Providers should be proactive in managing risk, learning from where things have gone right, not simply reacting when things have gone wrong. Procedures and processes should affect continual review and improvement in patient safety.

2.5.3 Effective change management

Providers should have a change management policy and documented procedures for the commissioning of new equipment or software, and the implementation of new procedures or techniques.

A new technology may change the tasks it is designed to support and replace, thus creating new pathways, capabilities, and complexities. For example, clinicians and planning staff should be mindful that auto-contouring and manual delineation errors are different in nature and both require systematic peer review (34 to 36). Therefore, providers must ensure sufficient training, quality assurance, and performance monitoring of new technologies is established to ensure that the systems are safe and effective.

A full exploration of organisational change management is beyond the scope of this chapter, as it represents a mature discipline with a substantial body of work already available (17, 37 to 40). To more effectively manage change consider the following key principles:

- change takes place more effectively when worked at 3 levels: organisational, team, and individual
- change is adopted by connecting individual beliefs to organisational results
- change requires a planned and disciplined implementation cascade
- change is accelerated by equipping leaders to lead through the transition
- change implementation calls for frequent and ongoing communication and collaboration
- the impact of change requires proactive assessment and risk management.

2.5.4 Performance variability

Systems are not flawless, and procedures can not specify all circumstances to which they apply or cover all eventualities. Therefore, safe care can be optimised where people learn to identify design and functional weakness and adapt their performance in response to demands or changing environments. When procedures are used, people can interpret and apply them to match the conditions. Healthcare staff are inherently resilient, anticipating potential issues and correcting when something fails or when it is about to go wrong (41).

This process describes work actually done (daily practice, (WAD)) rather than work as imagined (written rules and guidelines, (WAI)). Work systems are usually reliable but are so because people are flexible and able to adapt rather than because the system is perfectly designed (42). People adjust their performance for 3 main reasons (42):

- to maintain or create conditions that are necessary for them to do their work
- to compensate for something that is missing
- to avoid future problems

Organisations should monitor and understand the reasons for the gap between procedures (WAI) and practice (WAD) via continual quality improvement initiatives such as audits and inspections as well as radiotherapy event learning systems. The functional resonance analysis method (FRAM) may also be used for safety analyses to examine the variability in a range of the system's functions (43).

Key recommendation

Continual quality improvement initiatives and radiotherapy event learning systems should be used to examine Work As Done and identify areas for improvement.

2.5.5 Resilience education

All the above bring a focus on safety and risk management to one of building resilience. Resilience is an ability to anticipate, absorb, recover, and adapt to changes and disruptions that fall inside and outside what the system is designed or trained to handle (44). It is about identifying and enhancing the capacity of individuals and organisations and supporting them to safely adapt in varying circumstances.
There are limits on the ability to prepare individuals in detail for operational problems that may be encountered. Ongoing training and competency review should include areas such as communication, coordination, problem-solving and management of unanticipated and rapidly escalating situations to enhance resilience.

2.6 Summary

This chapter explores the relationship between quality, safety and governance. It promotes the application of systems thinking in response to radiotherapy events and safety management systems as part of quality management systems. It defines safety actions in radiotherapy and acknowledges the key challenges in advancing safety.

Chapter 3. Overview of radiotherapy event learning systems

The previous chapters have described methods to develop safer cultures and further advance quality and safety in radiotherapy practice. Reporting, analysing, and learning from events, including good catches, is a fundamental component of safe practice, acting as a positive feedback loop to continuously improve care (45). This chapter will provide an overview of local, national, and international event learning systems (ELS). It explores methods to optimise their application and considers some examples from the UK national radiotherapy ELS (46).

3.1 International event learning systems

There are several international event learning systems which provide resources to support learning from radiotherapy events (RTE). These can be used to inform local learning, for example, as part of process review and proactive risk assessments, and in consideration of safety actions following an RTE. Table 3.1 provides an overview of key international resources.

Table 3.1. Overview of international event learning systems

ELS	Overview
Autorité de Sûreté Nucléaire et de Radioprotection (ASNR)	ASNR is the independent administrative authority responsible for regulating civil nuclear activities in France. They produce in depth cases studies of incidents with appropriate mitigations identified
Radiation Oncology Incident Learning System (RO-ILS)	RO-ILS is a comprehensive system for documenting, tracking, analysing, and trending patient safety related incidents in radiation oncology
Radiation Oncology Safety Education and Information System (ROSEIS)	ROSEIS is a voluntary web-based platform designed as a reporting, educational and learning tool, and a platform to share information with the wider radiotherapy community
Safety in Radiation Oncology (SAFRON)	SAFRON is an integrated voluntary reporting and learning system for radiotherapy and radionuclide therapy incidents and near misses. Hosted by the IAEA, its aim is to improve the safe planning and delivery of radiotherapy by sharing safety related events and analysis from around the world.

When accessing these resources, it is important to consider the differences in service provision, professional roles and responsibilities internationally. It may not always be possible to make direct comparisons with data obtained in the UK.

3.2 Mandatory and voluntary reporting

3.2.1 Mandatory reporting

UK Law, the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (47 to 48) requires a system for analysis, recording and notifying actual or potential accidental and unintended exposures, proportionate to the associated risks. This requirement is met through effective local ELS. IR(ME)R also requires 'significant' accidental and unintended exposures to be notified to the relevant enforcing authority (49 to 52). Anonymised synopses of closed notifications are shared by enforcing authorities with UKHSA for inclusion in the national ELS and shared learning (3 to 4, 53). Information on IR(ME)R incident investigation requirements may be found in Chapter 4.

3.2.2 Voluntary reporting

RTEs are voluntarily reported by UK radiotherapy providers to UKHSA. The anonymised reports include coding of RTEs using nationally agreed definitions and taxonomies (2) to allow effective categorisation, analysis, and identification of trends. RTE analysis is published regularly, with a supporting E-bulletin containing key safety messages to promote learning nationally, highlight trends and propose improvement actions (3 to 4, 53).

The national radiotherapy ELS, introduced in 2008, is well integrated into the UK radiotherapy community and has become an established learning resource (46). All UK NHS providers have contributed to the national radiotherapy ELS and providers in the independent sector regularly submit reports to the national system. Monthly submissions are recommended to ensure timely inclusion of data and to support contemporary learning (3). The effectiveness of the ELS is dependent on collective participation of all radiotherapy providers submitting timely high-quality reports.

Recommendation

All classification levels of coded RTE should be reported both locally and nationally to facilitate timely learning from these events.

3.3 Local event learning systems

A 2024 survey indicated there is variation across radiotherapy providers as to how RTEs are collated, analysed, and shared (4). Whilst the majority use specialist electronic ELS, some respondents maintain local paper systems in addition to the provider's risk management ELS.

Reporting systems need to be accessible to all staff, with an intuitive interface containing mandatory fields for critical data. Transition to a single, fully electronic reporting system may

reduce duplication of effort and enhance accessibility, report escalation, monitoring of actions, feedback mechanisms, and multi-disciplinary involvement.

Management support in resourcing ELS expertise and infrastructure is strongly encouraged. Similarly, employing dedicated radiotherapy specialists to process and manage reported radiotherapy events at local level is recommended (3). This allows rapid, efficient, effective collation and assessment of RTE whilst also contributing data and insight into national trends, current issues and challenges facing clinical teams.

An open reporting culture, as described in Chapter 1, promotes a positive safety culture. It is fundamental that providers encourage the reporting and analysis of all RTE locally and nationally, including good catches and non-conformities. The more complete the data set the better the picture of potential vulnerabilities within departmental processes.

When radiotherapy specific configuration of an ELS is possible, consideration should be made both of local requirements and those at a national level, such as Learn from Patient Safety Events (LFPSE) in NHS England, and Once for Wales (OfW) for NHS Wales. Staff should be trained in the use of the system, data entry requirements and report escalation. Adapted from General guidelines on risk management in external beam radiotherapy (45), the following are principles considered fundamental in encouraging reporting:

1. Active support of leadership
2. Respect the reporter – avoid blame policy
3. Easy access and location of ELS
4. Educate on safety and use of local ELS
5. Confidential systems
6. Simplicity
7. Locally established minimum number of reports as a quality indicator
8. Feedback of information and lessons learnt
9. Look for solutions, not for culprits
10. Follow-up of the implementation of the corrective actions

Recommendation

Local event learning systems (ELS) should be appropriately supported and resourced by senior management. Single electronic solutions should be adopted to encourage efficiencies when reporting and learning from RTE.

3.4 Local approach to RTE data analysis

Timely local RTE analysis can produce actionable results by identifying trends and opportunities for changes in practice. Data analysis tools can range from in-house solutions, through third-

party vendor quality management systems to freely available software such as NHS England's improvement tools which utilise Microsoft Excel (54).

Recommendation

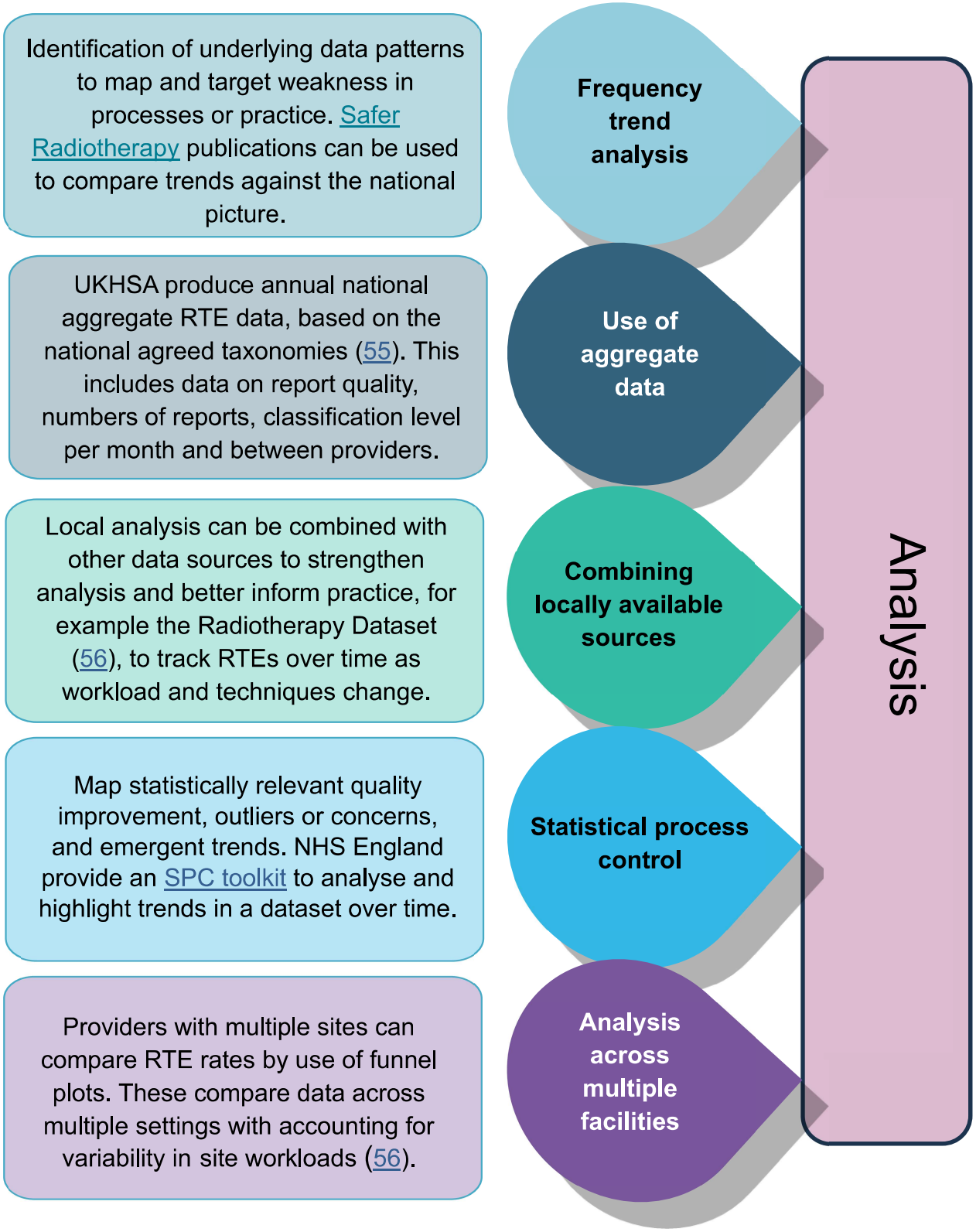
Timely reporting and analysis of RTE data at a local level is needed to inform practice and produce actionable results.

Retrospective analysis of RTEs is vital to improving safety actions. Data analysis should be capable of identifying key contributory factors and inform the development of appropriate safety actions to address defined areas for improvement. Figure 3.1 summarises some of the analytic approaches that departments may consider adopting.

When performing data analysis, it is important to have high confidence in the quality of the source data – for example, if a local procedure is to peer review and confirm RTE taxonomy coding before closing RTE stages, then data analysis should only include RTEs which have been peer reviewed and closed. If this is not practical it is important to highlight any potential limitations to the data integrity and revisit trends periodically to ensure any amendments are captured.

When analysing data, the narrative of the learning outcome should be considered and who the target audience and key stakeholders are. Providers should consider producing reports for local monthly RTE meetings and quarterly executive board meetings.

Figure 3.1. Different approaches to local RTE data analysis



Text version of Figure 3.1. Different approaches to local RTE data analysis

This graphic outlines the 5 main approaches of RTE data analysis:

1. Frequency trend analysis: identification of underlying data patterns to map and target weakness in processes or practice. Safer Radiotherapy publications can be used to compare trends against the national picture.
2. Use of aggregate data: UKHSA produce annual national aggregate RTE data. This includes taxonomic data on report quality, numbers of reports, classification level per month and between providers.
3. Combining locally available sources: local analysis can be combined with other data sources to strengthen analysis and better inform practice, for example the Radiotherapy Dataset (56), to track RTEs over time as workload and techniques change.
4. Statistical process control: maps statistically relevant quality improvement, outliers or concerns, and emergent trends. NHS England provide an SPC toolkit to analyse and highlight trends in a dataset over time.
5. Analysis across multiple facilities: providers with multiple sites can compare RTE rates by use of funnel plots. These compare data across multiple settings with accounting for variability in site workloads (56).

Most commercial ELS include data analytics to support learning outcomes. Where this function is not offered, data can be exported to Microsoft Excel, which is widely available, familiar to many users, and can produce tables, graphs, and trend charts to allow ease of data comparison across different systems of work and departments. Table 3.3 outlines several applications of RTE data to inform practice.

Table 3.2. Departmental applications of RTE data

Application	Rationale
Response to a single event	The investigation of a specific RTE can be strengthened by analysis of similarly coded RTEs to establish common themes and to avoid identified actions being of limited scope or benefit.
Audit and review of current practice	Coded and electronically recorded RTE allow for thematic analysis and targeting of audits. Frequency and level of RTE can indicate potential areas for improvement. Local data can also be reviewed against national data for comparison.
Prospective risk assessment and study of risk	Risk assessments can be informed by RTE thematic analysis, and by direct comparison between predictive and experienced RTEs to determine the efficacy of implemented safety actions. RTE data, particularly for formally investigated events, can inform a study of risk of accidental and unintended exposure as required by IR(ME)R. Following a notable event, the study of risk should be reviewed to ensure the type of event investigated is included.

Application	Rationale
To drive business plans and inform programmes of work	RTE data may identify equipment or systems at a greater risk of faults or breakdown. Analysis may also identify issues with specific processes, staffing levels, as well as with training and information gaps.
As an educational tool and to recognise good practice	Shared learning maximises the impact of RTE reporting and wider dissemination to front line teams is critical. Key messages and themes should be summarised. Examples where RTE are avoided or minimised due to staff action or process design should be highlighted.
To inform quality improvement frameworks and tools	RTE analysis can inform the quality improvement process. Care should be taken to avoid conflating reduced reporting as an improvement in quality as a high volume of low level RTE reporting can be indicative of a healthy safety culture.

3.5 National approach to RTE analysis

The national radiotherapy database, like all ELS, is a reactive reporting system which collates RTE that have already occurred and impacted on patient safety. This retrospective analysis promotes continual improvement by disseminating learning in the UK radiotherapy community.

Developing a successful national proactive systems-based approach is desirable, but also complex and challenging. To be effective this requires a consensus-building, coordinated approach. Of fundamental importance is that providers submit reports with taxonomy coding that fully describes commissions and omissions related to an event as it traversed the radiotherapy pathway, rather than simply where the RTE was detected or initially arose. In addition, the wider context of the event should be considered and fully mapped using the contributory factors taxonomy. This allows development of more refined analytical methods, for example heatmap visualisations that use visual data analytics to examine patterns of activity along RTE pathways.

Recommendation

To develop greater understanding of the systemic nature of radiotherapy events at a national level it is recommended that providers use taxonomy coding to fully describe the entire event pathway, including all contributory factors, when submitting reports to the national ELS.

3.6 Analysis at a local, regional, national, and international level

Analysis of RTE data should include review of local trends and comparison to available regional and national data. There are many routes for sharing and discussing this information at local, regional, and national levels. Figure 3.2 highlights some examples of good practice at each level.

Existing regional collaboration, such as Integrated Care Boards (ICB) and Radiotherapy Operational Delivery Networks (ODN), established in England, can facilitate sharing and comparison of analysis to support regional learning from RTE and the exchange of ideas for evidence-based practice (58). Increased, consistent cooperation will not be facilitated unless existing barriers are removed, examples of which are highlighted in a recent survey on radiotherapy clinical trials collaboration (59). Smaller group comparison studies can provide more nuanced learning as greater detail in the processes followed at individual centres can be explored.

Recommendation

Greater regional collaboration, fostered with the aim to support learning from RTE and the exchange of ideas for evidence-based practice, should be encouraged.

Nationally, learning from RTE uploaded to the ELS is shared widely by UKHSA through regular publications (3 to 4, 53), whilst engagement with international resources, as detailed at the beginning of this chapter, provides an opportunity to consider international practice and gain insight into how other countries approach patient safety.

Text version of Figure 3.2. Examples of dissemination of learning from RTE (below)

This graphic details examples of dissemination of learning from RTE. Dissemination of learning is fundamental for patient safety. The examples can be divided under 3 headings:

1. Local

- daily team huddles, weekly team brief, monthly bulletins
- monthly and quarterly RTE reports
- MDT information gathering, sharing, investigation
- quality, governance, risk, radiation protection meetings
- reflective learning, incident workshops

2. Regional

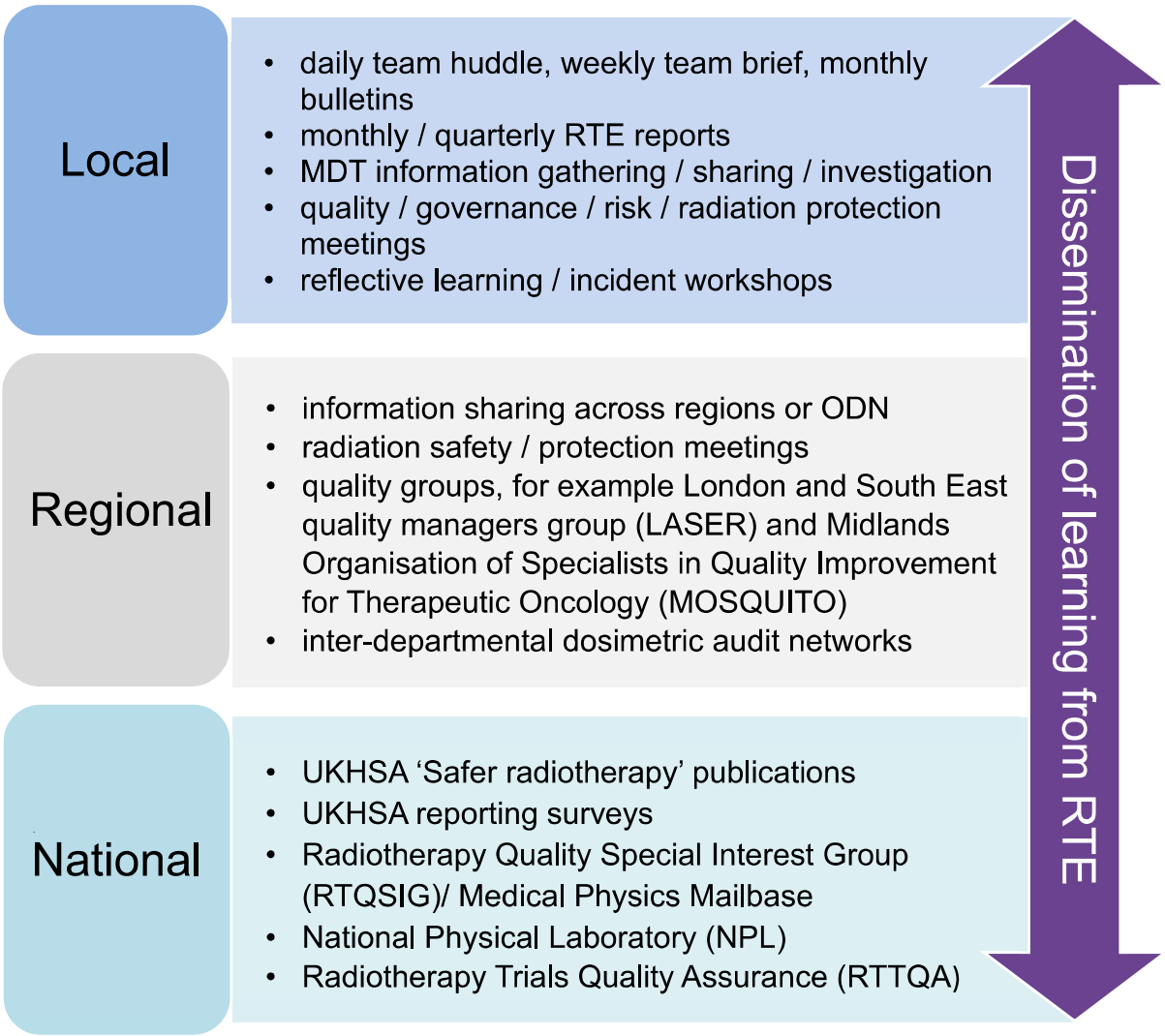
- information sharing across regions or ODN

- radiation safety or protection meetings
- quality groups, for example, London and South East Quality Managers Group (LASER) and Midlands Organisation of Specialists in Quality Improvement for Therapeutic Oncology (MOSQUITO)
- inter-departmental Dosimetry Audit Networks

3. National

- UKHSA Safer Radiotherapy publications
- UKHSA reporting surveys
- Radiotherapy Quality Special Interest Group (RTQSIG)/ Medical Physics Mailbase
- National Physical Laboratory (NPL)
- Radiotherapy Trials Quality Assurance (RTTQA)

Figure 3.2. Examples of dissemination of learning from RTE



3.7 Key learning points from the national RT ELS

Providers are encouraged to share the Safer Radiotherapy publications (3 to 4, 53) with staff at all levels within their service to incorporate learning from a national level into local practice.

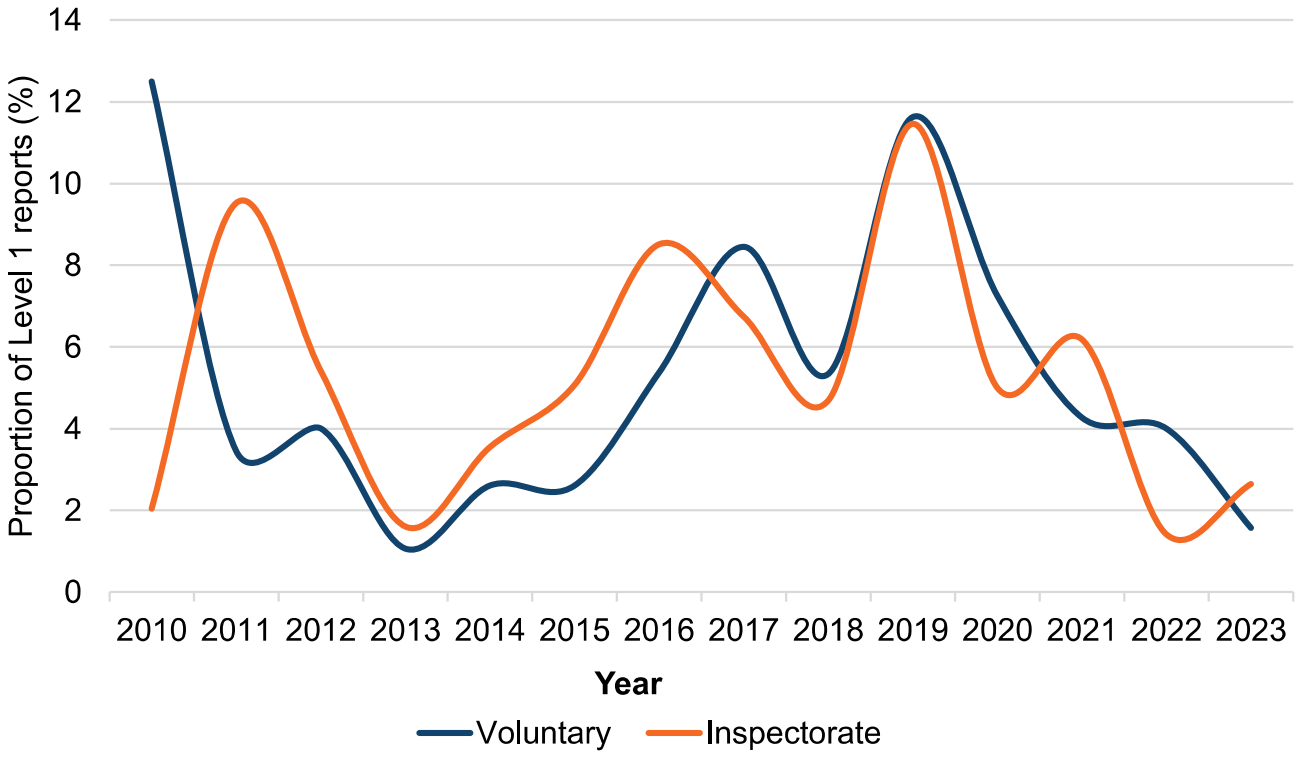
Although RTE reporting rates are broadly stable, as evidenced in the Safer Radiotherapy publication series, trends have changed over time, reflecting how risk has been identified and managed in some areas whilst newly emerging in others.

Establishing that an intervention has directly influenced an RTE trend is challenging. However, there are examples where an emergent growing trend was identified, feedback was disseminated to providers, and subsequently a reduction in report volume was demonstrated a seen in 3.7.1.

3.7.1 'Verification of diagnosis/extent/stage'

Figure 3.3 displays a line chart detailing the proportion of voluntary and inspectorate Level 1 reporting of primary pathway subcode 'verification of diagnosis/extent/stage'. In 2019 an increase of Level 1 RTE included 'verification of diagnosis/extent/stage' as the primary pathway subcode. It appeared to be an increasing trend, with 2018 an outlier. In response, the June 2020 'Safer Radiotherapy: triannual error analysis and learning report' contained a case study on 'verification of diagnosis/extent/stage' with recommended corrective actions to mitigate occurrences and examples of learning from excellence (4).

Figure 3.3. Proportion of Level 1 RTE with primary pathway subcode 'verification of diagnosis/extent/stage'



Voluntary and inspectorate RTE data for the following years demonstrated a notable reduction in both the volume of reports and the proportion contributing to Level 1 RTE. Whilst a correlation between the publication of advice and a subsequent reduction in RTE volume should be welcomed as possible evidence that local radiotherapy services are incorporating learning from national level into local practice, causation cannot be assumed. Future UKHSA UK radiotherapy surveys may seek to determine whether proposed corrective actions published are routinely adopted or undertaken by providers.

3.7.2 Transcription errors

Towards safer radiotherapy identified incorrect manual transcription as an area of vulnerable practice and recommended that data should be transferred electronically to improve patient safety (1). Pathway subcodes involving transcription failures remain some of the most frequently cited in the most recent UKHSA biennial report (3) and internationally (60 to 63).

Often the cause of transcription events is determined to be human error. These events should be considered a symptom of a system problem and the wider contributory factors considered. Organisations must focus on systemic review and redesign. For example, resources should be concentrated on improving the multistep workflow between planning to treatment delivery to reduce manual data transfer. In addition, many aspects of traditional processes are now subject to automation. It is anticipated that opportunities to further eliminate manual data transfer and develop automated processes will increase, supported by reliable and robust quality assurance tools (64 to 65).

3.7.3 Image guided radiotherapy (IGRT)

Image guidance is a fully integrated, indispensable tool in radiotherapy treatment workflows. On-treatment imaging consistently generates the largest proportion of RTE within nationally reported data. Combined reports relating to on-set imaging made up 22.6% (n = 5,006) of all RTE in the most recent 2-year reporting period (January 2022 to December 2023), broadly similar in proportion to the previous 2-year period (January 2021 to December 2022) where onset imaging constituted 23.7% (n = 4,425) of RTE (3).

The high incidence of on-set imaging associated RTE reflects the high volume of imaging taking place. Furthermore, IGRT has been a key driver in developing more advanced radiotherapy delivery, particularly in ultra hypofractionation treatments, whilst the development of a variety of high quality, fast acquiring imaging methods, has proven a key driver facilitating the introduction of online adaptive platforms (66).

Whilst these developments generate much promise in reducing toxicity and improving local control for many disease sites, they are often characterised by increasingly complex modern image guidance workflows. Consequently, contemporary IGRT continues to depend on skilled interpretation and decision-making during image acquisition and review. Comparatively high volumes of on-set image related RTE can be viewed as a result of those human and technological interactions within a complex system.

Mitigating the impact of human actions should include methods of creating more robust systems within the imaging workflow. For example, audit and review of relevant protocols, training and workflows to ensure they are clearly defined and easily understood. Protocols should outline scope of practice, imaging frequency and thresholds for escalation. Complex techniques, such as stereotactic ablative radiotherapy (SABR), and treatment areas vulnerable to misregistration, such as spine and oesophagus, should have sufficient, locally agreed safeguards in place. In addition, protocols should detail optimised site specific imaging pre-sets. It is also recommended that specific protocols should be in place using faster, lower dose pre-sets for paediatric patients. Departmental imaging audits should be considered to monitor image quality and to ensure image analysis remains at an acceptable standard (67).

3.7.4 Ensuring correct patient set up

The radiotherapy community continually strives for improvements in treatment, with new techniques driven by innovative technological advances. Patient positioning continues to remain a fundamentally important area of practice. A notable Level 1 RTE trend is the increase in proportion of pathway code ‘patient positioning’ from 3.6% during 2020 to 2021 data analysis to 10.9% for the most recent 2022 to 2023 2-year analysis, making it the second most frequently reported Level 1 RTE (3).

Many of these RTE appear to originate from immobilisation selection, placement or misinterpretation of documented patient set up information. The following mitigations are recommended:

- retain the original source data for patient setup for reference
- have one agreed source of information to which operators should refer when setting up a patient
- agree consistency of immobilisation for treatment techniques and for standard nomenclature to be used to document set up information
- ensure the IR(ME)R responsibilities are clear and auditable
- consider use of visual aids such as photographs and skin rendered images
- where possible, employ surface guided monitoring systems to mitigate patient positioning errors

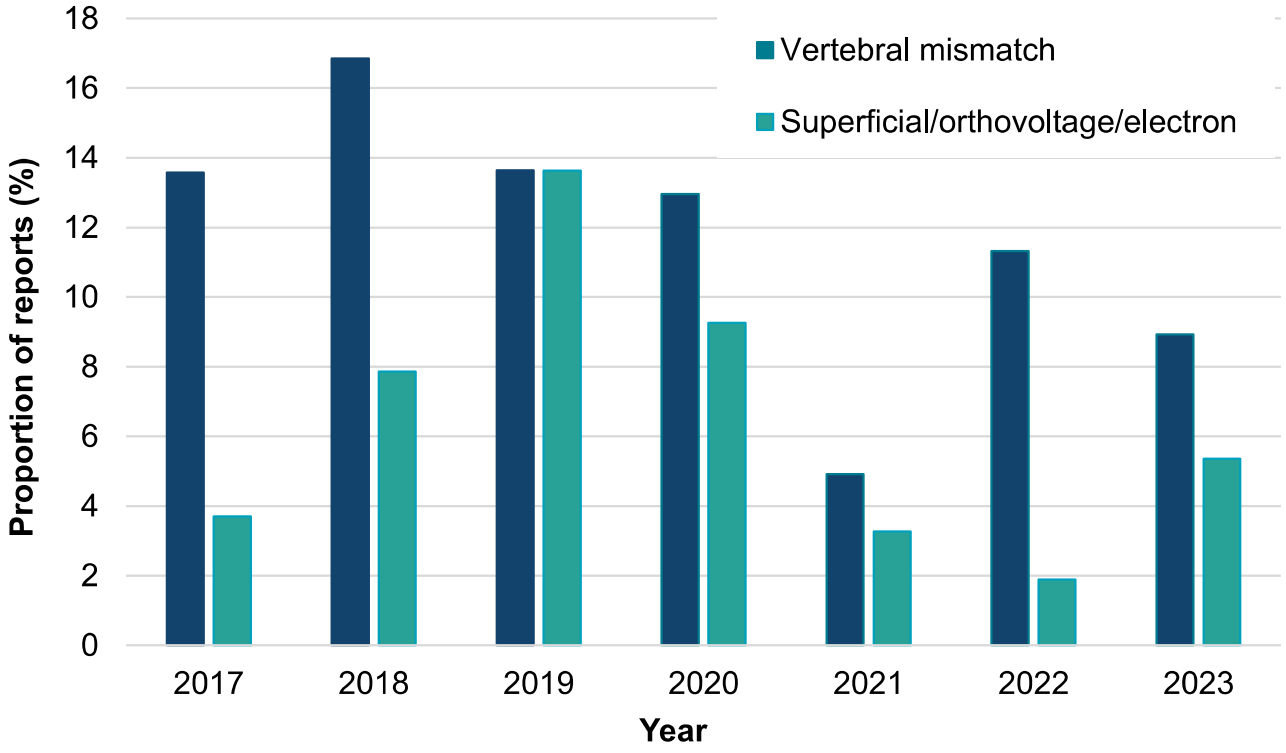
A range of risk factors should be considered when developing a local protocol for correct patient set up, to include patient comfort, confirmation of laterality and processes to ensure gantry and imager clearance.

3.7.5 Risks associated with simple radiotherapy techniques

Analysis of level 1 RTE data that occurred between April 2017 to December 2023 reported to IR(ME)R inspectorates (3) highlights that some established, traditional techniques continue to contribute a notable proportion of total notifiable events despite becoming less commonly practiced (56). Figure 3.4 demonstrates the proportion of total reportable events relating to 2 established processes within radiotherapy treatment:

- vertebral mismatches, generally for simple spinal or thoracic treatments
- RTE occurring during superficial, orthovoltage and electron treatments combined

Figure 3.4. Proportion of inspectorate Level 1 RTE for imaging involving vertebral mismatches and for superficial/orthovoltage and electron treatments



With continued radiotherapy development, older, simpler techniques may be less frequently employed, leading to less familiarity with the practices involved. Less experience and knowledge have been correlated to more frequent deviations outside of protocol within healthcare (68) and therefore may result in a higher potential risk of RTE due to an inability to maintain competence and confidence. Peaks in RTE reporting activity have been linked to occasions where new or inexperienced staff were operating in pretreatment and data entry areas (53).

For departments with dedicated machines practicing these techniques regular rotation of staff should be considered. Providers should aim to assess staff competency for rarer techniques on a regular basis. If staffing and logistics permit providers should facilitate periodic familiarisation of these simpler techniques through completion of workshops or supervision sessions to allow staff to maintain skills and confidence.

3.8 Summary

Developing a local reporting system that integrates a well-designed, easily accessed electronic ELS to identify, report and investigate RTE can allow for effective, meaningful learning from radiotherapy events, thereby driving forward patient safety and service improvements.

It is strongly encouraged for all radiotherapy providers in both public and private sectors to employ a standardised approach, embracing the elements detailed in this chapter to optimise patient safety. Local analysis is valuable in discerning departmental trends and meeting legislative requirements. However, the commitment to voluntarily report to national ELS allows characterisation of a national view of RTE trends to further inform local practice and to better understand potential emerging threats that may imperil safety of care for all radiotherapy patients.

Chapter 4. Overview of radiotherapy event (RTE) response

The previous chapter provided an overview of event learning systems used in radiotherapy and methods to optimise their application. This chapter considers the core principles and requirements for an effective RTE response. Contemporary approaches to patient safety and language used when describing an RTE response are used to reflect a move from linear root cause analysis to a wider system-based approach with continual learning and improvement.

Some patient safety events within radiotherapy may fall outside the scope of this chapter, for example slips, trips and falls, and may therefore require a separate response.

4.1 RTE response

The fundamental role of an RTE response is to maximise potential learning from each event, which in turn may be used to inform improvements and mitigate the risk of recurrence. An RTE response encompasses all types of activities which may be taken including an individual investigation or a thematic analysis of past RTE. The breadth and depth of any response is dependent on many factors including radiological risk, available resources and output requirements, whether local, regional, national, or regulatory.

An effective RTE response requires:

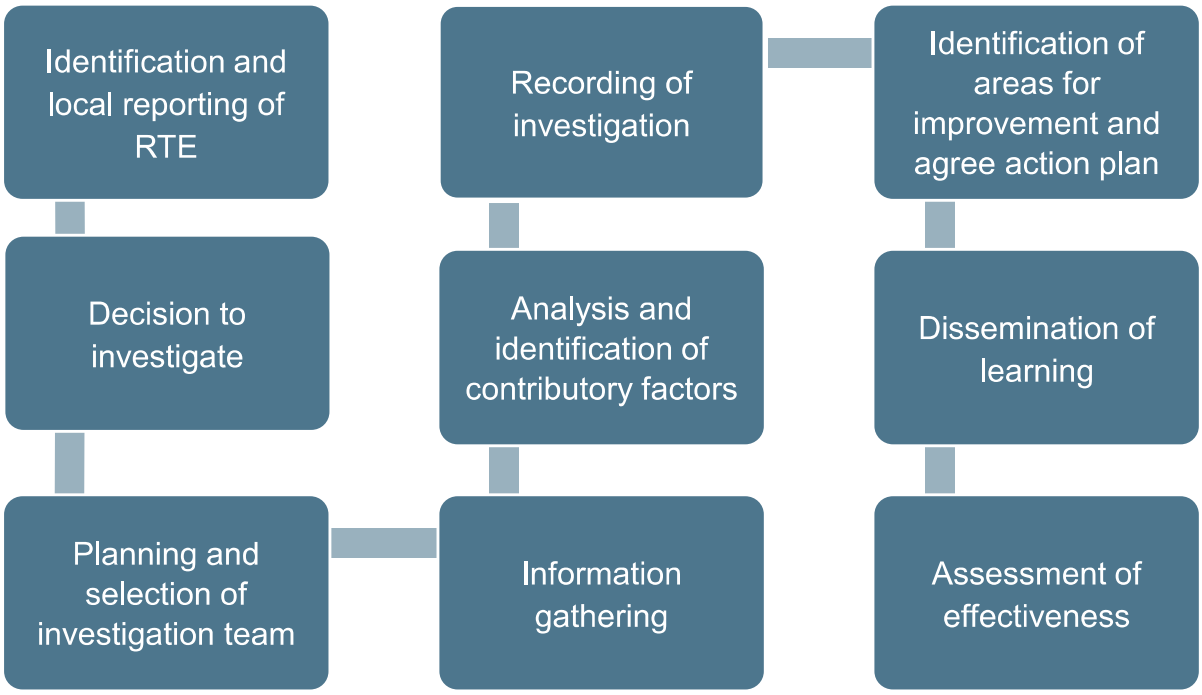
- robust supporting written procedures available to all staff, for example the local patient safety event response policy or RTE reporting procedure – this should include:
    - the requirement for reported RTE to be triaged in a timely manner to ensure appropriate management of risk and allocation of resources
    - potential RTE response pathways
    - applicable investigation methodologies
- all staff receiving appropriate local response training, according to their roles
- an interdisciplinary approach and focus on the assessment and improvement of local processes and systems – where there are concerns with individual performance this should be considered separately via appropriate routes
- patient and staff affected by RTE to be provided with timely communication and appropriate support (69)
- standardised reporting and response templates be available to staff (see Appendix 2)
- all staff should be aware of their role and responsibilities in accordance with:
    - local RTE reporting procedure or patient safety event response policy
    - IR(ME)R (47 to 48)
    - General Data Protection Regulations 2016 (70)
    - duty of candour requirements
    - relevant code of professional conduct

Recommendation

All staff should be appropriately trained and have access to supporting documentation to ensure RTE are identified, correctly reported and an appropriate response actioned.

Following the reporting of an RTE, a suitable response should be actioned. The response framework should consider the key stages, summarised in Figure 4.1.

Figure 4.1. Key stages to RTE response framework



Text version of Figure 4.1. Key stages to RTE response framework

This graphic details the radiotherapy event response which consists of 9 key stages:

1. Identification and local reporting of RTE.
2. Decision to investigate.
3. Planning and selection of investigation team.
4. Recording of investigation.
5. Analysis and identification of contributory factors.
6. Recording of investigation.
7. Identification of areas for improvement and agree action plan.
8. Dissemination of learning.
9. Assessment of effectiveness

The process starts with identification and reporting of the event followed by a decision to investigate. An investigation team should be selected and information gathered. Analysis of relevant information should be summarised in order to identify areas for improvement and an action plan. Dissemination of learning and assessment of desired outcomes should follow.

4.1.1 Identification and local reporting of RTE

All staff should be appropriately trained and supported to identify and report RTE locally.

4.1.2 Decision to investigate

All levels of RTE (Level 1 to 5 RTE) (2) should be locally reported and actioned in accordance with local procedures. The local procedure should include detail on how:

- each report is reviewed and themes identified where relevant
- appropriate remedial measures are taken
- a proportionate response is actioned in a timely manner

RTE response activity may include investigation of an individual event, or a thematic analysis of past RTE responses to inform the development of an action plan or safety improvement plan (71).

Local procedures may include several response pathways and investigation methodologies, commensurate with the risk associated with the RTE, or the frequency of occurrence. For example, section 4.2 details that all reportable radiation incidents (Level 1 RTE) will require a detailed investigation, with pre-defined regulatory output requirements and external notification criteria in accordance with significant accidental or unintended exposure (SAUE) guidance (49 to 52). The response, however, to a non-conformance (Level 5 RTE) may involve a focused, thematic analysis of past events to assess the effectiveness of current safety actions and inform the development of a local action plan.

4.1.3 Planning and selection of investigation team

An investigation can be a challenging process as such, it is important that:

- the roles of the investigation team and their responsibilities are clear
- the team includes individuals with a diverse range of skills and clinical expertise, which are crucial to provide a variety of perspectives and insight
- the team includes individuals who are suitably trained and competent to carry out an effective investigation

The requirements listed in Table 4.1 below should be considered when selecting individuals as part of an investigation team.

Table 4.1. Considerations when selecting individuals as part of an investigation team

Requirement	Rationale
Ability to understand context	Essential for understanding why decision and action were taken at the time of the event and provide a richer learning and improvement opportunity from work as done (WAD).

Requirement	Rationale
Appropriate training and expertise	The team should include individuals who: • are trained and competent to undertake systems-focused patient safety incident investigations, for example in accordance with patient safety incident response standards (72) • have knowledge of relevant legislative requirements • understand the radiological risk involved with RTE • have a knowledge of the national patient safety RTE taxonomy and learning system • where relevant, have a knowledge of clinical trials or research where standard procedural practices are not followed
Interdisciplinary approach	Ensures the team includes individuals with appropriate clinical knowledge and understanding, as well as helping empower and support colleagues and reinforces that the investigation is for the benefit of all.
Medical Physics Expert (MPE) involvement	IR(ME)R (47 to 48) requires the involvement of an MPE for radiation incident analysis (Regulation 14(3)(f)).
Patient engagement	As patients are at the centre of the radiotherapy pathway they should be compassionately and meaningfully engaged, including, where appropriate, involvement in investigations (73). Chapter 5 expands on patient engagement in safety.

If the initial event response or preliminary investigations highlight significant risks, investigation teams should immediately introduce actions to eliminate those risks to safeguard patient safety.

Recommendation

The investigation team should adopt an interdisciplinary approach with clear roles and responsibilities. The team should include individuals with clinical expertise as well as individuals who are trained and competent to carry out an effective systems-focused investigation.

4.1.4 Information gathering

Radiotherapy providers should ensure their investigation approach is documented and unambiguous. The overall objective is to gather meaningful information and insights surrounding the context of what happened which can subsequently be used to inform and prioritise safety actions. The information should be gathered as soon as possible after the event, remain factual and avoid bias. Information gathering can be in the form of interviews,

observations, walk throughs and reviews of related documentation. An essential part of the investigation is the engagement of others after the event. In such a potentially emotive area, compassion, understanding and empathy is required by those in the investigation team (74). Providers should ensure there are systems and processes in place to support meaningful engagement with those affected by RTE, where they wish to be involved (74).

Following collation of important information, timeline mapping can prove useful for building a narrative. There are a number of incident response or investigation frameworks available to providers; some examples are highlighted within section 4.3.

4.1.5 Analysis and identification of contributory factors

RTE may arise from multiple, interacting components of the radiotherapy system. The investigation should therefore adopt a system-based approach, which considers the processes, systems and interactions between the elements, rather than a root cause or linear causal analysis (6).

Analysis of the information gathered may allow the identification of multiple contributory factors and areas for improvement within the corresponding processes or systems. Approaches such as SEIPS (75), discussed in Chapter 2 should be considered. MDT review may also support the identification of contributory factors and system gaps to facilitate learning from incidents (76).

When undertaking an investigation, it is important to consider key stakeholders. AcciMap is a generic, flexible, systems-based tool for retrospective event analysis (77 to 79) that can support identification of stakeholders. It is designed to visually represent the interrelationships of contributory factors across an entire complex organisational system (79). By doing so it can remove apportioning of blame to individuals and promote the development of system-focused countermeasures. This stakeholder map can be used to inform patient safety event investigation and to support the consideration of the wider context of an event, the relationships between stakeholders and how they may have influenced an incident. Appendix 1 provides an example of an AcciMap demonstrating the relationships between different elements of the radiotherapy system.

Thematic areas identified from RTE analysis should be used to inform prospective risk assessments, as part of a study of risk of accidental and unintended exposures as required under IR(ME)R. This process will support service improvements and patient safety.

4.1.6 Record of investigation

A summary of the analysis should clearly outline findings from the investigation. An investigation template is recommended to guide a standardised process of reporting what happened, how and why it happened and whether there are learning points for the service, the wider organisation, or nationally. The investigation report, including relevant learning, should be timely and easily accessible for all relevant staff. The report should be written in neutral language,

avoiding the apportioning of blame, maintaining a 'systems' approach to safety. Considerations for inclusion in the investigation template can be seen in Appendix 2.

4.1.7 Identification of areas for improvement and action plan

Following an RTE response, it is essential that areas for improvement are agreed, an action plan is developed, and appropriate action is taken. Action plans should clearly identify actions to address areas for improvement, system issues or areas to reduce risk. To assist in the development and implementation of the action plan, each action recorded should be Specific, Measurable, Achievable, Relevant and Timely (SMART) (80). The action plan may also include tasks to investigate if similar, previous RTE have occurred, for example via retrospective audit. Appendix 2 contains considerations for inclusion in an action plan.

Recommendation

Following an RTE response appropriate action must be taken. This should include the development and implementation of an action plan to address areas for improvement, system issues or areas to reduce risk.

In collaboration with staff, a range of actions should be considered to ensure the most effective are put in place. There are a number of system-based tools available which may prompt ideas in regard to addressing areas for improvement, such as the SEIPS adaptation of the Human Factors Intervention Matrix (HFIX) (32), or how to prioritise actions, such as the iFaces tool (81). Consideration should be given to prioritising system-based actions.

Agreed actions may require external influence or time to progress (32). The action plan should detail if the development of actions may form part of a wider safety improvement plan or quality improvement initiative.

4.1.8 Dissemination of learning

Learning from the RTE and investigation should be shared with appropriate individuals as early as possible (1). This strengthens the opportunity for the timely application of lessons learned, reducing the likelihood of RTE recurrence.

Communication frameworks and systems should be in place to support ongoing safety dialogue amongst teams. This will provide an opportunity for all staff to learn from RTE, nurturing a learning environment, and communicate improvement activities.

Outcomes from RTE responses, including individual investigations and periodical local analysis, should feed into the organisational radiation safety governance and assurance structures, to facilitate wider shared learning and promote continual improvement across the organisation.

Recommendation

Providers should ensure there are communication frameworks and systems in place to support and enable an ongoing inbuilt regular safety dialogue among teams and across the organisation.

4.1.9 Assessment of effectiveness

The effectiveness of actions taken must be monitored to ensure that the desired outcomes have been achieved, for example, through audit. If feedback is delayed it can negatively impact safety management especially if the action taken has not had the intended effect.

4.2 RTE response and investigation outcome requirements

IR(ME)R (Regulation 8(4)) (47 to 48) outlines the response requirements when it is known or thought a SAUE has occurred in radiotherapy. A comprehensive local event response and investigation procedure should include the requirements of IR(ME)R Schedule 2(1)(l) (47 to 48) as well as the requirement to notify the relevant IR(ME)R enforcing authority of a CSAUE or SAUE in accordance with the guidance (49 to 52).

NHS England requires the development of a patient safety incident response policy and plan in accordance with the Patient Safety Incident Response Framework (PSIRF). The aim of these is to support more informed decisions and to set out how responses to patient safety incidents will be carried out over a period of time. This should also include the planned responses to regulatory notifications.

4.3 Incident investigation frameworks

4.3.1 Approaches to patient safety incident investigation

There are numerous approaches available to investigate patient safety incidents. In selecting an approach consider the requirement to understand the incident, gather information, identify contributory factors and areas for improvement to develop action plans for learning and improvement. The NHS England Patient Safety Incident Investigation (PSII) outlines the key stages to an incident investigation and consideration of contributory factors. The key stages can be seen in Figure 4.1. Other examples of investigation approaches include SEIPS (75), discussed further in Chapter 2.

4.3.2 Patient Safety Incident Response Framework (PSIRF)

PSIRF (71) sets out an approach to develop and maintain effective systems and processes for responding to patient safety incidents, to enable learning and improvements in patient safety. It is not an investigation tool.

PSIRF contains 4 key aims:

- compassionate engagement and involvement of those affected by patient safety incidents
- application of a range of system-based approaches to learning from patient safety incidents
- considered and proportionate responses to patient safety incidents
- supportive oversight focused on strengthening response system functioning and improvement

PSIRF is a contractual requirement for all care provided under the NHS Standard Contract in England, but the key principles should also be considered by all radiotherapy providers. Central to PSIRF is an understanding that patient safety events do not arise from a single action, but as a result of many interacting components of the system or service. Systems thinking provides a framework for identifying multiple interacting contributory factors, facilitating responses that promote a learning, restorative, just culture approach.

Those leading patient safety incident responses (learning response leads) and those involved in the oversight of learning and improvement emerging from patient safety incident response require specific knowledge and experience. These requirements are detailed in the patient safety incident response standards (72).

4.4 Summary

The primary objective of an RTE response is to maximise potential learning from each event, which in turn may facilitate continual improvement and mitigate the risk of recurrence.

Although the requirements of each RTE response may differ depending on numerous factors, there are core principles and processes, highlighted within this chapter, which should be in place including RTE reporting, response, analysis, learning and improvement.

There are a range of resources available to support system-based event investigations, however the local methodology applied should ensure an interdisciplinary approach is adopted by trained individuals with a focus on the assessment and improvement of systems, within a positive safety culture.

Chapter 5. Engaging patients in safety

The previous chapters have explored key concepts and methods within modern radiotherapy safety culture and safe practice, and how these can facilitate continual improvement and reduce the risk of patient safety events. The following 3 chapters introduce the primary users of radiotherapy – those people most familiar with the radiotherapy pathway, the patients – and explore the considerable merits of patient engagement in all areas of practice (82).

An effective safety culture needs engagement from all key stakeholders, and a focus on patient centred care means patients should be engaged as part of any safety activity alongside the healthcare workforce. Significant value can be gained from engaging patients as partners and learning from their lived experiences (83). The term patient as used here describes anyone who receives care from the NHS and clinical services provided by the independent sector or third party.

Within the NHS constitution it is a patient's democratic right to "be involved directly or through representatives, in the planning of healthcare services commissioned by NHS bodies, the development and consideration of proposals for changes in the way those services are provided, and in decisions to be made affecting the operation of those services" (84). The involvement of patients in their care and in the development of safer services is a priority for the NHS (84). Radiotherapy providers should consider how they can meaningfully involve patients as part of their own safety governance processes (6, 85).

5.1 Definition of patient engagement

Patient engagement is a multifaceted term, which holds different meanings and connotations. Carman and colleagues define patient engagement as: "patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system-direct care, organizational design and governance, and policy making to improve health and health care" (86).

This definition highlights 4 key principles that are essential to patient engagement:

1. The term 'active', illustrates patient engagement does not just simply happen. Opportunities need to be created and processes need to be developed, without this it cannot become embedded in services or routine practice.
2. The definition refers to engagement as a partnership between patients and health professionals and like any partnership it should be built on trust and include mutual respect for all. There should be an opportunity for all parties to make an equal contribution and for each contribution to be recognised as of equal importance.
3. Patient engagement should encompass not only patients but also their caregivers.

4. The definition states patient engagement should be present across all healthcare systems including policy, design, delivery, and care. It should extend through ‘levels’ from the clinical workforce to the board of directors and should contribute to the complexities and diversity of healthcare.

These key principles are considered to be the cornerstone of all patient engagement activity and, as such, should be adopted by providers to develop their own safety frameworks. The definition is also explicit regarding the purpose and desired outcome of patient engagement, namely to “improve health and healthcare”. Radiotherapy services, workforce and patients who access services will directly benefit when patient engagement is a core component of radiation safety.

5.2 Where to engage patients in safety

There are 2 key facets of radiotherapy where patients can be engaged in matters of safety; firstly, areas that relate to their own treatment and care and, secondly, the enhancement of services for the wider benefit of others.

5.2.1 Their own treatment and care

Current practice already integrates patients in matters of safety. Conversations with patients throughout the radiotherapy process necessitate and facilitate the sharing and discussion of key information about their treatment as part of informed consent. These conversations include, but are not limited to, the risks associated with radiation exposure, radiotherapy dose and both the early and late effects.

Effective communication that enhances a patient's knowledge helps to alleviate anxieties associated with treatment (87 to 88). This sharing of patient-specific information also enhances a patient's experience of care and supports autonomy and empowerment. Improving understanding of treatment by enhancing knowledge and instilling confidence promotes compliance to the procedural elements of radiotherapy (88 to 89).

This process can be enhanced by standardising communication, particularly in relation to side effects. Although many radiotherapy providers use site specific radiotherapy consent forms, no consensus exists in terms of side-effects that are included on the form and what is discussed with patients (90). The adoption of the Royal College of Radiologists (RCR)’s radiotherapy consent forms, co-designed and approved by a specialist consortium which includes lay experts, (91) helps standardise not only what information is shared, but also the process of patient engagement in matters relating to their consent.

Recommendation

All radiotherapy providers should adopt the RCR radiotherapy consent forms.

Healthcare professionals actively encourage patients to share information; enquiring daily about the patient's wellbeing, discussing how they are finding treatment and the potential issues they may be facing. These interactions help to establish rapport and provide a narrative dialogue about their radiotherapy treatment (92). It is often during these interactions that patients may inadvertently signal an issue related to their own safety. For example, an early or unexpected treatment reaction, or the patient who comments to the therapeutic radiographer how "things felt different today", perhaps believing the bed moved in the opposite direction or the numbers sounded different. These situations provide the opportunity for providers to listen and learn from patient concerns, investigating and addressing as required. These situations need to be managed respectfully with sensitive acknowledgement. Radiotherapy providers should have a formal process for capturing patient concerns and feedback.

Although daily communication may be informal, it is routine practice across radiotherapy services and can help providers to work in partnership with patients to enhance their own safety.

Recommendation

Patients should be seen by healthcare services and professionals as equal partners in safety. Patients should be encouraged and supported to be active and vocal participants in their treatment and care. Each radiotherapy provider should have a formal process for capturing patient concerns and feedback.

5.2.2 Service enhancement for the wider benefit of others

The engagement of patients in matters of safety can not only benefit their own safety, but it can also support wider service improvement. These strategies require the development of formal schemes of engagement. At present there are differing levels of engagement across the UK. Provided below are areas where patient engagement should be encouraged:

- developing, updating, and reviewing safety protocols
- patients as representatives on safety boards and quality committees
- assessing local safety practices as part of development and annual review
- review and analysis of safety data
- supporting staff training and record keeping
- department design and practical considerations (please see Chapter 6)
- involvement in RTE reporting, response, learning and improvement
- local and organisational protocol development
- involvement in patient safety improvement projects

5.3 How to involve patients

This section addresses how patients can be involved, and considers the systems required within clinical practice and across organisational processes. Communication is central to engagement, and so the following practices should be routinely adopted.

5.3.1 Establish communication preferences

Introductions, as established by the 'Hello my name is…' campaign (93), should be the foundation on which communication practices are built. A central component of rapport building (87), they also help to break down professional hierarchies (94) and support patient engagement in safety by creating the opportunity for a 2-way dialogue (95).

Finding out how patients want to be communicated with is crucial for providing effective healthcare and ensuring patient satisfaction. Getting communication right means that patients can understand, interpret and follow treatment guidance and recommendations made, which in turn supports better outcomes. Organisations and individuals should appreciate how "the meaning of the communication is the response you get" (96) and if patient compliance is low, consider that perhaps the way in which it was communicated was not personalised or appropriate to that individual (92). Table 5.1 highlights considerations and practices to help gather this information.

Table 5.1. Overview of communication considerations and practices

Method	Overview
Initial Assessment and Documentation	When a patient first attends radiotherapy, recommended standard practice is to question and document communication preferences. This includes asking whether they prefer phone calls, emails, text messages, or in-person communication. It is important to clarify with the patient what they prefer to be called, how to pronounce their name and if they feel comfortable sharing their pronouns, these should be recorded appropriately.
Patient Surveys	Patient surveys are valuable in gathering feedback on communication preferences, either via in person, email, or through patient portals. Appropriate questions include investigating preferred communication methods, what interactions patients value, and any specific concerns they may have (97).
Patient Portals	Many healthcare providers now offer patient portals where patients can access their medical records, test results, and communicate with healthcare professionals. These portals often allow patients to set communication preferences and control how they are contacted.
Consent and Permission	Healthcare professionals should obtain patient consent to communicate with them using their preferred methods. This is especially important for electronic communication due to privacy and security concerns.

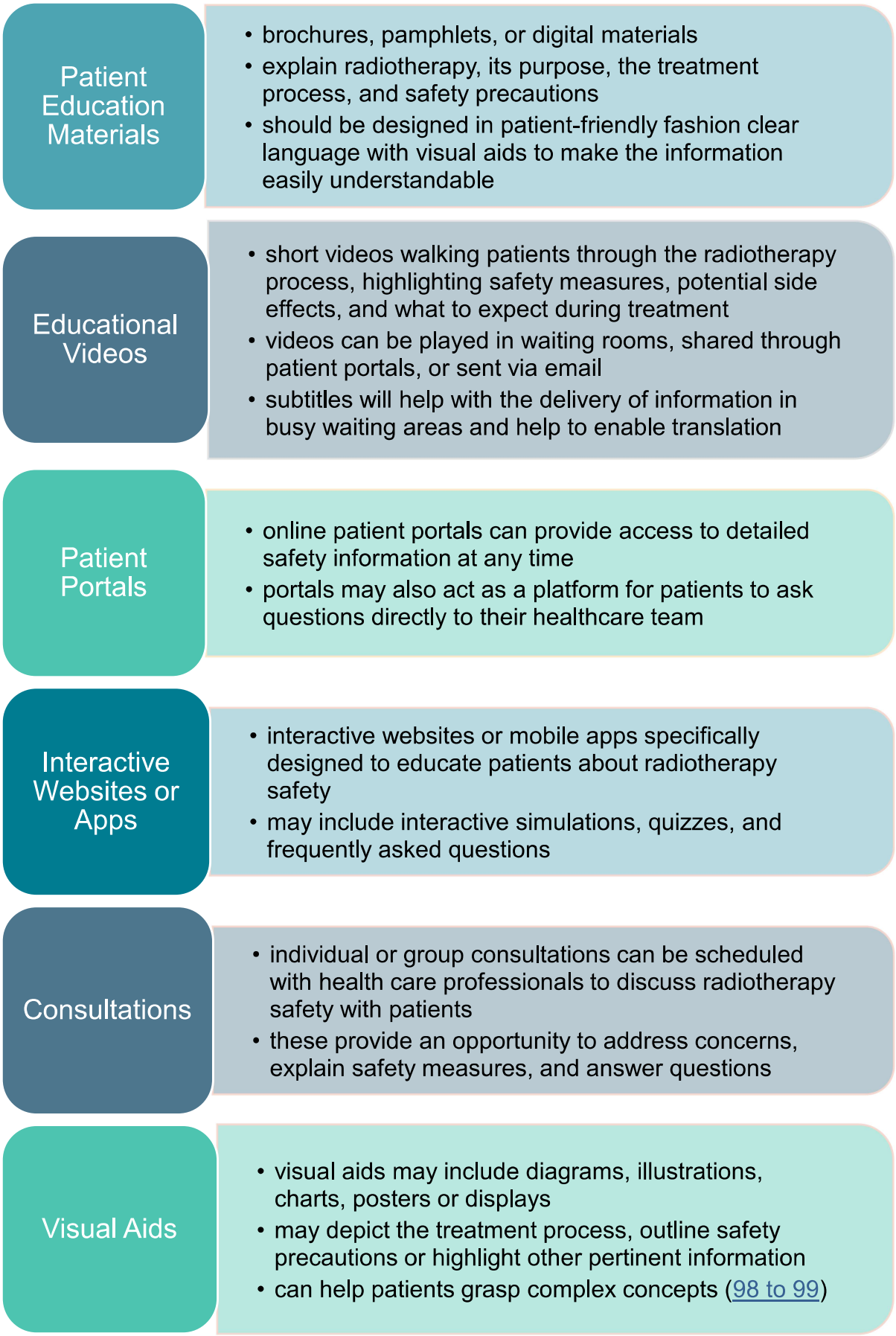
Method	Overview
Adaptability	Communication methods should be adapted based on individual patient preferences. Some patients might prefer phone calls for urgent matters, while others might prefer emails for non-urgent communications.
Language and Accessibility	Language preferences and accessibility needs should be considered and documented in record and verify systems. Communication methods need to be inclusive and cater to patients with different languages or abilities.
Educate Patients	Patients should be informed about the various communication channels available and their respective benefits. Relevant guidance should be readily accessible to allow them to use patient portals or other tools effectively.
Feedback Loop	Feedback should be continually gathered from patients about their communication experiences to help identify areas for improvement and make necessary adjustments.

Communication preferences can vary widely among patients and approaching this process with flexibility and a person-centred approach is necessary. By respecting and accommodating their preferences, patient engagement and satisfaction will be enhanced, ultimately leading to a better experience for the patient (94) and improved healthcare outcomes.

5.3.2 Utilising systems which facilitate communication

Effectively communicating radiotherapy safety information to patients is essential to ensure their understanding and cooperation throughout the treatment process. Some systems and strategies used to facilitate communication about radiotherapy safety to patients are detailed in Figure 5.1 below.

Figure 5.1. Examples of systems which facilitate patient communication



Text version of Figure 5.1. Examples of systems which facilitate patient communication

This graphic shows 6 systems which facilitate communication about radiotherapy safety to patients.

1. Patient education materials: these include brochures, pamphlets, or digital materials to explain radiotherapy, its purpose, the treatment process, and safety precautions. They should be designed in patient-friendly fashion clear language with visual aids to make the information easily understandable.
2. Educational videos: short videos walking patients through the radiotherapy process, highlighting safety measures, potential side effects, and what to expect during treatment. Videos can be played in waiting rooms, shared through patient portals, or sent via email. Subtitles will help with the delivery of information in busy waiting areas and help to enable translation.
3. Patient portals: online patient portals can provide access to detailed safety information at any time. Portals may also act as a platform for patients to ask questions directly to their healthcare team.
4. Interactive websites and mobile apps: these can be specifically designed to educate patients about radiotherapy safety and may include interactive simulations, quizzes, and frequently asked questions.
5. Consultations: individual or group consultations can be scheduled with health care professionals to discuss radiotherapy safety with patients. These provide an opportunity to address concerns, explain safety measures, and answer questions.
6. Visual aids: these include diagrams, illustrations, charts, posters, or displays. These can depict the treatment process, outline safety precautions or highlight other pertinent information and are a means of helping patients grasp complex concepts.

5.3.3 Effective staff communication

Effective communication skills not only enable the transfer of information to patients, but they also promote active listening, fundamental for establishing a therapeutic relationship built upon trust and rapport (92). The practice of active listening signals to patients it is safe to talk and share concerns, that their thoughts and experiences will be respected, and they will not be judged.

A diverse group of patients access radiotherapy services, and communication methods need to be equally diverse to promote equitable and meaningful patient engagement. Patients also have varying levels of health literacy and may process information differently (100).

All radiotherapy staff should be able, and have training available, to effectively communicate and to respond to individuals or situations that require adaptation to standard communication methods.

Staff need to personalise communication approaches to each patient’s needs and preferences and encourage them to ask questions and seek clarification whenever needed. By providing

comprehensive and easily accessible safety information, health professionals can empower patients to actively participate in their own care and enhance their overall treatment experience (88, 101).

Recommendation

Radiotherapy providers should have an accessible and diverse range of communication systems in place and processes to adapt them to individual or situational needs as they arise. Staff should be trained in how to communicate effectively with patients.

5.4 How to support active engagement

5.4.1 Operational systems (clinical level)

Patients should always be encouraged to contribute to the existing service improvement systems in place, as these can also feed into safety activities. These systems include the friends and family test (102), regular patient feedback surveys, national radiotherapy surveys, Patient Advice and Liaison Services (PALS), feedback and complaints procedures. Active signposting to these systems should be standard practice. It is often the case that these systems are only engaged with when something has 'gone wrong'. These systems are also valuable for gaining timely feedback from patients and enable organisations to start a more proactive, rather than reactive approach, to patient safety.

5.4.2 Organisational systems (managerial level)

To maximise benefits, providers are encouraged to actively promote patient safety roles within safety specific systems and frameworks. The development of formal engagement roles is strongly advocated and include the following:

1. Public and patient voice partners

These provide lived experience of the healthcare systems and services, providing invaluable insight into how services are received by patients. Partners are most effective when they represent a wide range of patient perspectives and not just their own, collating feedback from others to provide a wider vision of the services and a collective voice (103). Although often not specific to safety, they provide the opportunity to build upon an existing model of patient engagement.

2. Patient safety specialists (PSS) and patient safety partners (PSP)

Both these roles specialise in safety and can support staff and patients to engage in safety activities. These individuals bring a unique 'expert by experience' insight into safety activities.

The appointment of patients as safety partners is a key part of the NHS England framework and it recommends organisations appoint at least 2 to local safety committees (6). These individuals should be integral in improving safety standards and be considered as important as staff in this

process. These roles should be involved in all elements of safety and pathway design, safety governance as well as strategy and policy. Adequate mentorship and appropriate training should be provided and the roles should be monitored and annually reviewed. It is important to note that individuals within these roles should be appropriately remunerated for their time and engagement.

Local adoption of LFPSE principles in organisations across the UK enables patients to report safety events from their perspective (104). Providers should encourage the use of this and raise awareness for patients.

On a national scale, the NHS Patient Safety Strategy 2019 provides guidance on how patients can be involved in their own safety. Although an NHS framework, this can also be applied in private healthcare settings. The recommendations include appointing those aforementioned patient safety partners within organisations (6).

PSIRF is designed to help the investigation of incidents within organisations and is discussed in greater detail in Chapter 4 (71). PSIRF recommends organisations go beyond simply informing patients and their relatives of an on-going investigation and instead actively involves them. The benefits include gaining insight through seeing the incident from a patient perspective, and the opportunity to address salient needs patients may have following a safety event (71, 105).

It is important to remember there is an obligation to ensure equality and inclusiveness when involving patients in safety events. There should be clear procedures and guidance in place to ensure processes are accessible to all. Providers should actively seek inclusivity and encourage those in underrepresented groups to use and access safety tools and frameworks. Nationally, there should be appropriate inclusion on panels, steering groups, working parties and any other safety committees and representation on these should be reflective of the UK population.

Recommendation

Patients should be integrated into existing organisational improvement systems including a patient safety specialist role in collaboration with existing patient safety teams, whilst radiotherapy specific experience surveys should inform the design, development, and delivery of services. Providers should consider the diversity of the population they are engaging and ensure patient engagement is representative of local patient demographics.

5.5 Importance of leadership for patient engagement

Listening and learning from patient experience is vital as “everything else being equal, organisations will take the decisions they have the information to take” (106). Radiotherapy draws from a wide range of data sources to help contribute to the design and delivery of

services. Patient voices are a further valuable source (107) but the technological focus of radiotherapy can inadvertently silence patient voices (108).

To ensure their voice is heard and to maximise the benefits of patient engagement in the development of safe radiotherapy practice it is essential that organisations create formal structures and processes that can capture and triangulate a range of patient data and information. The leader's role is to establish the methods to capture those voices, listen to, learn from, and ultimately act upon them to ensure that patients inform safety practice. In practice, delivering patient engagement requires organisations and their leaders to provide effective communication structures and support.

Increasingly patient experiences should be considered alongside other conventionally favoured forms of evidence. For patients to be considered and respected as equal partners in safety it is important that the terminology used reflects how patient concerns are being taken seriously. Changing the language used supports this narrative, for example recognising that any patient who identifies an issue is raising a concern or reporting a safety issue and not simply ‘complaining’.

5.6 Engaging patients after a safety event

In the event of any safety event there is much that can be learnt by engaging with patients. The considerations and practices for engagement outlined throughout this chapter are still applicable and should be followed, but with appreciation of the sensitivities and emotion surrounding any event. Integrating systems which evidence to patients that radiotherapy services and professionals will learn from the event illustrates responsibility is being taken and can help patients to move forward from events whilst rebuilding trust (109).

5.7 Summary

This chapter has explored what patient engagement in safety looks like, how it can be captured and where it can be embedded. Creating a culture where patients are actively engaged in safety may require incremental stages of implementation supported by appropriate resources. By undertaking some simple procedural and practice changes will enable providers to embed patient engagement into routine safety activity. When designing their approach providers should remember that patient engagement is an ‘active and equal partnership with all patients and their caregivers across all systems and all levels’. Any safety system which fails to embed these 4 principles as the cornerstone of its engagement process will result in the loss of value which patient engagement affords.

Chapter 6. Patient comfort during radiotherapy

The previous chapter has emphasised the importance of patient engagement in radiotherapy practice. This chapter delves into patient wellbeing and comfort and how this may impact on outcomes. Patient comfort is defined holistically as a state of having met the basic human needs for ease, relief, and transcendence in 4 contexts: physical, psycho-spiritual, sociocultural, and environmental (110 to 111). In radiotherapy the role and purpose of holistic comfort is to make the experience more tolerable to patients, reducing discomfort, anxiety, distress, and claustrophobia (112). Where this is achieved the patient's dignity and vulnerability is respected. Beyond the importance of positive patient experience is the need to ensure patients are comfortable and receive radiotherapy safely.

This chapter uses the latest research to investigate patient comfort strategies and covers 4 main sections; hospitality and aesthetics, information and communication, supported coping, and supporting patients to maintain treatment position (89, 112 to 115).

6.1 Hospitality and aesthetics (environment)

The principal requirement of a radiotherapy department is functionality to facilitate the delivery of safe, efficient, and effective radiotherapy. Equally true is that all healthcare environments should strike a balance between the practicalities of clinical activities while simultaneously creating an environment that contributes to a positive experience for patients. A patient's first impressions are formed the first time they enter the radiotherapy department.

Increasingly healthcare architects are considering how spaces look and feel beyond the primary objective of function, adopting approaches traditionally seen in the hospitality sector to create a warm and welcoming environment (116). This section considers how patient experience, comfort and, ultimately, safety can be enhanced through the design and use of the building.

Assessments such as the NHS PLACE (Patient-Led Assessments of the Care Environment) emphasise the importance of the environment in a health care setting (117). They may be used to evaluate performance of various environmental parameters including privacy and dignity, cleanliness and building maintenance. For example:

- how the environment looks (aesthetics) – for example, material selection to look less clinical, more welcoming, creating similarities to a hotel or spa
- how the environment feels (sensory) – for example, ambient temperature, acoustics and lighting: within radiotherapy this might include the treatment room music or sound of the patient's choice, lighting above linac and the patient appointment alert – lights or buzzers

- how does the environment work function? – for example, extending beyond the delivery of radiotherapy towards the ease of negotiating around a department for both patients and staff

6.1.1 First impressions

Evidence shows that patients have concerns about the unknown aspects of visiting hospital, such as navigating their way around the hospital and what to expect from their radiotherapy treatment (89, 115). Pre-visits or open events have been shown to be beneficial for patients and their families in terms of meeting information requirements and reducing anxiety (118). A physical visit is not always practical or attractive, especially when people may be travelling a distance to access regional radiotherapy services. Therefore, alternatives include printed or online materials and videos of multimedia presentations. An example is the virtual tour of the Clatterbridge Radiotherapy department, which received a Health Service Journal Patient Safety Award in 2023 (119).

6.1.2 Waiting areas and times

As comfortable as the environment is, patients do not want to spend additional time in radiotherapy departments. Providers should employ strategies to ensure patients are efficiently checked in (for example, self-check in screens), that patient scheduling accurately reflects daily demand on treatment units, whilst electronic systems notifying delays should be available (120).

6.1.3 Privacy and dignity

The importance of dignified care cannot be overestimated. Ashmore and others present patient narratives detailing “lapses in providing dignified care” where the neglect of seemingly small things has a significant impact (121).

A recent regional patient experience survey reported issues of privacy and dignity relating to environment (lack of changing rooms), logistics (availability of gowns) and patients feeling ‘*rushed*’ (122). Two-pass through changing rooms per linac or scanner help to ensure that people have the space and time to undress and dress in a private, comfortable space. Changing rooms adjacent to the linac or scanner also support professionals in dealing with the conflicting requirements of workflow pressures and providing person centred, holistic care. Bathroom facilities, ideally single cubicles, should be sufficient in number, close to waiting areas and well signposted.

Recommendation

When considering the design of new clinical spaces and support accommodation, or the adaption of any existing facilities, the multidisciplinary design team should include any users of the space (professionals and patient representatives).

6.2 Information and communication preparation

6.2.1 Introduction and the importance of effective communication for safety

Effective communication is a fundamental component of the radiotherapy pathway and helps to create a situation in which the patients feel informed, relaxed, and comfortable. Improved knowledge is reported to provide patients with a sense of empowerment, as well as helping to reduce anxiety (92, 123).

It is important for providers and staff to consider how best to communicate with patients. Despite an increased awareness of the diverse communication needs of patients, there can sometimes be a disconnect between the information provided to patients and the content and format in which they would wish to receive it. Any failure to consider the patient as an individual can make the task of information appear perfunctory and lacking compassion (101). This can impact not only the patient's emotional state, heightening stress and anxiety, but potentially result in misinterpretation of the treatment process leading to compliance issues. Similarly, a lack of understanding about the significance of side effects may affect the patient's treatment decisions and quality of life (124 to 126).

The first point of contact with the patient offers the opportunity to start an effective conversation and should always begin with an introduction with name and profession shared (93). Relevant information which can aid comfort and compliance to treatment will typically include:

- information to support the process of informed consent
- information on the technical aspects of radiotherapy
- information on the care and support available during radiotherapy

Traditionally, information giving within radiotherapy has been delivered in a face-to-face environment and reinforced by information leaflets, which rely on the patients cognitive and reading abilities (124). However, approximately 50% of patients experience heightened anxiety prior to radiotherapy and this can impact on the ability to fully comprehend information provided (125). Neurodiversity, alongside age, gender, and education level of the patient, can also influence preferences for information quantity, delivery mode, and the timing (127).

Radiotherapy techniques and technologies have experienced rapid advances and the options available to the patient, what we require from the patient to achieve these, and what benefits these bring to the patient are becoming increasingly complex. Communicating this brings many challenges which the traditional information giving models of face-to-face and written information sometimes cannot overcome (124).

With the evolution of technology, radiotherapy has witnessed a move towards audio-visual materials and emerging multimedia tools to enhance patient education which help them to better prepare for what they are likely to experience (128 to 129). There is and always will be a

role for traditional information sharing models. However, understanding the factors associated with information provision and patient characteristics will help healthcare providers to deliver enhanced person-centred information by giving adequate information to those who need it, in the best format, at the right time and will help inform the design of strategies to support providers (92, 130 to 131).

The recommended formats included below have been divided into the 3 main stages of the patient pathway: pre-treatment, on treatment and post treatment – however, their use within each time frame should not be exclusive.

6.2.2 Pre-radiotherapy

The provision of open evenings provides the opportunity for orientation around a department for patients and their caregivers. It provides an ideal early opportunity to provide information and for patients to raise any concerns or issues.

A telephone call prior to the patient's pre-treatment appointment will provide the opportunity for information giving and provide a space for concerns or issues to be raised and addressed prior to attendance.

The use of virtual technology (including virtual and augmented reality) can prepare patients for the practical elements of treatment by immersion into their care path from simulation through initial treatment delivery, reducing anxiety and increasing familiarity with the treatment process (132).

6.2.3 During radiotherapy

Providers should ensure engagement of specialist healthcare professionals working in enhanced and advanced practice roles.

Healthcare professionals should be aware of, and signpost when required to, radiotherapy specific information and support groups.

6.2.4 Post-radiotherapy

Healthcare professionals should signpost to specific information, support groups and services that promote health via wellbeing, encourage a healthy diet and exercise. This may include local support and national and regional services such as Look Good Feel Better, Penny Brohn UK and Maggie's Centres.

6.2.5 Patient engagement

It is also paramount to understand the importance of patient engagement in the development of models of communication. It is important to make methods of engagement and giving feedback as accessible for patients and in as many forms as possible. Each of the practice examples

provided above will facilitate the gathering of feedback which can be used to further enhance service provision (see Chapter 5 for further information on patient engagement).

6.3 Supported coping

Supported coping typically refers to the various techniques and approaches that patients can use to manage discomfort, anxiety, stress, and difficult emotions, often with the help and support of others. Examples of supported coping strategies are shared here.

6.3.1 Empathetic approaches

Empathetic communication from healthcare professionals to patients includes nonverbal techniques that show engagement and investment, as well as simply treating patients with courtesy, dignity and respect. Human interaction as a key factor influencing patient experience. Consequently, it is important, as far as operationally possible, to ensure the continuity of staff for the duration of patient treatment (133).

6.3.2 Supported distraction and coping techniques

There are many methods to distract and cope. Some patients may like specific music, others prefer the lights dimmed. Some like to listen to religious verses or hold something significant like rosary beads or a teddy bear. Some patients prefer counting down, watching the machines, listening to the sounds of the CT or linac or talk to themselves (115). The emerging role of virtual reality tools in stress reduction for patients undergoing radiotherapy is currently being researched (134).

Keeping a journal to express thoughts, emotions, and experiences can be a therapeutic way to process feelings and track progress. Patients may benefit from resources for mindfulness and relaxation techniques.

6.3.3 Referral to external services and peer support

Participating in support groups with people who are going through similar experiences can provide a sense of belonging and shared understanding. Talking to friends, family members, or support groups about one's feelings and experiences can provide validation, understanding, and different perspectives on the challenges being faced. All of this may place patients at ease before attending radiotherapy.

Individual or group therapy sessions with trained mental health professionals can offer guidance, tools, and coping techniques tailored to their specific needs. Consulting a healthcare professional and accessing prescribed medications, if necessary, can help manage severe symptoms of distress and anxiety.

Recommendation

Supported coping strategies are not a one-size-fits-all solution. Different strategies may be more effective for different individuals and situations. Health professionals should explore what options optimally suit patients so as to maximise comfort and safety throughout radiotherapy treatment.

6.4 Supporting and adjusting patients' comfort to maintain position

Patients are positioned in radiotherapy to minimise motion and ensure reproducibility through a course of treatment. This is crucial for accurate treatment delivery, ensuring a tumour is targeted precisely and increasing the chances of successful outcomes, whilst minimising exposure to healthy tissues surrounding the tumour, reducing the risk of side effects and complications (135). However, the methods employed can be uncomfortable for patients and may prove counterproductive. Recent research has suggested that patient discomfort is associated with reduced treatment accuracy (136 to 137). Healthcare professionals should therefore actively assess patient comfort at the initial planning scan to maximise patient comfort and support throughout radiotherapy treatment.

With current advances in treatment techniques increasing treatment times, management of patient comfort is critical to safe and effective radiotherapy treatment. There are several solutions that radiotherapy providers can implement with little or no financial costs. Seeing familiar team members at each appointment promotes a sense of security and comfort. Good communication helps alleviate worries and concerns (115) and communication training should be available for all staff.

Simple equipment can be used to help patients relax, therefore improving reproducibility and accuracy (138). These options should be considered, particularly for patients who may have additional requirements and support needs. Adaptations for immobilisation should be available, particularly to patients with pre-existing health conditions. This can be done through soft comfort aids and adaptions to immobilisation masks and ensuring mask anxiety screening is considered prior to attendance (139).

Patient comfort goes beyond the immobilisation equipment used, and psychological and social factors should also be considered. Small interventions can alleviate treatment related anxiety. Staff should make patients aware of how to communicate any issues with staff during treatment (131). Patients find communication, visualisation techniques, and aromatherapy to be reassuring during radiotherapy treatment (112 to 113, 115). These should be considered for patients.

Healthcare professionals may struggle to spot the signs of anxiety in patients due to increasing pressures within their roles (114). Training for staff may be required in this area moving forwards.

Recommendation

Healthcare professionals should actively assess patient comfort at the initial planning scan to allow patients to be comfortably supported throughout radiotherapy treatment, accommodating pre-existing health conditions and amend positioning and immobilisation when required.

6.5 Summary

This chapter has explored how comfort is critical to patient wellbeing and for safe and accurate radiotherapy. Supporting a culture that considers comfort and how it may be improved is of vital importance. Next is to better understand what patients would like. This should be assessed at the start, and throughout, the patients' radiotherapy journey. This should include an assessment of treatment position and immobilisation devices. The fundamental message is that health care professionals should harness their humanity, their natural empathetic and caring ability to deliver optimal comfort and care for patient.

Chapter 7. Monitoring early and late effects of radiotherapy

The previous 2 chapters have explored the methods of how healthcare professionals can develop and deepen collaborative relationships with patients, and how working together can improve both radiotherapy services and individual patient care, with safety and quality at the core. Another important facet of patient care is the monitoring and management of toxicities that may occur when patients undergo radiotherapy. Currently, it is recommended that patients receiving radiotherapy are regularly reviewed to ensure early and late effects of radiotherapy are monitored, recorded, and appropriately managed (140). Patient review also provides an opportunity to identify unusual or unexpected effects as a safety concern. Concerns raised by patients and staff should be taken seriously and investigated promptly. However, radiotherapy safety systems in the UK do not universally use systematically collected clinical outcome data as a basis for learning. Better links between clinical outcomes and radiotherapy safety checks may improve detection and management of adverse effects, and their risk factors, and therefore improve patient safety. To achieve this requires the introduction of systematic collection of tumour-site-specific clinical outcome data, as well as updates to safety systems and infrastructure.

7.1 Defining adverse clinical effects

In general, adverse clinical effects depend on the anatomical site, volume irradiated, radiotherapy type (for example photon, electron or proton), technique, total dose, dose fractionation, age of patient, concurrent therapy, and biology of involved tissue.

Expected adverse clinical effects from radiotherapy are often classified as early or late. Early adverse clinical effects are expressed weeks to a few months after exposure to radiotherapy (usually defined as within approximately 90 days). Late adverse clinical effects are expressed months to years after exposure to radiotherapy (after approximately 90 days) (141). The severity of expected adverse clinical effects varies between individual patients such that some effects are more commonly recognised than others. It can be difficult to determine whether a clinical adverse effect is expected for an individual patient because available knowledge and understanding of individual risk factors may be incomplete. However, here we reserve the term unexpected adverse clinical effects for those effects as yet unrecognised across the population by published studies.

Adverse clinical effects from radiotherapy are influenced by radiotherapy types and techniques used for delivery as well as individual patients' radiosensitivity. Investigation of severe or rare expected adverse clinical effects, and unexpected adverse clinical effects may help us identify:

- instances of suboptimal planning or delivery of radiotherapy, including patient preparation and immobilisation

- patients with unusual radiosensitivity who may be less suitable for future radiotherapy
- associated clinical outcomes of new techniques and technologies, such as altered fractionation regimes including SABR
- patients that may benefit from additional surveillance or monitoring post-treatment,
- adverse effects as yet unidentified by published studies

Shared learning from these events may improve future clinical recognition and management of adverse effects and allow us to better identify patients who may be at lower and higher risk of developing adverse effects. It may also lead to prevention of harm through development of more personalised, safer, dose distributions (142).

7.1.1 Clinician-reported adverse clinical effects

Traditionally adverse clinical effects from radiotherapy have been assessed in person by trained healthcare professionals. This may include clinical oncologists, specialist therapeutic radiographers, clinical nurse specialists, dosimetrists, dieticians, speech and language specialists, physiotherapists and many more. Widely available terminologies for describing and grading clinician-reported adverse effects include:

- National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) (143)
- Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer (RTOG/EORTC) Late effects on normal tissues – Subjective Objective Management and Analytic (LENT-SOMA) (144)

The RTOG/EORTC LENT-SOMA grading system was the first to include both clinician- and patient-reported outcomes and was introduced to replace the pre-existing toxicity criteria of the RTOG/EORTC, subject to validation (145 to 146). The LENT-SOMA system has since been incorporated into the CTCAE (147).

However, unlike the LENT-SOMA scales, CTCAE combines multiple symptoms and signs into a single grade of severity, which leads to a loss of specific information useful when linking clinical outcomes with dosimetry (148).

Use of a recognized classification system facilitates analysis and sharing of this data and enhances shared learning. It is easier to capture this type of data while the patient is on active treatment. It is more difficult to collate this data once the patient is no longer undergoing radiotherapy and has led to the adoption of patient reported outcomes in some areas.

7.1.2 Patient-reported adverse clinical effects

Adverse clinical effects from radiotherapy reported by patients provide a much-needed and different perspective to clinician-reported outcomes. Increasingly patient-reported outcome measures (PROMs) are used in radiation oncology trials and their use in clinical practice has been shown to be feasible and to improve patient care (149 to 150). There are many different

types of PROMs available, ranging from those designed to measure general health-related quality of life to those specifically assessing a particular disease or symptom.

In UK radiotherapy trials, EORTC's general and tumour-site-specific quality of life tools have been identified as amongst the most commonly used PROMs (151 to 152). Outside of clinical trials, measurement, documentation and use of patient-reported outcomes from standard photon radiotherapy treatments is very variable across the UK with more than 50 patient-reported outcome measures currently being used (153). The EORTC QLQ-C30 forms part of the national Cancer Quality of Life metric in England, the updated results of which are available on the NHS digital platform (154 to 155). NCI have developed a patient-reported outcomes version of the CTCAE (PRO-CTCAE) and work has been started to empirically validate some tumour-site-specific PRO-CTCAE item sets for use in patients undergoing radiotherapy (156). PROMs can be completed at in-person reviews. However, improvements in technology have also led to the development of digital apps and platforms which are increasingly being introduced in the UK oncology clinics to support remote review of toxicities reported by patients (157 to 159).

There is a national system and infrastructure for collecting and responding to patient-reported clinical outcome data from proton beam therapy in the UK, that links with dosimetry data and other patient-, tumour- and treatment-related information (153, 158). Within this system, patients aged 16 years and older are sent a link via email or text to complete an online questionnaire that includes disease-specific symptom questions adapted using lay language from CTCAE as well as a general quality of life questionnaire. Patients are prompted to complete the form prior to the start of treatment, weekly during proton beam therapy and then at follow up intervals after completion of proton beam therapy (158 to 159).

Radiotherapy providers should have tumour-site-specific protocols and resources for patient review in place which will outline the adverse effects to be considered and how they are managed. This should include methods of investigating whether there may be links between development of clinical outcomes of concern, patient risk factors for developing radiation adverse effects, or the planning and delivery of the radiotherapy. This process should be interdisciplinary, with the adoption of quality-assurance and improvement programs to actively analyse late effects. Examples demonstrating current practice in gathering clinician and patient reported adverse clinical effects are summarized in Table 7.1.

Table 7.1. Examples of current practice of clinician- and patient-reported adverse clinical effects

Example	Frequency	Data collection	Grading criteria	Platform	Current use
Proton centre	Weekly	Interdisciplinary review team	CTCAE and RTOG	Electronic patient record (EPR)	The system facilitates patient review through accurate, consistent recording of data
Provider experience – prostate radiotherapy patients	Baseline pre-radiotherapy. Regular intervals post radiotherapy	Patient	EPIC 26, IIEF-5, I-PSS and ALERT-B	Paper-based questionnaire	Improve patient safety and local clinical services management of radiation adverse effects. Monitor safety and quality of new treatments. Used to inform new treatment business cases
Regional clinical late effects service	Patient referral and discharge	Patient	Data scored using EORTC manuals	Questionnaire	Data compared to published thresholds for clinical importance to evidence the burden of potential clinical needs
Large oncology centre	Weekly	Interdisciplinary review team Patient ePROMS	CTCAE and RTOG (skin toxicity only)	EPR and interactive commercial platform	Allows trends to be identified within the patients care and early identification of toxicity. Patients receive feedback dependent on ePROMS responses, which update to the EPR for clinician review

7.2 Expected adverse clinical effects

The RCR national radiotherapy consent forms provide tumour-site-specific details on expected early and late adverse effects. These are based on expert consensus opinion and the results of published results of randomised controlled trials (RCTs) where available (91). In addition to informing the patient of the effects of radiotherapy, they may provide a standard against which local services can benchmark their radiotherapy practice.

Recommendation

Early and late radiotherapy adverse effects should be audited both locally by radiotherapy providers, and nationally by the relevant professional bodies (RCR, SCOR) to inform practice.

7.2.1 Recording of adverse clinical effects

For individual patients, information from reviews of early effects of radiation should be made available and recorded within patients' hospital and primary care records as appropriate, so that it is accessible to professionals involved in providing their safe care.

To facilitate benchmarking of practice, and population-level patient safety strategies, radiotherapy providers should record early adverse clinical effects data from patient reviews so that it is also accessible for collation at local and national levels. When developing methods to record data it is important to consider the format and structure to ensure it can be linked to other data sources. To encourage standardisation questions and responses should be taken from established sets of criteria such as CTCAE and RTOG. Dropdown boxes to promote consistency and the avoidance of free text are also recommended.

Oncology management systems can include patient review modules and may allow local commissioning to include tumour-site-specific adverse clinical effects. Similarly, hospital information systems of electronic patient records often include this facility. These support standardisation of individual patient reviews and ensure that where patients have provided consent, patient adverse clinical effects can be easily extracted for analysis and used to inform practice. Some centres are already using their local systems in this way. This approach would also allow for this data to be collated nationally in the future.

NHS England's radiotherapy service specification currently outlines that most patients that develop late adverse clinical effects following radiotherapy treatment should be managed locally with options for referral to specialists in late effects (141). Specialist late effects centres are expected to manage and co-ordinate the provision of specialist services for complex late effects of cancer treatments and align to specialist cancer surgery and other treatment pathways as they arise. Therefore, to ensure information from reviews of late effects is accessible to professionals involved in providing safe care, it currently needs to be recorded in multiple places. Records of late effects reviews should be accessible to oncology management systems,

hospital records, primary care records, specialist late effect centres and the patients as appropriate.

Recommendation

Tumour-site-specific radiotherapy protocols for patient review should outline how and where review outcomes should be recorded.

It is acknowledged that routinely recording standardised individual late adverse clinical effect data within oncology management systems is currently challenging as, on completion of treatment, patients may only be followed up by a radiotherapy professional with access to the oncology management system for a short time. Recognition and reporting of late effects by patients and primary care providers to secondary care services may be variable. Further resources and systems are needed to improve the identification of patients with late adverse clinical effects. At a population level, recording of some late effects may require nationally commissioned and generated surveys of patients at specific time points after their radiotherapy. However, the development of a national late effects resource allows for the potential to predict the risk of late toxicity following radiotherapy with much greater accuracy. This approach has been shown to be feasible given adequate funding and resources (91).

Recommendation

To improve future identification of patients with radiotherapy late adverse clinical effects, national resources should be provided to allow key stakeholders; service users, radiotherapy providers, primary care providers, cancer charities and cancer alliances, to collaborate at a national level to develop coordinated systems for recording and coding patient radiotherapy late adverse clinical effects that are accessible to key care providers including specialist late effects centres.

7.3 Pre-radiotherapy assessments

A tumour-site-specific baseline assessment of each patient should be undertaken before starting radiotherapy including completion of clinician- or patient-reported outcome measures.

Baseline assessment may involve taking a history, performing clinical examination, and arranging appropriate baseline clinical investigations. Relevant information should be collected on the patient's physical condition, functional status, comorbidities and concomitant medications, family history, performance status, psychological well-being, social circumstances, and support networks. Other completed and planned anti-cancer treatments should be considered, with particular attention paid to those known to exacerbate expected radiotherapy adverse effects. For some expected radiotherapy adverse effects, there are established tools which can be used to assess patient's baseline risk of developing the adverse effect and clinical

guidelines on appropriate risk management strategies which should be signposted within tumour-site-specific protocols as appropriate.

Baseline assessment should support identification of established risk factors for developing adverse clinical effects, and therefore may inform patient consent for radiotherapy and facilitate initiation of appropriate primary and secondary prevention strategies. It should also facilitate the identification and management of radiation-related adverse clinical effects over time during and after radiotherapy. If recorded in a manner accessible for collation at a population level, such assessments may also support the recognition of previously unknown risk factors that might lead to expected severe or rare effects, or unexpected effects.

Recommendation

Tumour-site-specific protocols for patient review should include details of the components of pre-radiotherapy (baseline) assessments required.

7.4 Nature and frequency of assessments for adverse clinical effects during and after radiotherapy

The role and timing of subsequent in-person and remote patient reviews within local services should be considered so that tumour-site-specific adverse clinical effects may be appropriately identified and managed. A consistent approach to clinical assessments and their documentation should be encouraged even when reviews are undertaken by different healthcare professionals. There should be a documented policy for systematic, standardised review available that describes the minimum criteria for review of patients, an escalation process to ensure patients are seen appropriately in cases of non-scheduled review and consideration on including the requirements of local safeguarding policies. Completion of appropriate clinician- or patient-reported outcome measures that cover expected adverse clinical effects as outlined on the RCR consent forms is beneficial. It is recognised that selecting an appropriate outcome measure may be challenging for radiotherapy providers at present.

Recommendation

Tumour-site-specific protocols and resources for patient review should include details of the nature and frequency of adverse events and assessments required for monitoring during and after radiotherapy.

There is a need for development and validation of national tumour-site-specific PROMS for radiotherapy adverse clinical effects. There should be alignment between items included in these PROMs and national patient consent forms. In the interim, national expert consensus opinion on the most appropriate measures may be valuable.

Patient education on expected adverse effects during consent for radiotherapy should include information on whom to contact for advice and support (24 hours, 7 days a week) should they have concerns. Further information on this should be provided at the point of discharge from clinical oncology services.

Recommendation

Key stakeholders, service users and providers should collaborate to support development and validation of national tumour-site specific PROMs for radiotherapy adverse effects. There should be alignment between items included in these PROMs and national patient consent forms.

7.5 How to respond to concerns about adverse effects

Local protocols should include guidance for staff on how to respond to adverse clinical effects from radiotherapy.

These may include:

- acknowledgment that protocols apply to concerns raised by patients or their representatives as well as healthcare professionals
- acknowledgement that symptoms and signs of radiation adverse effects may overlap with those of other pathology including new or progressive cancer
- acknowledgment that determining which individual patients have had a clinically concerning response during or after radiotherapy can be complex. It may include those with expected severe or rare adverse effects, or unexpected adverse effects. Adverse effects can be exacerbated by patient radiosensitivity, enhanced reaction associated with concomitant treatments, progression of their cancer or other co-morbidities
- options for the clinical management of expected adverse effects including information regarding available specialist services, their referral criteria, and pathways
- guidance on review of those with expected severe or rare adverse effects, or unexpected adverse effects. It may include systematic review of the patient's radiotherapy consent form, prescription, plan, and delivery documentation in conjunction with local tumour-site-specific radiotherapy protocols to check whether the radiotherapy prescribed was indicated and delivered as per local protocols, whether the patient had any contraindications to receiving radiotherapy, or any known clinical risk factors for developing the adverse effect
- consideration should be given to the review of patients undergoing similar treatment that may be affected in the same way
- in the rare situation of nuclear and radiological emergencies, the IAEA provide guidance on the medical management of radiation injuries (160)

- to strengthen patient safety and ensure that learning is shared from patient's adverse effects, those with severe or rare expected, or unexpected adverse effects should be considered for departmental local patient safety review with the wider staff group

Recommendation

Radiotherapy providers should have procedures and resources in place to manage concerns identified as part of patient review.

Nationally, learning can currently be shared via the Safer Radiotherapy publications (3 to 4, 53). UKHSA publishes a Safer Radiotherapy E-bulletin 3 to 4 times a year. The E-bulletin is a vehicle for delivering key patient safety messages to the professional radiotherapy community. The E-bulletin is sent to the Heads of Service for clinical oncologists, medical physics and therapeutic radiographers. The publication includes materials from health professionals, patient representatives, professional bodies and healthcare organisations.

Additionally, the Central Alerting System (CAS) for cascading of significant events or National patient safety alerts can be used. The CAS is a web-based cascading system for issuing patient safety alerts and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Alerts are only issued for safety-critical issues. The threshold for these alerts is one or more potentially avoidable deaths or disability in healthcare in England in a year.

7.6 Working towards a national system for monitoring effects of radiotherapy

It is important to recognise that better integration of patients' clinical outcome data into national radiotherapy safety systems will make radiotherapy safer for future patients. National clinical cancer audits are becoming established within the UK under the National Cancer Audit Collaborating Centre umbrella to improve the quality of services and care of cancer patients. Similarly, a dedicated centralised database system for monitoring adverse effects of radiotherapy would provide the opportunity to capture and analyse comprehensive national scale data.

7.6.1 Improve the quality of patient consent

Currently in the UK, estimates of expected adverse outcomes from radiotherapy used in patient consent are based on expert consensus opinion of published studies. The quality of this varies between tumour sites and published estimates of adverse outcomes may carry some limitations, for example:

- studies may not be sufficiently powered to assess the frequency of adverse outcomes they report on

- studies may not follow up patients frequently enough, or allow for sufficient time, to assess adverse outcomes, and they may not actively seek the required information from patients
- studies may poorly represent some patient groups including those with less common risk factors for adverse outcomes, and those at highest risk for developing adverse outcomes
- there may be heterogeneity of terms and grading systems used to report adverse outcomes across different RCTs, limiting quantitative synthesis of the data
- patient reported outcomes are often poorly reported (161)
- there may be variation in recording methods and accessibility of data to wider care providers

Systematically collected patient outcome data may support ongoing evaluation and improvements to the quality of information used by clinicians and patients in shared decision-making. It may be especially useful in providing information to support patients in less common clinical situations in future.

7.6.2 Improve clinical services for management of radiation adverse effects, particularly late effects

Quantification of patient-reported adverse outcomes from radiotherapy in routine practice may improve identification of patients with adverse effects as well as development and allocation of resources and services for specialist management of adverse effects.

7.6.3 Support standardisation of radiotherapy protocols and practice

Radiotherapy protocols and practice likely vary between hospitals despite the coordination of NHS Operational Delivery Networks and integrated care boards, and national guidance from the RCR based on latest evidence. This may lead to geographical variation in patients' experiences of adverse effects from radiotherapy. Monitoring this variation may increase the chances that radiotherapy is delivered to a high standard across the UK, thereby reducing inequalities. Initiatives such as the provision of ProKnow ® (treatment plan analytics software package) by NHSE to English RT providers has helped facilitate the monitoring of cardiac and pulmonary vessel doses for patients undergoing radiotherapy treatment to the left breast nationally.

Monitoring of the systemic anti-cancer therapy (SACT) data set collated by NHS England led to the identification of factors affecting 30-day mortality after SACT, and its ongoing outputs are recommended by the national chemotherapy board to support standardised review of cases in local morbidity and mortality meetings (162 to 163). Similar work has been undertaken in radiotherapy and this could be taken further with the stratifying of the existing 30- and 90-day analysis by other health inequalities (162 to 163).

7.6.4 Support the development and evaluation of new technologies, protocols and practice

Information on patient-reported adverse effects from radiotherapy may support prioritisation of research agendas. If collected appropriately, for example via the Radiotherapy Dataset, national

adverse effect data may also support ongoing research efforts by allowing linkage of clinical outcomes with dosimetry data. Routine reporting of adverse effects may improve the availability and quality of data to evaluate new technologies and protocols. During NHS England's Commissioning through Evaluation (CtE) scheme for SABR for patients with extracranial oligometastatic cancer, treatment-related adverse events were collected effectively during follow up (164). Contrastingly, for the CtE assessing Selective Internal Radiation Therapy radiotherapy, outcomes were variably measured and reported by clinicians and patient-reported quality of life data was inadequate for the drawing of reliable conclusions (165). The learning points have been published so future projects may better consider the definitions and collection of radiotherapy adverse effects.

Potential barriers include lack of time and knowledge surrounding collection, use and interpretation of patient-reported outcome data reported by healthcare professionals (152). For example, the Trigger Project aimed to introduce electronic collection of a short, useable treatment-specific PROM for radiotherapy (ALERT-B, used to screen for late effects of radiotherapy on the bowel) into radiotherapy services at 3 UK cancer centres (166 to 167). Low patient registration was attributed largely to insufficient engagement from HCPs who lacked time to engage with the perceived extra work involved. Development of a future national system for monitoring adverse effects of radiotherapy requires national provision of further resources and training to counter the potential for similar barriers arising.

Recommendation

Key stakeholders, service users and providers should collaborate to support development of national training and resources for patients and healthcare professionals on recording and responding to patient-reported outcome data.

7.7 Summary

This chapter has examined the importance of monitoring early and late radiotherapy patient side effects. Various methods of recording clinical effects are appraised and guidance advising staff involved in the care of radiotherapy patients is outlined. Whilst the importance of effective local protocols and procedures to support patients encountering adverse clinical effects is clear, this chapter has sought to articulate a compelling case to establish a national system for monitoring the side effects of radiotherapy. The next steps require collaboration at a national level to develop coordinated systems for recording, collating and analysing patient radiotherapy late adverse clinical effects.

Summary of recommendations

Safety culture

1. Providers should establish and maintain a positive safety culture in which key traits are embedded and individuals are encouraged to speak up (see 1.3.10 Continuous learning).

Advancing safety practice in radiotherapy

2. The wider context of the system should be considered when reviewing radiotherapy events (RTE) to ensure all contributory factors are identified and addressed appropriately (see 2.2 Systems approach to safety).
3. Radiotherapy providers should ensure safety management system frameworks, to include safety policy, safety risk management, safety assurance and safety promotion are built into QMS and organisational quality governance structures (see 2.3 Safety management system (SMS)).
4. Safety actions should be applied against each area for improvement identified as part of an RTE response. Both people and system focused actions should be considered. These should be periodically reviewed to assess their efficacy or presence and amended, created or removed if redundant (see 2.4 Safety actions).
5. Providers should be proactive in managing risk, learning from where things have gone right, not simply reacting when things have gone wrong. Procedures and processes should affect continual review and improvement in patient safety (see 2.5.2 Risk management).
6. Continual quality improvement initiatives and radiotherapy event learning systems should be used to examine Work As Done and identify areas for improvement (see 2.5.4 Performance variability).

Overview of radiotherapy event learning systems

7. All classification levels of RTE should be reported both locally and nationally to facilitate timely learning from these events (see 3.2.2 Voluntary reporting).
8. Local event learning systems (ELS) should be appropriately supported and resourced by senior management. Single electronic solutions should be adopted to encourage efficiencies when reporting and learning from RTE (see 3.3 Local event learning systems).
9. Timely reporting and analysis of RTE data at a local level is needed to inform practice and produce actionable results (see 3.4 Local approach to RTE data analysis).
10. To develop greater understanding of the systemic nature of RTE at a national level it is recommended that providers use taxonomy coding to fully describe the entire event pathway, including all contributory factors, when submitting reports to the national ELS (see 3.5 National approach to RTE analysis).

11. Greater regional collaboration, fostered with the aim to support learning from RTE and the exchange of ideas for evidence-based practice, should be encouraged (see 3.6 Analysis at a local, regional, national, and international level).

Overview of radiotherapy event response

12. All staff should be appropriately trained and have access to supporting documentation to ensure RTE are identified, correctly reported and an appropriate response actioned (see 4.1 RTE response).
13. The investigation team should adopt an interdisciplinary approach with clear roles and responsibilities. The team should include individuals with clinical expertise as well as individuals who are trained and competent to carry out an effective systems-focused investigation (see 4.1.3 Planning and selection of investigation team).
14. Following an RTE response appropriate action must be taken. This should include the development and implementation of an action plan to address areas for improvement, system issues or areas to reduce risk (see 4.1.7 Identification of areas for improvement and action plan).
15. Providers should ensure there are communication frameworks and systems in place to support and enable an ongoing inbuilt regular safety dialogue among teams and across the organisation (see 4.1.8 Dissemination of learning).

Engaging patients in safety

16. All radiotherapy providers should adopt the RCR radiotherapy consent forms (see 5.2.1 Their own treatment and care).
17. Patients should be seen by healthcare services and professionals as equal partners in safety. Patients should be encouraged and supported to be active and vocal participants in their treatment and care. Each radiotherapy provider should have a formal process for capturing patient concerns and feedback (see 5.2.1 Their own treatment and care).
18. Radiotherapy providers should have an accessible and diverse range of communication systems in place and processes to adapt them to individual or situational needs as they arise. Staff should be trained in how to communicate effectively with patients (see 5.3.3 Effective staff communication).
19. Patients should be integrated into existing organisational improvement systems including a patient safety specialist role in collaboration with existing patient safety teams, whilst radiotherapy specific experience surveys should inform the design, development, and delivery of services. Providers should consider the diversity of the population they are engaging and ensure patient engagement is representative of local patient demographics (see 5.4.2 Organisational systems (managerial level)).

Patient comfort during radiotherapy

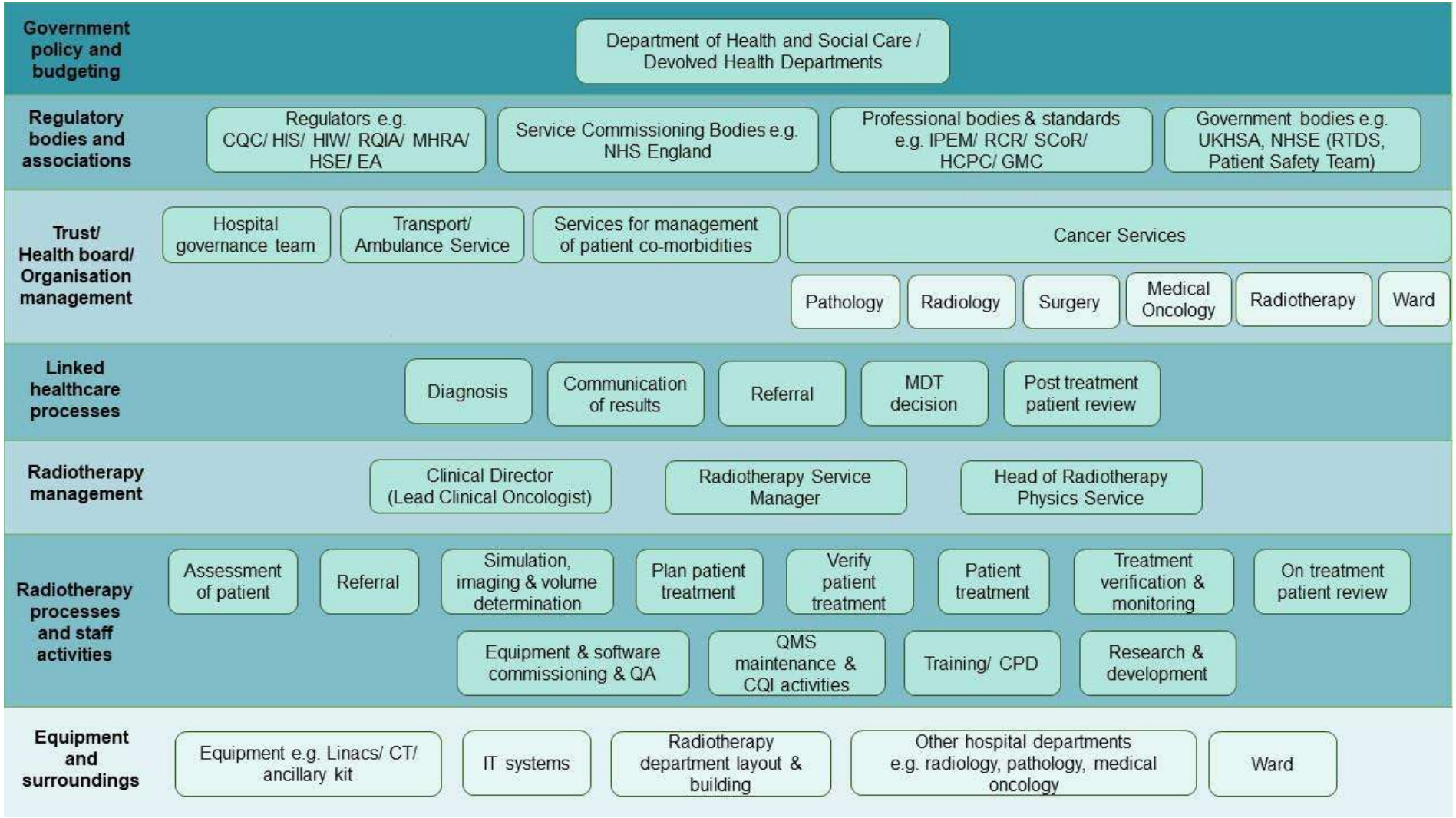
20. When considering the design of new clinical spaces and support accommodation, or the adaption of any existing facilities, the multidisciplinary design team should include any users of the space (professionals and patient representatives) (see 6.1.3 Privacy and dignity).
21. Supported coping strategies are not a one-size-fits-all solution. Different strategies may be more effective for different individuals and situations. Health professionals should explore what options optimally suit patients so as to maximise comfort and safety throughout radiotherapy treatment (see 6.3.3 Referral to external services and peer support).
22. Healthcare professionals should actively assess patient comfort at the initial planning scan to allow patients to be comfortably supported throughout radiotherapy treatment, accommodating pre-existing health conditions and amend positioning and immobilisation when required (see 6.4 Supporting and adjusting patients' comfort to maintain position).

Monitoring early and late effects of radiotherapy

23. Early and late radiotherapy adverse effects should be audited both locally by Radiotherapy providers, and nationally by the relevant professional bodies (RCR, SCOR) to inform practice (see 7.2 Expected adverse clinical effects).
24. Tumour-site-specific radiotherapy protocols for patient review should outline how and where review outcomes should be recorded (see 7.2.1 Recording of adverse clinical effects).
25. To improve future identification of patients with radiotherapy late adverse clinical effects, national resources should be provided to allow key stakeholders; service users, radiotherapy providers, primary care providers, cancer charities and cancer alliances, to collaborate at a national level to develop coordinated systems for recording and coding patient radiotherapy late adverse clinical effects that are accessible to key care providers including specialist late effects centres (see 7.2.1 Recording of adverse clinical effects).
26. Tumour-site-specific protocols for patient review should include details of the components of pre-radiotherapy (baseline) assessments required (see 7.3 Pre-radiotherapy assessments).
27. Tumour-site-specific protocols and resources for patient review should include details of the nature and frequency of adverse events and assessments required for monitoring during and after radiotherapy (see 7.4 Nature and frequency of assessments for adverse clinical effects during and after radiotherapy).
28. Key stakeholders, service users and providers should collaborate to support development and validation of national tumour-site specific PROMs for radiotherapy adverse effects. There should be alignment between items included in these PROMs and national patient consent forms (see 7.4 Nature and frequency of assessments for adverse clinical effects during and after radiotherapy).

29. Radiotherapy providers should have procedures and resources in place to manage concerns identified as part of patient review (see 7.5 How to respond to concerns about adverse effects).
30. Key stakeholders, service users and providers should collaborate to support development of national training and resources for patients and healthcare professionals on recording and responding to patient-reported outcome data (see 7.6.4 Support the development and evaluation of new technologies, protocols and practice).

Appendix 1. AcciMap illustrating the relationship between the different safety stakeholders in radiotherapy



Appendix 2. Considerations for RTE investigation template and action plan

Considerations for inclusion in investigation templates

- outline of what happened, how and why it happened
- detail remedial actions immediately taken to protect patient safety
- key aims of the investigation
- details of investigation team
- description of the RTE including the chronological description of events leading to event
- how the information for the investigation was gathered
- an estimate of the doses received by the exposed individuals
- detailed account of the contributory factors
- whether any similar previous RTE have occurred, or if there are any trends that show a possible systematic failure
- duty of candour details
- staff contributions or support required
- whether local procedure relating to SAUE or CSAUE, required under IR(ME)R (Regulation 8), (schedule 2(l)), has been met
- details of notification to external regulatory bodies and any corresponding advice or recommendations shared
- any learning from the investigation and how this has been shared
- where appropriate include nationally agreed taxonomies to categorise the event
- agreed areas for improvement

Consideration for identifying appropriate action plan criteria

- each action, prioritised
- responsible or accountable lead
- target date for implementation
- identify any resource requirement
- detail if action required forms part of wider safety improvement plan or quality improvement initiative
- evidence of completion and how this will be measured
- change management to track progress as the investigation is completed
- how is the effectiveness of the action to be measured and monitored

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Professional bodies or organisation reviewers

- British Institute of Radiology

- Institute of Physics and Engineering in Medicine
- Patient Advisory Group, Society of Radiographers
- Radiotherapy Board
- Royal College of Radiologists
- Society of Radiographers
- Society of Radiographers: Patient Advisory Group

PSRT steering group membership

- Sarah Allford (Lay Representative) (member 2024 onwards)
- Helen Best (UKHSA)
- Neil Burley (RT Quality Manager, University College London Hospitals NHS Foundation Trust) (member 2024 onwards)
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- Úna Findlay (UKHSA and Chair)
- Spencer Goodman (Professional Officer Society and College of Radiographers)
- Petra Jankowska (Consultant Clinical Oncologist, Somerset Foundation Trust; Quality and Safety Lead, RCR) (member 2019 to 2024)
- Cristiona Logan (UKHSA)
- Tony Murphy (Patient Representative, PSRT) (member 2011 to 2023)
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Acronyms

Table A.1 Acronyms

Acronym	Meaning
AAPM	American Association of Physicists in Medicine
ACCiMap	accident mapping
AI	artificial intelligence
ASNR	Autorité de Sûreté Nucléaire et de Radioprotection
ASTRO	American Society for Radiation Oncology
AXREM	Association of X-ray Equipment Manufacturers
CAS	Central Alerting System
CF	contributory factor
CPD	continual professional development
CQC	Care Quality Commission
CQI	continual quality improvement
CSAUE	clinically significant accidental and unintended exposures
CT	computed tomography
CTCAE	common terminology criteria for adverse events
CtE	commissioning through evaluation
EA	Environment Agency
ELS	event learning system
EORTC	European Organization for Research and Treatment of Cancer
EPR	electronic patient record
ESTRO	European Society for Radiotherapy and Oncology
FRAM	functional resonance analysis method
GDPR	General Data Protection Regulations
GMC	General Medical Council
HCP	health care professional
HCPC	Health and Care Professions Council
HFS	Health Facilities Scotland
HIS	Healthcare Improvement Scotland
HIW	Healthcare Inspectorate Wales
HSE	Health and Safety Executive
HSJ	Health Service Journal

Acronym	Meaning
HTA	hierarchical task analysis
IAEA	International Atomic Energy Agency
ICB	integrated care boards
IGRT	image guided radiotherapy
IMRT	intensity modulated radiotherapy
IORT	intraoperative radiotherapy
IPEM	Institute of Physics and Engineering in Medicine
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
IRR	Ionising Radiation Regulations
LASER	London and South East Quality Managers Group
LENT-SOMA	Late Effects on Normal Tissues – Subjective Objective Management and Analytic
LFPSE	learn from patient safety events
MDT	multidisciplinary team
MHRA	Medicines and Healthcare products Regulatory Agency
MOSQUITO	Midlands Organisation of Specialists in Quality Improvement for Therapeutic Oncology
MPE	medical physics expert
NCI	National Cancer Institute
NCRI	National Cancer Research Institute
NHS	National Health Service
NHSE	NHS England
NIAIC	Northern Ireland Adverse Incident Centre
NPL	National Physical Laboratory
OAR	organ(s) at risk
ODN	operational delivery networks
OMS	oncology management system
PALS	Patient Advice and Liaison Service
PLACE	patient-led assessments of the care environment
PRO	Patient-reported outcome
PROMs	patient-reported outcome measures
PSII	patient safety incident investigation
PSIRF	patient safety incident response framework

Acronym	Meaning
PSP	patient safety partner
PSS	patient safety specialist
QA	quality assurance
QC	quality control
QI	quality improvement
QL	quality of life
QMS	quality management system
RCR	Royal College of Radiologists
RCT	randomised controlled trials
RO-ILS	Radiation Oncology Incident Learning System
ROSEIS	Radiation Oncology Safety Education and Information System
RQIA	Regulation and Quality Improvement Authority
RTDS	radiotherapy data set
RTE	radiotherapy event
RTOG	Radiation Therapy Oncology Group
RTQSIG	Radiotherapy Quality Special Interest Group
RTTQA	radiotherapy trials quality assurance
SABR	stereotactic ablative radiotherapy
SACT	systemic anti-cancer therapy
SAFRON	safety in radiation oncology
SAUE	significant accidental and unintended exposures
SCOR	Society and College of Radiographers
SEIPS	systems engineering initiative for patient safety
SGRT	surface guided radiotherapy
SMART	Specific, Measurable, Achievable, Relative and Timely
SMS	safety management system
SOP	standard operating procedure
SPC	statistical process control
TPS	treatment planning system
TSRT	Towards Safer Radiotherapy
UKHSA	UK Health Security Agency
VMAT	volumetric modulated arc therapy
WAD	work as done

Acronym	Meaning
WAI	work as imagined
WHO	World Health Organization

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