RADIOTHERAPY RISK PROFILE

Technical Manual

World Health Organization

Radiotherapy Risk Profile WHO/IER/PSP/2008.12

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CONTENTS

"Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death"

Foreword by Sir Liam Donaldson

Radiotherapy saves lives, prolongs lives and improves the quality of life. For these reasons, millions of patients around the world, their families and the healthcare professionals who serve them have reason to be truly thankful. It is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death.

There is a long history of documenting incidents and examining adverse events in radiotherapy. From the study of these incidents and the factors underlying them it has been possible to map the risks.

When these serious incidents of harm were examined, slowly but surely a pattern became evident. Each of the incidents was associated with one or more particular steps in the process of care. From this, it was possible to identify a core process of care that was common to most radiotherapy treatment. On to that, the common and rarer risks could be mapped as a first step to reducing or eliminating them. This is the world's first risk profile developed by the World Health Organisation World Alliance for Patient Safety.

In this risk profile, an assessment of the extent of harm caused by radiotherapy internationally has been made. Many countries have suffered the same types of incidents in different places and at different times. In response, an international expert group was convened representing all those who participate in daily radiotherapy delivery. Other agencies, such as the International Atomic Energy Agency, that has a long and successful history of ensuring the safest practice in radiotherapy were also co-opted to the task. We are indebted to all of them for their work on this risk profile.

We hope that it will assist regulatory agencies, hospitals and individual departments to recognise and understand with clarity the risks inherent in radiotherapy. We hope that this healthcare risk profile will stimulate interest in the concept worldwide.

Sir Liam Donaldson
Chair, World Alliance for Patient Safety

1 AN INTERNATIONAL REVIEW OF PATIENT SAFETY MEASURES IN RADIOTHERAPY PRACTICE

EXECUTIVE SUMMARY

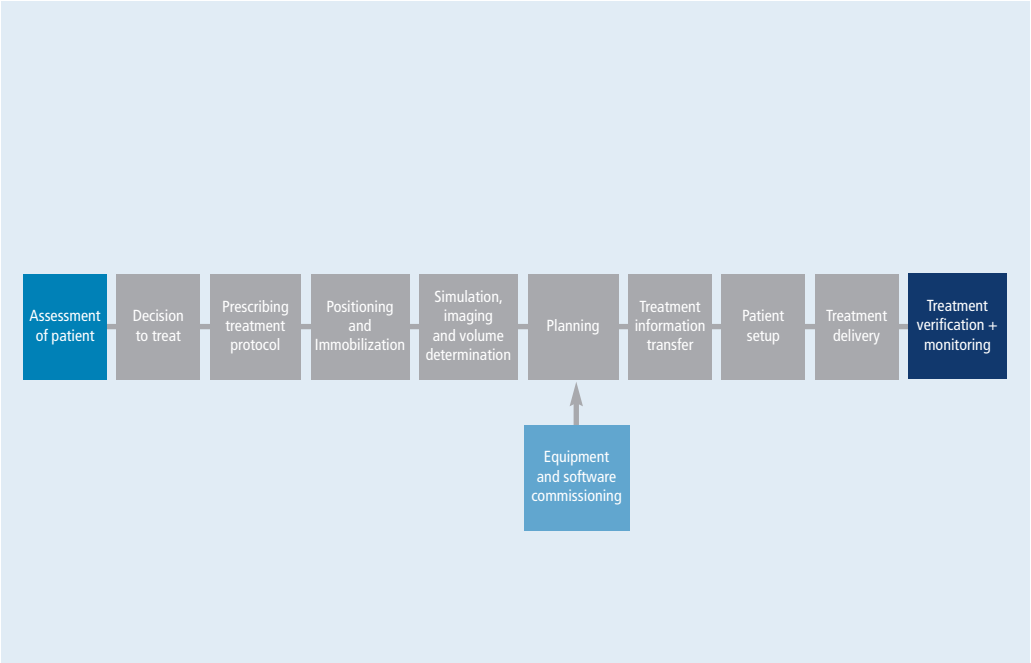
- The literature in the area of radiation safety is limited, and relates mainly to developed countries, or is the result of investigations of major errors.
- Review of available literature showed that in the years 1976 to 2007, 3125 patients were reported to be affected by radiotherapy incidents that led to adverse events. About 1% (N=38) of the affected patients died due to radiation overdose toxicity. Only two reports estimated the number of deaths from under-dosage.
- In the years 1992 to 2007, more than 4500 near misses (N=4616) were reported in the literature and publically available databases.
- Misinformation or errors in data transfer constituted the greatest bulk of incidents in modern radiotherapy services. Of all incidents without any known adverse events to patients, 9% (N=420) were related to the 'planning' stage, 38% (N=1732) were related to transfer of information and 18% (N=844) to the 'treatment delivery' stage. The remaining 35% of the incidents occurred in a combination of multiple stages.
- More system or equipment-related errors documented by medical physicists were reported, as compared to errors that occur during initial choice of treatment, dose prescription and other random errors not related to equipment or system faults.
- International safety guidelines have been developed and are regularly updated to deal with radiotherapy errors related to equipment and dosimetry. There is no consensus as yet as to how best to deal with errors not covered by regular system quality assurance checks.
- Initiatives are proposed to develop a set of patient safety interventions addressing the high risk areas in the radiotherapy process of care, especially those involving patient assessment and clinical decisions.

INTRODUCTION

Radiotherapy treatment

Radiotherapy is one of the major treatment options in cancer management. According to best available practice [1], 52% of patients should receive radiotherapy at least once during the treatment of their cancer. Together with other modalities such as surgery and chemotherapy it plays an important role in the treatment of 40% of those patients who are cured of their cancer [2]. Radiotherapy is also a highly effective treatment option for palliation and symptom control in cases of advanced or recurrent cancer. The process of radiotherapy is complex and involves understanding of the principles of medical physics, radiobiology, radiation safety, dosimetry, radiotherapy planning, simulation and interaction of radiation therapy with other treatment modalities. The main health professionals involved in the delivery of radiation treatment are the Radiation Oncologists (RO), Radiation Therapists (RT) and Medical Physicists (MP). Each of these disciplines work through an integrated process to plan and deliver radiotherapy to patients. The sequential stages of the radiotherapy process of care were recently agreed by the WHO World Alliance for Patient Safety Radiotherapy Safety Expert Consensus Group [Figure 1].

Figure 1: Stages of radiotherapy treatment



Risk management and quality assurance in radiotherapy

Radiotherapy treatment is a multi-stage, complex, process that involves treatment of a wide range of cancer conditions through utilization of various technologies and related professional expertise. A high level of accuracy is needed at every step so that the maximum tumour control is produced with minimal risk to normal tissue. Risks should be managed prospectively and dose errors should be maintained within acceptable tolerances; the radiation dose should be delivered within 5% of the prescribed dose [3]. Several studies have concluded that, for certain types of tumours, the accuracy should be even better (up to 3.5%) [4-6]. According to WHO guidelines:

> *Quality assurance (QA) in radiotherapy is all procedures that ensure consistency of the medical prescription, and safe fulfilment of that prescription, as regards to the dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel and adequate patient monitoring aimed at determining the end result of the treatment [7].*

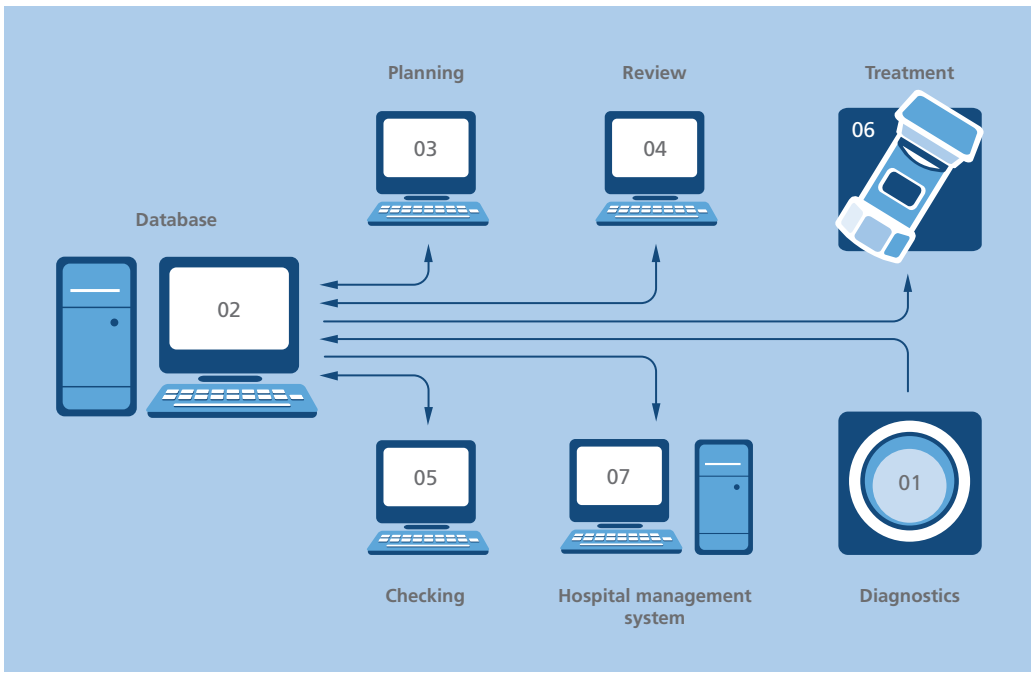
It is imperative that proper QA measures are in place in order to reduce the likelihood of accidents and errors occurring, and increase the probability that the errors will be recognized and rectified if they do occur. Radiation treatment-specific quality assurance guidelines have been issued by a number of worldwide organizations such as the World Health Organization (WHO), the International Atomic Energy Agency (IAEA), and the International Commission on Radiological Protection (ICRP) [7-10]. Radiation safety protocols should be adhered to for all stages of radiation treatment delivery, namely, tumour localization, patient immobilization, field placement, daily patient setup, dose calibration, calculation, treatment delivery and verification, as well as for equipment commissioning and maintenance. Skills and competences in radiation protection requirements are essential for all radiation treatment health professionals. Radiation protection includes the conceptual framework of radiation protection of patients, staff and the public, international radiation safety standards, safety and accuracy of equipment, radiation hazards in radiotherapy facilities, dosimetric and geometric quantities for accuracy in radiotherapy, radiobiology and radiation risks, treatment planning for optimizing delivery of radiation dose, optimal and safe use of different radiation sources in radiotherapy, radiation emergencies, physical protection and security of sources [11].

Protocols for individual countries have been developed, based on relevance to the work environment of the local departments [12-15]. Quality initiative reports published in Europe [13] recommend that QA should not be confined to physical and technical aspects of the treatment process only, but should also encompass all activities in a radiation oncology centre from the moment a patient enters until the time they leave, and should continue throughout the follow-up period. However, all of these aspects may not be the focus of individual facilities. As such, specific guidelines have also been developed in response to major radiotherapy incidents, highlighting individual issues to prevent future adverse events [16-17].

Radiotherapy treatment errors

Accidental exposures in radiotherapy may result from an accident, an event or a sequence of events, including equipment failures and operating errors [18]. The potential for errors in radiotherapy is high, as it involves a complete patient pathway with many links in the chain. At each link in the chain there are hand-overs between different health-care groups. The interaction of many health-care workers collaborating on highly technical measurements and calculations can in itself present a risk of error. Modern radiotherapy departments are multisystem-dependent environments that rely heavily on transfer of patient data between different units, systems and staff of different disciplines. The data transfer process in radiotherapy extends from diagnosis, to planning initiation and review, further

Figure 2: Data transfer elements of the radiotherapy treatment process



Source: Adapted from IAEA training material: 'Radiation protection in radiotherapy' [19]

checking, then to treatment machine, and finally to a centrally maintained hospital database as illustrated in Figure 2 [19].

Over the last decade, the rapid development of new technology has significantly changed the way in which radiotherapy is planned and delivered. Three-dimensional computed tomography (CT) based planning, multi-leaf collimation (MLC), improved immobilization, and more sophisticated planning and data management software now permit complex treatment plans to be prepared individually for many patients [20]. The increased complexity of planning and treatment, and rapid adoption of new technologies in the setting of increased patient throughput may thus create an environment with more potential for treatment-related incidents to occur. Especially in the low and middle income countries there may be old systems with less interconnectivity and fewer trained QA personnel. In addition, technologies intended to reduce the risk of treatment inaccuracy, might, if not used correctly, paradoxically act as a new source of error [21].

According to the IAEA safety standards [22], an "incident" is defined as:

> *Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.*

A "near miss" is defined as:

> *A potential significant event that could have occurred as the consequence of a sequence of actual occurrences but did not occur owing to the plant conditions prevailing at the time.*

Other terms for medical errors include "events", "mistakes", "misadministrations", "unusual occurrences", "discrepancies", and "adverse events".

The WHO World Alliance for Patient Safety general patient safety taxonomy contained within the International Classification for Patient Safety uses the following definitions [23]:

> *A patient safety incident is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.*
>
> *An adverse event is an incident which results in harm to a patient.*
>
> *A near miss is an incident that did not cause harm (also known as a close call).*
>
> *An error is a failure to carry out a planned action as intended or application of an incorrect plan, and may manifest by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase.*

We have used "incident" and "near miss" wherever possible within this report. However, this needs further discussion within the radiotherapy community to determine whether a uniform terminology as in other medical fields could be used in relation to radiotherapy safety.

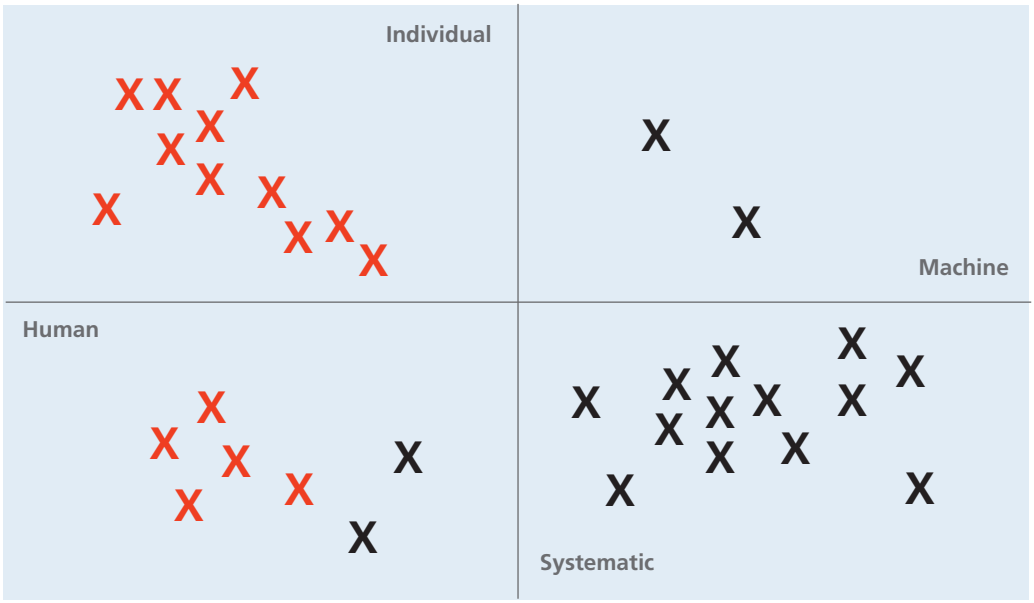
Although there are detailed reports on some major clinical radiation incidents that happened over the last 30 years [24], it is likely that many more incidents have occurred but either went unrecognized, were not reported to the regulatory authorities, or were not published in the literature [10].

Research on radiotherapy safety focuses on analyses of adverse events and near misses [25–26] as these might lead to identification of latent problems and weak links within a system that lie dormant for some time, and then combine with a local trigger to create an incident [27]. A health service research group in Canada developed a model for clinical incident monitoring specifically addressing the radiotherapy treatment service incidents. This model suggests an emphasis of incident investigation on causal analysis and corrective actions to improve care process performance so that identification and response to incidents occurs in a systematic way that supports organizational learning [28]. The reporting of near misses has been identified as a valuable tool in preventing serious incidents in the non-medical domain [29].

Studies in radiotherapy practice have shown that development of a comprehensive QA system, including an explicit and uniform protocol for implementation and timely assessment of error rate, may reduce the level of incidents [20, 30]. A recent evaluation at a cancer centre in the United Kingdom [31] reported a significant decrease in the number of recorded incidents over the past eight years. Changes in working practices during that time included: relocation of different procedures, increased use of specialist staff, and adaptation of working practices to reflect the requirements of new technology through regular discussion amongst staff. These factors were identified as factors promoting incident reduction [31]. In another institution, real time audits of 3052 treatment plans for a period of eight years provided important direct and indirect patient benefits that went beyond normal physical QA procedures, and addressed issues related to physician prescriptions [32].

The United States Nuclear Regulatory Commission (NRC) maintains a large database of radiotherapy incidents, and has estimated that about 60% or more of radiotherapy incidents are due to human error [33]. Human error can be reduced through education and training and changes in working practice within radiotherapy departments [Figure 3][1]. These findings, together with the fact that radiotherapy quality activities require involvement of a large group of professionals using a cooperative approach, justify the priority for developing a globally acceptable patient-centred safety guideline.

Figure 3: A conceptual framework to prioritize high-risk areas in radiotherapy practice[1]



Source: Dr. Claire Lemer, the WHO World Alliance for Patient Safety

Presented overleaf is a collation and synthesis of evidence on radiation incidents and the recommended safety measures. Both published literature and unpublished data sources have been reviewed. The riskiest areas in the process of care for radiotherapy have been identified. These require further attention, especially those relating to human error rather than to equipment and system failure.

1. A conceptual framework of work in radiotherapy has been designed by the WHO World Alliance for Patient safety that provides a framework for thinking about where work has occurred (black) and where less work has occurred (red). This may aid categorization of errors and influence development of an appropriate safety protocol.

AN EVIDENCE-BASED REVIEW OF CURRENT PRACTICE

Aim

To conduct an evidence-based review of current practice of patient safety measures in radiotherapy treatment facilities, including an analysis of previous incidents in radiotherapy delivery and identification of high-risk areas.

Materials and methods

Worldwide incidents of accidental errors during radiotherapy treatment in the last thirty years (from 1976 to 2007) were reviewed through appraisal of published materials (technical reports, journal articles, guidelines) and unpublished sources of information (departmental incident reports). A computer-based search of 'Google' and 'Google Scholar' search engines and a 'PubMed' search of the e-journal collections on radiotherapy, medical physics and nuclear medicine was performed using the key words: 'radiotherapy accident/s', 'radiotherapy incident/s', 'radiotherapy overexposure', 'radiation protection', 'patient safety', 'quality assurance', 'safety measures' and variations of these terms in combination. In addition, a broader search was performed for developing countries using the above key words combined with the terms 'developing countries', 'low income countries' 'Asia', 'Africa', and 'Latin America'. 'Grey literature' (material which is not formally published), such as working papers, organizational reports (e.g. IAEA and ICRP web/print publications) and conference proceedings were obtained electronically and through personal communication. The bibliography of the individual literature retrieved was iteratively searched for additional citations. For articles published in other languages (e.g. French, Japanese), the translated abstracts were identified and verified with the study findings from other sources in English (if available). A detailed search strategy and the search results are presented in Annex I.

Radiotherapy safety-related incidents and near misses that were reported to local and international databases were also reviewed, including the 'Radiation Oncology Safety Information System' (ROSIS) database, a voluntary web-based safety information database for radiotherapy, set up by a group of medical physicists and radiation therapy technicians in Europe and the Australian State-based Department of Radiation Oncology annual incident reports collection [34-35]. While reviewing the literature, a data form (Annex II) was used as a template to ensure uniformity and completeness of information.

The incidents were recorded according to the following categories:

- Description
- Direct cause(s)
- Contributing factors
- Stage of the treatment process during which the incident happened (as described in Figure 1)
- Reported impact or outcome
- Corrective actions and prevention of future incidents

The data available from all sources were reviewed and synthesized to determine: the stage at which most accidents or incidents occurred, what were the existing deficiencies and contributing factors that led to the errors, and how these errors could have been prevented. The incidents were grouped according to the income level of the countries (high income, middle and low income countries) as categorized in the World Bank list of economies [36]. Economies were divided among income groups according to the 2006 Gross National Income (GNI) per capita into low income: US$ 905 or less; lower middle income: US$ 906–US$ 3595; upper middle income: US$ 3596–US$ 11 115; and high income: US$ 11 116 or more. The overall summary of incidents, in terms of most common stage of occurrence and identified areas of need were drawn; a similar approach has been suggested in the 2006 Annual Report of the Chief Medical Officer for the Department of Health, United Kingdom [37].

SUMMARY OF LITERATURE

Radiotherapy incidents

A summary of all widely reported major radiotherapy incidents that led to significant adverse events to patients (such as radiation injury and death) and which have occurred in the last three decades (1976-2007) is presented in Table 1. The countries of occurrence were middle and high income countries in the United States of America, Latin America, Europe and Asia. In total, 3125 patients were affected and of them 38 (1.2%) patients were reported to have died due to radiation overdose toxicity. The number of incidents that occurred in the planning stage was 1702 (55%), and of the remaining 45%, incidents were due to errors that occurred during the introduction of new systems and/or equipment such as megavoltage machines (25%), errors in treatment delivery (10%), information transfer (9%) or in multiple stages (1%).

In the years from 1992 to 2007, 4616 incidents that led to near misses and which resulted in no recognizable patient harm were identified from the published literature and unpublished incident reporting databases from Australia, United Kingdom, other European countries, Canada and the United States (Table 2). A major source (N=854) of the recent incidents was the ROSIS database [34], a voluntary web-based safety information database for radiotherapy incidents in Europe, which had been set up by two radiation therapists and two medical physicists. Of all such incidents without any known adverse events to patients, 9% (N=420) were related to the 'planning' stage; 38% (N=1732) were related to transfer of information and 18% (N=844) to the 'treatment delivery' stage. The remaining 35% of the incidents occurred in the categories of prescription, simulation, patient positioning or in a combination of multiple stages.

Table 1: Chronological summary of radiotherapy incidents with adverse events by country and stage of treatment [white box indicates number of reported deaths from this incident]

Year(s)	Country	Economic group	Stage of therapy	Cause/contributing factors of error
1974– 1976	USA	High income	Commissioning	Calibration error of a Cobalt-60 Teletherapy unit and falsified documentation
1982–1991	UK	High income	Planning	Introduction of a new technique of treatment planning leading to miscalculation of radiation doses
1985–1987	USA & Canada	High income	Treatment delivery	Therac-25 Software programming error
1986–1987	Germany	High income	Planning	Cobalt-60 dose calculations based on erroneous dose tables (varying overdoses)
1988	UK	High income	Commissioning	Error in the calibration of a Cobalt-60 therapy unit
1988–1989			Treatment delivery	Error in the identification of Cs-137 Brachytherapy sources
1990	Spain	High income	Treatment delivery	Errors in maintenance and calibration of a linear accelerator combined with procedural violations
1992	USA	High income	Treatment delivery	Brachytherapy source (High Dose Rate) dislodged and left inside the patient
1996	Costa Rica	Upper middle income	Commissioning	Miscalibration of a Cobalt-60 unit resulting in incorrect treatment dose
1990–1991, 1995–1999	Japan	High income	Information transfer	Differences of interpretations for prescribed dose between RO & RT, lack of their communication
1998–2004			Planning	Wedge factor input error in renewal of treatment planning system

	Outcome/impact	Number affected	Safety measures recommended	Reference
	Radiation overdose toxicity	426	QA system development in all stages of radiotherapy treatment Organization of the radiotherapy departments (staff training, double independent audit)	[24]
	Radiation underdose of 5–35% About 50% (N=492) of these patients developed local recurrences that could be attributed to the error	1045	To ensure that staff are properly trained in the operation of a new equipment/system Independent audit of treatment time and outcome Clear protocols on procedures when new techniques are introduced System of double independent check	[38]
	Radiation overdose toxicity Patient deaths due to toxicity	6 3	Review of all root causes, e.g., organizational, managerial, technical Extensive testing and formal analysis of new software Proper documentation	[39]
	Radiation overdose toxicity	86	QA system update and organization of the radiotherapy departments (staff training, audit)	[24]
	Radiation overdose toxicity	250	QA system, inclusion of treatment prescription, planning and delivery in addition to traditional technical and physical aspects Organization of the radiotherapy department for staff qualifications, training and auditing provisions	[24]
	Radiation overdose toxicity	22		
	Radiation overdose toxicity Patient deaths due to overdose	18 9	Formal procedures for safety checks prior to treatment after any repair/ maintenance on machines	[40]
	Patient death due to overdose	1	Formal procedures for safety checks Staff training	[40]
	Radiation overdose toxicity Patient deaths due to overdose	114 6	Verification of the procedures Record keeping Staff training	[41]
	Radiation overdose toxicity	276	Cooperative efforts between staff members Enhanced staff training	[42]
	Radiation overdose toxicity	146	Appropriate commissioning in renewal of system, Improvement of QA/QC	

Year(s)	Country	Economic group	Stage of therapy	Cause/contributing factors of error
1999–2003	Japan	High income	Planning	Output factor input error in renewal of treatment planning system
1999–2004			Treatment delivery	Insufficient dose delivery caused by an incorrect operation of dosimeter
2000–2001	Panama	Upper middle income	Planning	Error shielding block related data entry into TPS resulted in prolonged treatment time
2001	Poland	Upper middle income	Treatment delivery	Failure of safety system on a Linac after power failure
2003	Japan	High income	Planning & Information transfer	Input error of combination of transfer total dose and fraction number
2003–2004			Planning & Information transfer	Misapplication of tray factor to treatment delivery without tray
2004–2005	France	High income	Planning	Wrong setting of the linear accelerator after introduction of new treatment planning system (TPS) (static wedges changes to dynamic wedges but dose intensity modification not done)
			Information transfer & Treatment delivery	Miscommunication of field size estimation, error in patient identification, incorrect implantation of source during brachytherapy
2004–2007	Canada	High income	Planning	Incorrect output determinations for field sizes other than the calibration field size for superficial skin treatments.
2005–2006	UK	High income	Planning	Change in operational procedures while upgrading the data management system resulting in incorrect treatment dose

	Outcome/impact	Number affected	Safety measures recommended	Reference
	Radiation underdose	31	Appropriate acceptance test and commissioning in renewal of system Improvement of QA/QC	
	Radiation underdose	256	Improvement of QA/QC	
	Radiation overdose toxicity Patient deaths due to overdose	28 11	Review of (QA) system Proper procedural documentation Team integration In-vivo dosimetry	[43]
	Radiation overdose toxicity	5	Beam output dosimetry recheck after any disruption Protocols for signed hand-over procedures Linacs non-compliant with IEC standards to be removed from clinical use	[44]
	Patient death suspected due to overdose	1	Improvement of QA/QC	[42]
	Radiation overdose toxicity	25		
	Radiation overdose toxicity Patient deaths due to overdose	18 5	Development of good practice and standards based on ISO 9000 QA standards Staff training for new equipment or new system Independent certification of the QA committee	[45-46]
	Radiation overdose toxicity Patient death due to overdose Unknown health consequence	2 1 5	Reinforcement of the safety measures (register of events, periodical review of the register and learn from the previous events) Regular supervision of the organizational and workforce factors	[45]
	Radiation underdose by 3-17% Unknown health consequences	326	Should have independent review of data used for machine output determinations.	[47-48]
	Radiation overdose toxicity Patient death due to recurrent tumour	5 1	Review of working practices Adherence to written procedures	[26, 49]

Table 2: Chronological summary of radiotherapy near misses by country and stage of radiotherapy treatment

Year(s)	Country	Economic group	Stage of therapy	Cause/contributing factors of error
1989–1996	Canada	High income	Assessment of patient & Prescription	Errors in indications for radiotherapy and choice of dose and target volume
			Planning	Insufficient target volume, critical structures at risk, inhomogeneous dose distribution
1992–2002			Planning	Intended parameters have not been used or used incorrectly in the treatment plan/isodose generation/dose monitor unit calculation
			Information transfer	Data transfer/data generation errors, mis-communication, no written procedure
			Treatment delivery	Errors related to radiation beam, Gantry/Collimator angle, isocentre, shielding, bolus, wedges, monitor units, field size
1993–1995	Australia	High income	Prescribing treatment & Planning & Information transfer	Errors in prescriptions and planning (percentage depth dose, inverse square law corrections, isocentric dose, equiv. sq. cut-out size) Calculation errors
1995–1997	Belgium	High income	Prescribing treatment	Incomplete/incorrect prescription due to changed medical prescription protocol
			Simulation	Incorrect procedures due to presence of new and inexperienced staff
			Planning	Same as above
			Information transfer	Errors due to lack of attention, human errors and calculation errors
1997–2002	Canada	High income	Planning	Incorrect programming of 'record and verify' (R & V) system
			Information transfer	Inadequate/incorrect documentation of technical changes
			Treatment delivery	Omission or incorrect placement of accessories
1998–2000	Ireland	High income	Planning & Information transfer	Errors related to TPS utilization, calculation, and documentation

	Outcome/impact	Number affected	Safety measures recommended	Reference
	No identifiable patient toxicity	110	Continuing the real time audit model with targeted feedback to staff	[32]
		124		
	No identifiable patient toxicity	81	Implementation of the QA checking program Continuing staff education (raised awareness)	[30]
		263		
		252		
	Dose error >=10% but no clinical significance	4	Rechecking of treatment sheets In-vivo dosimetry	[50]
	Dose error 5-10% but no clinical significance	2		
	Dose error <5%	229		
	No identifiable patient toxicity	620	New Quality Control (QC) system and assessment Acceptance of the QA concept	[51]
		343		
		79		
		727		
	Errors were of little or no clinical significance	87	Changes to planning and treatment processes within the high-risk group identified	[20]
	Errors were of little or no clinical significance	259		
	94.4% of errors were of little or no clinical significance	209		
	No identifiable patient toxicity	177	Multilayered QA system in place (2- step independent check-recheck)	[25]

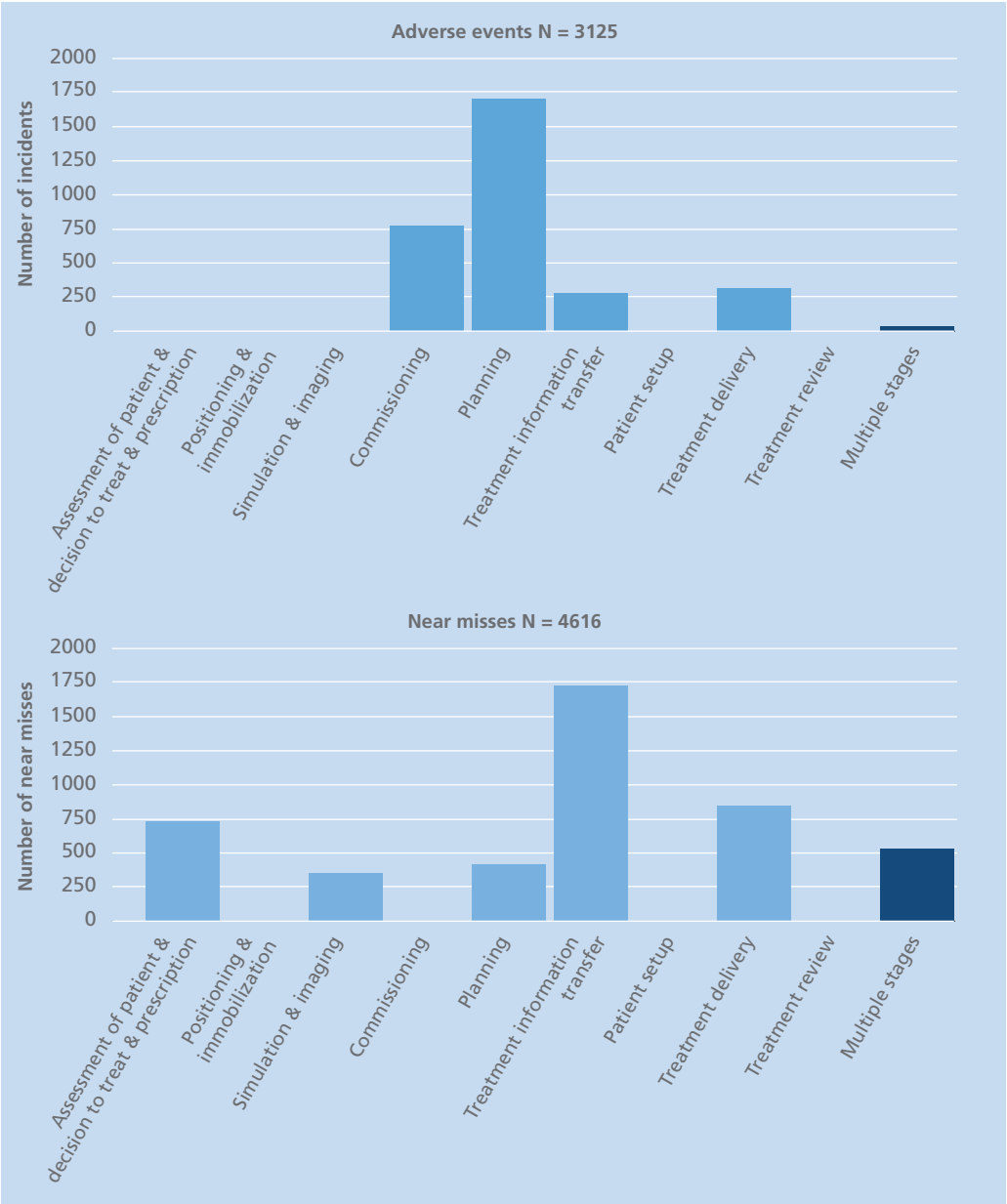
Year(s)	Country	Economic group	Stage of therapy	Cause/contributing factors of error
1999-2000	USA	High income	Information transfer	Incorrect data entry leading to incorrect treatment parameters
			Patient positioning	Incorrect placement of positioning device, error in placement of shielding blocks
			Treatment delivery	Patient identification error, staff miscommunication
2000–2006	UK	High income	Planning	Incorrect setup details, calculation errors, errors in prescription interpretation, incorrect data/dose per fraction into the planning computer. Wrong side/site being planned
			Information transfer	Incorrect patient setup details, Incorrect data entry into the 'Record & Verify' (R&V) system
			Patient positioning	Patient changing position after setup
			Treatment delivery	Technical complexity and overlap of concomitant treatment areas
2001–2007	Europe (Not specified)	High income	Simulation & Planning	Mould room error, incorrect virtual simulation protocol, incorrect calculation of monitoring unit (mu), couch distance, pacemaker etc.
			Information transfer	Errors in data transfer, inadequate communication
			Treatment delivery	Errors related to patient identification, radiation beam, isocentre, shielding, bolus, and wedges, field size etc.
2005	Australia	High income	Simulation	Simulation/virtual simulation error due to lack of attention to details while simulating
			Planning	Errors in which intended parameters have not been used or used incorrectly in the treatment plan/isodose generation/dose monitor unit calculation
			Information transfer	Unclear documentation, incorrect data generation, and inadequate communication
			Treatment delivery	Errors related to radiation beam, port film/EPI use, shielding, bolus, wedges, monitor units, field size

*The incidents described were the ones only related to the computerized 'record and verify' system
**Severity Assessment Code (SAC) is a numerical score applied to an incident based on the type of event, its likelihood of recurrence and its consequence. The scale ranges from 1 (extreme) to 4 (low) [53].

	Outcome/impact	Number affected	Safety measures recommended	Reference
	Error identified and corrected No identifiable patient toxicity	2	Staff training on electronic 'record and verify' (R & V) Advice to staff not to become too dependent on 'R& V' system	[21]*
	Error identified and corrected No identifiable patient toxicity	4		
	No identifiable patient toxicity	3		
	Radiation overdose > 10 Gy but no identifiable patient toxicity	14	Regular review of protocols, staff workload and error identification & analysis system Careful planning for new technique/ equipment including risk analysis, and proper documentation Regular staff communication In vivo dosimetry	[52]
		11		
		1		
		2		
	No identifiable patient toxicity	123	Check–recheck by multiple persons) before or at 1st treatment In-vivo dosimetry	[34]
		402	Clear documentation and verification	
		329	Attention to details Information verification from the previous stages	
	SAC** 1-3 (extreme risk to medium risk) No identifiable patient toxicity	7	QA procedure at every step Staff in-house training and regular continuing education programme	[35]
		35	Assign clear responsibility for QA performance	
		68	Clear and sufficient documentation for accurate treatment setup Proper instruction for new staff	
		49	Proper checking of setup data and double checking patient ID Confirmation of daily treatment sheet with attention to details	

The graph below (Figure 4) describes a summary of injurious and non-injurious reported incidents (near misses) for the last 30 years (N=7741). The highest number of injurious incidents (N=1702, 22% of all incidents) were reported in the 'planning' stage, and the highest number of near misses were related to the 'information transfer' stage (N=1732, 22% of all incidents).

Figure 4: Radiotherapy incidents (1976-2007) by the stages of treatment process



Radiotherapy incidents in developing countries

No detailed reports on radiotherapy-related adverse events were available from Asia or Africa. The only published studies are the evaluation of the dosimetry practices in hospitals in developing countries through the IAEA and World Health Organization (WHO)-sponsored Thermoluminescent Dosimetry (TLD) postal dose quality audits carried out on a regular basis [54, 55]. These studies reported that facilities that operate radiotherapy services without qualified staff or without dosimetry equipment have poorer results than those facilities that are properly staffed and equipped. Strengthening of radiotherapy infrastructure has been recommended for under-resourced centres, such as those in South America and the Caribbean, to improve their audit outcomes as comparable to those of developed countries [54].

An external audit of an oncology practice in Asia was able to identify 'areas of need' in terms of gaps in knowledge and skills of the staff involved. The study found that about half (52%) of the patients audited received suboptimal radiation treatment, potentially resulting in compromised cure/palliation or serious morbidity. Inadequate knowledge and skills and high workload of the radiation oncology staff were described as the reasons for poor quality of service [56].

Emerging issues

From our literature review, it is apparent that in the early 1990s major radiotherapy incidents occurred mainly due to inexperience in using new equipment and technology during radiotherapy treatment (Table 1), and these types of incidents are now much less frequent. More recently, misinformation or errors in data transfer constituted the greatest bulk of radiotherapy-related incidents (Table 2). The incidents that occur due to transcription errors, rounding off errors, forgotten data or interchange of data are mostly due to human mistakes or inattention [57]. It is now a well-recognized challenge in radiotherapy, and a large number of preventative guidelines and safety protocols have been established by the radiation safety-related authorities at the local and international level [58-64]. In some of the centres around the world, strict adherence to the radiotherapy QA protocols has resulted in reduction in the number of errors and related consequences [20, 30, 50]. It has also been suggested that continuous reporting and evaluation of incidents in radiotherapy is an effective way to prevent major mishaps, as demonstrated in the high ratio of near misses per adverse events (14 to 1) [25]. Thus, regular frequent QA review at the local level should be ensured, with adequate funding and expertise.

Another important initiative in preventing radiotherapy errors in decision-making and poor, or incorrect, work practice, could be behavioural modification, achieved through frequent audit and regular peer review of the specialist's protocols, processes, procedures and personnel involved [8, 65]. Shakespeare et al [56] observed that their audit acted as an informal learning needs assessment for the radiation oncology staff of the audited centre. They became more aware of their knowledge and skills gaps, and implemented peer review of all patients simulated. Additionally they implemented weekly departmental continuing medical education activities, a portal film review process, and have been performing literature search and peer discussion of difficult cases [56].

The incidents in radiotherapy that are mainly related to patient assessment prior to treatment involve history/physical examination, imaging, biochemical tests, pathology reviews and errors during radiotherapeutic decision-making including treatment intent, tumour type, individual physician practice and type of equipment used [66]. Comprehensive QA protocols have been developed that include medical aspects of the radiotherapy treatment, such as clinician decision and patient assessment [8],

and have been adopted in several centres in Europe. However, these protocols have not been widely adopted in radiotherapy centres worldwide.

An evaluation of radiotherapy incident reporting using three well known incident data sources, namely, IAEA, ROSIS and NRC datasets, reported relatively fewer incidents in the 'prescription' domain than in the 'preparation' and 'treatment' domains [67]. According to the report of a QA meeting in the UK in 2000 [68], much effort has been directed at QA of system and equipment-related components of radiotherapy, such as planning computers, dosimetry audit and machine performance. Little effort has been made so far to standardize medical processes, including target drawing, the application of appropriate margins and the verification of setup involved in radiotherapy. These errors cause variations in time–dose–fractionation schedules, leading to changes in the biological doses that have the potential for a significant impact on patient safety. European experts also suggested that taking initiatives to improve the culture of clinical governance, and setting the standards of practice through medical peer review of target drawing and dose prescription, would be a significant positive step in improving quality in radiotherapy services [8, 68].

A summary of potential 'risk' areas in the radiotherapy process, and the suggested preventive measures is presented in Table 3. The 'risk' areas and the proposed preventive measures have been generated through consultation with radiotherapy professionals and review of recommendations of both published and unpublished radiotherapy incident reports.

Costing

It is evident in the literature that the radiation treatment incidents are mostly related to human error. Hence, the safety interventions, such as regular training, peer review process, and audit of the QA protocols at various points of therapy, would involve investment in workforce resources (e.g. time, personnel, and training). The cost of workforce would vary from country to country because of the variability of the salary levels of the treatment personnel between high, low and middle income countries [69]. A detailed cost–benefit analysis however is beyond the scope of this report.

Table 3: Potential risk areas (•) in radiotherapy treatment

Stages	Patient factors			Equipment system factors
	History	Clinical examination	Pathology	
Assessment of patient & decision to treat	•	•	•	
Prescribing treatment protocol		•	•	
Positioning & immobilization	•	•		•
Simulation & imaging				•
Planning				•
Treatment information transfer				•
Patient setup	•	•	•	•
Treatment delivery	•	•	•	•
Treatment review		•	•	•

Staff factors				Suggested preventive measures
Communication	Guidelines/ protocol	Training	No. of staff	
●	●	●	●	Peer review process Evidence-based practice
●	●	●		Peer review process Standard protocol Competency certification Consultation with seniors
●	●	●	●	Competency certification QA check & feedback Incident monitoring
●	●	●	●	Competency certification QA check & feedback Incident monitoring
●	●	●	●	QA check & feedback New staff & equipment orientation Competency certification Incident monitoring
●	●	●	●	Clear documentation Treatment sheet check 'Record & verify' system In vivo dosimetry
●	●	●	●	Competency certification Incident monitoring Supervisor audit
●	●	●	●	Incident monitoring Imaging/Portal film In-vivo dosimetry
●	●	●	●	Competency certification Incident monitoring Independent audit

CONCLUSION

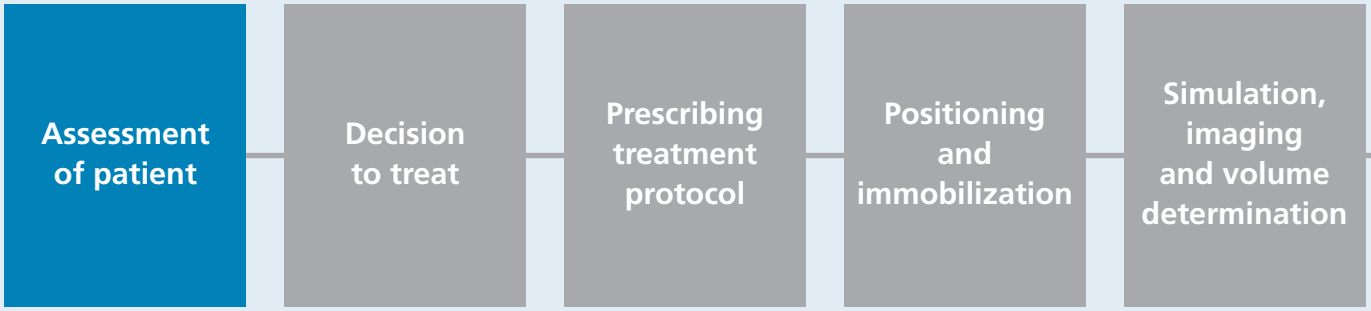
Radiotherapy-related errors are not uncommon, even in the countries with the highest level of health-care resources, but the radiotherapy-related error rate compares favourably with the rate of other medical errors. The risk of mild to moderate injurious outcome to patients from these errors was about 1500 per million treatment courses, which was much lower than the hospital admission rates for adverse drug reactions (about 65 000 per million) [70]. It is unrealistic to expect to reduce the error rate to zero, but every effort should be taken to keep the rates low. Risk model researchers Duffy and Saull comment:

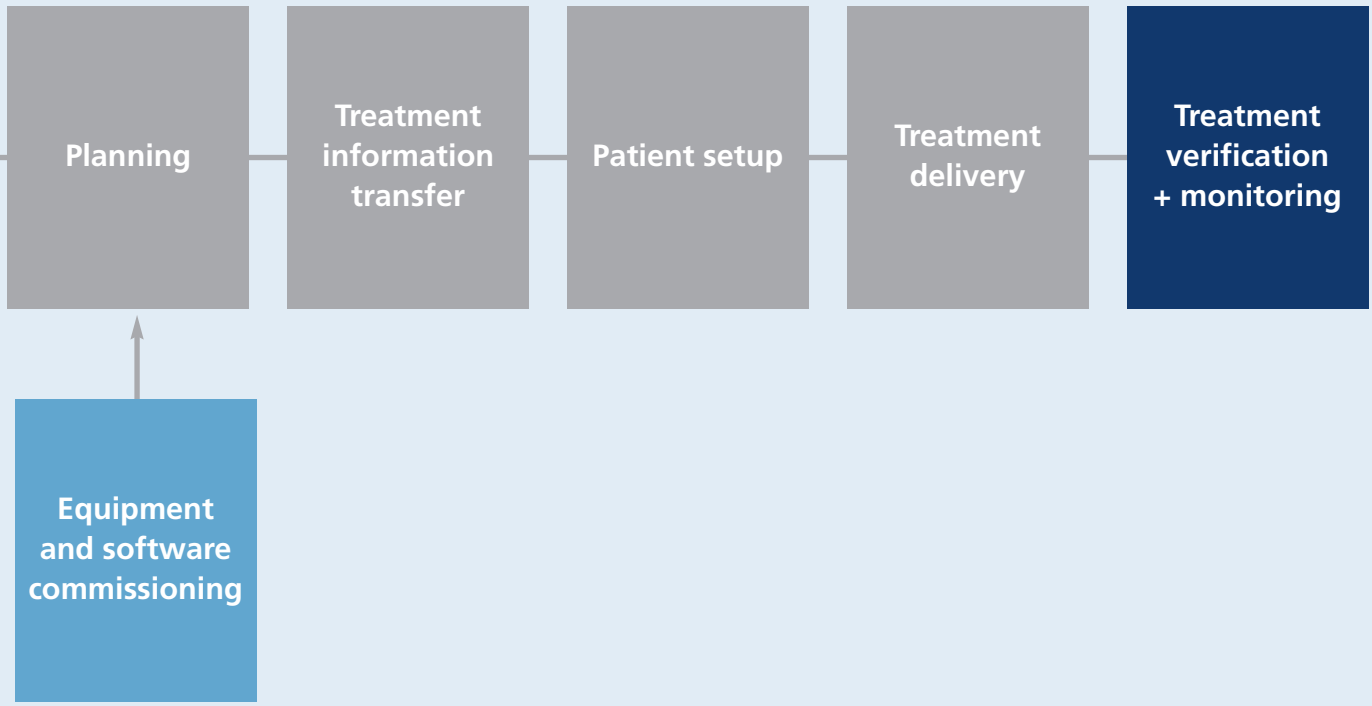
> *Errors can always be reduced to the minimum possible consistent with the accumulated experience by effective error management systems and tracking progress in error reduction down the learning curve* [33].

This can also lead to identification of incidents earlier in the process with less serious consequences.

Through our review we were able to confirm the stages of radiotherapy treatment where most incidents occur. Although a large proportion of reported incidents were related to system failures due to incorrect use of equipment and setup procedures, for a number of them the contributing factors were incorrect treatment decisions, incorrect treatment delivery and inadequate verification of treatment, due to inexperience and inadequate knowledge of the staff involved. These errors were not as well reported as the system-related errors documented predominantly by the medical physicists, as observed in our review. Hence, development of a set of standards highlighting the patient-centred 'risk' areas in radiotherapy treatment, together with suggested improvements tailored to the need of individual countries and specific departments may be relevant for all stakeholders.

The WHO World Alliance for Patient Safety has started an initiative to address the high-risk areas in the radiotherapy process of care, that is complimentary to the IAEA-developed safety measures and other previously developed standards, to address non-equipment, non-system faults associated with radiotherapy delivery. An expert group facilitated by the WHO World Alliance for Patient Safety has developed a risk profile to identify high-risk practices in radiotherapy and suggest specifically targeted interventions to improve patient safety (Part 2 of this document).


Assessment of patient
Decision to treat
Prescribing treatment protocol
Positioning and immobilization
Simulation, imaging and volume determination


Planning
Treatment information transfer
Patient setup
Treatment delivery
Treatment verification + monitoring
Equipment and software commissioning

RADIOTHERAPY TREATMENT PROCESS

The radiotherapy treatment process is complex and involves multiple transfers of data between professional groups and across work areas for the delivery of radiation treatment. A minimum of three professional groups are needed for successful and safe treatment. A brief outline of their roles is given in Table 4 below, although roles may be undertaken by different professions in some jurisdictions. Table 5 lists the treatment processes by stage, and identifies the professional groups most responsible at each stage. It is notable that most radiotherapy errors are reported from Stage 4 onwards, but research from other disciplines suggests that there are likely to be many errors in Stages 1 to 3 that may have a major effect on safe and appropriate treatment delivery.

Table 4: Professional groups involved in the delivery of radiation therapy

		Role
Radiation Oncologist	RO	Advice about treatment options and consent for treatment Target and normal tissue delineation Prescription of radiotherapy Planning review and approval Monitoring of treatment Patient follow-up
Radiation Therapist (Radiation treatment technicians, therapeutic or therapy radiographer	RT	Patient information and support Simulation Planning Producing and checking treatment plans Data transfer and monitor unit calculations Daily radiotherapy delivery Treatment verification Monitoring the patient on a daily basis
Medical Physicists	MP	Specification of equipment used in therapy and imaging Facility design, including shielding calculations Commissioning of diagnostic, planning and treatment equipment and software Dosimetry assurance Producing and Measurement and beam data analysis Checking treatment plans Quality assurance of diagnostic, planning and treatment equipment and software

Table 5:
Treatment processes and identification of the professional groups responsible for each process.

Stage	Description	Responsibility		
		RO	RT	MP
1 Assessment of patient	History taking, physical examination, review of diagnostic material	●		
2 Decision to treat	Consideration of guidelines, patient wishes	●		
3 Prescribing treatment protocol	Determination of site, total dose, fractionation and additional measures such as dental review or concurrent chemotherapy	●		
4 Positioning and immobilization	Setting up the patient in a reproducible position for accurate daily treatment		●	
5 Simulation, imaging and volume determination	Determining region of the body to be treated using diagnostic plain X-ray unit with the same geometry as a treatment unit (simulator) or dedicated CT scanner	●	●	
6 Planning	Determining X-ray beam arrangement and shielding then calculating dose to achieve prescription		●	●
7 Treatment information transfer	Transfer beam arrangement and dose data from treatment plan to treatment machine		●	●
8 Patient setup	Placing patient in treatment position for each treatment		●	
9 Treatment delivery	Physical delivery of radiation dose		●	●
10 Treatment verification and monitoring	Confirmation of treatment delivery using port films and dosimeters Monitoring of the daily setup Monitoring of tolerance by regular patient review	●	●	●

Note: Professions responsible for process stages vary between countries

RISKS INHERENT IN THE RADIOTHERAPY PROCESS

In December 2007, an expert consensus group met at WHO Headquarters in Geneva and identified the specific risks within the process of care. Forty-eight risks were assessed to have potential to result in high (H) impact adverse events and the other 33 risks were estimated to have a medium (M) impact. Low impact risks were not considered.

Risks have been categorized by the area to which they relate: patient, staff, system or information technology, or a combination of areas. Fifty-three risks were associated with staff alone, and less than 10 were associated with patients or the system.

We have listed the risks and potential mitigating factors by stage in the process of care, in the sections below. Some risks, such as automaticity, may affect many stages throughout the treatment delivery process. Automaticity has been defined as:

> *the skilled action that people develop through repeatedly practising the same activity* [71].

There are many checking steps in radiotherapy but the repeated execution of checklists may result in them being run through without conscious thought. It is thought to be common with verbal checking.

1. Assessment of patient

Risks	Potential impact	Solutions
Incorrect identification as of patient	High	ID check open questions, eliciting an active response a minimum 3 points of ID Photo ID Unique patient identifier
Incorrect attribution of as records	High	ID check open questions, eliciting an active response a minimum 3 points of ID Photo ID Unique patient identifier
Misdiagnosis including tumour stage, extent (histology, lab results,	High	Audit Multidisciplinary teams Quality Assurance rounds with RO, RP MP, RTT pre-treatment imaging)
Inattention to co-morbidities	High	Assessment checklist Clear record of co-morbidities
Inadequate medical records	High	Electronic medical record

The major risks in the assessment stage are misidentification of the patient, and misdiagnosis leading to the incorrect treatment advice being given to the patient. All risks were considered to be high-risk, resulting in the patient receiving incorrect management. Simple checks of identity were proposed. These could be elaborated with technical solutions such as bar-coded appointment cards and identity chips.

2. Decision to treat

Risks	Potential impact	Solutions
Lack of coordination with other disciplines	Medium	Case manager Record of MDTM discussion and decisions
Failure to identify "most-responsible physician"	Medium	Standardized protocols for each diagnosis Record of MDTM discussion and decisions
Failure of formal transfer to appropriate physician at correct time	Medium	
Failure of consent or understanding of issues	Medium	Full informed consent procedure with signed consent form Audit of consent forms
Wrong diagnosis/wrong protocol	High	Peer review audit
Absence of multidisciplinary discussion/protocol	Medium	Standard protocol checklist

MDTM: Multidisciplinary Team Meeting

The decision to treat is a crucial step in radiotherapy, which is often omitted from the quality pathway. However, errors at this early stage will be magnified through the treatment process. Wrong diagnosis or the use of the incorrect treatment protocol would have a major effect on treatment and outcome. Other errors would result in poor coordination, delays, and failure to properly inform the patient of their options.

Interventions such as standard protocols, a full informed consent process with signed consent form and peer review audit, are easy to implement with limited resource demands, and have been shown to result in major quality improvements [56]. Case management requires dedicated staff and role development, and is more demanding of resources.

3. Prescribing treatment protocol

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Lack of coordination with other treatment modalities	Medium	Case manager MDTM Standardized protocols for each diagnosis Protocol for prescription signatures
All components of radiotherapy prescription	High	
Inappropriate authorization of incomplete prescription	High	
Ad-hoc alterations of prescriptions	Medium	Competency certification Protocol for acceptance of alternations/signature rights

MDTM: Multidisciplinary Team Meeting

The radiotherapy prescription determines the dose that is delivered, and the fractionation treatment schedule. Errors may reduce tumour control and or increase the complication rate. Dose-response curves are steep, especially for complications, and small deviations may result in major biological effects.

There are risks associated with every component of the radiotherapy prescription, including treatment intention, the priority for treatment, dose, dose per fraction, treatment duration, immobilization, treatment accessories such as bolus or shielding, concurrent therapy, and verification protocol, all of which have the potential for major errors. Standard protocols may reduce the risks of inappropriate prescriptions being delivered without documented reasons for deviations. Simple measures, such as inbuilt redundancy, and standard comprehensive treatment prescription forms, may also prevent inappropriate dose, fraction size and treatment time combinations from being delivered. These are low resource interventions; case management and competency certification require more resources and development.

4. Positioning and immobilization

Risks	Potential impact	Solutions
Patient-related factors – co-morbid disease, inability to comply with instructions	Medium	Patient selection Comprehensive assessment and documentation of difficulties
Incorrect patient positioning	High	Planning protocol checklist Independent checking Adequate staffing levels and education In vivo dosimetry
Different positioning for different imaging modalities	Medium	
Incorrect immobilization position	Medium	
Wrongly applied immobilization device	Medium	
Inaccurate transfer of prescription	High	

Radiotherapy is given daily and a full course may take up to seven weeks or longer. Patients are positioned and immobilized so that they will be in the correct position for treatment during the course of radiotherapy. Incorrect positioning or poor immobilization will result in the tumour not receiving the intended dose, resulting in a greater risk of recurrence or in sensitive normal tissues being treated beyond tolerance. High-precision techniques such as radiosurgery and intensity modulated radiation treatment place great demands on accurate and reproducible patient positioning and immobilization.

Patients need to be able to comply with the requirements of positioning, and many factors may impede their ability to be correctly positioned and immobilized, including co-morbidities such as pain and orthopnoea, inability to comply with instructions due to poor communication or confusion, and psychological barriers such as claustrophobia. These are generally difficult to overcome and often reflect poor patient selection or poor choice of radiotherapy modality, and failure to identify patient-related problems at the time that the treatment decision is made.

All other risks identified could be reduced by the development and implementation of a planning protocol checklist, which would have low resource demands. Checklists are used in many departments, and some jurisdictions have developed checklists for this purpose [72].

5. Simulation, imaging and volume determination

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Incorrect positioning of reference points and guides	High	Competency certification Appropriate education Independent checking
Defining wrong volume	High	
Incorrect margin applied around tumour volume	High	
Incorrect contouring of organs at risk	High	
Incorrect image fusion	Medium	
Light fields and cross-hairs could be misaligned	Medium	Equipment quality assurance Quality control checks with protocol for sign-off procedures
Inability to identify the isocentre consistently	High	
Poor image quality	Medium	
Incorrect imaging protocol	Medium	Planning protocol checklist Independent checks Signature protocols
Incorrect area imaged	Medium	
Wrong side/site imaged	High	
Altered patient position	High	
Incorrect orientation information	High	

During simulation the treatment position is determined and using imaging such as plain films or computerized tomography, the target (tumour) volume is identified. The potential exists for random errors, such as defining the wrong volume, and systematic errors such as misalignment of lasers used in positioning. Errors at this stage are likely to have a high impact, because subsequent treatment stages are intended to reproduce the setup determined at simulation.

Planning protocol checklists are low resource interventions that may reduce errors of protocol, site and side. Equipment quality assurance and competency programmes are needed, to ensure safety of simulation, imaging and volume determination, and require major resource input. This is the reason for the development of medical physics in radiation oncology and the requirement for specialized training programs in all three radiation oncology professional groups.

6. Planning

Risks	Potential impact	Solutions
Incorrect calibration or incorrect output data generation	High	Equipment quality assurance External independent dosimetry comparison audits Protocols and sign-off procedures and audits
Incorrect physical data such as decay curves and tables of constants	High	Independent checks Planning protocols In vivo dosimetry
Faulty planning software Incorrectly commissioned planning software	High High	Commissioning Quality Assurance Sign-off procedures In vivo dosimetry
Misuse of planning software Erroneous monitor unit calculation	High High	Competency certification Manual check by independent professional In vivo dosimetry
Lack of independent cross-checking	High	Departmental policy
Incorrect treatment modalities and beam positioning Incorrect beam energy Incorrect beam size Incorrect normalizations Incorrect prescription point Incorrect inhomogeneity correction Incorrect use of bolus in calculation Wrongly sited blocks Poorly constructed blocks Wrong depth dose chart for wrong machine	High High High High Medium Medium High High High High	Planning protocol checklist Signature protocols and independent checking
Utilization of non-standard protocols	Medium	Standard protocol checklist

During radiotherapy planning, a software model is used to design treatment beam arrangements, shielding, and calculate dose. Software is individualized for each treatment machine to model the beam characteristics. Errors can arise in the commissioning process that will affect every treatment or, because the software is misused, to produce treatment plans under conditions it is not able to accurately model [43, 45-46]. In addition, random errors may occur due to incorrect inputs into individual plans. There are many steps in the planning and calculation of patient treatments. An exhaustive list can be found in the IAEA QATRO protocol [8].

Commissioning Quality Assurance and competency certification are needed to prevent major systematic errors. Protocols should be in place and checking should be undertaken by independent professional groups.

Planning protocol checklists will reduce the random errors in individual plans.

7. Treatment information transfer

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Manual data entry	Medium	Automated data transfer In vivo dosimetry
Incompatible chart design	Medium	Clear documentation and protocols
Illegible handwriting for manual transfers	High	
No independent check	High	
Incorrect or inadequate data entry on 'record & verify' system	High	Independent checking
Ambiguous or poorly designed prescription sheet	High	Model prescription sheet
Sending unapproved plan	Medium	Protocol checklist
Failure to communicate changes in plans	Medium	'Record and verify' systems Independent checks
Incorrect number of monitor units, accessories, wedges	High	In vivo dosimetry

The transfer of information from the plan to the treatment machine is a critical step. It may require software from different vendors to interface correctly, or require correct manual data entry. Random and systematic errors may occur. Protocol checklists will prevent the implementation of unauthorized plans, and clear documentation standards will reduce errors from poor record keeping and handwriting. Signature policies should be in place and audited.

Independent checking is a mainstay of error reduction from transcription and communication errors, but is subject to automaticity errors. Modern "record and verify" systems reduce random transcription errors, but require quality assurance regimens to prevent systematic errors.

8. Patient setup

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Failure to assess patient's current medical status	Medium	Competency certification Appropriate education and staffing levels
Wrong position Wrong immobilization devices Wrong side of body (left/right) Incorrect isocentre Incorrect use or omission of accessories Incorrect treatment equipment accessories Missing Bolus	High Medium High High High High High	Independent checking and aids to setup
Unnecessarily complex setup limiting reproducibility	High	Machine protocol check Treatment protocols Peer review audit
Patient changing position during setup	High	Visual monitoring during treatment

Because radiotherapy is delivered as a number of daily treatments, daily setup accuracy for treatment is crucial throughout the treatment process, to ensure that the patient is in the correct position each day. Patient position may be affected by changes in their medical status, such as increased pain, developing radiation reactions or the development of unrelated conditions during treatment. In addition, the patient may move during treatment, and video camera observation of the patient is standard in most departments. Organ movement may also occur during treatment and complex technologies such as fiducial markers, on-board CT imaging and 4D treatment systems have been developed to reduce the error from organ movement.

Many setup errors may be detected by independent checking, and it is a widespread practice to employ a minimum of two RTs at each patient setup. While independent checking is resource intensive it is a minimum standard in radiotherapy delivery to avoid errors from involuntary automaticity [71].

9. Treatment delivery

Risks	Potential impact	Solutions
Undetected equipment failure	High	Machine protocol check In vivo dosimetry
Operating equipment in physics mode rather than clinical mode	High	Machine protocol check In vivo dosimetry
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Poor patient handling and care	Medium	Competency certification
Incorrect beam energy	High	In vivo-dosimetry
Incorrect field size and orientation Too many fractions or too few Inadequate checking of treatment parameters	High Medium High	Independent checking In vivo dosimetry
Failure to follow machine start up procedures	Medium	Machine protocol check

The major risk in treatment delivery is incorrect beam output due to incorrect calibration of the beam at commissioning or at a later date, or the generation of incorrect data used to calculate treatment time or monitor units. This would result in a systematic error [38, 47] that could affect hundreds or thousands of patients. Considerable effort is dedicated to ensuring and maintaining beam output in high income countries [73]. An IAEA postal survey [54] of low and middle income countries showed that 84% of centres were within the 5% tolerance limit. Centres without radiation measurement devices and qualified physics staff were more likely to have doses outside the tolerance limits. Equipment quality assurance programmes are resource intensive and require specialist personnel (medical physicists and engineers), specialized equipment and replacement parts.

The other risks identified relate to random errors that may affect individual treatments or courses. Independent checking reduces the risk of many of these errors [71]. In vivo dosimetry using radiation detectors, such as diodes or thermoluminescent dosimetry, may reveal incorrect beam energy or incorrect calibration. In addition, if used systematically near the start of treatment, for the majority of patients it can provide an independent final check of many of the procedures involved in treatment planning and patient dose delivery, provided that it has not been calibrated with the same beam that it is supposed to be checking.

10. Treatment verification and monitoring

Risks	Potential impact	Solutions
Incorrect identification of patient	High	ID check open questions, eliciting an active response as a minimum 3 points of ID Photo ID
Incorrect use or no use of portal imaging	High	Periodic recorded check
Misinterpretation of portal imaging	Medium	Competency certification Position correction protocol
Failure to monitor outcomes	High	Clinical audit of outcomes
Lack of review of patient on treatment	Medium	Periodic recorded check
Lack of chart review	Medium	Periodic recorded check
Undetected treatment errors	Medium	Treatment database audit

Radiotherapy treatment is monitored by portal imaging; images are taken using the treatment beam on film or digitally using electronic imaging devices. Portal imaging detects positioning errors and confirms the site of treatment delivery. While portal imaging may be considered a solution to risks in sections 9 and 10, there are problems with the correct detection, interpretation and correction of deviations from the desired position that may result in the patient's position being incorrectly or unnecessarily adjusted. Competency certification and a protocol for error tolerances are required to reduce the risks of misinterpretation of portal imaging. Clear guidelines for the routine use and interpretation of portal imaging should reduce the risk of error.

Radiotherapy should also be monitored by regular patient review during treatment for acute reactions, and after treatment for unexpected long-term site effects. Regular review should be undertaken during treatment by competent medical, nursing or RT personnel. It is essential that concerns raised by staff are taken seriously [38].

Underdose is unlikely to be detected by clinical health-care professionals. Concerns raised by any health-care professional during review [49] must be referred to the Radiation Oncologist and investigated. Follow-up of long-term reactions requires a major investment in staff, databases and data analysis

RISK REDUCTION INTERVENTIONS

Several interventions are likely to be effective at reducing risks at multiple stages in the radiotherapy treatment process. Planning protocol checklists are relevant to 20 identified risks, independent checking to 12 risks, and specific competency certification to 11 risks (Table 6). This may be because there are more risks in these areas or because the individual risks have been better identified.

Other high impact interventions include:

- Equipment quality assurance to reduce the risk of systematic errors such as miscalibration that may affect very large numbers of patients.
- Peer review audit to improve decision making that will have flow-on effects throughout the treatment process.
- In vivo dosimetry may mitigate 24 identified risk areas and provide an important independent check of the planning, calculation and delivery elements of the pathway and address 12 of 16 risks in planning, 5 of 10 in treatment transfer, 4 of 11 in patient set-up and 3 of 7 in treatment delivery. The costs of establishing and maintaining a program of routine in vivo dosimetry for all treatments is likely to be high and resource intensive, which may place it beyond the reach of services in some countries.

In addition there are safety processes that apply to all stages of the delivery of radiotherapy:

1. Patient identification
2. Audit of equipment commissioning and processes
3. Staff competency assessment
4. Process and equipment quality assurance
5. Information transfer with redundancy
6. Process governance
7. Error reporting and quality improvement
8. External checking
9. Adequate staffing

Continuing to learn

This risk profile for the first time quantifies the process of care in radiotherapy, and systematically addresses the risks at each stage. Putting this knowledge to work will require innovative strategies on behalf of managers and health-care professionals alike.

Redesigning systems to reduce risk involves engaging policy-makers, managers and patients [74]. Central to this is an adequate and competent workforce, supported by an appropriate reporting and learning framework. Several efforts have been attempted, both nationally and internationally to this end, including the Radiation Oncology Safety Information System (ROSIS) [34], the Calgary incident learning system [28] and the recently described United Kingdom framework [52].

Technical solutions offer hope for the future, including in vivo dosimetry, which offers the opportunity to reduce some risk, but must be put in the context of an overall approach to patient safety in radiotherapy.

The use of simple checklists has been proved to be successful in other areas of patient safety as a way of systematically reducing risk [75]. Similar systems have been suggested in radiotherapy and should be further promoted and developed [76].

Table 6: The top three interventions

Solution	Stage	Risk
Planning protocol checklist	Positioning & immobilization	Incorrect patient positioning Different positioning for different imaging modalities Incorrect immobilization position Wrongly applied immobilization device Inaccurate transfer of prescription
	Simulation, imaging & volume determination	Incorrect imaging protocol Incorrect area imaged Wrong side/site imaged Altered patient position Incorrect orientation information
	Planning	Incorrect treatment modalities and beam positioning Incorrect beam energy Incorrect beam size Incorrect normalizations Lack of consistency on prescription point Incorrect inhomogeneity corrections Incorrect use of bolus in calculation Wrongly sited blocks Poorly constructed blocks Wrong depth dose chart for wrong machine
Independent checking	Treatment information transfer	Incorrect or inadequate data entry on record & verify system No independent check
	Patient setup	Wrong position Wrong immobilization devices Wrong side of body (left/right) Missing Bolus Incorrect isocentre Incorrect use or omission of accessories Incorrect treatment equipment accessories
	Treatment delivery	Incorrect field size and orientation Too many fractions or too few Inadequate checking of treatment parameters
Competency certification	Prescribing treatment protocol	Ad-hoc alterations of prescriptions
	Simulation, imaging & volume determination	Incorrect positioning of reference points and guides Defining wrong volume Incorrect margin applied around tumour volume Incorrect contouring of organs at risk Incorrect image fusion
	Planning	Misuse of planning software Erroneous monitor unit calculation
	Patient setup Treatment delivery	Failure to assess patient's current medical status Poor patient handling and care
	Treatment verification and monitoring	Misinterpretation of portal imaging

ANNEX I:
LITERATURE SEARCH STRATEGY AND RESULTS

SEARCH STRATEGY FOR ARTICLES

An extensive search of the 'Google' and 'Google Scholar' search engines was conducted for online publications and a search of the 'PubMed' database was conducted for relevant journal publications, supplemented by searches of 'relevant links' for appropriate citations and article bibliographies for further relevant sources. Articles published in all languages between 1976 and 2007 were included. Unpublished materials (e.g. ROSIS database, Liverpool Hospital incident report collection) were collected from personal communication with the radiotherapy professionals locally and internationally. The summary of the most relevant search engines, search terms with number of hits and the search results (carried out in August-September 2007) are as follows:

Annex I: Literature search strategy and results

Search terms	Google Scholar		PubMed 'review' articles	Search results
	No. of hits	As a "Phrase" anywhere in text	No. of hits	
Radiotherapy incident/s	7410/8130	4/4	24/11	Total no. sites searched: 1330
Radiotherapy overexposure	670	1	3	⇓
Radiation protection AND radiotherapy	462000	26	358	No. of abstract reading of relevant references: 86
Patient safety AND radiotherapy	234000	3	4	⇓
Quality assurance AND radiotherapy	7670	199	526	No. of full text/executive summary readings of most relevant references (articles, reports, websites): 68
QA AND radiotherapy	7940	20	12	⇓
Safety measures AND radiotherapy	8880	12	10	References included in this report References for incident data: 26 Other references: 47 Total references: 73
Radiotherapy accidents AND developing countries	2200	2	2	

ANNEX II: DATA FORM USED TO COLLECT INFORMATION ON ACCIDENTS, INCIDENTS & ERRORS

Annex II: Data form used to collect information on accidents, incidents and errors

Country & year	Description of accident/ incidence	Direct cause	Contributing factors	Stage at which error happened	Outcome /impact	Existing safety measures	Safety measures proposed
				Assessment of patient & decision to treat			
				Prescribing treatment protocol			
				Positioning & immobilization			
				Simulation & imaging			
				Hardware & software commissioning			
				Planning			
				Treatment information transfer			
				Patient setup			
				Treatment delivery			
				Treatment review			

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