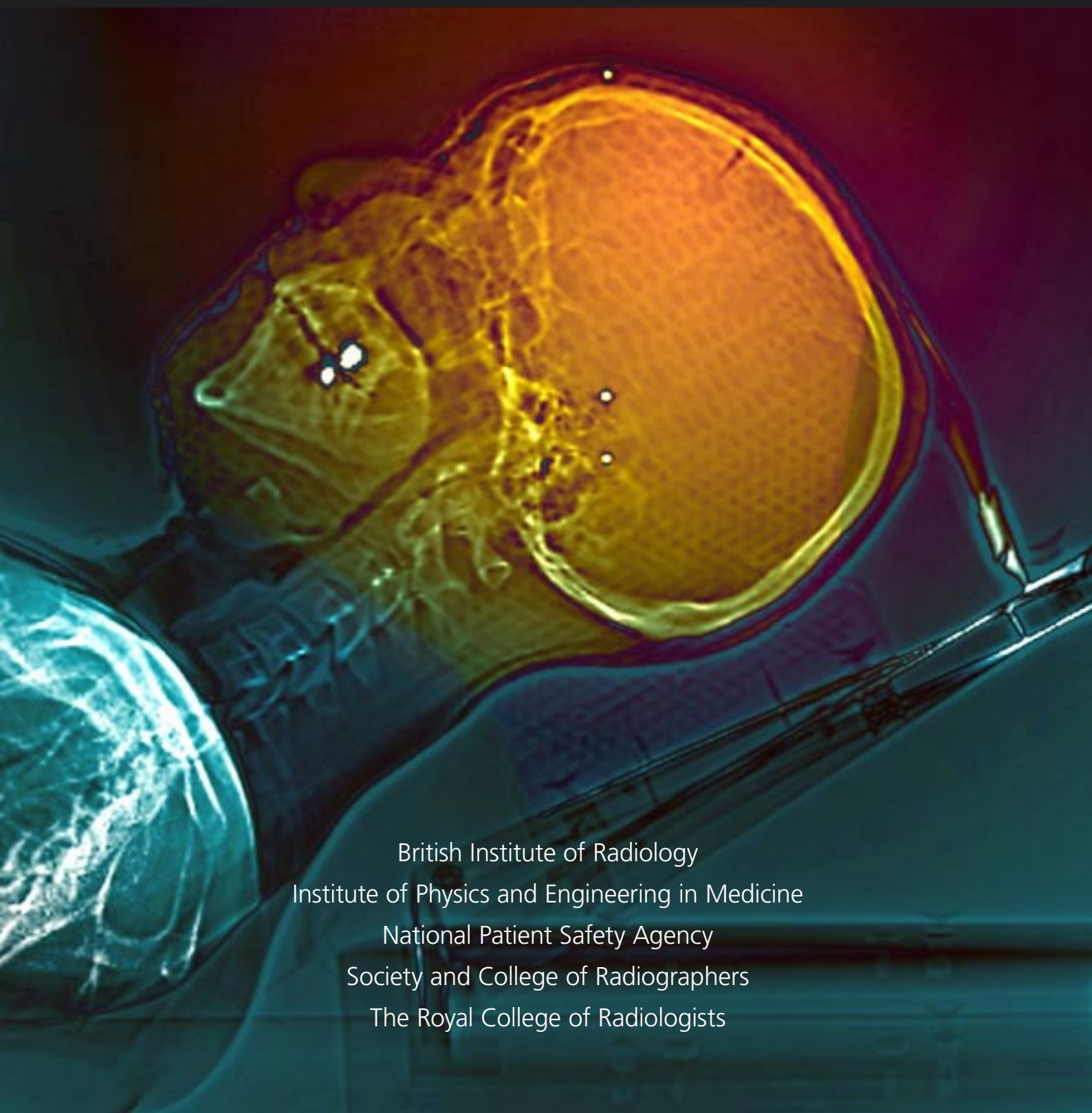


Towards Safer Radiotherapy



British Institute of Radiology
Institute of Physics and Engineering in Medicine
National Patient Safety Agency
Society and College of Radiographers
The Royal College of Radiologists

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Foreword

In my Annual Report on the State of Public Health in 2006,¹ I drew attention to the problem of radiotherapy safety. Overall, radiotherapy in the United Kingdom offers a first-rate service providing high-quality care to the vast majority of patients every year. However, in a number of unfortunate cases over the last few years, overdoses of radiation led to severe harm to patients. It is recognised that these are uncommon events, yet their impact on the patient, staff involved and the wider health service are devastating. Not only does it compromise the delivery of radiotherapy, it calls into question the integrity of hospital systems and their ability to pick up errors and the capability to make sustainable changes.

While further investment in radiotherapy is a continuing desirable goal, the patient safety movement has started to establish that changing the culture of an organisation involves steps more sophisticated than just investment and human resources.

I am delighted that the inclusion of a key role for the Chief Executive Officer of NHS trusts has been touched upon, in addition to key recommendations about communication and multidisciplinary procedures. We need to strengthen our reporting mechanisms at both a local and national level, and I strongly support the involvement of every staff member in this process. The advent of regular departmental and divisional meetings to review incident reports is a step forward, not just for those that plan action but also for those that communicate mitigating factors to all involved, including the patient.

It would appear that *in vivo* dosimetry offers an opportunity to add another safeguard in the process of care to protect patients and its promotion, in line with the recommendation I made in my annual report in 2006, is to be applauded.

We still have not yet mastered the art of harnessing all available knowledge, both national and international, to reduce adverse events in healthcare. This report represents another important effort to achieve this goal and to ensure we give every patient the care they rightfully deserve.



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DEPARTMENT OF HEALTH

Reference

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Executive summary

Background

Radiotherapy is a highly complex, multi-step process that requires the input of many different staff groups in the planning and delivery of the treatment. Though errors are rare, when they do occur the consequences can be significant for the patient.

Radiotherapy is generally safe. During the period May 2000 to August 2006, 181 incidents affecting 338 patients were reported in the UK under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000; an incidence of approximately 40 per 100,000 courses of radiotherapy. Of these, 24 were likely to have a clinically significant adverse outcome, which equates to around 3 per 100,000 courses of radiotherapy.

Complexity arises from the wide range of conditions treated, technologies used and professional expertise needed. This complexity is compounded by the multiple steps involved and the fact that processes are continually changing in the light of research and the introduction of new technologies.

Key recommendations

- The delivery of accurate treatment is the responsibility of all staff and each department must develop a safety-conscious culture. The chief executive should ensure that such a culture exists and that the processes for safe delivery of radiotherapy are in place and appropriately resourced.
- All departments should have an externally accredited quality management system to monitor that radiotherapy is delivered as intended and in accordance with protocols, to maintain and continually improve the quality of the service and to investigate and learn from incidents, errors and near misses. However, for such systems to function, they must have the commitment from senior management of the healthcare organisation and be properly resourced.
- Regular reviews should be conducted to ensure that protocols remain up to date, and that the staffing levels and skills mix are appropriate for the numbers of patients treated and complexity of treatments delivered. Excessive workload and a poor working environment can endanger patient safety.
- Good multidisciplinary working with clear communication is essential for a safer radiotherapy department and such a culture must be actively developed. Patients and staff should be encouraged to question and raise concerns to which the healthcare organisation is required to respond.
- The training records of all staff should be kept up to date and support for training provided to maintain competency, particularly when new techniques are introduced.
- The working environment needs to be carefully designed to ensure staff can work without inappropriate interruptions.
- The introduction of new techniques needs to be carefully planned with thorough risk assessment, review of staffing levels and skills required, and documentation updated. All staff involved in the process should undergo specific training in the new treatment technique or process prior to clinical use.

- This report contains detailed recommendations about making the radiotherapy process safer. The fine details of checks and verification procedures and how they are performed are critical in ensuring that they are effective and have the greatest chance of detecting an error.
- Such checking procedures should be regularly reviewed to ensure that they add value and to eliminate those that have become redundant.
- All radiotherapy centres should have protocols for on-treatment verification imaging. This should be used to ensure there is no gross positional error.
- *In vivo* dosimetry, which is the use of detectors to measure the amount of radiation delivered, can detect some significant errors. It is recommended that all radiotherapy centres should have protocols for *in vivo* dosimetry and this should be in routine use at the beginning of treatment for most patients. Patients should only be excluded from this procedure according to clear departmental protocols.
- When a clinically significant incident occurs, it is essential that the patient is informed and offered appropriate support. It is also important to offer support to the staff involved in such an incident.
- Each department must have a system for reporting and analysing errors. The lessons learnt should be fed back to the staff in multidisciplinary meetings. It is recommended that the radiotherapy pathway coding system set out in this report is used to aid the sharing of information and learning between centres.
- A new UK reporting, analysis and learning system for radiotherapy is proposed and it is recommended that all healthcare organisations with radiotherapy facilities should participate in this to facilitate the dissemination of knowledge throughout the UK on how to prevent errors in radiotherapy.

Chapter 1: Introduction

Radiotherapy has been an essential component of the treatment of cancer for many years, with approximately half of all cancer patients requiring radiotherapy at some time in their illness.¹⁻³ It forms part of the treatment of 40% of patients who are cured of their cancer.⁴

Radiotherapy is a highly complex process, involving many steps and many individuals in the planning and delivery of the treatment. Such complexity leads to a multitude of opportunities for errors to occur. Though major incidents are infrequent, the consequences can be extremely serious, as evident from the few, but disturbing high-profile incidents that have been reported recently.⁵⁻⁷

All parties involved in radiotherapy have a personal and collective responsibility for patient safety. Accordingly, in June 2006, The Royal College of Radiologists established a multidisciplinary working party to:

- Review the causes of errors and incidents
- Find ways of reducing occurrence of errors
- Increase detection before harm can occur
- Find ways of reporting errors and near misses to the whole radiotherapy community, thereby facilitating knowledge and learning which might prevent repetition
- Make recommendations on the role of education in developing a risk-aware culture.

The working party consisted of representatives from The Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR), the Institute of Physics and Engineering in Medicine (IPEM), the National Patient Safety Agency (NPSA), the Health Protection Agency (HPA), the British Institute of Radiology (BIR) and patients who worked together to produce this report, with a view to finding practical and cultural solutions which will result in patient safety being optimised.

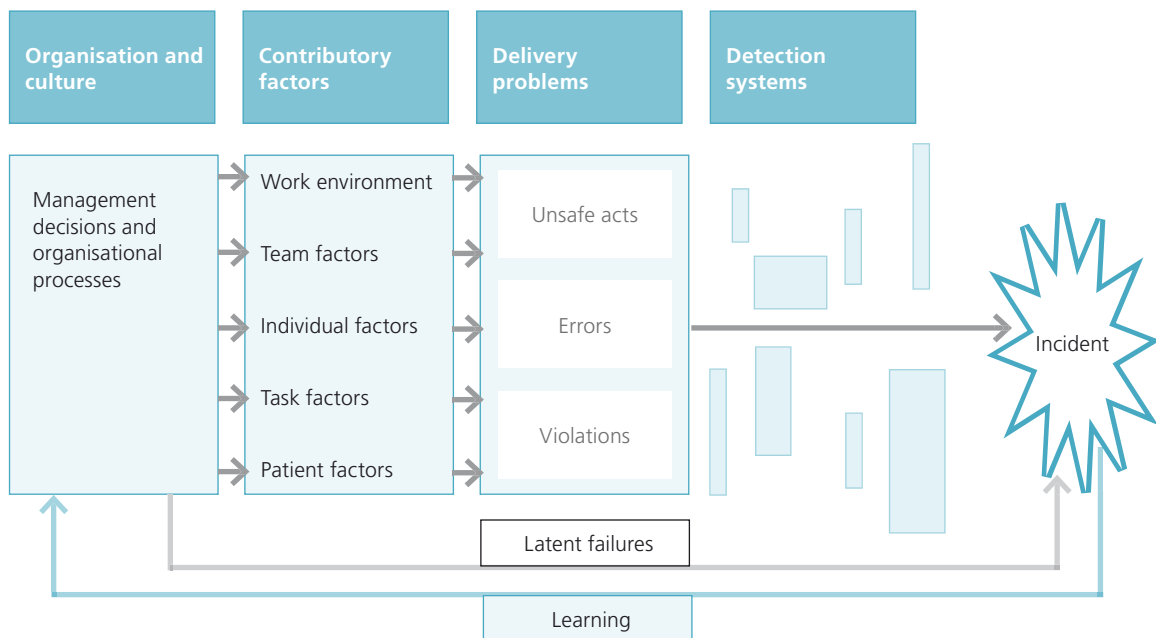
The purpose of this document is to look at ways of reducing errors in radiotherapy which are caused by individual human error or failure of systems of work. Where evidence exists to support recommendations it has been quoted. The analysis does not include errors which resulted from failure of equipment. Clinical decision-making about indications for treatment, dose and fractionation is not reviewed. This is increasingly becoming subject to protocol and peer review in multidisciplinary meetings, although there is substantial variation in practice.⁸ It is known that there are considerable differences between clinicians in target delineation⁹⁻¹³ and guidance is now becoming available to inform practice.¹⁴⁻¹⁹

Though this report is primarily aimed at the radiotherapy community and healthcare organisations with radiotherapy facilities, it is hoped that it will also provide a source of information for other healthcare professionals, patients and other interested parties. The report has, therefore, been written in a way that also enables non-specialists to understand and appreciate the issues under consideration without the need for extensive additional reading.

Chapter 2: Nature and frequency of human errors in radiotherapy

In any system errors are inevitable but, by understanding why they occur, systems can be put into place to minimise their frequency and maximise detection before harm can be done. The actions and failures of individual people play a central role, but their thinking and behaviour is strongly influenced and constrained by their working environment and by wider organisational processes.²⁰ Major incidents almost always evolve over time, involve a number of people and a number of broader contributory factors. For example, a change in a radiotherapy planning system without matching changes to other procedures may unexpectedly result in an error being made when a number of events converge many months later.⁵ This scenario has been most clearly delineated in Reason’s model of organisational accidents which provides the basis for a practical approach to incident analysis (Figure 2.1).²¹

Figure 2.1 Reason’s model of organisational accident



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There is extensive literature on errors and their causes and it is not possible to cover all the issues within this report. For a fuller account, the reader is referred to the Further Reading section on page 77. When analysing incidents we can distinguish three key steps. First, one has to consider the chain of events leading up to the incident, the narrative of events and problems. Second, one examines this narrative to identify specific errors and problems that occurred during the process. This report provides a template list of possible errors to aid this process. Third, one looks for the causes of these errors that, in the terms of the framework, are referred to as contributory factors. The identification of the process problems and contributory factors shows the vulnerabilities of the system and provides the basis for safety enhancement and quality improvement initiatives discussed later in the report.

2.1 Contributory factors

Here, by way of introduction to the report, we outline some of the contributory factors that are of particular importance in radiotherapy incidents. These issues are discussed in greater detail in later chapters.

2.1.1 Lack of training, competence or experience

Training and experience alone do not provide protection against an individual making a mistake. However, one benefit of experience is the ability to recognise one's own and one's colleagues' mistakes and to rectify these before they lead to an adverse event. UK departments historically have a variety of equipment often of differing ages from multiple manufacturers. This combined with different staffing mix means that very different protocols and policies exist locally (itself a source of error) so it is imperative that new staff receive specific local training when they move departments.²²

2.1.2 Fatigue and stress

Fatigue and stress affect both experienced and inexperienced staff and can be caused by a number of issues within work and their personal life. Staff who are suffering from fatigue and stress may function less efficiently so it is important that healthcare organisations (trust, health board or private radiotherapy facility) consider strategies to reduce these negative influences in the workplace when assigning tasks. It is worth noting that whereas it might seem that the less experienced person is more likely to make mistakes, the more experienced person, by reason of having a greater number of responsibilities, may be more prone to errors due to distraction and workplace stress.

One such task which requires intense concentration and carries a high level of responsibility is data checking. It can be tiring and difficult to do for long periods due to the repetitive nature of some elements of the process. It is important that this is recognised by management so that staff only carry out such tasks for short periods with sufficient breaks from these duties. Therefore, they should be able to alternate data checking with other more diverse activities.

2.1.3 Poor design and documentations of procedures

The more complex the process, the more opportunities there are for errors to occur. If steps are not clearly laid out and documented in protocols (standard operating procedures), then staff may be unclear about the proper sequence and the likelihood of error is increased, particularly for procedures that are rarely performed. There are enormous challenges in documenting procedures, in particular to find the balance between simplicity and completeness. As a general rule, the more difficult the process is to perform, the greater the need for clear instruction and the more difficult it is to document.

Though ideally procedures should be written for all scenarios, inevitably in healthcare some situations cannot be predicted and treatments will have to be designed on a one-off basis. In such cases, it is important that this is carried out by experienced staff with the appreciation of the risks and potential implications of decisions.

2.1.4 Over-reliance on automated procedures

It is important to recognise that automated systems can go wrong, particularly in complex circumstances that the programmer cannot predict or for which a programmed system may be inappropriate. Without experience, it is difficult to recognise that an error has been made because the system has been seen to be safe and reliable in the past. Over-reliance on such

technology tends to impair individuals' expertise if they no longer have to exercise their skills on a regular basis.

2.1.5 Poor communication and lack of teamworking

This is one of the most frequent causes of errors, and misunderstandings and incorrect assumptions have been implicated in a number of radiotherapy incidents.⁶

Poor communication is more likely if staff roles and responsibilities are not clear. Units which maintain strong professional boundaries, rather than fostering multidisciplinary working, are likely to experience communication problems between professions.

2.1.6 Hierarchical departmental structure

Historically, the hierarchical structure in healthcare has made junior members of the team reluctant to question senior staff. Hierarchical structures make it more difficult to point out failure to comply with protocol.

All healthcare professionals have a responsibility as defined in their code of conduct to question decisions that affect patient care.²³⁻²⁵ However, a junior member of staff may feel uncomfortable in questioning the work of a much more senior colleague whom they observe to be ignoring the established protocol that they have been trained to use. Conversely, a more senior person may also feel constrained from pointing out the non-compliance of a junior, particularly in a different professional group, for fear of their comments being seen as a form of bullying. Managers should be aware of these issues and seek to establish and maintain an open and fair culture which encourages the discussion of safety issues.

2.1.7 Staffing and skills levels

There must be adequate resources in place to meet the demands of the service with sufficient staff, of the correct skills and experience, to carry out the workload. Staff should be given time to carry out the necessary tasks without undue pressure.

Inadequate support services may also be a threat to safety if staff are diverted from their clinical duties to deal with routine administrative matters.

2.1.8 Working environment

Errors may be precipitated by such factors as poor design of equipment, poor room layout or the physical features of the workplace; for instance, excessive heat or cold.⁶

Staff cannot provide a safe and effective service with poorly designed, poorly maintained or out-of-date equipment. The support and active engagement of management is critical to maintaining and operating a safe service.

2.1.9 Changes in process

In complex processes, any alteration may have an unexpected knock-on effect many steps downstream. This particularly applies to the implementation of new technology; for example, new computer planning systems.^{5,7,26}

One of the effects of introducing new processes and equipment may be to make redundant the checking and verifying procedures that had previously been considered as essential. This should be considered in the introduction of change because continuing with an unnecessary step is potentially harmful because it distracts from remaining critical procedures.

2.2 The frequency of errors in radiotherapy in the UK

- 2.2.1 Recently published articles and broadcasts^{27,28} have led to the perception in some quarters that radiotherapy is a treatment where a patient is at higher risk of an adverse event occurring than in other medical specialties. While there are inevitably risks of human error in any medical procedure, the available data detailed below show that the risks are relatively low in radiotherapy. Since the majority of radiotherapy treatment is delivered on an outpatient basis – where the diagnosis is known and the patient is not at any immediate risk of injury or death – this is to be expected.
- 2.2.2 Prior to 2000, although it was custom and practice for radiotherapy incidents to be recorded and investigated locally, there was no legal requirement to report radiotherapy errors other than those attributed to equipment failure.^{29–31} However, a number of incidents occurred that led to external investigation, in particular due to the number of patients affected. Two such incidents, which occurred in the late 1980s and early 1990s, are briefly described in Table 2.1, overleaf.
- 2.2.3 In May 2000, the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R)³² came into force in England, Wales and Scotland, with separate, but equivalent, legislation in Northern Ireland. These regulations are laid down as criminal law. The Regulations state: ‘Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received’.

Table 2.1. Examples of radiation incidents reported to Department of Health prior to IR(ME)R

Centre A
Incident 207 patients received doses 25% higher than intended
Error Miscalibration of the radiation output from a new Cobalt-60 source
Underlying cause Failure explicitly to include a factor required for the calculation of radiation output and the lack of an independent check
Contributory factors Understaffing of physicists and clinical oncologists, unclear management structure, poor communication
Centre B
Incident 1,094 patients received doses between 20% and 30% lower than intended
Error Use of inappropriate correction factors when introducing isocentric treatment techniques
Underlying cause Misunderstanding of algorithm used in treatment planning system
Contributory factors Lack of full commissioning of planning computer before first use. Understaffing, lack of training on new ways of working, unclear management structure and responsibilities, unclear protocols

- 2.2.4 Guidance to the legislation issued by the Department of Health in 2000 indicated that the term ‘much greater than intended’ should be interpreted as 10% or more than that intended for a whole course of treatment, or 20% or more than that intended for any given fraction. This threshold was based on a judgement of the level of overexposure that would place the patient at risk of adverse outcome from their treatment. However, it should be noted that only incidents where the dose is *greater* than that intended are reportable, even though underdose can also result in adverse outcome for the patient. This guidance is currently under revision.³³
- 2.2.5 The exact number of incidents which result in under exposures is unknown because these are not reportable under IR(ME)R,³² though if detected before completion of the course they can often be corrected. Some incidents resulting in underdose have been reported (Table 2.2) and have been fully investigated and measures put in place to minimise the risk of recurrence.

Table 2.2. Example of a radiation underdose incident reported to Department of Health after May 2000

Centre C
Incident 132 patients received doses lower than intended (including 20 patients 5–10% and 5 patients >10% lower than intended)
Error Incorrect application of wedge factor
Underlying cause Misunderstanding of the meaning of the wedge factor for asymmetric, dynamically wedged beams when the dose prescription point is not on the central axis
Contributory factors Complexity of process

2.3 Incidents reported under IR(ME)R 2000 in England, Scotland and Wales

- 2.3.1 The appropriate authorities in England, Wales and Scotland have permitted this working party to carry out an analysis of their anonymised data on incidents reported under IR(ME)R³² between May 2000 and August 2006. This is the first time these data have been published.
- 2.3.2 During this period, 181 incidents involving radiotherapy were reported under IR(ME)R to the appropriate authority in England, Scotland and Wales. The numbers reported each year are given in Table 2.3a and outlined in Table 2.3b.

Table 2.3a. Annual numbers of incidents reported under IR(ME)R in UK

Period	No. of incidents
May–Dec 2000	7
2001	13
2002	19
2003	36
2004	32
2005	35
Jan–Aug 2006	39
Total	181

Table 2.3b. Outline of causes of the 181 radiation incidents reported under IR(ME)R

Cause	No. of incidents
Incorrect referral information	5
Patient identification error	4
Element of the design or delivery of an individual treatment	167
Inadvertent exposure of a foetus	3
Equipment error rather than human error (and therefore reportable to Health and Safety Executive)	2
Total	181

- 2.3.3 There was an average of 30 incidents reported per year from the 60 radiotherapy departments in the UK; that is, an average of three reported incidents per department during 2000–06.
- 2.3.4 One incident was an underexposure and as such there was no legal requirement to report it.
- 2.3.5 Three incidents involving the unintended exposure of a foetus throughout a radical treatment course also did not technically need to be reported, as protocols were in place and had been followed. In each case, it had been documented that before treatment the patients had been asked their current pregnancy status and advised they should avoid becoming pregnant during treatment. In each case, the patient failed to disclose her pregnancy to treatment staff.

2.4 Analysis of incidents reported under IR(ME)R in England, Scotland and Wales

- 2.4.1 A number of key features should be noted.
- All reported incidents were investigated by the appropriate IR(ME)R authority. Subsequently, the healthcare organisation was required to put systems in place locally to minimise the risk of such an event occurring again.
 - In about 80% of the 181 cases, the patient was not expected to suffer any adverse clinical effects from the error.
 - Three incidents occurred as a result of a patient not being identified correctly on one single visit (fraction) for treatment, which was part of a longer course.
 - Four incidents involved systemic failures that affected the treatment of more than one patient. The numbers of patients who potentially could have experienced adverse clinical effects due to the error were four, 11, 14 and 132 patients respectively. In all cases the clinical impact of the errors was small.
 - Over 90% of incidents were attributed to an error in carrying out a practical aspect of the treatment design, preparation or delivery.
 - The other 10% occurred as a result of a failure to supply correct details at referral or an incomplete or erroneous treatment prescription.
- 2.4.2 Two examples of incidents that have been reported and investigated under IR(ME)R by the appropriate authority are described briefly in Table 2.4.

Table 2.4. Examples of radiation incidents investigated under IR(ME)R

Centre D
<p>Incident</p> <p>One patient treated for 14 fractions without the planned wedge on one of two fields, resulting in an overdose of approximately 135%</p>
<p>Error</p> <p>The wedge data was not entered into the treatment record and verify system</p>
<p>Underlying cause</p> <p>Transcription error from paper to electronic system, not detected on data entry check before treatment started</p>
<p>Contributory factors</p> <p>Manual entry of data required. Poor working environment at the treatment unit with frequent interruptions and distractions. Daily pretreatment checks were not effective on several levels</p>
Centre E
<p>Incident</p> <p>One patient received an overdose of 58% during cranio-spinal irradiation</p>
<p>Error</p> <p>A correction factor was not applied</p>
<p>Underlying cause</p> <p>When a new planning process was introduced, the method of calculation of daily dose was changed for majority of treatments, but not for highly complex plans. Not all staff were aware of this</p>
<p>Contributory factors</p> <p>Staffing and skills mix inadequate, lack of training and supervision, potential impact of a change of process not being adequately analysed, documentation for a complex procedure not kept up to date, poor management and unclear accountability</p>

- 2.4.3 Of the 181 incidents, 34% involved a dose of ≥ 2 Gy, 40% 2–5 Gy, 10% 5–10 Gy and 16% ≥ 10 Gy. Those involving < 5 Gy were mainly during fractionated courses and therefore could be compensated and those 5–10 Gy mainly in patients receiving single fraction palliative treatments.
- 2.4.4 For the purposes of this report, the 29 incidents involving > 10 Gy were analysed in detail. Five of these incidents were assessed as not expected to have adverse clinical consequences because the error was detected early and could be compensated for during the remaining fractions of treatment, such that the originally intended radiobiological effect could be achieved.
- 2.4.5 The causes of error for the subgroup of 29 patients are summarised in Table 2.5.

Table 2.5. Errors with ≥ 10 Gy than the dose intended over course of treatment

Cause	Number
Wrong side/site being planned or wrong prescription	7
Technical complexity and unintended overlap of concomitant treatment areas	2
Patient changing position after set-up by therapeutic radiographers	1
Error in calculation – failure to interpret prescription correctly – failure to use the correct data or input the correct dose per fraction into the planning computer	5
Incorrect manual data entry into the LinAc Record & Verify (R&V) system	4
Incorrect set-up details being recorded at treatment preparation stage	3
Incorrect interpretation of, or failure to follow, patient set-up details on the LinAc	7
Total	29

2.5 Risk to patients of an adverse incident during radiotherapy treatment delivery

- 2.5.1 To place the number of incidents in context, it is necessary to consider the numbers of courses and fractions of treatment delivered. There are no definitive data on radiotherapy activity within the UK for the period covered by this review (2000–06). However, a survey conducted by the RCR showed that in England, in 2005, 110,344 patients were prescribed 1,414,192 fractions.⁸ Validation was obtained from the Radiotherapy Episode Statistics (RES) project. A sample of activity for the financial year 2004–05 from 36 English centres allows an estimate for the whole of England of 107,219 patients prescribed 1,503,474 fractions.³⁴ The RES figures are in line with the RCR findings. Scaling these figures to include Scotland, Wales and Northern Ireland, the total courses and fractions for the UK in 2004–05 were approximately 130,000 and 1,740,000 respectively.⁸
- 2.5.2 The 181 incidents reported in the UK during the first 6.3 years of IR(ME)R being in place affected 338 patients. Based on a figure of 130,000 courses of radiotherapy delivered annually, this equates to a reported incidence rate of approximately 40 per 100,000 courses of radiotherapy. Of these, 24 (all involving >10 Gy above the dose prescribed) were predicted to result in an adverse clinical outcome for the individual patients, which equates to around 3 per 100,000 courses of radiotherapy.
- 2.5.3 It is recognised that the data presented here may not fully represent the rate of clinically significant radiotherapy errors. There may be under-reporting of incidents and significant errors involving doses much less than intended are not reportable under IR(ME)R.³² There may also have been error due to equipment failure that would have been reported to the Health and Safety Executive (HSE) under the Ionising Radiations Regulations 1999²⁹ (IRR99) rather than IR(ME)R.³²
- 2.5.4 Safety is a concern across the whole of healthcare not only within the UK but worldwide. It is reported that 10% of people who receive healthcare in industrialised countries will suffer

because of preventable harm and adverse events.³⁵ Although the definition of an adverse event may be much broader in this context than the specific criterion for reporting incidents under IR(ME)R in the UK, it is apparent that the frequency of harm caused by radiotherapy incidents in the UK is not exceptional by these standards. Therefore, the available evidence suggests that, in the broader context of healthcare, radiotherapy is not a major cause of harm to patients.

- 2.5.5 Comparison with the incidence of significant radiotherapy errors in other countries would not be helpful in the context of this report. Principally, this is because the basis on which errors are reported vary from country to country and the few reports that are available tend to concentrate on those incidents in which multiple patients are affected.³⁶ Some single centres have published their local safety data.^{37,38}

Chapter 3: Defining and classifying radiotherapy errors

When discussing radiotherapy errors and incidents, it is essential to have a clear definition of these terms to aid interpretation, reporting and comparison.

In the UK, following the report into the Exeter incident,^{39,40} all radiotherapy centres were encouraged to develop a quality management system; generally known as a 'QART' (quality assurance in radiotherapy) system. One of the functions of the QART system is to record and report errors, to examine what has gone wrong and why, to effect actions to correct the immediate situation and prevent recurrence. Most, if not all, departments will analyse their statistics to identify systematic problems, see what lessons can be learnt and improvements made. However, a major difficulty arises when attempts are made to share and compare error data between centres due to the individuality of the systems developed.

Information on reportable radiotherapy errors is collected nationally via the statutory bodies (see Chapter 6). However, analysis of errors of lesser magnitude and 'near misses', at anything other than local level, is hampered by a lack of consistency in terminology and agreement on definitions at national level.

There is a wealth of literature pertaining to error terminology in medical practice and the effect this terminology has on how collected data are interpreted. A key point reflected by Tamuz *et al*⁴¹ is that the capacity for learning and the accumulation of knowledge is directly affected by how potentially dangerous events are categorised and interpreted. There is also evidence that for effective analysis, medical error should be defined in terms of failed processes that are clearly linked to adverse outcomes.⁴²

An error classification system is thus proposed which seeks to:

1. Define the terms used to avoid ambiguity
2. Provide a decision grid to arrive at an outcome-based severity classification for each event
3. Provide a detailed radiotherapy pathway coding system, which enables definition and coding of the point along the pathway at which the event occurred.

The overall objective is to enable departments to not only review their own practice, but also to provide a framework that can be used to share data nationally, potentially via a database (see Chapter 6). It is recognised that some departments already use a similar approach, but national consistency is required for meaningful analysis and learning to be achieved.

3.1 Terminology and definitions

3.1.1 The problem

Confusion can occur because the same term is used with different meanings, and the same event may be described using different terms. In his book *Human Error*, Reason defines an error as 'a failure of a planned sequence of (mental or physical) activities to achieve its intended outcome when the failures cannot be attributed to chance'.⁴³

However, any literature review or discussion with a group of professionals involved in this field will reveal a wide range of terms in use, including: error, fault, mistake, clinical adverse event, clinical incident, radiation incident, serious untoward incident, reportable error, correctable error, potential error, non-compliance, non-conformance, near miss, exception, to name but a few.

3.1.2 Proposed solution

To avoid such confusion, it is proposed to limit radiotherapy error terminology to the following terms, defined below. Each of these occurrences is a 'non-conformance' in the parlance of radiotherapy quality systems. In this context, a non-conformance is an all-embracing term that includes any deviation of a process from that specified.

Radiotherapy error A non-conformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol. Following an incorrect radiotherapy protocol is also a radiotherapy error and can lead to radiation incidents (defined below) such as those in Centres B and C in Tables 2.1 and 2.2.

Not all radiotherapy errors lead to radiation incidents – for example, because the error is detected before the patient is treated or because the error happens not to affect the treatment delivery.

Radiation incident (RI) A radiotherapy error where the delivery of radiation during a course of radiotherapy is other than that which was intended by the prescribing practitioner as defined in IR(ME)R and which therefore could have resulted, or did result, in unnecessary harm to the patient.

Correctable RI An RI that can be compensated for, such that radiobiologically the final outcome is not different in terms of clinical significance from that which was intended. The term 'non-correctable' is not used in this terminology.

Reportable RI An RI that falls into the category of reportable under any of the statutory instruments – IR(ME)R,³² IRR99²⁹ and so on. A reportable RI will generally be clinically significant, but may not be if it is a correctable RI (such as a 20% overdose on the first fraction where the doses in the remaining fractions have been reduced to compensate).

Non-reportable RI An RI not reportable as above, but of potential or actual clinical significance. An example would be a 10% underdose over the whole course of treatment due to a calculation error. Underdoses are not reportable under IR(ME)R. However, reporting clinically significant RIs to the statutory authority is good clinical governance even if there is no legal requirement to do so.

Minor RI A RI in the technical sense but one of no potential or actual clinical significance. The term 'major' RI is not used in this terminology.

Near miss	A potential radiation incident that was detected and prevented before treatment delivery. However, mistakes in plans, calculations etc do not constitute near misses if they were detected and corrected as part of the checking procedure before authorising for clinical use. Notice that the term 'miss' is used in the context of falling short of being an actual RI, rather than in the narrower sense of a geometric miss.
Other non-conformance	None of the above; that is, non-compliance with some other aspect of a documented procedure but not directly affecting radiotherapy delivery.

3.1.3 Consistency with the WHO classification

The World Health Organization (WHO) has produced a list of preferred terms and definitions in connection with patient safety.⁴⁴ The above uses of the terms 'error' and 'incident' are consistent with the WHO definitions. In the WHO list, the term 'near miss' is defined as an incident that did not cause harm. In the error classification grid (Figure 3.1), a 'near miss' is shown as arising from a radiotherapy error that did not result in a radiation incident, which is an apparent contradiction to the WHO definition. However, a near miss does indeed arise from an incident (the commission of the radiotherapy error) which does not result in a radiation incident (because, for instance, it is detected in time). Hence, the usage of the term here is consistent with that of the WHO. The term 'minor radiation incident' is also a near miss in the WHO parlance, since it is a radiation incident that did not cause harm. Nevertheless, the term 'minor radiation incident' is used to distinguish between the near miss that is not a radiation incident and that which is a radiation incident.

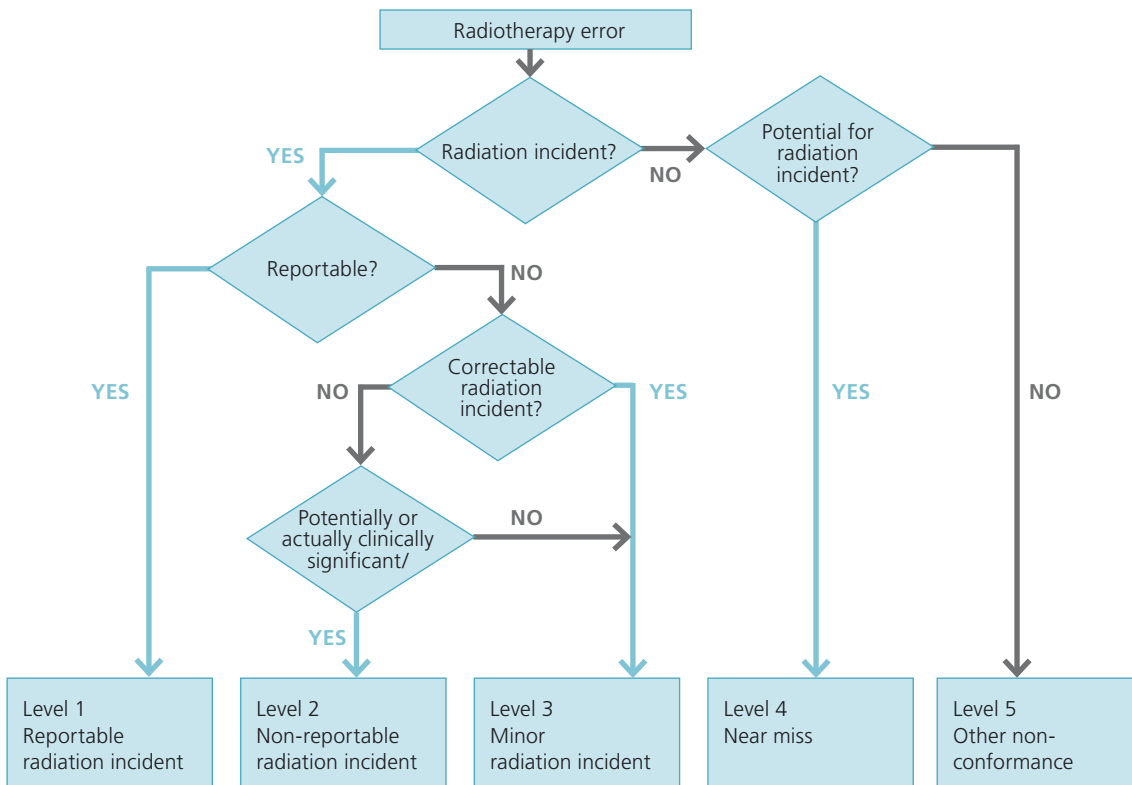
3.2 Correctable radiation incidents

- 3.2.1 When an error is detected after only a few fractions, an alteration in the field parameters or the dose delivered can usually ensure that the final treatment delivered to the patient is within tolerance of the intended dose. Examples of such calculations have been published elsewhere.^{45,46} The incident is then called a 'correctable radiation incident' as defined above.
- 3.2.2 However, if an error is not detected until late in a course of treatment complete compensation may not be possible. In such cases, the exact radiobiological consequences of an error can be difficult to establish due to the numerous factors involved.⁴⁷ In these circumstances, external advice may be sought from an expert in clinical radiobiology. A number of specialists in the UK currently offer advice, but the final decision and responsibility as to the correct course of action rests with the practitioner who prescribed the treatment.

3.3 Radiotherapy error classification grid

A decision grid is proposed (Figure 3.1) that enables the error to be graded into one of five severity classifications (Levels 1–5), using the definitions given above. Note that, while a level 1 reportable radiation incident may not be clinically significant if it is correctable, it is nevertheless considered to be of the highest severity by virtue of the requirement to report it to the appropriate statutory authority.

Figure 3.1. Classification of radiotherapy errors



3.4 Radiotherapy pathway coding system

In order to enable classification of the point(s) where errors occur, the radiotherapy pathway has been broken down into constituent elements and each one assigned a code (Appendix 3.1). It is recognised that while the pathway will be broadly similar, the specific steps may vary between departments due to local variations in protocols. The intention is to be as inclusive as possible. If a step does not occur in a given department, it will obviously not feature in any statistics generated by their error data within their QART system. Equally, it may occur but not feature if no errors are recorded at this point.

Errors are generally multi-factorial and will therefore generate more than one coding. There will usually be a primary point along the pathway at which the error is initiated, and additional points which contribute to the outcome.

By examining internal error reports and establishing where along the pathway errors occur, departments can produce a clear picture of where problems originate and, by using the decision grid, assign a severity grading to each event.

Table 3.1 demonstrates the classification of a variety of errors according to Figure 3.1, and their coding according to Appendix 3.1. It is intended to be illustrative rather than exhaustive.

Table 3.1. Examples of classification of radiotherapy errors using Figure 3.1 and Appendix 3.1

	Description of error	Severity classification (Figure 3.1)	Pathway coding (Appendix 3.1)	
			Primary point	Additional points
1	Wrong side of body planned and treated for whole course due to incorrect volume outlining	1 Reportable RI (IR(ME)R)	11i	11t, 5a, 10c
2	Identification procedure not followed, incorrect patient taken into simulator and irradiated	1 Reportable RI (IR(ME)R)	10a	
3	Wedged treatment beam delivered with wedge out for whole course due to data transcription error results in dose much greater than intended	1 Reportable RI (IR(ME)R)	12f	12g, 13v
4	Wedged treatment beam delivered with wedge out for whole course due to equipment failure results in dose much greater than intended	1 Reportable RI (IRR99)	3f	
5	Staff receive an overexposure while working outside linear accelerator due to excess scatter from maze	1 Reportable RI (IRR99)	1b	3k
6	Position of isocentre tattoo poorly documented and treatment field centred on mole. Chest fields treated for 1 of 12 fractions with isocentre 2 cm from intended position	2 Non-reportable RI (non-correctable to area overdosed, non-reportable due to dose level)	10j	10l
7	Field treated for all 30 fractions with incorrectly programmed monitor units delivering 5% above intended dose. No correction possible.	2 Non-reportable RI (Dose below IR(ME)R threshold)	12f	12g
8	Field treated for 10 of 30 fractions with incorrectly entered monitor units delivering 5% above intended dose; radiobiological equivalence calculation done and dose compensated over rest of course	2 Minor RI (Correctable RI, non-reportable due to dose level below IR[ME]R threshold)	12f	12g
9	Patient identified and set up correctly using hardcopy plan, different patient's plan selected on computer but sufficiently similar for treatment parameters to be within machine tolerance, incorrect monitor units delivered to 20% below intended dose for one fraction	2 Non-reportable RI (Correctable RI, non-reportable under IR[ME]R as underdose)	13c	13hh
10	Bolus omitted from treatment field for 2 of 10 fractions	3 Minor RI	13s	13hh
11	Processor chemicals not replenished as protocol and films consequently of such poor quality that had to be repeated with consequent additional patient exposure	3 Minor RI	3h	
12	Patient treated with 6MV when linear accelerator designated non-clinical for this energy in logbook due to query over output. Subsequent investigation shows no actual problem with output and patient has received correct treatment	4 Near miss	3j	
13	Incorrect monitor units programmed into R&V computer, checked to protocol, signed as correct. Verbal checks in treatment room identify error before irradiation occurs	4 Near miss (NB: but had error been detected via 12g checking procedure it would not constitute a near miss, merely part of that checking process)	12f	12g
14	Treatment plan completed by junior dosimetrist but not checked and signed to protocol by senior before issue and input into R&V system. Patient received 5 of 20 fractions before omission noticed, plan then checked found to be correct and signed off	4 Near miss	11k	11t
15	TLD readings within tolerance but not shown to clinician and signed off within timeframe defined in departmental protocol	5 Non-conformance	13h	
16	Patient not told to wait for review clinic and misses skin check required in treatment protocol	5 Non-conformance	14a	

Recommendation

Radiotherapy centres should use:

- The decision grid to classify the severity of radiotherapy errors and
- The radiotherapy pathway coding system in Appendix 3.1 to identify where errors occur in a consistent manner.

3.5 Analysis of the data

This system can define what has happened rather than determine the reasons for the error. As discussed in Chapter 2, the causes of errors are complex and require in-depth analysis. However, by highlighting frequently occurring problems, the system can aid further investigation and suggest generic recommendations applicable to all radiotherapy centres. This will be discussed further in Chapter 6.

Chapter 4: Prerequisites for safe delivery of radiotherapy

Patients undergoing radiotherapy expect the best possible care with the minimum risk of side-effects or complications. The balance between disease control and side-effects means that treatment should only commence after a detailed consultation with the patient, leading to explicit consent to treatment.^{48–50}

In addition, it is incumbent on organisations providing radiotherapy and on all the professional staff involved in its delivery to ensure that this delicate balance is not adversely affected by errors and untoward incidents in any part of the delivery process. This chapter addresses the prerequisites for the safe delivery of service and reviews the recommendations that contribute to this overall objective.

4.1 Radiotherapy services are complex and dynamic

Complexity arises from the wide range of conditions treated, technologies used and professional expertise needed. This complexity is compounded by the fact that processes are dynamic, continually changing in the light of research and the introduction of new technologies. Complexity and change increases the probability of incidents and errors reinforcing the need to design delivery systems which, as far as possible, ensure safety and efficacy.

Safe radiotherapy depends on:

- An adequately trained professional workforce practising together in a multidisciplinary environment
- Robust operational and management systems which facilitate safe and effective practice
- Equipment which is designed with safety in mind and which is up to date and maintained to high standards.

4.2 Workforce

- 4.2.1 The professional workforce directly involved in the delivery of radiotherapy includes, for example, clinical oncologists, therapeutic radiographers, clinical scientists and clinical technologists. Tasks should be assigned in relation to competency rather than professional background, so as to maximise the benefits of skills mix.⁵¹ More details of the training and qualifications required can be found by referring to professional organisations and regulatory bodies.^{52–54}
- 4.2.2 In addition to the achievement of core qualifications, competence to practise in a particular centre depends on specialised training in local procedures and practices. There is considerable diversity in operational practice and equipment throughout the UK and internationally. This diversity is one of the drivers for local training.
- 4.2.3 Following initial attainment of competence, all professional staff need to maintain their skills by lifelong learning through continuing professional development (CPD), which is a requirement for the maintenance of registration in most regulatory frameworks. Maintenance of competency is particularly important in radiotherapy due to the fast pace of change as new techniques and equipment are introduced. Training should include safety aspects, learning from radiotherapy incidents and quality assurance methodology. This should form an essential part of CPD. The maintenance of up-to-date training records is essential as is adequate funding for staff training.

- 4.2.4 A safe radiotherapy service is dependent on an appropriate number and mix of staff. Advice on staffing requirements is available from professional bodies. The actual number and skills of staff required depends not only on the number of patients treated but also on other factors, such as complexity of treatment and local equipment.^{3,55}
- Currently the recommended number of clinical oncologists per centre is based on the number of new patients referred per year, but account should be taken of the case mix, complexity of treatments and other factors such as peripheral clinics.⁵⁶
 - The baseline figure for the complement of therapeutic radiographers and support staff required for core service delivery is based upon the number of linear accelerator (LinAc) hours within a centre.⁵⁷ Additional therapeutic radiographers will be required to support functions beyond those listed as core and this must be borne in mind when considering staffing numbers and skills mix.
 - The numbers of radiotherapy physics staff and clinical scientists can be calculated by following guidance from the Institute of Physics and Engineering in Medicine.⁵³
 - Other departmental duties, such as teaching, research and development, should be taken into account when establishing appropriate staffing levels.
- 4.2.5 As neither the number of patients nor technical complexity remains constant and particularly because these changes often occur progressively rather than by significant incremental change, it is necessary to continually review staffing requirements and to review skills mix in the light of change.

Recommendation

To ensure that the safe delivery of radiotherapy is maintained, each centre should formally review its skills mix and staffing levels at intervals of no more than two years and ensure these comply with national guidance. Additional reviews should be carried out during the planning of new treatment techniques or procedures and before they are introduced.

- 4.2.6 The safe delivery of radiotherapy is highly dependent on communication at many different levels and between different staff groups and with patients. Clear communication reduces the risk of incidents and errors.
- The Baldwin Report²⁶ following the discovery of underdosage of patients treated over a ten-year period concluded that a failure of effective communication between the different professional groups was at least contributory to the initial error and to the delay in its discovery.
 - Clear job descriptions should be available for the clinical head of radiotherapy and for all those involved in work done for the radiotherapy department. There should be a written service agreement for providers of essential support services to radiotherapy. The responsibility and authority for the clinical management of a radiotherapy department should rest with a clinical oncologist to whom the lead radiotherapy physicist and the radiotherapy service manager should be accountable for these elements of their work. Regular meetings should be held between the clinical head of radiotherapy, the lead radiotherapy physicist and the radiotherapy service manager (lead therapeutic radiographer) to ensure integration in service provision.⁵⁸

- The multidisciplinary team of professionals involved in radiotherapy has a common goal including the avoidance of errors and untoward incidents. Vincent²⁰ has pointed out that teams can erode or create safety. Erosion is a consequence of members of the team working alone, perhaps assuming the roles and functions of others. In contrast, creation, or at least improvement, of safety follows from continual effective communication in a climate of supportive interprofessional reinforcement.
- Communication in this environment has to find the delicate balance between respect for specific knowledge, skills and status and the right of each member of the team and patients to challenge statements and assumptions which bear on the safe outcome of the process.

Recommendation

Each radiotherapy centre should hold regular multidisciplinary management meetings. In addition, there should be regular multidisciplinary meetings to discuss operational issues, including the introduction of new technologies and practices. These meetings should be informal to encourage interprofessional challenge, while respecting professional boundaries and qualifications.

4.2.7 While the multidisciplinary team has a role in the general management of each centre, it is also necessary to recognise that specific multidisciplinary teams will need to be formed for more specific tasks.

Examples include:

- Individual patient reviews of complex cases
- Technique development, such as introduction of intensity modulated radiotherapy (IMRT) for a particular tumour site
- Equipment procurement.

While multidisciplinary communication is important, one must also recognise that communication within each professional group is equally important. In this environment, there are particular dangers that can arise from hierarchy where those at lower levels can be reluctant to challenge their senior colleagues who are likely to have been involved in their training and are equally likely to be involved in their future career progression.

4.2.8 The ability of staff to talk to their colleagues and superiors about safety incidents is an important feature of creating a culture which is open and fair, and which is non-punitive. This does not mean that staff are not accountable for their actions but rather organisations need to demonstrate the right balance between both accountability and openness.⁵⁹ Deference is little defence against the adverse effects of errors and untoward incidents.

4.2.9 Based on a model developed by Professor James Reason, the National Patient Safety Agency (NPSA) has created the Incident Decision Tree (IDT) to help organisations take a systematic, transparent and fair approach to decision-making with staff who have been involved in a safety incident (Appendix 4.2).⁵⁹ More information on the use of the IDT is available on the NPSA website: www.npsa.nhs.uk

Recommendation

Multidisciplinary working with clear communication is essential for a safe radiotherapy department and such a culture should be actively developed. Questioning irrespective of position within the organisation should be actively encouraged. Those reporting uncertainties and errors should be given due credit for professional behaviour.

4.3 Systems

- 4.3.1 Radiotherapy treatment may be delivered by external beam radiotherapy, or via the application of sealed radioactive sources (brachytherapy), or through a combination of the two. For treatments to be delivered as intended, tasks have to be correctly executed according to well-defined protocols as part of the QART system.

The need for procedures to be documented, audited and continually reviewed has been recognised and a framework based on the International Standard ISO9001:2000 (formerly BS5750 / ISO 9000)⁶⁰ was recommended by the Bleehe report *Quality Assurance in Radiotherapy*.⁴⁰

A requirement for each radiotherapy department to have documented quality systems has subsequently been included in the English Department of Health's *Manual of Cancer Services* 2004.⁶¹ The QART system should cover all radiotherapy processes, from the time of the decision to treat the patient, up to the first outpatient follow-up appointment and include radiation therapy equipment quality control.

To function properly and remain up to date, the QART system requires the commitment and financial support of the management of the healthcare organisation.

Recommendation

Each department should have a fully funded, externally accredited quality management (QART) system in place.

- 4.3.2 The underlying objectives of a QART system are:

- To deliver radiotherapy treatment as intended by the prescriber and in accordance with departmental protocols
- To continually improve the quality of treatment delivery by reviewing non-conformances
- To involve all staff in learning from incidents, errors and near misses.

- 4.3.3 To achieve these objectives, all routine procedures should be carried out in accordance with documented and approved management protocols and all non-routine work that may affect treatment outcome is to be approved through a system of written 'concessions'. The management protocols, management structure and organisational charts should be subject to continual review (at a minimum every two years), and changes introduced wherever and whenever appropriate to improve the effectiveness and efficiency of the radiotherapy department.

Recommendation

All procedures should be documented and subject to review every two years or whenever there are significant changes.

The radiotherapy department management structure should be reviewed every two years.

- 4.3.4 While the radiotherapy department can ensure the establishment of a quality management system, it is vital that it is supported by the healthcare organisation at the highest level. Responsibility for the control of the quality management system should be vested in a quality management representative, appointed by the healthcare organisation, who is entrusted with the necessary authority together with senior managers from the relevant operational sections. The quality management representative should be a member of the radiotherapy risk management committee which reports directly or ultimately to the clinical governance/ clinical risk assurance committee at the executive level of the healthcare organisation. Quality policy and objectives should be reviewed at least annually. This review will include setting objectives for the coming year that will demonstrate commitment to continual improvement.

Recommendation

Quality policy and objectives should be reviewed at least annually and reported to a management representative appointed by the healthcare organisation.

- 4.3.5 For a quality management system to be effective, participation of all personnel within the radiotherapy centre must be mandatory, and knowledge and understanding of the quality policy disseminated to all staff. This should include training in how errors may occur in radiotherapy and how they may be detected and prevented.

Recommendation

Training in the operation of the quality management system should be part of the mandatory induction for all staff in each radiotherapy centre.

- 4.3.6 The IR(ME)R require detailed accountability.³² This requirement may be fulfilled by a quality system, but only after revision in the light of the regulations. A radiotherapy department working under an accredited quality system will not necessarily satisfy all the requirements of IR(ME)R.

4.3.7 Documentation

A key element of a quality system is its supporting documentation which must be maintained by a robust system for document control. The documents should include:

- Quality management procedures and protocols (standardised operating procedures)
- Detailed work instructions
- Data sheets (such as machine output factors)
- Departmental forms, such as radiotherapy treatment request forms

- Electronic information; for example, programmes and data within treatment planning systems and treatment machines.

In addition to these classes of documents, the operation of the system will generate records – for example, of the treatments delivered or quality control checks – which are also subject to strict controls. Each radiotherapy centre should maintain lists of records that will include a description of the relevant records and identify storage requirements including location and retention period.

4.3.8 Non-conformance and concessions

Management procedures and work instructions cannot apply on every occasion and may need modification to take account of individual circumstances. When this is decided on prospectively, it is termed a concession. This should be documented in writing and should include consideration of the risks involved in the change. An unintended change is termed a non-conformance and may or may not be detected and unreported. Any work activity that does not comply with a documented management procedure and/or work instruction is defined as non-conformance.

Any non-conformance that arises through equipment malfunction, operator error etc that is identified retrospectively should be documented and corrective action taken to minimise any consequences and prevent recurrence. Not all non-conformities will result in errors and incidents as defined in Chapter 3 but all should be analysed and used as a prompt for the continual improvement of systems.

In some circumstances, non-conformances are anticipated, but judged to be unavoidable due to unforeseen circumstances. Such non-conformances may be authorised by issuing a concession, which will be limited either to a specific occurrence or for a specified time to allow remedial action to be taken. A concession must not be used as a way of avoiding the rigours of the quality management system, rather as a pragmatic solution to imperfect conditions. As with non-conformances, all concessions should be analysed and used as a prompt for the continual improvement of systems.

An example of a concession

A small centre with three linear accelerators is in the process of replacing one of them. The working day for the remaining two machines has been extended and there is pressure on the physics department's quality control programme. The schedule of testing within the quality assurance system includes monthly checks on beam flatness at all gantry angles. After careful consideration of the risks involved including a review of the records of machine performance, it is agreed that the frequency of this test be reduced to every three months.

A concession is written to relax the schedule for a limited period of nine months.

4.3.9 Audit and review

The purposes of audit and review within a quality management system are related but distinct.

- Audit is a process to ensure that procedures are being followed.
- Review is a process to ensure that the procedures and work instructions are fit for purpose.

The audit process should ideally:

- Be carried out by auditors who are independent of those whose procedures are being audited
- Provide an opportunity for multidisciplinary co-operation and for cross-disciplinary appreciation of all the tasks that comprise the overall process
- Be thorough and challenging but not prescriptive.

If problems are identified, a review of the process and, if required, remedial action should be agreed by the auditor and department.

4.3.10 Multidisciplinary review of procedures especially when they are to be modified is essential.

For example, a modification in a pretreatment procedure such as change from conventional to CT simulation might require new data (or at least review of the old data) from the medical physics team and also changes in working practices for clinical oncologists and therapeutic radiographers.

4.3.11 Audit in the context of quality management systems is usually considered at two levels:

- Internal audit carried out within the radiotherapy organisation
- External audit, by an appropriate inspection body, necessary to achieve and maintain external registration.

External and therefore independent registration is not a prescriptive requirement of the Bleehen Report⁴⁰ but it is recognised as being beneficial in terms of public confidence and provides an incentive to maintain the quality system which is somewhat onerous. A further benefit of registration is that it can be used to promote radiotherapy as a generally safe medical intervention.

4.3.12 Comparative audits between departments can provide valuable opportunities to ensure safe delivery of radiotherapy and consistency of patient outcomes. Examples include:

- Audits based on the peer-review process designed to assess centres against the cancer standards⁶¹
- Audits with the initial purpose of testing the dissemination of dosimetry standards from the National Physical Laboratory (NPL) to individual centres. These were introduced by IPEM (previously the Institute of Physical Sciences in Medicine) in the early 1990s and are organised on informal, geographically based networks with the support of the NPL.

As these dosimetric audits have developed, some networks have extended the purpose to include an in-depth audit of specific clinical techniques.

- Quality assurance for clinical trials has ensured consistency between those centres participating. This has led to substantial changes in practice in both prostate cancer with the RT01 trial⁶² and in breast cancer with the Standardisation of Breast Radiotherapy (START) trials.⁶³
- In addition, national audits of radiotherapy practice have been shown to improve treatment delivery. For example, an audit to assess interruptions to radical radiotherapy in head and neck cancer has been undertaken.⁶⁴ This demonstrated that compliance with the agreed standards was best when there was a formal departmental protocol. A repeat audit has shown improvement.⁶⁵

Recommendation

All centres should participate in dosimetric audit networks.

4.3.13 Training and recording of training

Within a quality management system, each procedure and work instruction should either state or imply the level of training and qualification required for each task, recognising that in many cases the requirement is for competency-based training in addition to minimum academic or professional qualifications. This should be resourced appropriately by the healthcare organisation.

These training records are an essential requirement of IR(ME)R and should be reviewed regularly. Further training or retraining must be provided if staff do not meet the requirements.

Evidence of competency should be held in training records which are controlled documents within the quality management system.

Features within the NHS electronic staff record (ESR) and the Electronic Tool for the Knowledge and Skills Framework (e-KSF) may simplify achievement of this requirement.

Recommendation

Training records should be created and maintained for all staff involved in radiotherapy. They should be detailed and specific to particular procedures. Funding to support training should be available.

4.4 Equipment

The manufacture and supply of radiotherapy equipment is highly regulated at a national and international level.

Basic standards of safety are ensured by compliance with standards; for example, the British Standards Institution *Medical electrical equipment. Particular requirements for safety of electron accelerators in the range 1 MeV to 50 MeV*⁶⁶ and standardisation of functional performance specification is given in the associated standard, *Medical electron accelerators. Functional performance characteristics*.⁶⁷

In addition to those items covered by specific standards, all commercially available medical devices supplied in the European Community must be 'CE marked' – a requirement that ensures certification of fitness for state purpose and safety.

While these arrangements provide a degree of confidence that the vast majority of radiotherapy equipment is well designed and manufactured, they do not provide a guarantee that risks related to the use of equipment are eliminated.

4.4.1 Procurement

The procurement of radiotherapy equipment is the opportunity to specify requirements which will enhance overall safety of the service. Major items are usually procured by a

tendering process in which the radiotherapy department specifies a series of requirements against which potential suppliers offer their products.

Consideration with respect to safety should include:

- Compatibility with other equipment to enable easy transfer of patients between machines
- Ease of connection with existing equipment
- Training requirements; for example, many different types of machine will require specific training
- Appropriateness to meet clinical needs.

Recommendation

The criteria used in the evaluation of equipment with the procurement process should include a review of both the positive and negative implications of performance specifications for patient and staff safety.

4.4.2 Commissioning of radiotherapy equipment

The commissioning of radiotherapy equipment prior to clinical use is critical to its future safe operation. It is at this point when specific work instructions are developed and data that will be used during its operation (for example, for treatment planning) are collected and processed. Any errors that are introduced at this stage and not detected will potentially affect all patients for whom the equipment is used.

The commissioning process for linear accelerators is discussed in depth in *Acceptance Testing and Commissioning of Linear Accelerators*⁶⁸ by IPEM and while this is specific to one class of radiotherapy equipment, the same principles can be applied to other machines and software, such as simulators, including CT simulators, and treatment planning systems.

In addition to the individual items of equipment, radiotherapy centres have become increasingly dependent on information technology and electronic communication. This is an inevitable consequence of the introduction of computer-controlled devices, such as multi-leaf collimators. Manual transcription of such a large quantity of data is impractical and if attempted would be error prone.

Indeed, there is abundant evidence that error rates have been significantly reduced after the implementation of electronic transfer of data between planning systems and treatment machines.^{69,70} However, because electronic transfer is accepted as being highly reliable, it is extremely important to ensure that any electronic links including networks are rigorously tested as they are established. The IPEM report 93 *Guidance for the Commissioning and Quality Assurance of a Networked Radiotherapy Department*⁷¹ provides detailed and specific guidance on this topic. Failure to identify incompatibilities between data structures across a networked facility would embed errors which, particularly for data items that are perhaps accessed infrequently, could be the source of error for the life of the network.

Recommendation

Commissioning of radiotherapy equipment should be carried out against a written plan taking into account factors, including:

- Compliance with functional specification
- Clinical requirements
- Statutory and regulatory requirements
- Appropriate good practice guidance
- Safety issues.

- 4.4.3 Commissioning is usually associated with new equipment but also applies to equipment returned to service after major maintenance activity or enhancement by the addition of new features and functions.
- 4.4.4 In particular, in the case of linear accelerators and other treatment machines, the concept of a definitive calibration to establish the radiation output upon which all future treatment will be based is an important requirement to ensure a safe service. Definitive calibration requires two separate measurements – the results of which should be reconciled before the equipment is used clinically.
- 4.4.5 In addition to the commissioning of equipment including software, similar processes have to be followed in the development of a local application of specific clinical techniques; for example, the implementation of 3D conformal radiotherapy for the treatment of breast cancer. Commissioning of new clinical techniques requires documentation of the method employed and collection and presentation of the data which will be used. Ideally, it will include rigorous testing of the technique including, where possible, the application of the technique to an appropriate anthropomorphic phantom during which verification measurements can be taken.
- 4.4.6 For new or changed techniques, additional verification procedures should be considered for the initial cohort of patients. This might include more frequent portal imaging and *in vivo* and transit dosimetry.

Recommendation

When new or changed treatment techniques or processes are to be introduced, a risk assessment should be undertaken and consideration given to additional verification procedures for the initial cohort of patients.

4.4.7 Quality control

A comprehensive quality control programme is vital to ensure the correct and safe functioning of all radiotherapy and radiotherapy-related equipment throughout its operational life.

A comprehensive guide to physics aspects of quality control in radiotherapy has been published in Report 81 by IPEM.⁷²

In addition to these scientific and technical activities, radiotherapy departments require effective planned preventative maintenance (PPM) and repair arrangements to be implemented. This may be carried out by the manufacturers or by in-house engineering personnel.

The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on equipment management in *Managing Medical Devices. Guidance for healthcare and social services organisations*.⁷³

In all cases, as a requirement of a safe and effective service, responsibility for ensuring that adequate quality control checks are carried out following any PPM or repair work, prior to the equipment being handed back for safe clinical use is vested in a medical physics expert.

Recommendation

All departments should have an agreed schedule of equipment quality control and planned preventative maintenance.

Chapter 5: Detection and prevention of radiotherapy errors

5.1 Detection procedures

The previous chapters have identified the causes and classification of errors and set out the prerequisites for a safe service. These include robust systems for the detection of errors so that they can be corrected and harm to patients avoided.

This chapter describes a range of procedures for the detection of errors at the different points along the patient pathway. There are five general principles.

- Departmental protocols must clearly define two types of procedures: i) checks (confirmation of data generated by calculation or by some other manipulation, such as image fusion) and ii) verifications (confirmation that data recorded are consistent with source data). There should be explicit instructions about what should be checked, how this should be performed and the criteria against which the result will be judged; for example, a tolerance of 2% in dose or 2 mm in positional accuracy.
- Procedures to verify data should be active, eliciting a specific detailed response rather than a passive reaction in which case the answer 'yes' might suffice. This principle applies both to questioning of patients or colleagues (where open questions should be used; see Table 5.1, page 37), and to interaction with computerised systems in which case entering data is an active response. Simply approving data that is presented is passive. Active procedures can help to overcome the problem of involuntary automaticity,⁷⁴ where one perceives what one is expecting rather than what is actually present.
- The checking of any procedure or calculation should usually be carried out following a different method from that originally used (see Box 5.1 and Section 5.7.1). Checking a result by a different method avoids the possibility of repeating the same mistake.
- To avoid distraction, all radiotherapy planning, checking and verifying procedures should be carried out in a quiet, undisturbed environment.⁷⁵
- The frequency and effectiveness of checking and verifying procedures should be audited to ensure they are of value.

Box 5.1. Reverse checking in everyday life

Reverse checking is relatively common in everyday life. For example, it is used when reading back a telephone number which has been taken down as dictation. Similarly, the addition of a column of figures can be checked by adding in reverse from below rather than going down from above. Reverse checking of subtraction calculations is also common.

Forward calculation	Reverse check
1134	276
-858	+858
<hr/>	<hr/>
276	1134

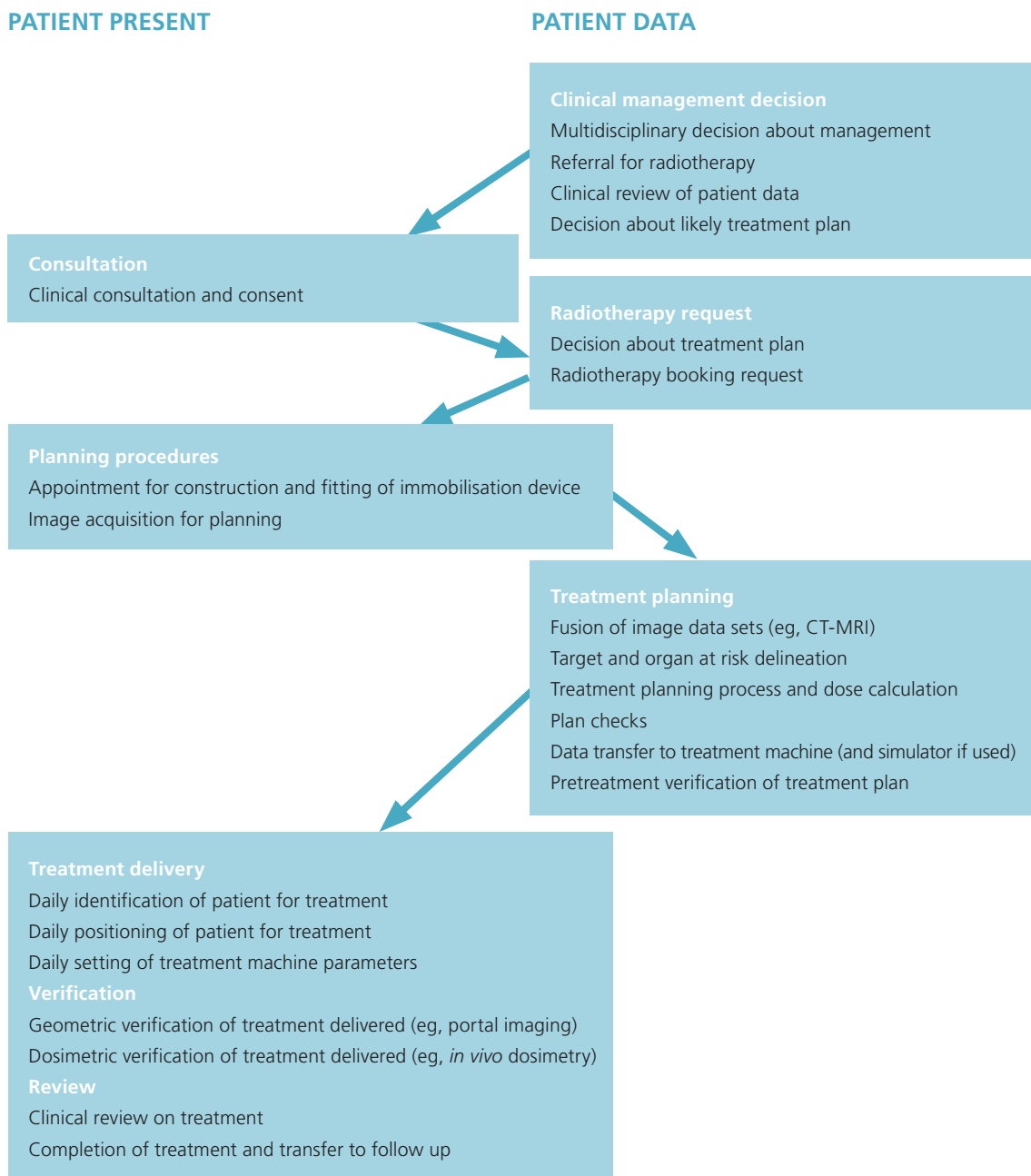
Recommendation

The precise details of checking and verifying procedures are vital to their value. Procedures used should elicit an active response and should, as far as possible, be independent of the original method. Interruptions during radiotherapy planning and checking procedures should be minimised.

5.2 Patient pathway

Figure 5.1 shows a diagram of the patient pathway. It involves a large number of steps, some of which do not directly involve the patient. Many different professionals are involved. Not all steps are relevant to all patients.

Figure 5.1. The patient pathway



5.3 Patient identification

Correct identification is crucial, not only of the patient at all points in the pathway, but also of the correct diagnostic data and specific devices used in treatment.

It is vital that identification verification is performed by asking open questions, which elicit a positive response from the patient (see Table 5.1). It is also essential that they are used on every occasion to verify the correct match of the patient and their data. Patients who cannot identify themselves pose particular problems and the employer must specify the steps to be taken in these circumstances.

Table 5.1. Examples of effective and ineffective methods during patient identification

Effective	Ineffective
Open questions, eliciting an active response	Closed questions eliciting a 'yes/no' response
What is your full name?	Are you John Smith?
What is your date of birth?	Were you born on 13 January 1949?
Where do you live?	Do you live at 12 Church Street?

Formal identification must be carried out for all procedures even when the patient is well known. Mistakes are more likely later in treatment than at the beginning.

Automated identification devices have been little used in radiotherapy, but bar-coded wristbands are now being introduced to reduce medication errors and are in use in two radiotherapy departments in the UK. Outpatients may prefer a bar-coded credit card. Some record and verify systems can integrate a photograph of the patient into the treatment room set-up data.

Biometrics are starting to be used in Europe and have the advantage that they cannot be lost or passed between patients. One department uses fingerprint identification at the entry of the department to notify staff of the patient's arrival and then at the entrance of the room to verify that the correct dataset has been called up from the computer. The advantage of such systems is that they compel the use of the identification process and directly link it to treatment.

Recommendation

Correct patient identification is essential at every step. Procedures eliciting an active response from the patient must be used. The use of new technology to assist patient identification should be explored.

5.4 Data identification

CT scans and other datasets can be mislabelled. Extreme care should be taken with this apparently routine procedure.

5.5 Patient documentation

All relevant notes and imaging should be easily available throughout the planning process to facilitate verification that the treatment being developed is correct.

It is not safe to rely on data entered onto secondary documents (such as radiotherapy request forms).

5.6 Verification and checks of treatment plans

All treatment plans must be subject to a series of well-defined checks and verifications, documented in protocols. In general, the number of procedures will be greater as the complexity of a treatment increases. However, even the simplest palliative treatment plans require rigorous if simple checks.

The planning process usually requires input from more than one operator. In particular, the role of the prescriber and planner overlap, but are distinct. The term 'planner' is used here to cover a member of a professional group who is entitled by the employer on the basis of assessed competence to carry out defined treatment planning tasks as an operator.

Radiotherapy protocols generally require that the prescriber signs both the prescription and the radiotherapy plan to authorise it. However, other staff groups – such as appropriately trained dosimetrists – can authorise plans according to locally agreed protocols. The precise responsibilities under IR(ME)R should be specified by the employer. The prescriber is acting as a practitioner justifying the exposure, and the dosimetrist, if authorising plans, is acting as an operator.

There are several aspects of treatment plans that must be checked before the planned parameters are transferred, either manually or electronically through a network, to the treatment machine. These can be categorised broadly as:

- Verification of input information
- Checks during the planning process
- Verification of the output information.

Examples of checks and verifications are given in Table 5.2. This is not an exhaustive list. Individual departments need to ensure that their checks and verification procedures are appropriate for their equipment and practice.

Table 5.2. Example of checks and verification procedures required during planning of radiotherapy

	Planner	Prescriber
Input information		
• Correct patient being treated	✓	✓
• Patient properly referred under IR(ME)R requirements and local procedures	✓	✓
• Indication for treatment		✓
• Outline of target and planning-at-risk volumes based upon: <ul style="list-style-type: none"> – Clinical examination – Surgical findings – Imaging results <p style="text-align: right;"><i>Note 1</i></p>		✓ ✓ ✓
• Total dose, fraction size, number of fractions		✓
• Correct side being treated		✓
Planning process		
• Has there been a left–right inversion of the image (verify consistency with patient notes, surgical reports etc)?	✓	✓
• Has the appropriate target been outlined (verify consistency with departmental protocol, patient notes, surgical reports etc)?	✓	✓
• Does the dose and fractionation schedule conform to departmental protocol? If not, has reasoning been documented?	✓	✓
• Have all appropriate vulnerable organs been outlined according to protocol? <p style="text-align: right;"><i>Note 2</i></p>	✓	✓
• Are the beam orientations as would be expected for the type of plan?	✓	✓
• Is the geometric relationship between GTV, CTV and PTV consistent with local protocols?	✓	✓
• Is the beam arrangement and use of wedges appropriate?	✓	✓
Output information		
• Dose distribution within and outside the PTV? <p style="text-align: right;"><i>Note 3</i></p>		✓
• Are the DVHs for the vulnerable organs acceptable? <p style="text-align: right;"><i>Note 4</i></p>		✓
• Is the displayed focus-skin distance (FSD) for each beam consistent with the measured distance from the axis to the skin?	✓	
• Are the displayed wedge orientations as would be expected?	✓	✓
• Are monitor units reasonable compared to expectation?	✓	✓
• Are monitor unit calculations correct?	✓	

Note 1: In clinical practice in the United Kingdom, the decision to treat a patient is usually taken or reviewed in a multidisciplinary meeting. However, the details of target volume, planning-at-risk volumes and dose prescription are not usually reviewed by a separate clinician. In view of the

known discrepancies between clinicians^{9–13} such reviews should be incorporated into clinical practice where time can be identified in job plans.

Note 2: This is a task which requires clinical judgement and is usually within the role of the clinical oncologist. Other radiotherapy professionals might be authorised to carry out such checking against departmental protocols on the basis of specific training and assessment of competence. Such training and competence will be documented within departmental training records.

Note 3: Normally, the planning target volume (PTV) should conform to ICRU 50 and 62 and be within the range of 95–107% of the prescribed dose. This should be checked by the prescriber both by inspection of the dose-volume histogram (DVH) and also by checking the isodose coverage of the PTV on each CT slice in turn.

Note 4: This includes checking that normal tissue dose constraints required by treatment site protocols are met. Again, the prescriber should inspect the dose distribution within these vulnerable organs visually, and not rely solely on the DVHs.

Recommendation

Each radiotherapy centre should have protocols within its quality system which define what data are to be checked by planners and prescribers along the radiotherapy pathway and how the results of these checks are to be recorded.

5.7 Monitor unit calculation checks

The calculation of monitor units is a critical element for a safe treatment planning process as covered in the above section. It is essential that checks of the monitor unit calculation are carried out before treatment commences and that this check goes back to the prescription in Gy. It is critically important to check both that the correct calculation method has been followed and that the arithmetic result of the calculation is correct.

5.7.1 Independent checks

In England, independent recalculation is mandated under the Cancer Peer Review measures⁶¹ and defines this as: 'A method which is independent of the planning computer and independent of the person producing the computer generated plan, should be in place for checking the monitor unit calculation, based on the following criteria:

- The method should be the responsibility of a Medical Physics Expert, as defined previously
- The method should only be carried out by staff approved by the Medical Physics Expert
- The data used should be independent of the planning computer
- The result of the check using independent data should be within a defined tolerance of the computer'.

For plans generated by treatment planning computers (producing isodose distributions resulting from the combination of two or more beams), calculation of the monitor units and dose to the reference point must be independently checked either by hand using tabulated data or by using another computer program.

Table 5.3 illustrates how such a check can be performed in reverse so that the first calculation gives the monitor units to deliver a chosen dose and the second uses the monitor units to calculate the dose which will be delivered.

Table 5.3. Example of reverse checking of monitor units

Parallel pair to chest		
Prescription 30 Gy in 10 fractions mid-plane dose		
Field size 8.5 x 16 cm		
Separation 22 cm		
Isocentric treatment SSD 89 cm		
Forward calculation	Data entry	Equivalent square 10.95 (tables) Separation 22 cm Daily TD 3 Gy (calculated) Machine: LA5
	Computer	Looks up depth dose + output factor
	Output	Applied dose 189 mu Manual correction for couch position field Applied dose under couch 192 monitor units
Reverse calculation	Data entry	Isocentric parallel pair Expected dose 3 Gy Field size 8.5 x 16 cm Depth 11 cm Monitor units 189
	Computer	Calculates concordance in terms of percent
	Output	Issues alert if difference $\geq 5\%$ Data rechecked if difference is $\geq 2\%$

Recommendation

Calculations should be checked by a different entitled operator, preferably using a different method and a separate data set. Reverse checking is an example of the use of a different method.

For IMRT, and other very complex plans, manual checking is not practicable and reliance must be placed on independent computer systems to check the calculated monitor units.

When introducing IMRT, centres should use the planned beams to 'treat' a phantom and compare the measured doses with those calculated for the phantom using the planned beams. Full 3D measurement of dose for the combination of modulated beams is time-consuming and resource-intensive.

However, at the present time and in the absence of simple independent calculation methods, best practice is to carry out measurements of dose from the individual modulated beams as a minimum. An IPEM report *Guidance for the Clinical Implementation of Intensity Modulated Radiation Therapy* is due to be published in 2008 and will provide a comprehensive discussion of this emerging technology including the requirements for checking.⁷⁶

5.7.2 Calculation of monitor units for prescribed dose

There must be a clear pathway extending from the prescription in Gy initiated by the prescriber through to the delivered monitor units. It is essential that checks cover the whole pathway and not just a part.

Some centres have a policy for the treatment planning system to calculate the monitor units required to deliver a normalised dose (for example, 1 Gy) to the International Commission on Radiation Units and Measurements (ICRU) reference point. This system has been implicated in high-profile errors.⁵ It is recommended that this additional step be eliminated to remove the requirement for a manual calculation to translate from the normalised to the prescribed dose. However, any change will bring its own risks, and a thorough risk analysis must be undertaken before embarking upon such a project.

Recommendation

Protocols should stipulate the calculation of monitor units for the actual dose to be delivered, rather than a normalised dose, to eliminate the need for additional manual calculations. It should be possible to check this as a single procedure.

5.7.3 Standardised treatment protocols

For some commonly delivered treatments, such as those for prostate and breast cancer, the range of monitor units per fraction falls within a predictable range for the majority of patients. Centres should consider which kinds of treatment fit into such categories and draw up lists of ranges of expected monitor units for certain beam configurations to assist staff in establishing familiarity with standard protocols. This is one of the benefits of experience.

Recommendation

The use of standardised treatment protocols allows the definition of an expected range of monitor units, which provides an additional safeguard.

5.8 Data transfer

The output from computerised treatment planning systems includes beam settings and monitor units and so on. These data should be transferred electronically to the treatment machine to avoid transcription errors. If this is not possible because of equipment incompatibility this should be highlighted as a risk and an action plan should be developed to remedy it. Meanwhile, additional verification procedures should be established. It should be recognised that the replacement of equipment provides an opportunity to improve safety in this respect.

When data transfer systems are installed, it is absolutely essential to test their integrity and accuracy during acceptance testing and commissioning.⁷¹

Where manual data entry is necessary, careful and detailed verification is required and systems should be established to avoid the dangers of passive acceptance of data.⁷⁴

Recommendation

Departments should eliminate manual data transfer between computer systems. If this is not possible, then an action plan should be developed to remedy the problem and in the interim the added risk should be recognised and careful additional verification procedures established.

5.9 Pretreatment verification

Having completed a treatment plan, steps must be taken to ensure that the correct region is being treated and that there is adequate coverage of the target. This can be carried out either using a simulator or by portal imaging on the treatment machine; images so obtained should be compared to digitally reconstructed radiographs (DRR) produced by the planning system. In the future, volumetric imaging using tomographic or cone beam techniques may fulfil this role.

Whatever verification procedure is employed, it should be carried out following protocols which define the responsibilities of each operator, detail the method to be employed and the tolerances which are required.⁷⁷

5.10 Treatment checks and verifications

Radiographers undertaking final verification of treatment immediately prior to irradiation act as operators under IR(ME)R.³² The employer should maintain a list of entitled operators and specify precise responsibilities in written procedures.

Setting the patient up accurately on the treatment machine is crucial to the delivery of the prescribed treatment. This process can conveniently be considered in two parts:

1. The physical position and orientation of the patient in relation to the isocentre and direction of the treatment beams
2. The setting of the treatment machine, including monitor units, and any beam modification devices, such as wedges or compensators.

5.10.1 Positioning of the patient and treatment fields

Correct side

During the set-up process, it is essential that the correct side is identified from the source data which will have previously been verified against the original imaging data, surgical reports, histological reports and clinical observations (including the position of scars) etc. Some centres routinely confirm with patients which side is to be treated: this is good practice. Treatment of the correct side should also be confirmed at the set-up for each fraction during a course of treatment.

Set-up to field centre

It is necessary to verify the correct set-up in relation to reference marks such as the tattoos. The use of three tattoos should be considered as this may reduce the risk of incorrect set-up.

Staff should be provided with some or all of the following:

- Clear documentation of the treatment position with any specific immobilisation requirements
- Skin marks outlining the relevant tattoo and field borders
- Clinical photographs of the proposed set-up
- Digitally reconstructed radiographs of the field
- Computer-generated images showing the projected field
- References from surface landmarks, so the location of tattoos can be checked
- Description of tattoos from previous treatments and a clear indication of their relative position to new tattoos.

If a small shift from a previous tattoo is required, the use of asymmetric fields might be preferable to daily shifts.

Recommendation

Each radiotherapy centre should have a clear protocol outlining the steps to be taken to ensure correct patient set-up.

5.10.2 Treatment unit verification

In most cases, record and verify (R&V) systems include features which allow for the automatic loading of the machine settings for each patient and for the automatic positioning of the treatment machine. Overall, such systems contribute to the avoidance of errors but care has to be taken to avoid the introduction errors by incorrect loading of verification data.^{78,79}

Clear protocols should exist for the use of R&V systems in assisting treatment set-up. The source documentation should be used by operators to confirm the patient set-up and the beam parameters set on the linear accelerator. This is a particularly challenging situation as operators understandably expect the equipment to perform accurately. Verification should be performed using active rather than passive procedures to reduce the risk of involuntary automaticity.⁷⁴

Prior to turning on the treatment beam, the key parameters of monitor units, beam energy and beam modification should be verified and confirmed by both operators using the source documentation. This process should be performed using active verification procedures.

An explicit protocol should be in place specifying accountability when undertaking a treatment exposure and detailing the responsibilities of each signatory when energising the beam. This should emphasise that active witnessing means that both operators are accountable.

There are occasions when it is necessary to either record or change machine parameters; for example, couch position on the LinAc. There are risks associated with this task. Protocols should exist detailing the procedures and the responsibilities of each operator and action levels defined within departmental protocols when further action such as resimulation or

discussion with physics should occur. Changes should be documented and the entire prescription verified in accordance with written procedures to ensure accuracy of the data.

Recommendation

Checks and verification should be performed independently by entitled operators working to clear protocols, which make explicit the individual's responsibilities and accountability.

5.11 On-treatment imaging

All the check and verification procedures in radiotherapy leading up to treatment are checks of the individual steps of the process. Only two types of checks currently available monitor the outcome of the overall process for individual patients; these are:

- i. Portal imaging which can detect geometric errors
- ii. *In vivo* dosimetry which may detect dose errors.

Geometric verification is critically important in the delivery of radiotherapy but is not dealt with in detail here as guidance is provided in *Geometric uncertainties in radiotherapy: defining the target volume*⁸⁰ and one forthcoming publication.⁷⁷ Portal imaging used at the start of a treatment course provides an opportunity to ensure that there is not a gross set-up error.

Recommendation

All radiotherapy centres should have protocols for on-treatment verification imaging. This should be used as a minimum at the start of a course of radiotherapy to ensure there is no gross positional error. If there is no electronic portal imaging available then film verification should be used if technically possible.

5.12 *In vivo* dosimetry

5.12.1 *In vivo* dosimetry not only has the potential to detect dosimetric errors but also, if carried out at an early stage in the course of treatment, may allow corrective action to be taken. It is, therefore, an effective method of reducing potential harm to patients and has been recommended by the International Commission on Radiological Protection (ICRP).⁸¹

The uptake of routine *in vivo* dosimetry for all patients has been patchy in the UK and only 30 to 40% of centres currently practise routine *in vivo* dosimetry at the beginning of treatment either for all patients or for subsets of patients.⁸² Cost and practicality have been cited as reasons for not implementing *in vivo* dosimetry widely. These issues have been summarised elsewhere.⁸³ It is accepted that the setting of priorities has to balance the costs and benefits. However, the potential benefits to patients are reinforced by the imperative to maintain public confidence in radiotherapy as a safe form of treatment. *In vivo* dosimetry has now been recommended as a routine procedure by the Chief Medical Officer for England.⁸⁴ It is already a legal requirement in Denmark and Sweden and will shortly be so in France.⁸⁵

It is unusual to detect an error using this method,⁸³ but major overdoses do, on rare occasions, occur and should be detectable using this system.⁵⁻⁷

Recommendation

Each radiotherapy centre should have protocols for *in vivo* dosimetry monitoring. *In vivo* dosimetry should be used at the beginning of treatment for most patients. Patients should only be excluded from this procedure according to clear departmental protocols.

5.12.2 The issues to be considered in providing an efficient and cost-effective service have been considered in detail elsewhere.^{83,86,87} The technical details of dosimeter placement are critical, particularly in breast patients. A departmental database should be established to capture the data and permit analysis of trends. This will also assist in setting appropriate action levels as it is important to ensure that small measurement discrepancies do not precipitate needless investigation. The details of implementation and the action to be taken by different staff groups are the key to avoiding unnecessary disruption of patients' treatment. It is essential that any anomalies which exceed agreed action levels are investigated promptly following a departmental protocol.

Because of daily variation in set-up and the precision of the method, *in vivo* dosimetry is not considered a more accurate approach to patient dosimetry than standard planning and calculation: it is a final check of the calculation pathway. It is common to set an action level of 5% for most sites. For glancing breast and chest-wall fields, difficulties in reproducible diode placement and the intrinsic imprecision of diode measurements may lead to a greater action level, for instance, 10% at such sites. The planned implementation of an *in vivo* dosimetry programme can lead to progressively lower action levels.⁸⁸

It is imperative that the calculation of the dose expected at the position of the dosimeter is based on verified and appropriate information. In some circumstances, it is possible to obtain the expected reading even though the dose delivered was not as intended: it certainly will not detect an erroneous prescription and other errors are also possible unless the calculation pathway is carefully considered.

Recommendation

Each radiotherapy centre's protocols for *in vivo* dosimetry should specify action levels and the procedures to be followed for results outside the tolerance range.

5.12.3 It is now possible to use electronic portal imaging devices (EPIDs) to measure the dose absorbed by the patient (transit dosimetry). This technology is still being developed and is not routinely available. It may have particular application in the verification of IMRT dose delivery. In the future, these technologies will also permit verification of the total dose delivered to the planning target volume, even allowing for changes in the shape of the patient and the tumour over the course of treatment. Research into these technologies should be encouraged and supported.

5.13 Clinical review during treatment and its role in error detection

In the practice of radical radiotherapy, it has been estimated that, in some circumstances, observation (for example, of the skin reaction) can detect those differences of 10% and in some settings 5%.⁸⁹ Clinical observation in 'on-treatment review clinics' thus has an important role in monitoring the treatment of patients. It will not detect underdose,²⁶ but can detect a systematic

overdose affecting a series of patients.^{39,90} Review clinics can be delegated to appropriately trained and experienced staff. It is important that any concerns raised are investigated promptly.

Recommendation

Each radiotherapy centre should have an agreed policy for systematic review of patients on treatment. Concerns raised by staff must be investigated promptly.

5.14 Patient concerns and their role in error detection

Patients are often keen observers of their own treatment. When a change occurs they are likely to remark on it: 'It lasted longer today?' or 'Where is the filter you usually put on the machine?' A clear answer must be given to any concern as it may point to an error. As mentioned earlier (5.10.1), it is good practice to verify with the patient at the start of a treatment course that the correct side is being treated.

Recommendation

Concerns raised by patients must be taken seriously and investigated promptly.

5.15 Communication with patients during treatment

Patients should be fully informed about the procedures they are to undergo and should have given consent before arrival at the treatment machine.

Some patients are particularly concerned about being alone and immobilised in the treatment room. It should be explained that closed circuit TV is used to observe patients closely and treatment can be suspended if they move or signal. There should be an agreed method of communication between patients and staff, which the patients should be made aware of before the first fraction. It is good practice for this information to also be detailed in written information given to the patient. This could involve raising a hand, speaking through a two-way intercom or an alarm button might be preferable, especially for those patients in head and neck immobilisation shells.

Recommendation

Patient communication with staff during treatment should be facilitated.

Chapter 6: Learning from errors

Though preventing and detecting errors before harm can occur is important, so is changing practice to prevent recurrence. At present, many opportunities to improve patient safety are lost because information is not shared. Learning from incidents, errors and near misses should be local, national and international.

6.1 Local learning

All UK radiotherapy centres have QART systems, a core function of which is to regularly analyse errors and other non-conformances for trends and pointers for improving the quality and safety of treatment. The impetus for QART itself originated from the investigation into the multiple-patient radiotherapy accident in Exeter.³⁹ The need for formal, comprehensive quality assurance programmes in radiotherapy is perhaps the most important lesson that has been learned from a single radiotherapy accident.

6.1.1 Analysis of incidents and near misses

When an incident or near miss occurs, it is important to look at the underlying causes to understand not only what happened, but also why. As discussed in Chapter 3, there are a multitude of human, procedural and environmental factors, which can be contributory (Table 3.1, page 22). For each radiation incident, there is a chain of events that formed the exact circumstances in which error occurred and went undetected. It is important that the investigation is conducted in a timely manner so that important factors are not missed.

A chronological investigative technique used most commonly in the UK is called 'root cause analysis' or, more broadly, 'systems analysis'. The process is described fully in *The London Protocol*⁹¹ but, in essence, involves obtaining information from all possible sources (such as patient records, planning data, staffing rotas) and conducting semi-structured interviews with all individuals concerned, including the patient, to understand the sequence of events, what actually went wrong, and all contributory factors. This information is then compiled to produce a flowchart, which depicts the sequence of events and contributory factors. The most commonly used format is the 'fish-bone' diagram or 'cause and effect' diagram (see Appendix 6.1 and Patton *et al*⁷⁹). Each incident will have factors in most categories.

Root cause analysis is time-consuming, but can provide valuable information on the workings of a department and may identify other potential problems. Root cause analysis should be conducted for all level 1 and 2 radiation incidents and other radiation incidents and near misses identified as potentially important by a systematic analysis of less detailed investigations. Practical support for using root cause analysis can be found at the NPSA's web-based e-learning toolkit at

<http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/rootcauseanalysis/>

Once the issues have been established, recommendations and an action plan can be developed to prevent recurrence. This should be disseminated throughout all staff groups involved in the relevant part of the patient pathway.

The Princess Margaret Hospital in Toronto, Canada, has demonstrated such an approach can reduce the error rate in complex radiotherapy by a third.³⁸

Recommendation

Following a level 1 or 2 radiation incident, a systematic investigation should be conducted to identify the root causes. To prevent recurrence, the lessons learnt from root cause analysis should be disseminated locally and through a national anonymised learning system.

6.1.2 A well-designed quality system should not only learn from local incidents, but also implement best practice from national and international sources such as:

- Notifications of safety issues in England can be transmitted via the Safety Alert Broadcast System (SABS), which are issued by the Medicines and Healthcare products Regulatory Agency (MHRA – Devices), the Department of Health Estates and Facilities and the NPSA
- Recommendations from published inquiries into radiotherapy incidents, such as those that occurred in Exeter, North Staffordshire Royal Infirmary and Glasgow and the recommendations published by the RCR, IPEM and SCoR in response to these incidents
- Analyses of radiotherapy incidents from around the world, such as those published by the Radiation Oncology Safety Information System (ROSIS),⁹² the International Atomic Energy Agency (IAEA)³⁶ and the ICRP.⁸¹

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Recommendation

Each radiotherapy centre must operate a quality system, which should ensure best practice is maintained by applying lessons learnt from radiotherapy incidents and near misses from other departments as well as in-house.

6.2 National learning

Though local reporting, investigation and learning following an incident is important, other radiotherapy centres may be equally vulnerable to the same problems. Therefore, the transfer of the knowledge acquired is also an important step to make radiotherapy safer across the country and internationally.

6.2.1 National reporting systems

Reporting systems can be divided into two types – statutory and voluntary.

6.2.1a Statutory reporting system

In a statutory system, the reporting of defined incidents is required by law and not to report would be a criminal offence. There are two functions of statutory reporting systems.

1. They provide assurance that serious incidents, resulting in harm or death to patients, are reported, investigated and that appropriate action is taken to prevent recurrence.
2. They encourage radiotherapy centres to improve the safety of their radiotherapy practice by increasing accountability.

As discussed in Chapter 2, in the UK, statutory reporting is required under UK law by both IR(ME)R 2000³² and the IRR99.²⁹

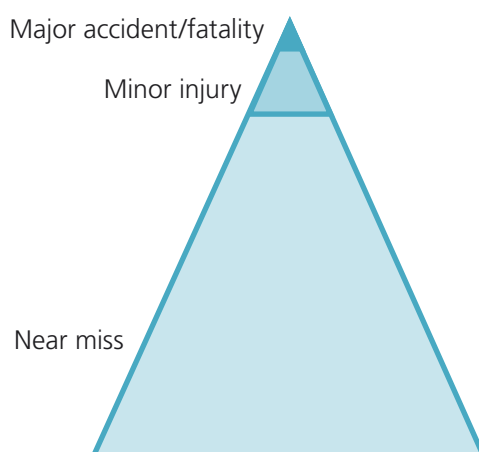
6.2.1.b Voluntary reporting systems

In a voluntary reporting system, no penalties are imposed for not reporting. Generally, the severity of incidents reported under such a system is relatively low, with patients suffering little or no injury. Most of the reported episodes are 'near misses'; errors that are detected before starting treatment and before harm can occur.

For every reportable radiation incident, many more near misses or incidents resulting in minimal harm occur. Figure 6.2 shows a diagram originally used in 1931 by Herbert Heinrich, a pioneer of industrial safety, to illustrate the fact that in the workplace, for every fatal incident, there were 30 minor and 300 near misses.⁹³ Root cause analysis of the minor events and near misses has been shown to provide valuable lessons, which can prevent serious incidents.

Therefore, voluntary, non-statutory reporting systems offer the potential to build a large database of near misses and incidents of low severity, and these data can then be available for analysis and learning by the radiotherapy community in the UK and worldwide.

Figure 6.2 Heinrich's triangle⁹³



6.2.2 Current voluntary reporting systems in the UK

Currently, voluntary reporting is available in England and Wales through the NPSA. Reports to the NPSA are derived from across all areas of healthcare and are by no means exclusive to radiotherapy.

The ROSIS database is a European collaborative which collects and analyses errors and near misses, but to function fully a long-term guarantee of resources is required, which is difficult for an international venture to secure.⁹²

6.3 Proposed voluntary UK radiotherapy reporting, analysis and learning system

The importance of widespread reporting and learning from mistakes was highlighted by the NHS in the publications *An organisation with a memory*⁹⁴ and *Building a safer NHS for patients*,⁹⁵ which first announced the establishment of the NPSA.

Currently, the NPSA collects data on radiotherapy incidents, which occur in England and Wales, but does not have the dedicated specific expertise to analyse data related to radiotherapy. Also, the wide variation in the way in which the errors are recorded means that meaningful analysis must include review of free text of individual incidents. Therefore, the Radiation Protection Division of the

Health Protection Agency has been given resources that will enable it to work with the NPSA and other UK organisations to analyse data on non-reportable radiotherapy incidents, minor radiation incidents and near misses and to disseminate the information to the radiotherapy community.

To be an effective resource for learning from incidents and errors, such a system for radiotherapy in the UK should:

- Be operated independently from any enforcement authority
- Receive reports in which the centre can be identified (but treated with total confidentiality) so the centre can be contacted if clarification is required
- Maintain patient confidentiality in accordance with NHS guidelines
- Have the formal endorsement of stakeholders, through their professional bodies.

Proposed system

- All UK centres will use their existing QART systems to identify all radiation incidents and near misses. In order to harmonise the data recording, the codes for type of error (Figure 3.1) and where in the process the error occurred (Appendix 3.1) will be logged.
- Data will be provided to the HPA for England and Wales by the NPSA and other organisations as necessary. At present, there is no equivalent body to the NPSA in Scotland and Northern Ireland so this would have to be achieved through agreements to share information directly between the HPA and individual centres.
- The HPA will collate the information and analyse the data for frequently occurring problems and trends. Where required, it will request more specific information from centres.
- Using its expertise in radiotherapy practice and previous experience of investigating incidents, the HPA will perform analysis on the data, identifying specific topics (which could include frequently occurring problems or potentially more hazardous infrequent events), and investigate the causes.
- Any recommendations for changes in practice, with regard to the delivery of radiotherapy and the prevention of errors, will be made in collaboration with the professional bodies.

Recommendation

A specialty-specific voluntary system of reporting, analysis and learning from radiation incidents and near misses should be established. All radiotherapy centres should participate in this to enable national learning from safety learning.

6.4 Feedback to radiotherapy centres and staff

The lessons from radiation incidents and near misses should be disseminated to all radiotherapy centres, front-line staff and healthcare organisations. At present, this occurs formally via safety alert broadcasts (see Section 6.1) and informally via the professional networks of physicists, therapeutic radiographers and clinical oncologists. However, only a minority of possible learning episodes are fed back by these routes and it is anticipated that the proposed system will improve this by improving analysis of incidents and making reporting more worthwhile.

To avoid incorrect speculation and consequent inappropriate change of practice, it is important that accurate, if outline, details of a major radiation incident are fed back to other radiotherapy centres as soon as possible. This will help to ensure the safety of other patients.

However, as clearly illustrated by a number of rail accidents⁹⁶ actually changing practice can be difficult.

A variety of approaches have been used⁹⁷ such as:

- Newsletters
- Emails to front-line staff
- Targeted staff education programmes
- Error prevention manuals
- Regular departmental safety seminars.

Exactly which approach is most effective at producing a sustained change of practice is uncertain, but the development of the proposed UK radiotherapy reporting, analysis and learning system affords a valuable opportunity to evaluate the different approaches and make recommendations which could be applied to other branches of healthcare.

Recommendation

Information about the error should be shared as early as possible during or after the investigation.

Research into the optimal methods of feeding back lessons learnt from radiotherapy errors should be conducted.

Chapter 7. Dealing with consequences of radiotherapy errors

Generally, the consequences of an error in radiotherapy delivery will be proportionate to the severity of its outcome, both for patients and staff.

The following are possible examples of effects of such an error.

For patients:

- Increased normal tissue toxicity due to overdose
- Reduction in tumour control due to under dose
- Anxiety and fear (of future effects)
- Anger
- Loss of confidence in RT process and staff.

For healthcare professionals:

- Diminished morale
- Feelings of guilt
- Loss of self-confidence
- Anxiety of professional reprisal.

Following the discovery of a clinically significant radiotherapy error (that is, one of level 1 or 2 as set out in Figure 3.1, page 21) both the affected patient(s) and involved healthcare professionals will need support to mitigate adverse effects, physical and psychological, both actual and potential.

7.1 General principles of actions to be taken following an error

7.1.1 Healthcare organisations should operate in a culture of openness with both patients and staff, and have a local protocol based on the NPSA's 'Being Open' policy, adapted to suit local requirements.⁹⁸

7.1.2 All radiotherapy departments should have clear guidelines in their quality system on error management, and actions to be taken when errors occur.

7.1.3 For clinically significant errors, or those that are potentially so, (level 1 or 2) these should:

- Prevent or minimise further injury to the patient
- Assess the significance of the deviation in dose before further radiation is delivered
- Assess if correction can be applied taking into account radiobiological consequences
- Establish if any other patients on treatment may be similarly affected
- Prevent or minimise any injury to other patients receiving similar treatment.

- 7.1.4 Some errors may require a retrospective review of previously treated patients to determine whether a similar event has occurred. Following the Stoke incident, the records of more than 1,000 patients were reviewed to assess the impact of a systematic error that resulted in underdosage.⁴⁷
- 7.1.5 If a level 1 or 2 clinically significant error is discovered in the treatment of a patient who has completed their radiotherapy course, a clinical decision needs to be made as to whether their subsequent management needs to be altered.

7.2 Errors without clinical significance (level 3–5): patient considerations

- 7.2.1 The majority of errors in the radiotherapy pathway fall into these categories and by definition have no consequence to the patient in terms of either tumour control or normal tissue toxicity. An example is given in Box 7.1.

Box 7.1

Treating a single field for one fraction of a 30-fraction course of radiotherapy centred on a mole adjacent to the tattoo. The difference to the tumour control and normal tissue toxicity is within the range of variation accepted in the delivery of radiotherapy. In such a case the treatment can continue as originally intended.

Level 3 (Minor radiation incident). Code 13k Identification of reference marks

7.3 Clinically significant errors (level 1–2): patient considerations

- 7.3.1 In the event of a clinically significant error, or one that is potentially so, it is important that the patient is kept informed throughout the process.^{98,99}

The consultations should:

- Involve the clinical oncology consultant
- Involve other staff to provide technical information if required
- Take place in a timely manner
- Include an independent carer or support worker to support the patient
- Be handled in a sensitive and open manner, but without causing unnecessary distress: the response should be proportionate to the potential severity of the outcome of the error
- Describe accurately the circumstances of the error, enabling the patient to have a clear understanding of what has happened and why
- Inform the patient of the most likely clinical consequences of the error
- Describe the recommended corrective action or other treatment
- Inform the patient that the incident will be investigated and reported under appropriate procedures to prevent a recurrence
- Include an apology
- Be accurately documented in the patient's healthcare record.

7.3.2 Advice and support should be offered to the patient. This should include:

- Written information
- The opportunity to discuss the issues in a supportive environment with partner or other family members present
- Referral to support groups if required
- Referral to independent expert advice if requested
- Referral for external professional counselling if required
- Information about who to contact to raise further concerns should the patient wish to escalate the process.

7.3.3 When a major error occurs and reaches the public domain, other patients receiving radiotherapy understandably become anxious about their own treatment. It is important that staff:

- Support and reassure patients whose treatment is unaffected
- Avoid speculation and discuss only known facts.

7.3.4 In circumstances where an error has been detected that affects a number of patients, many of whom have completed treatment, the potentially affected individuals should be contacted and asked to attend for an appointment to discuss the implications. In such circumstances it is recommended that:

- A telephone helpline be set up to advise other patients who have previously been treated in the department and who may be worried
- Staff dealing with telephone calls should be trained and work to a script
- Staff should know how to refer on complex queries
- All calls should be logged and the advice given and subsequent action recorded and followed up.

Recommendation

When a clinically significant radiation incident (level 1 or 2) occurs, the patient should be informed that it has occurred and be supported in the management of any potential consequences.

7.4 Reporting of incidents or concerns by patients

Patients and their carers should be given information on how they should raise any concerns they might have or report any incidents which might occur. This information should be given as part of the information, or information pack, provided to patients and their carers at an early stage of their pathway.

- Internally: This should normally be done by the patient initially contacting his or her named nurse/therapeutic radiographer/oncologist. Patients should also be advised of the procedure within the healthcare organisation to escalate the issue beyond this level should they wish to do so. Additional information on this can be found at: www.healthcarecommission.org.uk/aboutus/complaints/complaintsaboutthenhs.cfm

- Externally: Patients should use the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card form or the NPSA website www.npsa.nhs.uk/public/reporting. Alternatively, in Wales concerns can be reported to www.patienthelp.wales.nhs.uk
- Patients unhappy with the way in which their complaint has been handled by the NHS can contact the Healthcare Commission: <http://www.healthcarecommission.org.uk/aboutus/complaints/complaintsaboutthenhs.cfm> gives information about how this can be done and the information required.

7.5 Staff support

7.5.1 If a significant or potentially significant incident occurs it is not only distressing for patients, but also staff. Staff involved may need:

- Information on the process of investigation and reporting
- Reassurance that blame will not be attributed in cases of inadvertent error or system failure
- Support from colleagues
- Support from line managers
- Support from their professional body or trade union
- Counselling facilitated either by the healthcare organisation or externally
- A period of re-training following investigation of the error.

7.5.2 When an error occurs, it is important that all staff involved are informed of the nature of the problem to diminish the probability of a repetition before the investigation process is complete. A balance needs to be struck between informing staff and not prejudging the causes.

Recommendation

When an error occurs, the staff involved should be offered appropriate support.

7.6 Informing the wider community

The need to inform the professions within the wider radiotherapy community when a serious radiotherapy error has occurred has already been discussed in Section 6.4.

There will also be a need to inform management personnel outside the radiotherapy department but within the healthcare organisation. They may need specialist advice from radiotherapy professionals due to a lack of understanding about the details of radiotherapy treatments.

The management of press interest in the event of a serious radiotherapy error should be planned for. Patient confidentiality and the possibility of prosecution may limit publication of details of the incident. It is essential that:

- Healthcare organisations publish clear protocols for staff on how to handle enquiries from the media
- All patients who may have been affected are informed by personal contact before any press release is issued

- General practitioners of affected patients should also be informed before any press release is issued
- Professional bodies that may become involved should be informed before any press release is issued to enable them to handle media enquiries appropriately, and provide support to their members as necessary
- The healthcare organisation's public relations officer should be contacted for expert advice
- A short clear press statement should be drafted by a trained professional
- A trained spokesperson should be identified and likely press questions should be considered and answers prepared
- The press release should clearly describe the nature of the error if possible
- The risks to other patients in the same and other departments should be explicitly addressed
- The anxiety of other patients caused by media interest should be addressed.

Summary of recommendations

Departmental culture, resources and structure

1. Multidisciplinary working with clear communication is essential for a safe radiotherapy department and such a culture should be actively developed. Questioning irrespective of position within the organisation should be actively encouraged. Those reporting uncertainties and errors should be given due credit for professional behaviour (page 27).
2. To ensure that the safe delivery of radiotherapy is maintained, each centre should formally review its skills mix and staffing levels at intervals of no more than two years and ensure these comply with national guidance. Additional reviews should be carried out during the planning of new treatment techniques or procedures and before they are introduced (page 25).
3. Training records should be created and maintained for all staff involved in radiotherapy. They should be detailed and specific to particular procedures. Funding to support training should be available (page 31).
4. The radiotherapy department management structure should be reviewed every two years (page 28).

Working practices

5. The precise details of checking and verifying procedures are vital to their value. Procedures used should elicit an active response and should, as far as possible, be independent of the original method. Interruptions during radiotherapy planning and checking procedures should be minimised (page 36).
6. Each radiotherapy centre should have protocols within its quality system which define what data are to be checked by planners and prescribers along the radiotherapy pathway and how the results of these checks are to be recorded (page 40).
7. Checks and verification should be performed independently by entitled operators working to clear protocols, which make explicit the individual's responsibilities and accountability (page 45).
8. Correct patient identification is essential at every step. Procedures eliciting an active response from the patient must be used. The use of new technology to assist patient identification should be explored (page 37).
9. Each radiotherapy centre should have a clear protocol outlining the steps to be taken to ensure correct patient set-up (page 44).
10. The use of standardised treatment protocols allows the definition of an expected range of monitor units, which provides an additional safeguard (page 42).
11. Calculations should be checked by a different entitled operator, preferably using a different method and a separate data set. Reverse checking is an example of the use of a different method (page 41).
12. Protocols should stipulate the calculation of monitor units for the actual dose to be delivered, rather than a normalised dose, to eliminate the need for additional manual calculations. It should be possible to check this as a single procedure (page 42).

13. Departments should eliminate manual data transfer between computer systems. If this is not possible, then an action plan should be developed to remedy the problem and in the interim the added risk should be recognised and careful additional verification procedures established (page 43).

Safety management

14. All departments should have an agreed schedule of equipment quality control and planned preventative maintenance (page 34).
15. All centres should participate in dosimetric audit networks (page 31).
16. All radiotherapy centres should have protocols for on-treatment verification imaging. This should be used as a minimum at the start of a course of radiotherapy to ensure there is no gross positional error. If there is no electronic portal imaging available then film verification should be used if technically possible (page 45).
17. Each radiotherapy centre should have protocols for *in vivo* dosimetry monitoring. *In vivo* dosimetry should be used at the beginning of treatment for most patients. Patients should only be excluded from this procedure according to clear departmental protocols (page 46).
18. Each radiotherapy centre's protocols for *in vivo* dosimetry should specify action levels and the procedures to be followed for results outside the tolerance range (page 46).
19. Each radiotherapy centre should have an agreed policy for systematic review of patients on treatment. Concerns raised by staff must be investigated promptly (page 47).

Patient and staff involvement

20. When a clinically significant radiation incident (level 1 or 2) occurs, the patient should be informed that it has occurred and be supported in the management of any potential consequences (page 55).
21. Concerns raised by patients must be taken seriously and investigated promptly (page 47).
22. When an error occurs, the staff involved should be offered appropriate support (page 56).
23. Information about the error should be shared as early as possible during or after the investigation (page 52).
24. Patient communication with staff during treatment should be facilitated (page 47).

Change management

25. Each radiotherapy centre should hold regular multidisciplinary management meetings. In addition, there should be regular multidisciplinary meetings to discuss operational issues, including the introduction of new technologies and practices. These meetings should be informal to encourage interprofessional challenge, while respecting professional boundaries and qualifications (page 26).
26. When new or changed treatment techniques or processes are to be introduced, a risk assessment should be undertaken and consideration given to additional verification procedures for the initial cohort of patients (page 33).
27. The criteria used in the evaluation of equipment with the procurement process should include a review of both the positive and negative implications of performance specifications for patient and staff safety (page 32).

28. Commissioning of radiotherapy equipment should be carried out against a written plan taking into account factors, including:
- Compliance with functional specification
 - Clinical requirements
 - Statutory and regulatory requirements
 - Appropriate good practice guidance
 - Safety issues (page 33).

Quality assurance systems

29. Each department should have a fully funded, externally accredited quality management (QART) system in place (page 27).
30. All procedures should be documented and subject to review every two years or whenever there are significant changes (page 28).
31. Quality policy and objectives should be reviewed at least annually and reported to a management representative appointed by the healthcare organisation (page 28).
32. Each radiotherapy centre must operate a quality system, which should ensure best practice is maintained by applying lessons learnt from radiotherapy incidents and near misses from other departments as well as in-house (page 49).
33. Training in the operation of the quality management system should be part of the mandatory induction for all staff in each radiotherapy centre (page 28).
34. Radiotherapy centres should use:
- The decision grid to classify the severity of radiotherapy errors and
 - The radiotherapy pathway coding system in Appendix 3.1 to identify where errors occur in a consistent manner (page 23).
35. Following a level 1 or 2 radiation incident, a systematic investigation should be conducted to identify the root causes. To prevent recurrence, the lessons learnt from root cause analysis should be disseminated locally and through a national anonymised learning system (page 49).

Recommendations for national implementation

36. A specialty-specific voluntary system of reporting, analysis and learning from radiation incidents and near misses should be established. All radiotherapy centres should participate in this to enable national learning from safety learning (page 51).
37. Research into the optimal methods of feeding back lessons learnt from radiotherapy errors should be conducted (page 52).

Appendix 3.1. Radiotherapy pathway coding

NB: This coding system was developed and tested with the help of members of the London Radiotherapy Quality Assurance Network. All coding systems are dynamic as systems change and new procedures invented therefore further codes will have to be added as required.

Process code	Activity code
0	Scientific infrastructure
0a	Implementation of national and international codes of practice for radiation dosimetry
0b	Development of dosimetry algorithms for local application
0c	Development of treatment planning algorithms for local application
0d	Other
	Equipment-specific activities
1	Room design
1a	Patient safety
1b	Staff and public safety
1c	Environmental controls
1d	Access control
1e	Other
2	New equipment
2a	Installation
2b	Manufacturer's tests
2c	Acceptance tests
2d	Critical examination under IRR99
2e	Customisation and configuration of equipment
2f	Commissioning
2g	Data recording
2h	Preparation of data files for planning computers
2i	Other
3	Routine machine QA
3a	Daily consistency checks – geometric parameters

- 3b Daily consistency checks – dosimetric calibration
- 3c Daily consistency checks – safety (IRR compliance)
- 3d Daily verification of accuracy of data transfer between TPS, R&V system and treatment equipment
- 3e Planned QA programme checks – geometric parameters
- 3f Planned QA programme checks – dosimetric calibration
- 3g Planned QA programme checks – safety (IRR compliance)
- 3h Planned QA programme checks – image quality parameters (including CT, MR, portal, cone-beam, film processor)
- 3i Regular preventative maintenance and repair programme
- 3j Handover of radiotherapy equipment after planned QA and maintenance
- 3k Routine radiation safety checks
- 3l Other

Patient-specific activities

4 Referral for treatment

- 4a Identification of patient
- 4b Verification of diagnosis/extent/stage
- 4c Choice of dose
- 4d Choice of modality
- 4e Choice of energy
- 4f Choice of fractionation
- 4g Choice of start date
- 4h Consideration of patient condition/co-morbidities
- 4i Choice of other interventions and their sequencing
- 4j Consent process
- 4i Other

5 Communication of intent

- 5a Completion of request for treatment (paper/electronic)
- 5b Recording of patient ID
- 5c Completion of required demographics
- 5d Completion of tumour-specific information

- 5e Completion of radiation-specific information
- 5f Completion of details of other professionals
- 5g Completion of administrative data
- 5h Recording of previous treatment details
- 5i Recording of patient's specific requirements
- 5j Recording of non-standard information/protocol variations
- 5k Authorisation to irradiate (IR(ME)R)
- 5l Other
- 6 Booking process (pretreatment and treatment)**
- 6a Bookings made according to protocol
- 6b Bookings made according to request details
- 6c Recording of booked appointments
- 6d Communication of appointments to patient
- 6e Other
- 7 Processes prior to first appointment**
- 7a New patient: registration with healthcare organisation's PAS
- 7b New patient: registration with department PAS
- 7c New patient: generation of notes
- 7d Old patient: location of healthcare organisation's notes
- 7e Old patient: location of department notes/previous treatment details
- 7f Availability of reports/imaging required by protocol for treatment
- 7g Availability of consent documentation
- 7h Other
- 8 Pretreatment: preparation of patient**
- 8a Confirmation of ID
- 8b Confirmation of consent
- 8c Confirmation of fertility/pregnancy status
- 8d Advice on procedure
- 8e Other

- 9 Mould room/workshop activities**
- 9a Confirmation of ID
- 9b Pre-mould room diagnostics/interventions
- 9c Production of immobilisation devices
- 9d Checking/fitting of immobilisation devices
- 9e Production of other accessories/personalised beam shaping device
- 9f Checking of other accessories/personalised beam shaping device
- 9g Labelling of mould room/workshop outputs
- 9h Recording of information in patient record
- 9i Instructions to patient
- 9k End of process checks
- 9l Other
- 10 Pretreatment activities/imaging (to include CT, simulation, clinical mark-up)**
- 10a Confirmation of ID
- 10b Positioning of patient
- 10c Localisation of intended volume
- 10d Production of images using correct imaging factors
- 10e Production of images using appropriate field sizes
- 10f Production of images demonstrating correct detail
- 10g Labelling of images
- 10h Saving of planning geometry data
- 10i Recording of radiation data
- 10j Documentation of instructions/information
- 10k Marking of patient or immobilisation device
- 10l End of process checks
- 10m Identification of staff
- 10n Other
- 11 Pretreatment planning process**
- 11a Verification of patient ID to include all patient data, imaging etc
- 11b Recording of patient ID on plan

- 11c Importing of data from external administrative sources
- 11d Importing of data from external imaging sources
- 11e Choice of data
- 11f Choice of dose and fractionation inputs
- 11g Availability of source data
- 11h Choice of technique
- 11i Target and organ at risk delineation
- 11j Generation of plan for approval (to include DVH etc as app.)
- 11k Authorisation of plan
- 11l Verification of plan/identification of responsible staff
- 11m Recording of definitive treatment prescription
- 11n Recording of patient-specific instructions
- 11o Management of process flow within planning
- 11p Management of authorisation process
- 11q Timeliness of plan production
- 11r Calculation process for non-planned treatments
- 11s Calculation checking process for non-planned treatments
- 11t End of process checks
- 11u Identification of responsible staff
- 11v Other

12 Treatment data entry process

- 12a Pre-data entry verification
- 12b Choice of data entry method (input vs transcription)
- 12c Use of correct data
- 12d Correct ID of patient/all patient input data
- 12e Correct ID of patient output data
- 12f Accuracy of data entry
- 12g End of process checks
- 12h Identification of responsible staff
- 12i Other

13	Treatment unit process
13a	Availability/timeliness of all required documentation
13b	Patient ID process
13c	Patient data ID process
13d	Explanation/instructions to patient
13e	Confirmation of pregnancy/fertility status
13f	Assessment of patient prior to treatment
13g	Patient positioning
13h	Use of IVD according to local protocol
13i	Use of on-set imaging
13j	Transfer of marks
13k	ID of reference marks
13l	Movements from reference marks
13m	Setting of treatment machine parameters
13n	Setting of collimator angle
13o	Setting of jaw position
13p	Setting of asymmetry
13q	Setting of couch position/angle
13r	Use of immobilisation devices
13s	Use of beam shaping devices
13t	Use of beam direction aids/applicators
13u	Use of compensators
13v	Use of wedges
13w	Availability of treatment accessories
13x	Setting of energy
13y	Setting of monitor units
13z	On-set imaging: production process
13aa	On-set imaging: approval process
13bb	On-set imaging: recording process
13cc	Management of variations/unexpected events/errors

- 13dd Communication between treatment unit and V&R
- 13ee Recording of patient attendance
- 13ff Recording of delivered treatment data
- 13gg Recording of additional information
- 13hh End of process checks
- 13ii Identification of responsible staff
- 13jj Other

14 On-treatment review process

- 14a On-treatment review of patient according to protocol by RT staff
- 14b On-treatment review of patient according to protocol by other professional
- 14c On-treatment review of notes/data to according protocol
- 14d Actions following on-treatment review
- 14e Other

15 Brachytherapy

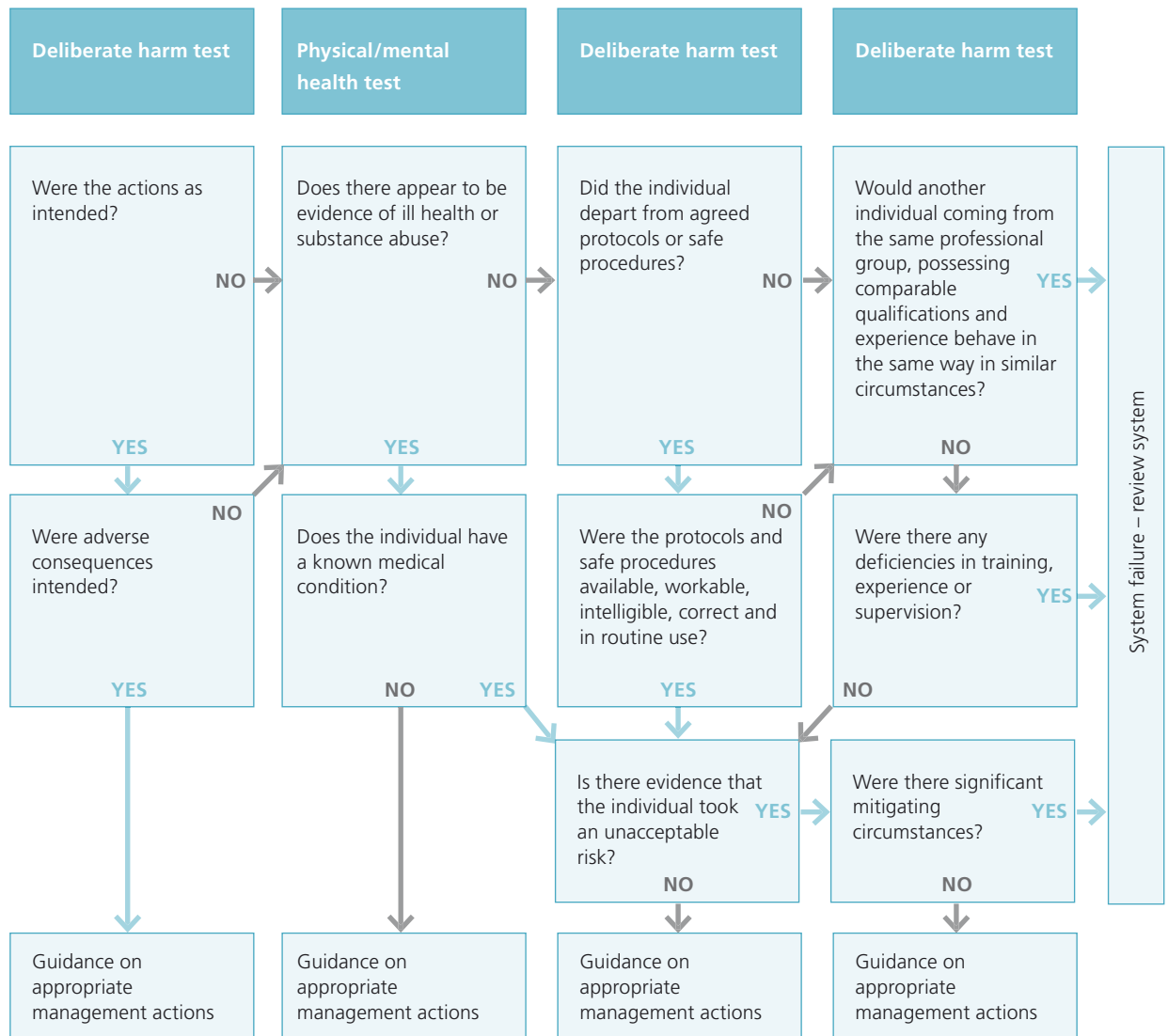
- 15a Ordering of sources
- 15b Delivery of sources
- 15c Source calibration
- 15d Sterility of sources
- 15e Correct applicators/sources
- 15f Correct theatre equipment
- 15g Initial positioning of applicators/sources
- 15h Planning of treatment
- 15i Maintenance of position of applicators/sources
- 15j Removing of applicators/sources
- 15k Other

16 End of treatment process

- 16a Communication of appropriate end of treatment information to patient
- 16b Recording of treatment summary information in notes
- 16d Communication of information to referring clinician/GP/CNS etc
- 16e Organisation of follow-up appointment to protocol

- 16f Communication of follow-up to patient
- 16g Other
- 17 Follow-up process**
- 17a Follow-up consultation and documentation
- 17b Management of non-attendance
- 17c Archiving of details of treatment
- Other activities contributing to protocol violations***
- 18 Timing**
- 18a Timing of chemo/irradiation
- 18b Transport issues
- 18c Portering issues
- 19 Document management**
- 19a Availability of current protocol documentation
- 20 Staff management**
- 20a Availability of staff with competency appropriate to procedure

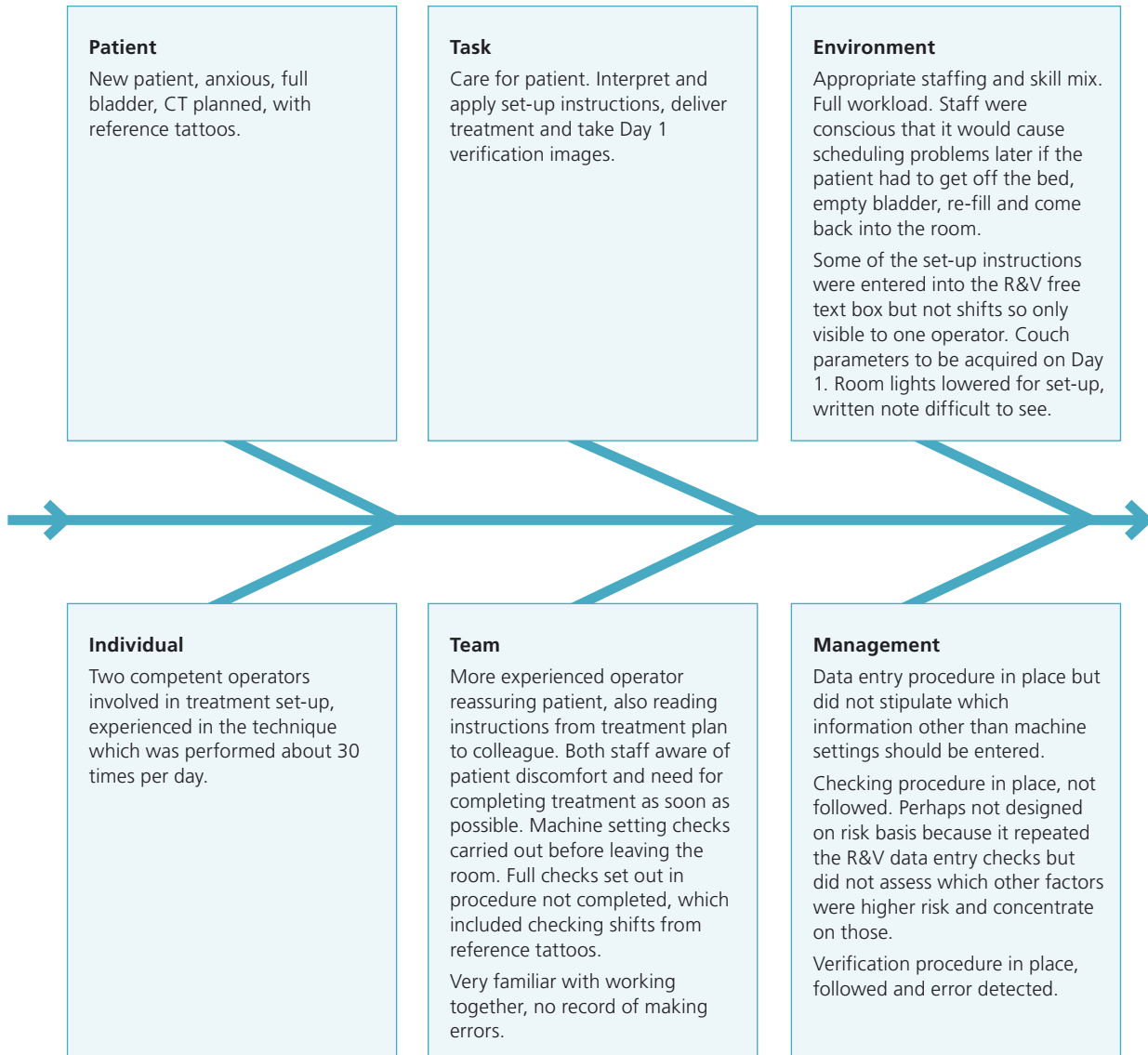
Appendix 4.1. Incident Decision Tree based on James Reason's culpability model



(reproduced with the permission of NPSA)

Appendix 6.1. Care delivery problem

Geographical miss, set-up to left instead of right of reference tattoo by 1.2 cm for 1 #, detected by off-line review of Day 1 verification images



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Glossary of terms

Anthropomorphic phantom	A model of a human into which radiotherapy detectors are placed to measure dose delivered. Used prior to very complex treatments or during developmental work
Asymmetric fields	Where the radiotherapy fields are set up so one half of the beam is larger than the other. This is usually used to avoid critical structures or plan the treatment around a specified point
Bolus	Tissue equivalent material laid on skin to increase the surface dose
Brachytherapy	Radiotherapy administered by implanting or placing a radioactive material into, or close to, a tumour minimising the dose to surrounding normal tissue
Clinical oncologist	A doctor who specialises in the treatment of cancers using radiotherapy and chemotherapy
Clinical scientist	A specialist with scientific understanding providing advice and innovation in the planning and delivery of radiotherapy treatment and services
Clinical target volume (CTV)	The area of the body at risk of having tumour cells present, included the GTV and areas of possible microscopic spread
Clinical technologist	A specialist in radiation treatment tasks such as planning and verification, preparation of brachytherapy sources or manufacture of immobilisation devices
Cobalt-60	A radiotherapy machine which uses radioactive cobalt as a source of radiation
Commissioning	When baseline data and characteristics of the equipment are acquired to support the clinical delivery of precise and safe treatment
Concession	Where a planned deviation from standard protocol is planned and approved
Conformal radiotherapy	Treatment technique, which aims to shape the 3D high-dose volume to the planning target volume while minimising dose to healthy tissue
Correctable radiation incident	See Section 3.1.2
Course(s)	A pre-planned set of fractions of radiotherapy given to a part of the body
Cranio-spinal irradiation	A specialised technique used to treat the brain and spinal cord

CT simulation	CT scanner with flat top couch and laser positioning system that can simulate a patient's treatment
Definitive calibration	The measurement of radiation dose under reference conditions as delivered by a treatment machine at the time of commissioning or subsequent to major changes in configuration during the lifetime of the machine
Dose	A quantity of radiation
Dosimetrist	An individual who designs treatment plans and/or conducts measurements of radiation dose
Dosimetry	The measurement of the dose of radiation
Dose volume histogram (DVH)	A graph showing the dose distribution to an outlined structure used to assess the dose to the target or normal tissues
Exposure	Each time the radiation beam is turned on to treat the patient from a new direction
External beam radiotherapy	Most common form of radiotherapy. High-energy electromagnetic radiation delivered from outside the body, directed towards the target region
Fraction(s)	Radiotherapy is usually delivered as a series of small, usually daily, fractions in order to minimise damage to normal tissues. Up to 36 fractions may be given
Focus skin distance (FSD also called SSD 'source to skin distance')	Distance from radiation source to patient's skin
Gray (Gy)	The unit of measure of absorbed radiation dose
Gross tumour volume (GTV)	The tumour palpable or visible on imaging
Ionising radiation	Energetic particles or waves that have the potential to ionise an atom or molecule
Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R)	Regulations that require employers undertaking medical radiation to ensure patient and public safety
IMRT	Intensity modulated radiotherapy. Treatment delivery technique that modulates the intensities of the beams, as well as geometrically shaping them. IMRT can enable the high-dose volume to be shaped to avoid critical structures

<i>In vivo</i> dosimetry	Measurement of actual dose delivered to patient, usually with an electronic detector (eg, a diode) or TLDs (see below) placed on the skin or sometimes with electronic portal image detector (EPID)
Isocentric	Radiotherapy which is delivered using a number of beams which intersect at the same point
Isocentre tattoo	A reference skin mark placed overlying the position of the isocentre
Isodose	A line which passes through points in the tissue receiving a specified dose of radiotherapy
LinAc	See linear accelerator
Linear accelerator	A machine that produces high-energy radiation. Most external beam radiotherapy in the UK uses these machines
Medical physics expert	A suitably qualified and experienced physicist whose knowledge and training in radiation physics permits him or her to advise or act on all aspects of radiation physics pertinent to radiotherapy
Minor radiation incident	See Section 3.1.2
Monitor units	The units set on the LinAc in order to deliver the intended dose of radiotherapy
Near miss	See Section 3.1.2
Non-conformance	Non-compliance with some aspect of documented procedures
Non-reportable radiation incident	See Section 3.1.2
Overexposure	When more radiation was delivered than was intended
Palliative radiotherapy	Radiotherapy which is given with the intention of alleviating symptoms or prolonging survival, but not to cure the patient
Planning target volume (PTV)	The area to which the radiotherapy is delivered and encompasses the GTV and CTV with a margin for tumour movement and variations in day-to-day patient set-up
Portal imaging	Image taken on LinAc at time of treatment to ensure correct positioning of patient. Usually taken with electronic portal imaging device (EPID) or X-ray film
QART (Quality assurance in radiotherapy)	Quality management system aimed at ensuring safe delivery of radiotherapy
Radical treatment course	A course of high-dose radiotherapy given with curative intent
Radiobiological	The biological impact of a dose of radiotherapy

Radiotherapy	The treatment of disease, usually cancer, using high-energy electromagnetic radiation or particles
Radiotherapy error	See Section 3.1.2
Radiotherapy treatment pathway	The route that a patient will take to the completion of their treatment
Radiation incident	See Section 3.1.2
Record and verify system (R&V)	Computerised system into which planning data is entered and transferred to LinAc and used each fraction to set up the field size and dose to be delivered
Reportable radiation incident	See Section 3.1.2
Simulator	X-ray device used in radiotherapy to plan the radiotherapy and provide geometric verification of treatment position and set-up
Specialist registrar	A doctor who is receiving advanced training in a specialist field of medicine to become a consultant
Therapeutic radiographer	An individual trained to plan and deliver radiotherapy and all aspects of associated patient care along the radiotherapy treatment pathway
Thermoluminescent dosimetry (TLD)	A small chip of a special absorbent material (eg, lithium fluoride) is placed in the radiation beam to measure the dose delivered
Transit dosimetry	The process to calculate the actual dose delivered to a patient by measuring the dose entering and exiting from the patient
Treatment parameters	Size of treatment fields, use of wedge, angles of beam, number of monitor units etc used to deliver the required radiation dose
Treatment planning system (TPS)	Computers and specialised software which enables planners to design treatment plans
Underdose	When less radiation has been delivered than was intended
Verification	The process by which data is confirmed to be correct. For example, confirming data entry or acquiring images to ensure correct patient set-up
Wedge	Used to vary the radiation intensity across a treatment field. Can be used in a treatment plan to ensure an even dose distribution
Yellow Card scheme	A British scheme for reporting information on adverse events by healthcare professionals and patients to the MHRA

Abbreviations

BIR	British Institute of Radiology
BSI	British Standards Institution
CNS	Central nervous system
CPD	Continuous professional development
CT	Computer tomography
CTV	Clinical target volume
DRR	Digitally reconstructed radiograph
DVH	Dose volume histogram
EPIDs	Electronic portal imaging devices
ESR	Electronic staff record
e-KSF	Electronic Knowledge and Skills Framework
FSD	Focus-skin distance
GP	General Practitioner
GTV	Gross tumour volume
HPA	Health Protection Agency
HSE	Health Services Executive
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IMRT	Intensity modulated radiotherapy
IPEM	Institute of Physics and Engineering in Medicine
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations 2000
ISO	International Organisation for Standardisation
IVD	<i>In vivo</i> dosimetry
MHRA	Medicines and Healthcare products Regulatory Agency
NATCANSAT	National Cancer Services Analysis Team
NHS	National Health Service
NPL	National Physical Laboratory

NPSA	National Patient Safety Agency
NRAG	National Radiotherapy Advisory Group
PAS	Patient administration system
PPM	Planned preventative maintenance
PTV	Planning treatment volume
QA	Quality assurance
QART	Quality assurance in radiotherapy
RI	Radiation incident
R&V	Record and verify
RCR	The Royal College of Radiologists
RES	Radiotherapy Episode Statistics
ROSI	Radiation Oncology Safety Information System
SABS	Safety alert broadcast system
SCoR	Society and College of Radiographers
SOPS	Standard operating procedures
SpR	Specialist registrar
TLD	Thermoluminescent dosimetry
TPS	Treatment Planning System
3D	Three dimensional

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