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Original Article

Preventing treatment errors in radiotherapy by identifying and evaluating near misses and actual incidents

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Abstract

When preparing radiation treatment, the prescribed dose and irradiation geometry must be translated into physical machine parameters. An error in the calculations or machine settings can negatively affect the intended treatment outcome. Analysing incidents originating in the treatment preparation chain makes it possible to find weak links and prevent treatment errors. The aim of this work is to study the effectiveness of a multilayered error prevention system by analysing both near misses and actual treatment errors.

The system utilised in this centre has primary and secondary checking as two layers of independent calculation-checking. We studied near misses as well as the actual errors which were not picked up by these pre-treatment checking procedures over a year (5154 treatment plans). Furthermore, the primary checking was studied in more detail over three years (15,386 treatment plans) to increase the statistical accuracy.

For each reported actual treatment error originating in the treatment preparation chain, 13.8 near misses were found by primary and secondary checking and thereby prevented from becoming actual errors. The total frequency of near misses was 34.4 per 1000 treatment plans. The primary checkers reported 23 types of errors for manual treatment plans (without dose distribution) and 30 types of errors for computer plans. Computer plans also showed a near miss rate that was 42% higher than for manual plans. The high ratio of near misses per actual error demonstrates an effective error prevention system, independent of the quality of the initial treatment preparation. Complex treatment plans were shown to be particularly error-prone, thereby requiring extra vigilance when checking.

Keywords

Risk management; quality assurance; incident; error; near miss

INTRODUCTION

Ensuring the safety of a patient entering a hospital is a complex task, requiring the active identification, analysis and management of risks encountered in the clinical environment. In a study of adverse events in medical practice,[1] 3.7% of admitted patients were found to be affected by injuries caused by medical management. In another clinical setting,[2] a retrospective analysis of medical records found a rate of 4.9% of patients died from adverse events of which half were considered to have been preventable. Irrespective of methodology in recording medical errors, these events occur in all disciplines of medicine and require considered management to minimise their frequency and impact.

There is a numerical dimension to radiotherapy, which makes it well suited for analysis of incidents

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compared with many other medical disciplines with less clear-cut error-events. The International Atomic Energy Agency (IAEA) has devised a classification system of accidents in radiotherapy.[3] Of the accident-categories in this system, the present analysis investigates errors and near misses in prescription and treatment planning for individual patients. For prescriptions, only the arithmetical aspect is under investigation. Errors in the medical basis for dose and volume prescription are not considered in this study.

Preparing a radiotherapy treatment prescription for clinical implementation involves a number of treatment preparation procedures and calculations performed by several categories of staff. The importance of adhering to prescribed dose and irradiation geometry when treating a patient is demonstrated by the dose-response relations for tumours and organs at risk, leaving little margin for treatment errors. Clinical dose-response relations have shown that a dose deviation of 5% from the intended might have a clinical impact.[4] Some data[5] suggest that an even higher degree of precision is necessary for sites with a steep dose-response gradient for severe complications. This necessitates a comprehensive system for the prevention of actual incidents (i.e. treatment errors), through the monitoring and analysis of potential incidents (i.e. near misses) in radiotherapy delivery.

The system of preventing incidents in this centre, aims for several check-stations (Fig. 1). The system is established by written procedures as well as quality control of treatment parameters.[6] Independent external audits monitor adherence to this. The initial treatment plan calculations are verified independently through a primary and a secondary check, performed by different staff categories. Prescriptions are peer-reviewed in-house and the geometric settings of treatment plans are verified on a simulator. Weekly overview checks of major parameters in treatment charts and the record and verify system (RVS) are performed as well as some in-vivo dosimetry. Portal imaging is used to control geometric irradiation accuracy. An RVS aims to ensure consistency of parameter settings and integrity of information transfer. Patients also undergo regular clinical reviews monitoring side effects, which can indicate unintended overdose. Any detected treatment errors coming through the system are recorded and analysed for trends. Finally, procedures are reviewed and audited. An integral part of this system of incident prevention is to form closed loops from all check-stations to earlier stages of the process, so that any trends of incidents can be fed back for the benefit of performing checks.

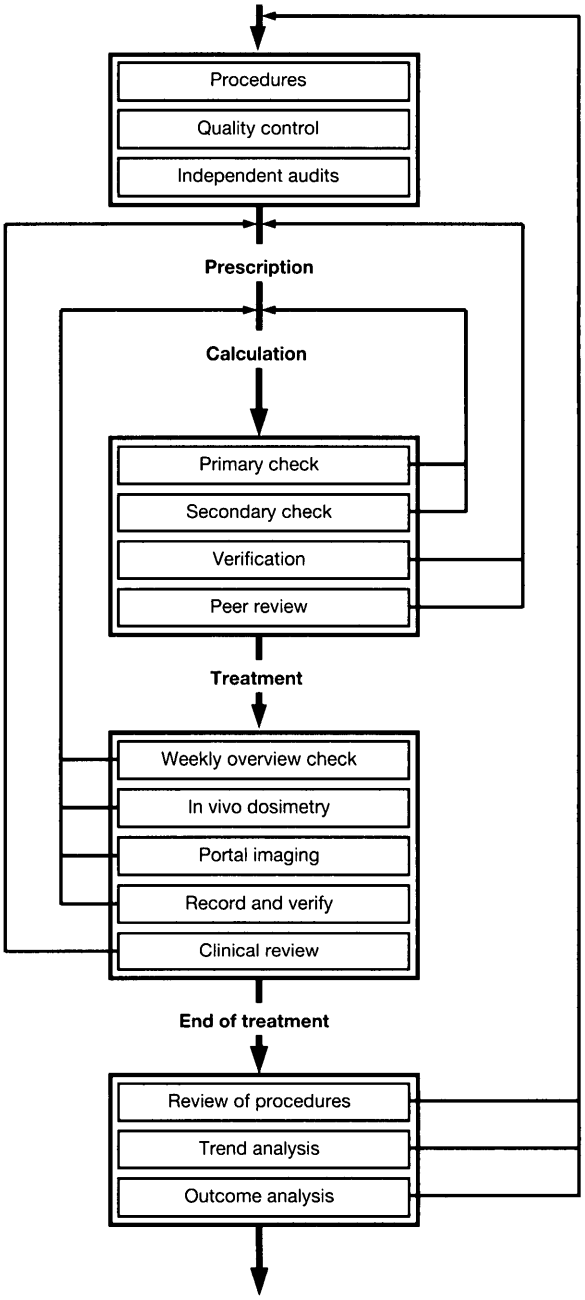

Figure 1. Flowchart of system to prevent potential incidents in the radiotherapy prescription and treatment planning procedures from becoming actual incidents. There are several check-stations to ensure the safety of the patient, each of which should also feed back results to earlier stages in the process.

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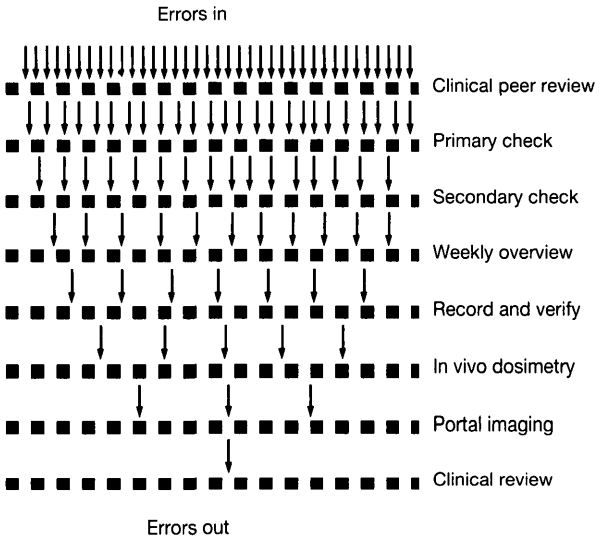

Figure 2. The error prevention system seen as a multilayered filter. Each filter has the ability to remove some of the potential incidents. The filters should be independent procedures of preventing errors, thereby minimising the number of errors exiting the system unnoticed.

Another way of viewing this error prevention system is as a multilayered filter-system (Fig. 2). Each layer of the system acts as a filter by preventing errors in the treatment preparation process to go undetected. By making all layers as independent as possible and preferably of different modalities, treatment errors are controlled. Examples of different check-modalities are calculation-checking and in vivo dosimetry, whereas two layers of independent calculation-checking would be of the same modality. In nuclear weapons safeguarding, this is referred to as protection by means of a multilayered system encompassing technical means (i.e. equipment and other direct applications of technology), procedures and personnel.[7] There is a tendency for such a multilayered protective system to create a synergistic effect where the protection by the whole is greater than the sum of its parts. As a feature of this system, means of error prevention include having qualified and well-trained staff and open lines of communication. It is also vital to keep the workload in the clinic at a realistic level.

While other studies have quantified near misses[8–12] or actual errors[13–17] in radiotherapy, the aim of this work is to study the effectiveness of an error prevention system by analysing both the near misses found at the primary and secondary calculation-check stations and the actual treatment errors originating in the treatment preparation chain.

MATERIALS AND METHODS

Three check-stations utilise independent checking and calculation as a means to verify parameters (Table 1). These are the primary, secondary and weekly overview check-stations. All external beam treatments in this centre undergo a primary and a secondary check prior to, or in conjunction with, the initial treatment fraction. Weekly overview checks are performed once the treatment has started.

During the period January 1998–December 2000, 15,386 plans underwent calculation checks at the primary check station and near misses were recorded. A total of 250,000 treatment parameters were checked as part of this procedure. Furthermore, for the year 1999, 5154 plans underwent primary and secondary calculation checks with near misses recorded. During this latter time period, the actual incidents originating in the treatment prescription, preparation and calculation were also recorded.

Treatment prescription, preparation and calculation procedures

There are different procedure-levels in the approach to the treatment of an individual patient, depending on, for example, treatment intent,

Table 1. *Verification of treatment prescription, preparation and calculation*

	Primary check	Secondary check	Weekly overview check
Staff category	Physicist	Radiotherapy technologist	Radiotherapy technologist
Method (manual plan)	Manual calculation	PC-based application	Manual calculation
Method (computer plan)	PC-based application	Manual calculation	Manual calculation
Error recorded	Near miss	Near miss	Actual error

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patient status and treatment site. Level 1 is to utilise either a single field or two parallel and opposed fields without computerised treatment planning. Monitor units are calculated manually according to the dose prescribed at a certain depth along the central beam axis. The target-size and location is determined from the simulated fields only. This procedure is referred to as manual planning in the text. For level 2, targets are also determined on the simulator, but a simple two-dimensional treatment plan without inhomogeneity corrections is calculated on the treatment planning system (TPS) based on the outline of the patient. Level 3 is to construct a fully three-dimensional treatment plan using a CT-study as a basis, with organs at risk and planning target volume outlined in each slice.[18,19] These last two procedure-levels are referred to as computer planning in the text. The computer-planned treatment is prepared by calculating the monitor units from the printout of the TPS. Treatment parameters are transferred manually to the RVS for manual plans and computer plans of level 2 and are networked directly for computer plans of level 3. Treatment parameters are also entered manually into the paper-version of the patient's treatment chart.

Checking the treatment prescription, preparation and calculation

Primary check: The primary check (Table 1) of a manual plan consists of an independent re-calculation of the monitor units on a separate check-sheet by a physicist. When performing a primary check of a computer plan, an independent PC-based spreadsheet is used to check the integrity of the TPS-based monitor unit calculations. Other parameters relating to prescription, data transfer and geometric configuration, are also checked during these verifications. An error found in a manual or computer plan through primary checking is corrected and recorded as a near miss.

Secondary check: A radiotherapy technologist uses a different independent PC-based program for calculation of monitor units (MU) as a secondary check (Table 1) of the manual plans. The secondary check of a computer plan is manually performed by calculating the monitor units required for the prescribed dose to be given to the ICRU dose prescription point[18] from the TPS-protocol. The integrity of the prescription and geometry of the irradiation are also controlled as part of these processes. An error found in a manual or computer plan through secondary checking is corrected and recorded as a near miss.

Weekly overview check: There is a weekly overview check (Table 1) of both manual and computer planned irradiation after the treatment has started, where a radiotherapy technologist verifies the major parameters (e.g. dose per fraction, number of fractions and monitor units) in the treatment chart and RVS. An error found in a manual or computer plan in the weekly overview check is corrected, if possible, and recorded as an actual error, since it has not been found before the treatment started and has thus affected the treatment of the patient.

Reporting near misses and errors

Near misses: If a near miss is picked up through the secondary checking procedure before reaching the actual treatment stage, the radiotherapy technologist discovering the error completes an incident form. When a near miss is discovered at the primary check-station, the type of plan and the type of near miss are the only parameters reported. These near misses are then collected, categorised and analysed for trends every few months. Discrepancies in monitor unit calculations are only referred to as near misses if the monitor units in the check differ more than 1% from the original calculations. When a computer plan is checked and the independent spreadsheet show a discrepancy of more than 2% between TPS-calculated computer plan and basic data, further investigations are launched. Only if discrepancies cannot be explained by inhomogeneities in the CT-plan or other factors would this be logged as a near miss. Other potential incidents in prescribing, calculating and recording a treatment are also logged for all plans.

Errors: When an actual error that has affected the treatment of an individual patient is found, it is reported on an incident form. This incident form requires a description of the event, when and how it was found, an assessment of the consequences and details of the actions taken. A response mechanism is initiated. This includes modification

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of treatment for the individual patient, if possible, through change in dose per fraction, extra fractions, etc. If the error is regarded as serious, an immediate root cause analysis is started and an estimation of the effects to the patient is performed. A review of current patients is also undertaken to determine if the same error has occurred for other patients, followed by a retrospective investigation if required. If the error is regarded as less serious, the same chain of events as above occurs, with the exception of the investigation of current and previous patients. Written procedures are then evaluated and amended if necessary to prevent similar incidents from occurring in the future.

Categorising near misses and errors

Near misses and errors relating to the prescription, preparation and calculation processes are categorised according to whether they originated in the prescription, calculation, TPS-utilisation or recording. Furthermore, they are categorised into manual plans or computer plans. In total, there are six categories of near misses and errors (Fig. 3). For manual plans, the errors can have their root cause in the calculation or the recording. For computer plans, the corresponding origin of the error can be in the TPS-utilisation, calculation or recording. Both types of plans can furthermore have an error or near miss with the origin in the prescription. Within each of these six error categories, there are details of the exact type of error. Some of the error types would only have a minor impact on the patient's treatment while other types could have a major impact. The classification of a minor/major (potential) impact of an error or a near miss on the treatment outcome is a very complex task, not only depending on (potential) dose deviation but also on parameters such as treatment intention, total dose, tumour parameters and organs at risk. In this study the errors and near misses have not been categorised as major and minor due to these complexities.

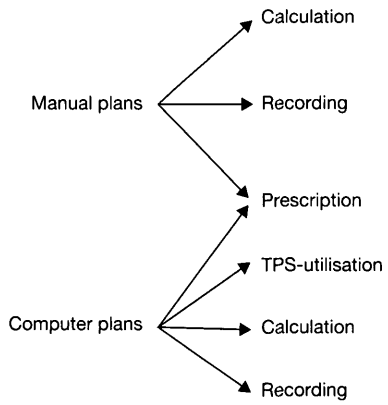

Figure 3. Categories of errors and near misses relating to manual plans (i.e. without dose distribution) and computer plans. The categories are related to where in the process the incident originated. Prescription error is common for both types of plans.

RESULTS

Overall results

In 1999, the total number of plans (both manual and computer plans) was 5154. The number of potential incidents found during the primary checking procedure was 154, or 29.9 plans per 1000. In the same year, the secondary checking procedure reported 23 near misses, or 4.5 plans per 1000. In 13 cases an error was not found until the patient had started treatment, or 2.5 actual incidents per 1000. The total frequency of near misses from either primary or secondary checking was 34.4 per 1000, giving a ratio of near misses per actual treatment error of 13.8. Additionally, the ratio of the number of irradiation fractions affected by an actual incident and the total number of treatment fractions in the year was found to be 0.09%.

In the period January 1998–December 2000, the primary checking procedure underwent a closer investigation. The total number of plans checked during this time period was 15,386. Manual plans accounted for 61.6% of these plans and computer plans were representing the remaining 38.4%. The number of primary checks per month had a steady increase during this time period (Fig. 4). The total frequency of near misses found through the primary checking procedure was 36.9 per 1000 plans, which is somewhat higher than during 1999 as detailed above. The percentage of near misses per primary check per month is presented in Figure 5. Values range between 14.5 per 1000 and 71.4 per 1000. 302 near misses were found in the 9482 manual plans during this time period, which translates to a near miss frequency of 31.8 per 1000 plans. The corresponding figure for the computer plans was 45.0 per 1000 plans, a figure that is 42% higher than for the manual plans.

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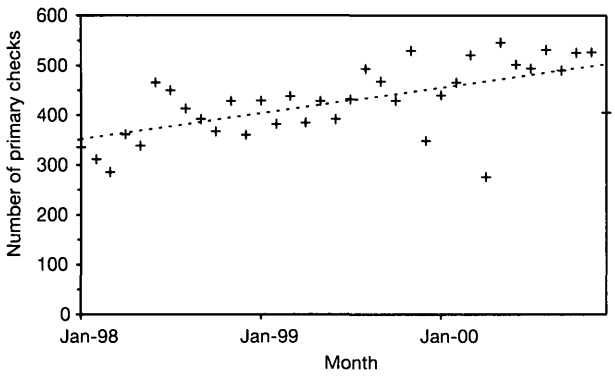

Figure 4. Time-trend for the number of patient-charts checked per month as part of the primary checking procedure between January 1998 and December 2000.

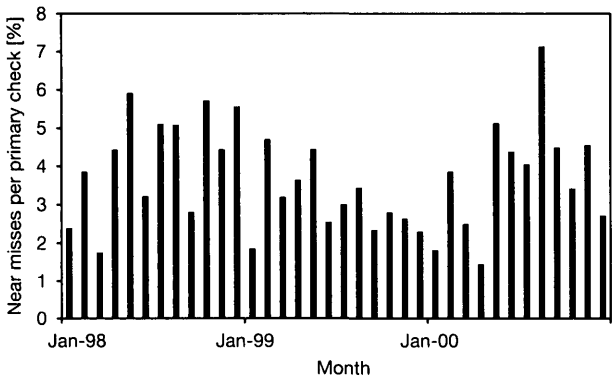

Figure 5. Percentage of charts checked per month containing a near miss found at the primary check-station between January 1998 and December 2000.

Table 2. *Near misses found through primary checking per 1000 computer plans during January 1998–December 2000 (N = 5904)*

Category of near miss	Type of near miss	Frequency [per 1000]
TPS-utilisation	Planned isocentric, should be fixed SSD	2.0
	Field size	1.2
	Energy	0.8
	Volume matrix	0.8
	Collimator angle	0.8
	Bolus	0.7
	Offset	0.5
	Moves from CT reference point	0.5
	SSD	0.5
	Patient orientation	0.5
	Field name	0.5
	Position of normalisation point	0.2
	Position of isocentre	0.2
	Position of spinal cord	0.2
	Position of beam	0.2
	Wedge direction	0.2
Calculation	Tray factor	10.8
	Arithmetic	9.8
	Dose per fraction	4.4
	Isodose level	2.7
	Equivalent square	0.7
Recording	Monitor units (MU) assigned to wrong field	3.0
	Open + Wedged MU wrong addition	1.0
	Recording incomplete	0.5
	Phase I/Phase II switched	0.2
	Wedge angle recorded incorrectly	0.2
	Recorded for wrong treatment unit	0.2

Near misses found through primary checks of computer plans

Table 2 is a list of the types of near misses found through the primary checking of computer plans during January 1998–December 2000, categorised according to where the root cause of the near miss belongs.

TPS-utilisation (Computer plans): The category 'TPS-utilisation' indicates that an error was made when using the treatment planning system. The most common near miss in this category was to plan an isocentric beam arrangement when the request had been for a set-up technique using a fixed source-skin distance (SSD), or vice versa. Other common near misses included using the wrong field size, energy, collimator angle, bolus or wedge direction. Some geometric errors entered the planning process, through the wrong positioning of normalisation point, isocentre, spinal cord and irradiation beam in the TPS. Two important types of near misses are the wrong patient orientation, where right and left have been shifted, and field naming, where the naming of a field in the TPS indicates that it is entering the patient from a direction other than in the plan.

One particular type of near miss logged was the incorrect creation of a volume matrix. This occurs when the patient volume in the TPS has been generated in a way that makes it unphysical. An example is when planning is performed on a single, non-CT, contour where the volume has not been extended up or down from this slice so that the patient is 'cut in half' in the TPS. The error in dose from the TPS calculations would be in the region of 5–15% through lack of scatter to the normalisation point from the missing tissue. Another example

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is when a head has been CT-scanned up to the top, and the last slice is extended incorrectly so that the patient gets a "hat"-volume extending above the last slice. If a vertex field is used when planning the irradiation of such a patient, there will be a significant difference between actual and calculated monitor units to achieve a certain dose at the normalisation point. Of the 5904 computer plans calculated, five of these errors were found before reaching the treatment stage. These were the only near misses found by the spreadsheet application monitoring the integrity of the TPS calculations independently. Overall the frequency of near misses in the category of TPS-utilisation for computer plans was 9.8 per 1000.

Calculation (Computer plans): A much higher frequency of near misses (28.4 per 1000) was found for the category of calculation for the computer plans. This category contains errors related to any subsequent manual calculation when a computer plan has been produced, to obtain the actual number of monitor units to apply for the individual field. The TPS produces a protocol that quotes the number of monitor units to apply for each field in order for the patient to receive 1 Gy to the normalisation point. This number has to be modified manually to take into account the prescribed dose per fraction being different to 1 Gy, and also if the radiation oncologist has prescribed the dose to a certain dose level, i.e. 95%, instead of the ICRU dose prescription point. The monitor unit calculation presented by the TPS-protocol does not take into account the presence of a shielding tray. Therefore a tray factor must be applied manually. One in every hundred computer plans had the wrong tray factor applied (or none when required) in the monitor unit calculations. Another type of near miss, listed as 'arithmetic', indicates that all factors used in the calculation were correct but that the end-result was wrong through an arithmetical error.

Recording (Computer plans): When recording the planned and calculated parameters, errors were found at the primary check-station in 5.1 of every 1000 computer plans. One type of incident was that the monitor units had been calculated correctly but assigned to the wrong treatment field. It was also noted when the wrong treatment unit, wedge angle or phase had been recorded in the patient's treatment chart and when the recording was incomplete. An error with a potentially large impact, is when a motorised wedge is used with a certain proportion of the monitor units being applied with the wedge in the field, but the wedged and non-wedged monitor units have been added incorrectly. This type of error can mean that the patient will receive a significantly different dose than prescribed.

Near misses found through primary checks of manual plans

The types of near misses specific to the manual plans and found through the primary checking procedure were divided into calculation errors and recording errors (Table 3).

Calculation (Manual plans): The majority of near misses were related to the look-up tables used to calculate monitor units. Parameters contained in the tables include percent depth dose values, output, tray and dose rate factors. Other near misses include the wrong equivalent square of a field or the wrong TMR-value, or looking up the wrong

Table 3. Near misses found through primary checking per 1000 manual plans during January 1998–December 2000 (N = 9482)

Category of near miss	Type of near miss	Frequency [per 1000]
Calculation	Percent depth dose	5.9
	Arithmetic	4.9
	Output factor	4.1
	Tray factor	2.5
	Equivalent square	2.5
	Cobalt dose rate factor	2.0
	Dose per fraction	1.8
	Separation	1.1
	Tissue maximum ratio	0.9
	Depth	0.8
	Field size	0.8
	SSD factor	0.6
	Treatment unit	0.4
	Energy	0.3
	Calculated SSD, should be isocentric	0.1
	Electron factor	0.1
	Electron applicator	0.1
	Beam location	0.1
	Calculated as single field, should be two	0.1
Recording	More than one field recorded per column	0.9
	Recording incomplete	0.1

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energy or treatment unit data. An incorrect depth to the prescription point or separation between two parallel and opposed fields was found in 1.9 per 1000 plans. Serious near misses found included the wrong dose per fraction used in the calculations and also that the monitor units were calculated for delivering the prescribed dose with a single field but entered into the chart for two parallel and opposed fields, thereby doubling the prescribed dose. Near misses in the calculations were found in 29.1 per 1000 manual plans.

Recording (Manual plans): The incidence of near misses in recording parameters for manual plans was much lower than for the calculation of manual plans. Near misses in this category occurred in 1 plan per 1000.

Near misses in prescription found through primary checks of all plans

The type of errors included in this category reflects instances when the prescribed total dose and number of fractions do not relate to the dose per fraction prescribed. Near misses found in prescriptions of either computer or manual plans were divided into incomplete and incorrect prescriptions (Table 4). The incidence rate is low, with a total frequency of 1.9 per 1000. It should be noted that these figures do not include any non-compliance with treatment protocols or any errors in the medical basis for dose prescription.

Near misses found through secondary checks of all plans

Table 5 lists the near misses found through the secondary checking procedure in 1999. Reported potential incidents have been categorised into TPS-utilisation, calculation, recording and prescription without separating manual and computer plans.

Table 4. Near misses found through primary checking of the prescription process per 1000 plans (any category) during January 1998–December 2000 (N = 15386)

Category of near miss	Type of near miss	Frequency [per 1000]
Prescription	Incomplete prescription	1.4
	Wrong prescription	0.5

Table 5. Near misses found through secondary checking per 1000 plans (any category) during January 1999–December 1999 (N = 5154)

Category of near miss	Type of near miss	Frequency [per 1000]
TPS-utilisation	MLC shape	2.1
	Offset	0.4
	Patient orientation	0.2
	Collimator angle	0.2
Calculation	Field size	0.2
	Arithmetic	0.2
Recording	Monitor units (MU) assigned to wrong field	0.6
Prescription	Wrong prescription	0.6

The largest number of potential incidents (2.1 per 1000) was for the incorrect shape of an MLC-field. An example of this is when a computer plan has been produced using a non-CT patient contour (level 2) and the MLC shape has been digitised separately on a multileaf planning device using a simulator film as the basis for the shape. The primary check station does not check a plan for this particular type of error, but the secondary check station on the treatment unit performs a check.

Taking into account both primary and secondary checks for both manual and computer plans, it can be seen from Tables 2, 3 and 5 that the most common type of near miss is purely arithmetical, i.e. using the correct factors but getting the wrong result, with an overall incidence frequency of 14.9 per 1000 plans checked. The next most common near miss is using the wrong tray factor, with a corresponding rate of 13.3 per 1000. An error in the tray factor can, in some instances, make the dose delivered to the patient deviate from the prescribed dose by up to 13%.

Actual incidents affecting the treatment of patients

The reported type and frequency of errors affecting the treatment given to patients, having their origin in the prescription, calculation and recording procedures, are shown in Table 6. When an MLC shape is found to have caused an actual incident, this would typically mean that the problem was seen first after reviewing a portal image of an irradiation field. This occurred in 0.8 per 1000 plans. The incorrect use of bolus was another type of error

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Table 6. Actual errors per 1000 plans (any category) during January 1999–December 1999 (N = 5154)

Category of error	Type of error	Frequency [per 1000]
TPS-utilisation	MLC shape	0.8
	Bolus	0.4
Calculation	Field size	0.4
	Arithmetic	0.4
	Tray factor	0.2
Recording	Transfer of monitor units	0.4

from the utilisation of the TPS. Errors in the calculation were reported with a frequency of 1 per 1000. Errors in the transfer of correctly calculated monitor units to a different page in the patient's treatment chart occurred at a rate of 0.4 per 1000 plans. The primary checkers do not check this particular step in the procedures.

DISCUSSION

A patient treated with radiotherapy should expect a high degree of precision and certainty in the implementation of the prescription. Deviations in radiation dose and irradiated volume from the intended can put at risk the successful outcome of a treatment strategy.[20–22] It is important to actively assess and manage the inherent risks and uncertainties in the radiotherapy process in order to maximise the benefit of the treatment to the patient.[23] One aspect of this is to have a system for preventing errors occurring in the treatment preparation process that might affect the treatment given to the patient. Regardless of the quality of input from the treatment preparation chain, this system should aim to stop potential errors from becoming actual errors. In this study, the dual independent chart checking in place was found to do this at a rate of 13.8 near misses per recorded error. The additional workload from chart checking was found to be of the same magnitude as that reported by Duggan et al.[10] of 0.3 full-time staff per 1000 patients per year.

Severity-classification of incidents

Categorising severity levels for near misses and errors is a very complex task. If a categorisation of minor/major incidents is performed, it should preferably be based on the probability of the incident affecting the intended treatment outcome. Radical radiotherapy would in itself have a probability of less than 100% for tumour control and more than 0% for normal tissue complications. Palliative radiotherapy would have a different intention of outcome than radical radiotherapy and be less sensitive to dose deviations. An analysis of the clinical basis for dosimetric accuracy in radiotherapy was performed by Mijnheer.[21] Based on a review of clinical dose-effect curves, it was concluded that a combined uncertainty in absorbed dose of 3.5% (1 standard deviation (SD)) at the specification point should not be exceeded. For other points in the planning target volume, the corresponding figure was 5% (1SD). It was also concluded that an even higher accuracy was necessary during conformal therapy and dose escalation studies. Furthermore, the relative steepness of dose-response gradients[20] will vary considerably for different tumour sites and normal tissue reactions. When considering the inherent dosimetric uncertainties in radiotherapy originating in, for example, planning system algorithms, tolerance levels of accelerator parameters and measurement uncertainties, it can be concluded that any additional uncertainty in the absorbed dose, introduced by errors in the treatment preparation chain, may not need to be large in order to increase the combined uncertainty over the recommended limit.

In view of these complexities, we chose to regard any error that would lead to a deviation in monitor units or treatment time of more than 1% from the intended as an incident (potential or actual). We did not further subdivide the incidents into serious and minor. Other authors approached this matter differently. Macklis et al.[16] utilised a stratification of errors into three risk levels. Level 1 errors were dose discrepancies that resulted in less than 5% overall calculated change in dose to the target volume over the whole course, whereas level 2 errors would either imply more than a 5% change, a clinically detectable increase in acute radiation toxicity caused by the error, or a systematic calculation or operational systems error. Level 3 errors result in a substantially increased risk of long-term treatment toxicity, decreased tumour control or other adverse clinical outcome, in the opinion of a review panel. Leunens et al.[11] divided deviations into minor (causing deviations in final

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tumour dose or dose to critical organ of less than ±5% if uncorrected) and major (±5% or more). Calandrino et al.[8,9] had a similar division of errors to the above study, but were also considering the impact on the daily dose and the total dose separately. The simplistic incident cut-off definition of ±1% used in the present study might lead to the recording of clinically irrelevant incidents for palliative treatment, but will ensure that incidents that might have clinical relevance for conformal dose-escalated treatment are recorded. It also enables increased capture and trend analysis of error-types that have a variable magnitude from event to event.

Near misses

The reporting of near misses can be a very valuable tool in preventing actual incidents, as has been shown by reporting systems outside the medical domain (e.g. aviation safety reporting systems[24]). The higher frequency of near misses than actual errors enables more accurate quantitative analysis of potential problems in the treatment preparation chain when these are studied. We found 51 different types of near misses originating in the radiotherapy preparation process at a total rate of 34.4 per 1000 treatment charts. Two types of near misses were common for manual and computer plans. Calandrino et al.[9] reported a frequency of 34.6 near misses (serious and minor) per 1000 independently checked treatment charts. Since the error rate was found to be strongly operator dependent in the latter study (ranging from approximately 1.4% to 6.7% depending on the individual), this could indicate an added value of utilising two independent calculation-checking stations after the initial calculation, as in this centre.

In a study by Duggan et al.,[10] near misses were categorised into:

a) Queries or interpolation differences (<1%).
b) Minor corrections (1–5%).
c) Errors in excess of 5%.

The total frequency of near misses is quoted as 100.9 per 1000, but this figure includes category (a) where discrepancies are less than 1%, and therefore are not included in our study. Since no figure is presented for the combined frequency of near misses from categories (b) and (c), direct comparison with this study is not possible. Similarly, Valli et al.[12] reported the frequency of wrong data in the compilation of treatment plans as 105.7 per 1000. No indication of a cut-off value for what is considered a near miss was given.

Leunens et al.[11] studied the errors arising specifically from the transfer of information in the different steps of the treatment preparation chain. An acceptance level of 1% variation in dose to the specification point was utilised. Data transfer errors due to "transcription errors, rounding off errors, forgotten data or exchange of data" over this acceptance level amounted to 78 when 464 new treatments had been checked. The importance of using additional modalities of incident prevention (in vivo dosimetry and portal imaging) was also emphasized in this study.

Errors

The frequency of actual incidents found in the present study was 2.5 per 1000 plans, while the number of treatment fractions found to be affected by an actual error in the treatment preparation chain represented 0.09% of all treatment fractions given. Other published incident data are sparse, when analyses of actual incidents in radiotherapy are seldom reported to the medical community unless they are part of larger systematic incidents relating to a whole group of patients. There are, however, a few studies with data of actual incidents in radiotherapy.

Macklis et al.[16] collected data for incidents where some part of the treatment had been carried out erroneously in comparison with the prescribed dose and method of delivery. Incident reports were collated and errors were categorised as mentioned in an above section. Near misses were not considered in the study. When specifically examining incidents primarily related to an error by the simulator staff and/or the treatment planning dosimetry group, the error rate was found to be 4.7 per 1000 patients. All errors were classified as level 1. It should be noted that an error rate of 30.6 per 1000 patients was found when including errors originating at the treatment unit (e.g. field size set up) and mould room (e.g. block shape). In another study, Walker[17] analysed actual incidents occurring

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over a 4-year period. An approximate incident frequency of 4.2 per 1000 patients was recorded. When comparing the error-rates in these studies with the present study, it is important to remember that all figures represent the errors that were found. This means that a high incident frequency could either represent a high error rate in the clinic or a good system for finding and reporting actual errors in ongoing treatments.

Impact of technology on errors

Radiotherapy is becoming increasingly complex, with the introduction of treatment modalities such as three-dimensional conformal radiotherapy and intensity modulated radiation therapy. These developments are often technology driven and rely heavily on progress in information technology. The number of irradiation-parameters (number of fields, shape of field segments, incidence-angles, etc.) per treatment is increasing steadily with these new modalities, up to a point where manual checking of the correctness of these parameters becomes very difficult. In our study, we found a 42% increase in near misses for the computer calculated plans in comparison with manually calculated plans. The number of error types also increased from 23 to 30.

As in other areas of medicine, information technology can be utilised to prevent potential errors from becoming actual errors.[25] Record and verify systems[13–15] and automatic MLC-data transfer systems[26] have been reported to have an impact on the error rate in radiotherapy treatment delivery. The main aim of these systems is to ensure consistency of irradiation-parameters between treatment preparation and actual treatment and also from fraction to fraction. It has, however, been highlighted that when the input-parameters are wrong, over reliance on this type of system can lead to systematic errors if used as an uncontrolled set up system.[11] It must be complemented with other modalities of error-prevention to filter the input-data, as shown in our study.

Another utilisation of information technology to prevent actual incidents is to use a computer that is independent from the TPS to check the validity of computer calculated monitor units.[27] In our study, only 0.8 per 1000 computer plans contained a near miss found by this type of independent MU verification. It is worth noting, though, that these near misses would have become actual errors without the independent spreadsheet and would have introduced a significant deviation in total dose to these patients. Knöös et al.[28] approached this potential problem in a different way, suggesting the use of a hand-held PC to feed in actual treatment parameters used at the first treatment fraction and calculate the MU from these, in order to compare with the TPS-calculated MU. This ensures an even higher degree of independence in the check.

Safety management – what can we learn from disciplines outside radiotherapy?

Safety management has always been performed in radiotherapy, but it is perhaps time to approach this complex task in a more systematic way as shown by some non-radiotherapy disciplines. Incident reporting systems focussing on near misses have evolved for a long time in complex non-medical industries, such as aviation and nuclear power.[24] These systems have been proven to benefit their organisations more than they cost. Adopting a non-punitive approach to errors can help the establishment of such systems. Recurrent training and feedback have also been shown to be of value in reducing the frequency and severity of adverse events.[29] Nolan[30] suggested three tasks for making systems of care safer:

- Design the system of care with error prevention in mind (e.g. multilayered incident prevention).
- Design procedures so that errors are visible when they do occur (e.g. near miss reporting).
- Design procedures for mitigating the adverse effects of errors when they are not detected and intercepted.

It is emphasized in some studies[31,32] that nearly all adverse events involve a combination of two sets of factors: active failures and latent conditions. Active failures are unsafe acts by people with direct involvement in the system (slips, lapses, mistakes, procedural violations, etc.). Latent conditions are the 'resident pathogens' in the system arising from its design, often by people without direct involvement in the system. This could include strategic decisions translating into error-provoking conditions

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where the unsafe acts occur. Weingart et al.[33] warned that clinicians, patients and policymakers might underestimate the magnitude of risk and the extent of harm from medical errors. In order to make radiotherapy safer for patients, it should now be time to translate the knowledge in error-prevention that has been gained in other areas, into the area of radiotherapy.

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