Treatment errors and near-misses in a radiotherapy department

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Abstract

Radiotherapy procedures are susceptible to errors due to their multi-step and multi-disciplinary involvement. Although rare, the clinical detriment of radiotherapy errors to the patient can be significant. Process control techniques and risk reduction measures should therefore be applied continually as an integral part of the radiotherapy processes.

Given the patient workloads, the number of planning mistakes in busy radiotherapy departments remains relatively high. Therefore, most radiotherapy steps have checking processes to identify and correct such mistakes. The purpose of this study was to apply a procedure for mistake detection and risk analyses with a view to error probability reduction in radiotherapy physics planning.

Mistakes detected by the checking processes were analysed for 1210 treatments and a classification and risk analysis method was applied to the data. Results showed an overall average of about 0.5 mistakes per treatment in the planning and calculation procedures. However, it was found that only a few of the mistake types scored a high risk ranking i.e. could potentially lead to significant radiotherapy incidents if undetected. It was found that a number of these high risk ranked mistakes had relatively significant occurrence rates and possible solutions to counteract the risk from this group of mistakes were identified.

Furthermore, twenty radiotherapy incidents were investigated using Root Cause Analysis. For each incident root (first) causes, main causes and contributory factors were identified and the associated unintended / erroneous doses were quantified. The classification and coding method suggested by the multi-disciplinary working party in the UK publication, Toward Safer Radiotherapy (TSR2008) was applied. The root (first) causes for most of the incidents were identified to be due to human errors. However, process control systems were thought to be the main causes for most of the incidents.

Key Words

Radiotherapy, mistakes, errors, risk, analysis

1- Introduction

Radiotherapy is a multi-step and complex treatment modality requiring the linkage of many different systems and staff groups and therefore lending itself to potentially significant dose delivery errors. Fig.1 shows the main stages in the radiotherapy patient pathway.

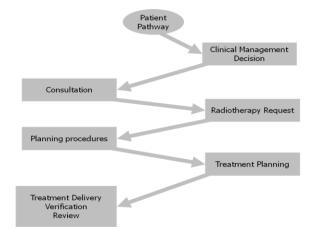


Fig. 1 Main stages in radiotherapy patient pathway

Despite technological and process control advancements, a very small number of clinically significant errors in radiotherapy still occur, necessitating therefore continued risk reduction measures. There exist extensive national and international requirements and guidelines for reducing and reporting of radiotherapy errors and also for detriment limitation. In United Kingdom, these are mainly covered by the Ionising Radiation Regulations 1999 (IRR99), the Ionising Radiation (Medical Exposures) Regulations 2000 (IRMER2000), the Health and Safety Executive Guidance Note 77 (Third Edition) on Equipment Used in Connection with Medical Exposures (PM77) and the multi- disciplinary report entitled Towards Safer Radiotherapy (TSR2008).

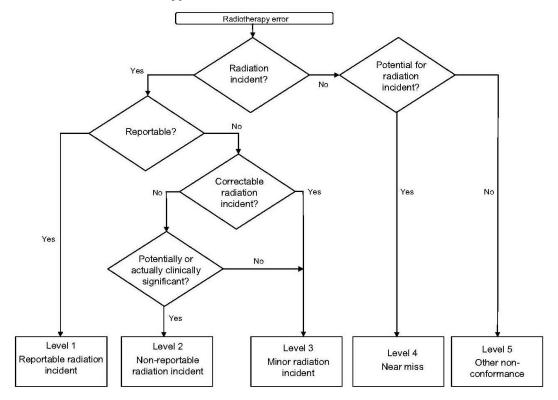


Figure 2 Radiotherapy Error Classification Grid (reproduced from TSR2008)

TSR2008 proposes the decision grid shown in Figure 2 for grading of errors to five severity classifications / levels. A National Reporting and Learning Service (NRLS) has also been set up by the National Patient Safety Agency to record unintended or unexpected incidents and near misses with the aim of facilitating analysis of errors and providing feedback to the radiotherapy community.

Under the TSR2008 classification system, a near miss is defined as "a potential radiation incident that was detected and prevented before treatment delivery". However "mistakes in plans, calculations etc, do not constitute near misses if they are detected and corrected as part of the checking procedure before authorising for clinical use". Since such mistakes, when undetected, have the potential to lead to radiation incidents, identification of their root causes and incorporation of preventative measures may be considered as good practice. The purpose of this study was to incorporate a process of mistake detection and risk analyses with a view to error probability reduction within a busy radiotherapy physics department; also reported is a review of the root and main causes of a number of radiotherapy incidents.

2- Materials and Methods

Mistakes detected in the checking processes of physics planning services were analysed for 1210 treatments and a scoring method was developed to enable application of a risk analysis procedure.

Based on the local practice, fifty one mistake codes were generated which also included three codes for miscellaneous mistakes at different parts of the service. For consistency, a five level classification system similar to that suggested by TSR2008 (Figure 1) was adopted. Depending on the clinical severity to the patient of the potential error, levels 1, 2 and 3 were assigned a high severity ranking. Level 3 and level 5 were assigned moderate and insignificant severity rankings respectively. Each mistake type was also assessed for likelihood of remaining undetected through the rest of the radiotherapy chain. A colour coded risk ranking system was then developed for each mistake code from the product of the potential severity and the likelihood of the mistake remaining undetected through the radiotherapy chain. A red ranking was assigned to high risk mistakes, an amber ranking was assigned to moderate risk, a yellow ranking was assigned to low risk and a green ranking was assigned to very low risk mistakes. Of the identified mistake types, six were ranked red, seven were ranked amber, eleven were ranked yellow and twenty four were ranked as green. The three miscellaneous mistake codes were thought to have a low to very low risk ranking and were assigned a colour ranking of blue to distinguish them from the other mistake codes.

Furthermore, the TSR2008 classification and coding method was applied to twenty radiotherapy incidents which were investigated using Root Cause Analysis. For each incident, root (first) causes, main causes and contributory factors were identified and the associated unintended / erroneous doses were quantified.

3- Results and discussion

3.1- Radiotherapy Physics planning and calculation mistakes

Analysis of the radiotherapy physics planning mistakes showed that of the 1210 plans and calculations, there were 756 (about 62%) which did not have any mistakes identified by the checking processes. Of the remaining 454, a total of 584 mistakes were detected giving an overall average number of mistakes per plan or calculation of about 0.5. Figure 1 shows the variation of the mean number of mistakes per plan with service throughput.

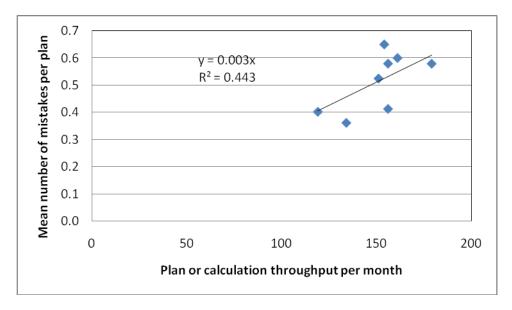


Figure 3 Variation of the mean number of mistakes per plan with service throughput

Of the plans and calculations with one or more detected mistakes, 57 ($\approx 10\%$) and 43($\approx 7\%$) had red and amber risk rankings respectively. Of the remaining, 108 ($\approx 19\%$) had yellow risk ranking, 300 ($\approx 51\%$) had green risk ranking and 76 ($\approx 13\%$) were mistakes that had blue risk ranking (un-coded; low to very low risk); see Figure 4.

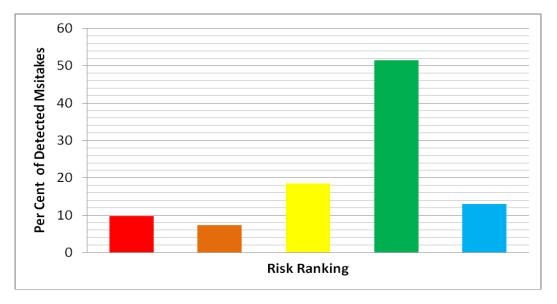


Figure 4 Proportion of detected mistakes in each risk colour ranking

Figure 5 shows in detail the proportion of each detected mistake code. Table 1 and Table 2 summarise details of the red and amber risk ranked mistake codes; also indicated are the corresponding potential TSR2008 coding (TSRC) and Level classification (C), the per cent of detected mistakes to the total and their respective identified root causes. The results show that for most of the red and amber risk ranked mistakes, the probability of occurrence may be reduced through the inclusion of the corresponding data within the DICOM RT Plan electronic dataset transfer. Reducing the number of the remaining red and amber risk ranked mistakes may be possible by a reduction in human errors through for example incorporation of alternative data pathways, improved standard work instructions and further staff training.

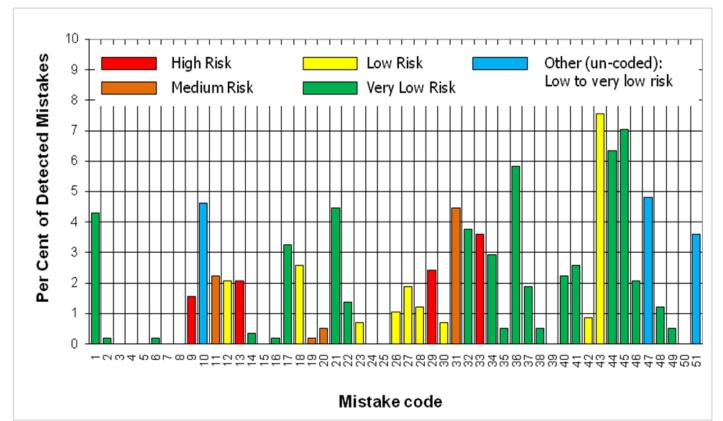


Figure 5 Proportion of each detected mistake code

TSRC	Description of Error	С	%	Root Cause
11e	Incorrect studyset used (rescan / re-plan)	L2	0.2	Human Error possible
11r	Incorrect calculation reference used (applied instead of at depth)	L1	0	Human Error Possible
11r	Incorrect OF / PTR / DD used in calculation	L1	1.5	Human Error Possible
11n	Isocentre position description incorrect	L1	2.1	Not part of DICOM PLAN
11m	Wedge and/or bolus information incorrect or missing	L1	2.4	Not part of DICOM PLAN
11m	Isocentre position incorrect	L1	3.6	Not part of DICOM PLAN

Table 1	Mistakes	with	red	risk	ranking
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Table 2 Mistakes with amber risk ranking

TSRC	Description of Error	С	%	Root Cause
11i	Incorrect site planned	L1	0	Part of main end of process checks
11f	Dose does not match CCO prescription	L1	0	Part of main end of process checks
11r	Request for 'weighted' contribution not recognised	L3	0	Human Error Possible
11e	Markers/tattoos incorrectly positioned / coordinates not correct or missing	L3	2.2	Human Error Possible
11j	Constraint values exceed CCO request	L2	0.2	Human Error Possible
11j	Constraint values could be significantly lower (plan approach incorrect)	L3	0.5	Human Error Possible
11m	Couch / board corrections incorrect or missing	L3	4.5	Not part of DICOM PLAN

3.2- Radiotherapy incidents

Of the twenty TSR2008 L1-classified radiotherapy incidents investigated, 11 were related to External Beam Radiotherapy (EBRT) and 9 were related to brachytherapy implant procedures.

Of the eleven EBRT incidents (4 had radical and 7 had palliative prescriptions), (a) Seven involved radiotherapy erroneous doses of which six were due to geometric misses and one involved an incorrect SSD set-up and (b) Four had given rise to unintended or redundant CT imaging doses.

Furthermore, of the seven EBRT erroneous treatment doses only one (palliative treatment) could have been picked up by in vivo dosimetry. Of the remaining six errors, five could have been detected by enhanced treatment verification processes and one could have also been detected at simulation.

The nine brachytherapy implant treatment incidents were classified as having given rise to redundant CT imaging doses.

4- Conclusions

A process of risk analysis was applied to mistakes in a busy radiotherapy physics planning service.

A small group of mistake types with high risk ranking were identified of which some were made with sufficient frequency to merit suggestion of targeted intervention. The analysis showed that the occurrence of these mistakes could be reduced through electronic transfer of the corresponding data and also by the targeted utilisation of available on-set verification technologies.

The root (first) causes for most of the investigated radiotherapy incidents were identified to be due to human errors. However, process control systems were thought to be the main causes for most of the incidents.

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PM77 Health and Safety Executive Guidance Note 77 (Third Edition) on Equipment Used in Connection with Medical Exposures http://www.hse.gov.uk/pubns/guidance/pm77.pdf
NRLS National Reporting and Learning Service of the National Patient Safety Agency http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/