Independent review of the circumstances surrounding a serious adverse incident that occurred in the

.....REDACTED.....

Professor Brian Toft
BA (Hons) Dip Comp Sci (Cantab) PhD, MInstD FIOR FIRM FIOSH FIIRSM Hon FICDDS Dpl

Chairman
Review Panel

brian.toft@ntlworld.com
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Background

On the REDACTED following an open tender competition the author of this report was commissioned by the Board of the REDACTED teaching hospital, to investigate the circumstances surrounding a serious adverse incident that had occurred in the Department of Radiotherapy, the cancer centre which is a satellite operation of the Trust. Three expert assessors were also appointed to assist me in the review. This report sets out the conclusions that I have reached and my recommendations as to how such events might be prevented in the future.

The starting point for the Review Panel and the Trust is that patient safety is paramount. As a result, since we started our work in REDACTED, the Trust have started to put in place the necessary processes to support the recommendations made by the review team. We believe that the Trust have made significant progress.

Serious adverse incident

On the REDACTED, it was discovered that a major treatment parameter that had been prescribed for a patient undergoing radiotherapy had not been inputted to the computer database that controls the linear accelerator that delivers the treatment. As this error had gone undiscovered during the patient’s 14 previous treatments it was calculated that the patient had received approximately 2.5 times the prescribed radiotherapy dose of 40 Gray. The patient is currently receiving remedial medical treatment for the overdose of radiotherapy that was inadvertently administered to her.

Safety culture

The evidence suggests that the radiographers who were involved in the provision of radiotherapy for this patient were working in organisational surroundings that unwittingly provided an opportunity for them to be unconsciously influenced by a previously unrecognised social-psychological phenomenon that has been termed ‘involuntary automaticity’ in this report (Chapter 4). As this phenomenon does not appear to have been identified in the national or international medical literature a paper discussing involuntary automaticity has been submitted for publication in the peer-reviewed journal ‘Healthcare Services Management Research’.

The phenomenon that has been identified appears to have unconsciously undermined the robustness of the double-checking process that the radiographers used when treating the patient. For while the radiographers undoubtedly performed all the double-checks required on the patient’s treatment parameters the error that was present remained undetected by them. Thus the radiographers carried out the double-checks without being effective.
The Review Panel has concluded that this serious adverse incident was caused through inadvertent human error due to a systems failure.

Professor Brian Toft
BA (Hons) Dip Comp Sci (Cantab) PhD,
MInstD FIOR FIRM FIOSH FIIRSM Hon FICDDS Dpl

Research Director
Marsh Risk Consulting Practice, London

May 2005
Chapter 1

Introduction

The .....

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... teaching hospital provides radiotherapy treatment for patients at the cancer centre. Following surgery for cancer of the right breast...

...

...

patient A was referred to the cancer centre for ongoing care and treatment as an outpatient. However, because patient A was experiencing problems with the wound care and the healing process it was agreed to halt the chemotherapy treatment that had been prescribed and embark upon a course of external beam radiotherapy. The total dose of radiotherapy prescribed for this patient was for 40 Gray (Gray is a unit of absorbed radiation dose) to be delivered in 15 separate treatments (known as fractions).

It was also explicitly stated in the prescription for this patient that a physical attenuating device known as a `wedge filter' or simply a `wedge' was to be inserted into the right lateral field (treatment beam) to ensure that the distribution of the dose delivered to the patient’s breast would be homogenous.

The radiation dose delivered by a linear accelerator is controlled by an internal system known as a dose monitor. The dose to the patient is controlled by setting a predetermined number of so called `monitor units' determined during the treatment planning process. During the exposure, once the pre-set number of monitor units has been accumulated the beam is automatically switched off. The absorbed dose delivered to the patient is directly proportional to the set number of monitor units. Because the attenuating wedge filter is positioned in the beam path closer to the patient than the radiation monitor, for a given dose to the patient relative to an open (unwedged) field, an increased number of monitor units must be set to make allowance for the attenuation of the beam in the wedge. Hence, if a wedge is prescribed for a particular radiotherapy treatment and it is inadvertently omitted the patient receiving that treatment will suffer an overdose of radiation.

On the .....

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... while carrying out their pre-treatment checks, the two radiographers treating patient A discovered that the right lateral field wedge that had been prescribed for this patient had not been in place when the previous 14 fractions had been administered. As a result it was calculated that the patient had received approximately 94 Gray or roughly 2.5 times the dose prescribed. At the time of writing this report patient A is being treated for the overdose she received.

Terms of reference

In order to ensure that the maximum amount of learning would be drawn from this adverse incident it was decided by the Trust’s Management Board to put out to tender a brief for an independent root cause analysis to be undertaken.
Following completion of the tender process the author of this report was commissioned to undertake an Independent Review with a remit:

‘To investigate the circumstances leading to the incorrect dosage of radiation being administered to a patient receiving treatment for Breast cancer.

‘To review the incident, identify and make recommendations in order to develop a plan of implementation.

‘The report to be delivered to .....REDACTED.....

Acknowledgments

Subsequently, three Assessors, clinical experts in the field of radiotherapy who are highly regarded in their respective fields, were appointed to assist this Independent Review. These were:

......REDACTED......

......REDACTED......

......REDACTED......

I would like to express my most sincere thanks to the Assessors for the assistance and support that they have provided during this Review. However, the conclusions expressed in this report are my own and therefore, any errors are solely my responsibility.

Prior to commencing the formal hearing, the author visited the site where the adverse incident took place in order to gain first hand knowledge of the physical characteristics of the premises and to be taken through the different sequences of actions that was believed to have taken place. I would like to thank all those concerned for their assistance during my visit for it was very useful and helped to increase my understanding of the evidence that was presented.

I should also like to thank all the staff at the Trust who gave evidence to the Review Panel for the forthright answers they provided in response to the questions put to them. From our first contact with the Trust the staff have at all times been open and cooperated fully with the Review Panel. Additionally, as issues have come to the attention of the Review Panel, possible recommendations have been discussed so that they could be addressed by the Radiotherapy Department and others in the field of radiotherapy as early as possible.

I would also like to thank the following for their assistance:
Methodology

One of the conditions for undertaking this review was that the methodology to be used by the Review Panel would broadly conform to that devised by the National Patient Safety Agency (NPSA). To that end the author of this report attended the three days of the ‘Root Cause Analysis Workshop’ organised by the NPSA.

Thus, as recommended by the NPSA, this report draws upon a number of sources of information, the written and oral statements of witnesses who appeared before the Review Panel, confidential clinical papers, confidential internal reports, publicly available documents and a limited amount of research carried out by the author.

It should also be noted that the patient concerned was invited by the author of this report to discuss the circumstances surrounding her serious adverse incident using a format of her own choice. The patient however declined the offer.

As noted above, a multi-professional Review Panel was convened and conducted using the ‘Cognitive Interview’ technique. During the interviews free recall and a semi-structured questionnaire was employed. The mapping of data has been undertaken using a Narrative Chronology. An explanatory synthesis of the data was undertaken by drawing upon the knowledge base of the Review Panel.

While many of the other techniques discussed in the NPSA Root Cause Analysis Toolkit could have been utilised to investigate this serious adverse incident it is the opinion of the author that the time required to use them would have been disproportionate to their exploratory value. Or, on the other hand, appeared to have little probative merit and therefore were unlikely to have produced the insight into this serious adverse incident that has been achieved (See Chapter Four).

A review of the circumstances surrounding the serious adverse incident to patient A using the NPSA ‘Incident Decision Tree’ model leads to the conclusion that the incident was caused by a ‘System Failure’ (appendix 1). This determination is strongly supported by the evidence presented to the Review Panel and discussed in this report.

Reliability of evidence

It should be noted that the serious adverse incident described above occurred months before the Review Panel was convened to take evidence from those involved. Thus, it is perhaps not surprising that when questioned most of the radiographers involved in the treatment of patient A had no clear recollections regarding the specific events that took place. The
only reliable evidence available to the Review Panel relating to the circumstances surrounding this incident has been that obtained from the patient’s records and other documentary sources.

The verbal evidence provided by many of the witnesses is for the most part generic and often based upon indistinct memories of what they believe occurred at the time.

**External beam radiotherapy**

Radiotherapy is used to treat or palliate the symptoms of diseases by the use of ionising radiation. In external beam radiotherapy the beam is generated outside the patient, usually by a linear accelerator (Linac), and is targeted at the site requiring treatment. However, while ionising radiation destroys unhealthy tissue, such as cancers, normal tissue is also damaged by the radiation. Provided the damage is sub-lethal, normal tissue is usually able to repair more efficiently than tumour. Therefore, radical radiotherapy is given not in one large dose, but in multiple small doses or ‘fractions’ given each day for several weeks. The cumulative dose to the tumour is such that it is unable to recover whereas the adjacent normal tissue is able to recover most of the damage sustained over time. It is important that great care is taken to limit the amount of healthy tissue exposed to radiation and thus every patient’s treatment is prescribed, planned and administered with considerable care.

Because the complexity of radiotherapy treatments is varied the time taken to treat individual patients also varies. Generally, the more complex the treatment the longer it takes radiographers to carry out a patient’s treatment. There are also times, for example, when a Linac will break down unexpectedly, that patients will take longer to treat than expected or a patient will be referred for immediate emergency treatment and consequently the predicted rate of patient throughput can be severely compromised. Moreover, in a recent audit by Ash et al into radiotherapy waiting times in the UK it was observed that:

> ‘Waiting times have lengthened in most centres for all categories of patients…fewer patients in all categories are being treated within the Joint Collegiate Council for Oncology (JCCO) guidelines…There was [however] no obvious simple correlation of radiographer, physicist or treatment machine numbers with waiting times…The results of this survey suggest a continuing mismatch between capacity and demand’.

**Transcription of theraplan data to linac computer database**

Treatment planning systems are computer systems that model the dose distribution in tissue from radiation beams. For each patient planned, a description of the patient’s external and ideally their internal anatomy is input from a computerised tomography (CT) study. An optimum treatment is designed by directing a number of radiation beams to overlap the designated
volume of tumour so that it receives a high but uniform dose whilst the dose to adjacent normal tissue is minimised. Treatment planning systems also compute the number of monitor units required to be set for each beam on the linear accelerator in order to achieve the intended treatment plan. A number of commercial treatment planning systems are in use within the National Health Service (NHS), one such system is called ‘Theraplan Plus, Version 3.8’ (Theraplan) and is one of 2 systems in routine use at the cancer centre. All the treatment data produced by this system at the cancer centre has to be manually transferred to the computer database that controls the Linac because the Theraplan system has no direct electronic data network transfer facility. The Royal College of Radiologists’ Clinical Oncology Information Network (COIN) warns however that:

‘The transfer of treatment data sets should be by local area IT network as far as possible. Manual transfer of data either from [treatment] planning to treatment units [Linac’s] or between treatment units is associated with a high risk of transcription errors’.

The hardcopy treatment plan produced by the Theraplan system consists of two documents one containing numerical data and labelled ‘Isocentric Plan’ (plate 1). The second document is a diagram that shows a sectioned outline of the area to which a radiotherapy beam is to be applied (plate 2). Amongst the data that should be provided by this diagram is a diagrammatic symbol of a wedge if one has been prescribed. Once a patient radiotherapy plan has been computed by the Medical Physics Department, it is sent to the Radiotherapy Department for the data to be entered on to the Linac database. Prior to entering data from a Theraplan hardcopy the radiographer concerned should first of all ‘log on’ to the record and verify system (colloquially known as ‘Vericord’). The record and verify system allows a radiographer to store the data they transcribe from the hardcopy treatment plan into the Linac computer database and then to ‘check’ or ‘verify’ that input against the primary or source data set at any time, including just before treating a patient. At the end of data entry a document is printed out that shows the specific values that have been entered on to the database by the radiographer.

The document produced by the Vericord system is two sided. On one side it is entitled ‘Prescription Sheet’ (plate 3) this side identifies the patient and contains all the treatment control values that have been entered into the database. The other side of the document it is entitled ‘Session Sheet’ (plate 4) again the patient is identified but this time the parameters recorded by the system are those pertaining on the Linac at the time treatment was delivered. The parameters include the date and time of each treatment, the designation of the Linac used to administer the treatment, the orientation of the field of radiation, the number of monitor units used and the absorbed dose (in Gray) administered by each field where more than one field is used to treat a patient. However, COIN notes with regard to this system that:

‘Machine linked record and verify systems can improve the safety of treatment but can lead to systematic errors if used as a
Transcription of theraplan data to patient treatment card

Some of the data from a patient’s Theraplan hardcopy is also transcribed to the patient’s ‘Treatment Card’ as this is a patient’s formal Treatment Prescription. Of all the data elements transcribed from the hardcopy to the Treatment Card, of particular importance with regard to this serious adverse incident are the numerical values placed in the boxes with the following categories ‘Energy’, ‘Wedge or Filter’ and ‘Monitor Units’ (plate 5). These values are critical because they determine the amount of radiation that will be administered to a patient at any one treatment. Thus, if any of these values are incorrectly transcribed from the hardcopy treatment plan on to a patient’s Treatment Card or into the Linac computer database a patient could be under or over exposed to the ionising radiation produced by the Linac.

Transcription of theraplan data to set-up sheet

Data is also transcribed from the Theraplan hardcopy to a document known as the patient’s ‘Set-up Sheet’ (plate 6). Radiographers use the Set-up Sheet to ensure that a patient is correctly orientated with respect to the beam of radiotherapy to be delivered by the Linac on each occasion that they are treated.

Transcription of theraplan data checks

Having input a patient’s treatment data into the Linac database from the primary sources of data, the radiographer concerned must then check the hard copy of the patient’s treatment parameters produced by the Vericord system, then sign and date the patient’s Treatment Card. The radiographer then ‘logs out’ of the Vericord system. Following this a second (different) radiographer must carry out a (second) separate and completely independent check on the patient’s treatment data using the primary sources of data and the hard copy produced by the Vericord system before the first treatment session. One of the radiographers involved in these first two checks must be a senior or superintendent radiographer.

Where a patient is having more than seven fractions of radiotherapy a third (again different) radiographer must carry out a further much wider check on all the sources of primary data used to ascertain if any changes have been made. This third check must be undertaken before a patient is provided with their fourth treatment.

On each occasion that checks are carried out the radiographer involved has to sign and date the patients Treatment Card to indicate that the check has been carried out separately and independently and that the data stored in the Linac computer database has been ‘Cross-checked with machine data books and other relevant sources of information and correctly transferred to the
treatment card$^4$.

**Treating a patient**

When a patient comes for in for treatment they are normally asked to remain in the waiting room until their name is called. Once their name has been called the patient is asked to identify themselves and their physical and mental condition is ascertained by one of the radiographers who will be treating the patient. When it has been established that a patient is well enough to undergo their radiotherapy, they are taken into the treatment room where the Linac is situated. Using the Set-up Sheet and the Theraplan data the patient is put into the position required to receive their radiotherapy by the radiographers. Checks are then carried out on the Linac parameters displayed on the computer screen in the treatment room to ensure that they correspond with those on the Set-up Sheet. Once the radiographers are satisfied that all the settings are correct and that it is safe to treat the patient they leave the treatment room. The Theraplan Treatment Plan and Set-up Sheet are left in the room.

Once outside the treatment room and prior to administering the patient’s treatment the two radiographers check that the ‘Energy’, ‘Wedge’ and ‘Monitor Units’ data on the patient’s Treatment Card is identical to that on the Linac computer screen. The check consists of the radiographer who is to initiate the exposure reading out aloud the above data settings from the patients Treatment Card. The other radiographer present checks that the parameters on the Linac computer console screen are identical and verbally reports back her or his findings (plates 7 and 8). Plate 9 has been provided to help the reader visualise the work environment where the final Linac computer checks are carried out.

Once the final verbal double checks have been carried out and are perceived to be satisfactory the radiotherapy beam is energised. Every time a patient is given radiotherapy regardless of the specifics of the treatment prescribed the radiographers at the cancer centre carry out the identical final verbal checking procedure.

It should also be noted that, while the radiographers treating patients enquire as to the health of those who they are treating, a doctor or a specially trained nurse also sees patients periodically as an additional check on their welfare.

**Serious adverse incidents**

Reason$^5$, Turner and Pidgeon$^6$, Toft and Reynolds$^7$ and others have comprehensively argued that the precursor conditions required for the creation of a serious adverse incident may lay cloaked in the social and technical fabric of an organisation for many years before an untoward incident occurs. Similarly, an organisation’s culture, i.e. the commonly accepted way of behaving within any given organisational settings, does not spring into existence overnight as an established phenomenon. It takes time for the complex sets of
individual and collective perceptions to develop and coalesce into a system of commonly shared values (Johnson). Therefore the actions that individuals take within an organisation are determined by the understanding that they have of any particular situation. People try to make sense of their organisational settings and then act in the belief that the assumptions that they have made are facts (Weick). Moreover as will be recognised the serious adverse incident suffered by patient A did not occur on one single occasion but on multiple occasions over a period of three weeks. ‘It is therefore imperative to understand the organisational setting in which the adverse incident took place’.

The different organisational contexts in which the adverse incident noted above took place will be described in the following chapters.

Observations

The administration of radiotherapy therapy is a highly skilled profession for which there is a great demand nationally. However, it would appear currently that the resources available are not sufficient to reduce patient waiting times in most hospitals.

On a day-to-day basis a patient’s treatment can be delayed for a variety of reasons and this can create a backlog of patients waiting to be treated.

COIN suggests there is a high risk of transcription errors being inadvertently introduced whenever a patient’s treatment data is manually transferred from a planning system to a Linac or between Linac’s. It is therefore recommended that all such transfers of patient treatment data should be carried out electronically.

COIN also observes that while record and verify systems can improve patient treatment safety that when used as a set-up system they may lead to the unintentional introduction of systematic errors.

While it is vital that all of a patients treatment parameters are accurately recorded and stored in the Linac computer database it is the Energy, Wedge and Monitor Units factors that primarily determine the amount of radiotherapy that will be administer to a patient on each treatment. Consequently, if any of those particular parameters have inadvertently been programmed or recorded incorrectly the patient concerned will receive either an over or under dose of radiation.

The Theraplan and Set-up Sheet are left in the treatment room. The radiographers then compare the numerical values recorded on a patient’s Treatment Card against those displayed on the Linac computer monitor prior to energising the treatment beam.
The final verbal checks carried out by all radiographers at the cancer centre just prior to administering a patient’s radiotherapy are identical on every occasion.

In addition to the radiographers who are treating a particular patient enquiring as to their health a doctor or a specially trained nurse also sees each patient periodically as an additional check on their welfare.
References


4 Duxbury, M (09.10.03) ‘Preparation of the Treatment Prescription at the Treatment Machine’, Radiotherapy Technique Protocols


Chapter 2

Radiotherapy departmental organisational culture

When reviewing the circumstances surrounding the serious adverse incident described in this report, the reader should keep in mind the backcloth to those events as described in this chapter.

In a very general sense the concept of culture is widely used in social science and a multiplicity of definitions are available. For present purposes, culture can be regarded as being the collection of beliefs, norms, attitudes, roles and practices of a given group, organization, institution or society. A culture is created and recreated as members of it repeatedly behave in ways which seem to them to be the natural, obvious and unquestionable ways of acting, and as such will serve to construct a particular version of risk, danger, and safety. Waring draws the conclusion from his research that, ‘Culture is not a “thing” but a complex and dynamic property of human activity systems’.

Thus an organisation’s culture does not spring into existence overnight as a mature phenomenon. It takes time for the complex sets of individual and collective perceptions to develop and coalesce into a system of commonly shared values.

One of the values that appears to be shared by all the radiographers interviewed by the Review Panel is the professional trust that they place in their colleagues. Radiographer 1 (R1) observing:

‘We are a trust profession, we work in teams, so you trust the person who has gone before you and the person who comes after trusts you because they know you and they know how you work’.

While Radiographer 2 (R2) similarly noted in relation to the work done by others ‘I suppose it is having a bit of trust in what previous people have done...’.

A second belief that appeared to be widely held was that in general the checking protocols used in the Radiotherapy Department are fit for their purpose. Radiographer 3 (R3) stating that ‘I felt our checking procedures were adequate. We go through it day after day’. Radiographer 4 (R4) said ‘I thought it [the protocol] was very robust’. While Radiographer 5 (R5) stated:

‘I thought it [the protocol] was adequate. If I had thought there was something wrong with them I probably would have questioned it but I never questioned it so I probably thought it OK’.

Consultant 1 (C1) also remarked that he:
‘…considered the checking procedures to be very robust. A lot of staff checking a lot of things on a regular basis and different staff through physics and through radiotherapy, my perception of that process was one of extreme robustness’.7

It should also be noted that the Radiotherapy Department has a current International Standards Organisation (ISO) 9000 certificate for the quality of its management8.

On the other hand while the protocols were felt to be adequate R1 did make the point that:

‘We knew that we had problems with the pre-treatment checking system because that was reflected in some of our potential incidents and some of our minor reported incidents and we knew it was not good the distractions the radiographers had so we had plans to introduce the pre-treatment team anyway. We also had plans to look at the amount of checks that they did as part of the pre-treatment process because they were trying to check the monitoring units on Helax plans, which is a waste of time…I thought there was an issue there anyway around that pre-treatment checking process’.9

Additionally, it was also noted during the Review Panel interviews that random observations were not made of the Linac teams while they were operational10. Thus, there was no formal system in place to afford the Department opportunities to help identify any potential weakness in the protocols being used or the Linac teams working practices.

Safety culture

Levitt and March have observed that:

‘Routines are based on interpretations of the past more than anticipations of the future. They adapt to experience incrementally in response to feedback about outcomes’.11

Therefore since the Radiotherapy Department has been operating successfully for many years the staff would have had no reason to question their behaviour or the procedures that they have adopted. Indeed, the actual number of recorded errors in 2003 – 2004 was 48. Taking an average of two fields per treatment fraction and the number of fractions as 50,506 gives a rough total of 101,012 of fields administered to patients during that year. This yields a crude radiation delivery error rate of 0.047% per field, which compares favourably to 0.063% delivery errors per field reported by Macllis et al12.

However Miller warns that:
Failure teaches leaders valuable lessons, but good results only reinforce their preconceptions and tether them more firmly to their "tried-and-true" recipes.\textsuperscript{13}

Thus, success can lead to people being unaware that they are unconsciously becoming complacent and that their organisational culture is being affected. The importance of any organisation creating and maintaining a robust safety culture is clearly spelled out by the Department of Health where it is suggested, ‘People may come and go, but an effective safety culture must persist\textsuperscript{14}.

Unfortunately, the safety culture surrounding the administration of patient A’s radiotherapy appears to have been compromised. Conversely, it should not be forgotten that it was the radiographers who were about to administer the final fraction of patient A’s treatment who identified that a serious adverse incident had taken place. However, the working environment in which the serious adverse incident was discovered was significantly different from the norm described below. Radiographer 6 (R6) observing that on the day that Radiographer (R7) and her treated patient A ‘….there was only the two of us and we were pretty much in a quiet space at that time\textsuperscript{15}.

Linac team structure

At the time the serious adverse incident took place the radiographers working in the department were assigned to teams with five members of staff working on each Linac. However, one radiographer of the team would always be on their ‘rolling’ day off thus on any given day only four radiographers would be present\textsuperscript{16}. Therefore since radiographers always work in pairs when they treat patients’, while one pair of radiographers would undertake the provision of radiotherapy to patients’ the second pair would undertake organisational duties. This would include the inputting of patient treatment data into the Linac computer database, answering telephone calls and fielding any other enquiries made by patients or members of staff. The following day the two pairs of staff on a Linac would swap duties in line with job rotation principles.

In an effort to be more adaptable and increase patient throughput a number of radiographers in the department volunteered to work what was termed ‘compressed hours’. This entailed the radiographers, all of whom were assigned to Linac D, working four long days (07.30-18.00hrs) and taking the fifth day off. R1 observing that at the time of the incident:

‘Staff were working a variety of flexible working patterns which resulted in them being rota’d to the same place for long periods, often in the region of 12-24 months\textsuperscript{17}.

For example, Radiographer 9 (R9) noted with respect to the team she worked in that ‘The four of us always work together\textsuperscript{18}.

However, because of planned building work near Linac D and the noise that this would generate it was decided to switch the compressed hours team from
Linac D to Linac B and vice versa. But because not all the patients being treated on Linac B could be treated on Linac D a straight swap of patients between the two machines could not be undertaken. Consequently, a number of the patients being treated on each Linac did not move with the radiographers who had been treating them and this resulted in a significant amount of additional administration having to be undertaken.

The move between the two machines occurred shortly after patient A commenced her treatment on Linac B. However, while there is no evidence that the movement of staff and patient’s between Linac’s had any direct bearing on the adverse incident it should be noted that a number of radiographers reported that it was a very stressful time.

**Pressure of work**

While some members of staff had been working together for some time because of the number of vacancies in the department (15 out of a full complement of 75), a high level of absence due to illness (13%), plus long term sick and holidays, radiographers were changing teams quite often to substitute for missing colleagues. Hence, R1 recalled that the department:

‘...had problems with long-term sick and staff absences there was a fair amount of people being substituted in at the last minute, which was to fill in rota places.’

Radiographer 11 (R11) when reporting on staff pressures at that time noted that:

‘We were under a huge amount of pressure and I think the fact that 14 radiographers were involved in the delivery of this one person’s treatment speaks volumes. There was no continuity of staff at that particular time, we were stretched to capacity.’

Indeed, as observed in Chapter One the waiting times for patients requiring radiotherapy treatment in the UK are not getting any shorter and the cancer centre was no exception. R1 making the point that:

‘The department was very busy due to increasing referrals and over booking of work to maintain a low level of patient waiting for treatment. There was a lot of pressure to maintain maximum capacity and keep the waiting list at a minimum in the face of this increase in referrals (of about 10%)’

Therefore in an effort to ensure that the number of patients’ waiting for treatment was kept to the minimum R1 recalled that:

‘...we ran all the Linac’s at that time so if we had a breakdown or a service [stoppage] we would have to transfer patients... and that meant longer working days for some machines. We
would also have to send patients home if the Linac’s broke down. In a similar vein R9 observed that the pressure of work also increased when:

‘…a patient’s treatment [was] delayed because of severe side-effects and things like that, which are things that always happen or patients are admitted because they are too poorly, they miss treatment which then has to be added on at the end of their treatment to not compromise their own treatment, which is fair enough, and then you have no spare space to put them in so you end up putting people in the dump [unallocated appointment spaces at the end of a working day] because of things like that...If necessary we work until we have finished all the patients so we don’t go home until then.’

Additionally R1 also observed that in an effort to maximise the departments throughput of patients there:

‘…was a system where you booked as many [patients] as you could knowing that some of them would not turn up so we overbooked the system. Some days it was awful and some days it was not quite so bad.’

With regard to the pressure felt by staff to ensure patients received the best possible care and were treated on time R6 echoed a sentiment expressed in one form or another by all those who took part in the review:

‘I think it is always at the back or forefront of everybody’s mind that we are here obviously to treat these patients as best we can, to manage the waiting list and get, without sounding too crude, getting them through as quickly as possible…I think we are in a position where there are only so many hours in a day, there are only so many slots [appointments] in a day and we will do our best while we are there but that is as much as we can physically do.’

Radiographer 12 (R12) echoed the above theme when she said ‘There is always pressure to get patients through. None of us want patients waiting any longer than is absolutely necessary.’ While R7 made the point with regard to the departments workload ‘You just try and work as efficiently as you can.’

It was made very clear by every witness interviewed by the Review Panel that regardless of the number of patients waiting to be treated they were of the opinion that their working practices would not be affected. R11 exemplifying that notion when she said ‘Yes, there is pressure. [But] I don’t let that affect my working practice.’

However, it should be noted that at the time of writing there are no professional or regulatory guidelines for calculating the number of
radiographer required in a radiotherapy department having regard to their workload and case mix\textsuperscript{31}.

**Protocols**

Written treatment protocols are extensively used in radiotherapy and a copy of the document containing those to be used in the Radiotherapy Department at the cancer centre are to be found on every Linac. Furthermore every radiographer in the department must sign to say they have read and understood the protocols. However, because of the extensive training undertaken by radiographers they are not expected to read the protocols each time they treat a patient\textsuperscript{32}. Any changes to the protocols are issued to the radiographers as technical memos and then incorporated in the protocol manual at a later date. A check is made by one of the superintendent radiographers each year to ensure that all radiographers are up to date with the current protocols\textsuperscript{33}.

The written protocols however do not make it clear that each radiographer who inputs a patients treatment data on to the Linac computer database (known as prepping) or treating patients’ should ‘log in’ to the system and when finished ‘log out’, so that a chain of accountability for the activities concerning each patient is electronically recorded. As a consequence, although different radiographers may input patient data or energise the treatment beam on any given day, if the first person carrying out either of those activities does not log out, then that person may be the only individual recorded as responsible for inputting patient data or treating them on that day. For example, R3 noted with regard to the checks undertaken by radiographers just prior to treating a patient on a Linac that:

‘...you have two people working together and at present only the [one] person logged in, when you go back to your data logs that is the only person's name you would see, so although two people potentially, one has pressed the button [energised the radiotherapy beam] but two of you have checked and switched on, you could only go back and find the one that is logged in\textsuperscript{34}.

Although custom and practice appears to dictate that the initials of the person in the first box in the section entitled ‘Monitor units per fraction/time per fractions’ and categorised as ‘TRT BY’ (treated by) on the patient’s Treatment Card (plate 10) will be the person who energised the beam. The initials in the box adjacent are deemed to be those of the person responsible for checking the console screen. However, the protocol regarding those checks, as can be observed below, does not appear to make any such formal distinction between the radiographers treating a patient nor set out their individual accountability:

‘A further verbal check to ensure that the correct patient, field number, energy, and monitor units (wedged and un-wedged) MUST be undertaken by two radiographers (one of
whom is energising the beam and one of whom is a senior), who have participated in and verified that the patient set up is correct (as above). Therefore, it should perhaps be no surprise, that when the radiographers involved in this serious adverse incident were asked who they believed was responsible for the final checks they were all of the opinion that it was both radiographers. Moreover, when the final verbal check was being read out by the person energising the treatment beam, it was firmly believed by all the radiographers interviewed, that both the radiographers carrying out a patient’s treatment would visually check the console screen for accuracy against the Treatment Card, which is the primary data source.

Similarly, the checks to verify the accuracy of a patient’s treatment data on the Linac computer database are not explicitly described in the protocols. Nor is the accountability of a radiographer responsible for such checks articulated. As R1 observed:

‘At the time [of the serious adverse incident] our protocols were not terribly terribly clear about what that first inputting and the checking was about, it was all about checking without any clear responsibilities in there and we are re-looking at those to make them more IR(ME)R compliant and make responsibility much clearer.’

**Interruptions while working**

As described earlier, radiographers typically work in teams of two pairs. One pair treating patients while the other pair attends to the requisite paperwork and deal with enquiries. However, it would appear that the level of interruptions to those undertaking the administrative tasks can be extremely intrusive, for example, R6 remarked that:

‘There are constant disruptions and the way our system of work works is that the people who are physically in the room take responsibility for the patient and their treatment and the other two have to get on with whatever.’

In a similar vein R4 also observed that:

‘The phone ringing, people coming round and asking you things, helpers. Sometimes patients will come round as well with their appointment letters if there is nobody sat on the desk, physios, dieticians, everybody.’

Indeed, all the radiographers interviewed attested to the considerable number of disruptions experienced by teams on the Linac’s. Consequently, the two radiographers undertaking the administrative work on a Linac would often be required to stop work and attend to the cause of an interruption.
Observations

The evidence suggests that organisational culture of the Radiotherapy Department at the cancer centre at the time of the serious adverse incident was permeated by an implicit trust in all their colleagues’ profession competence and a belief that the checking procedures in use were robust. Although, it had been recognised by management that the interruptions experienced by the radiographers working on the Linac’s caused problems with the pre-treatment checking process. However, there were no random observations made when the Linac’s were operational to ensure that the checks were working as intended or to identify opportunities for improving them.

The very low numbers of errors recorded in the Radiotherapy Department appear to be comparable to those noted elsewhere in the world and thus there was no indications that the typical operational environment in which the radiographers worked was anything other than safe for their patients. This perception was however misleading.

Because of the building work that was to be undertaken the D Linac radiographers and most of their patients were moved to Linac B. This resulted in a great deal of work for the team as patients had to be informed and in some case their appointments had to be rearranged. Thus, the team experienced a great deal of additional stress during this period. Moreover, all the radiographers in the department were already under a great deal of stress due to shortages of staff, increased referrals, machine breakdowns and the vagaries associated with patients undergoing radiotherapy.

The pressure of work in the Radiotherapy Department appears to have been significant and unremitting which in part was due to the practice of overbooking patients. However, the radiographers appeared to be convinced that even with such work pressures placed upon them it would not affect their operational performance. This is briefly discussed again in Chapter Four. There are however no regulatory guidelines at the present time for calculating the number of radiographers required for a particular workload and case mix and thus it is should perhaps not be surprising that such situations can occur.

The chain of accountability as to which radiographer was responsible for what actions during a patients’ treatment is often broken with the present arrangements. This is because the protocols dealing with such events do not explicitly make any formal distinction between radiographers treating a patient nor do they set out their individual accountability. Similarly, the ‘log in, log out’ procedure is not universally followed by each radiographer nor does the protocol concerned with ‘prepping’ a patients Treatment Card state that they must do so. Thus the radiographers appear to believe that the accountability for treating the patient is shared rather than each radiographer being accountable solely for their own actions.

The radiographers carrying out the administrative work on the Linac’s, in particular, were subjected to a large number of interruptions and distractions
while working.
References


2 R1 transcript, page 17, line 1.

3 R2 transcript, page 27, line 17.

4 R3 transcript, page 75, line 16.

5 R4 transcript, page 103, line 25.

6 R5 transcript, page 124, line 23.

7 C1 transcript, page p155, line 33.

8 R1 transcript, page 18, line 28.

9 R1 transcript, page 21, line 2.

10 R1 transcript, page 17, line 50.

11 Levett and March quote safety culture.


15 R6 transcript, page 40, line 18.

16 R8 personal communication, email 20/01/05 and 22/04/05.

17 R1 personal communication, email 04/10/04.

18 R9 transcript, page 3, line 36.

19 R10 transcript, page 101, line 36.

20 R1 personal communication, email 04/10/04.

21 R1 transcript, page 4, line 32.

22 R11 transcript, page 66, line 8.
23 R1 personal communication, email 04/10/04.

24 R1 transcript, page 9, line 3.

25 R9 transcript, page 9, line 51 – page 10, line 8.

26 R1 transcript, page 7, line 37.

27 R6 transcript, page 40, line 33.

28 R12 transcript, page 39, line 5.

29 R7 transcript, page 56, line 50.


31 College and Society of Radiographers

32 R1 transcript, page 11, line 7.

33 R8 personal communication 21/01/05.

34 R3 transcript, page 67, line 4.

35 Radiotherapy Technique Protocols, RT3.Tec 3, Treatment Card Checks, Section 2.7’, issued 09/10/03.

36 For example, R2 transcript, page 26, line 28.

37 Radiotherapy Technique Protocols, RT3.Tec 3, Section 2, Prescription Calculations and Checks’, issued 09/10/03.

38 R1 transcript, page 13, line18.


40 R4 transcript, page 102, line 14.
Chapter 3

Chronology of events leading to the serious adverse incident

Although the actual radiotherapy treatment regime that led to the serious adverse incident occurring commenced on the \textit{...REDACTED...}, similar errors regarding the inputting and the checking of patient A’s treatment data on the B Linac Database occurred prior to that date. Thus, for the sake of completeness, regarding the activities surrounding the provision of patient A’s radiotherapy treatment, these earlier errors will also be discussed in this chapter.

\textit{...REDACTED...}

Broadly following the pattern described in Chapter One, R3 input patient A’s first Treatment Plan data on to the Linac B computer database. She did this however ‘…sat in a room just adjacent to where the SLB [Linac B] machine is’\textsuperscript{1}. But, as noted in Chapter Two, typically the inputting of a patient’s treatment data on to a Linac’s database is done at the machine. R3 explained that:

\begin{quote}
One of the reasons I took it [primary data] into the room was purposely to take myself off the machine because it was manic, it was very chaotic, so the whole reason I did it in the little room opposite was to try and prevent myself becoming bogged down into all the comings and goings on the machine but I can’t remember whether I got dragged into anything or whether I broke away to do anything else during this card…’\textsuperscript{2}.
\end{quote}

R3 inputted patient A’s treatment data on to Linac B’s computer database from the primary documentation. The plan had been correctly computed using the Theraplan Plus Version 3.8 and the data was correctly transferred to patient A’s Treatment Card. However, R3 did not realise that the wedge prescribed for patient A had not been recorded in the database. When asked by the Review Panel if she could explain why the error had occurred R3 replied, ‘I can’t tell you why. When I looked at the screen I did not notice’\textsuperscript{3}.

With respect to inputting of a patient’s treatment data on to a Linac’s computer database R3 remarked:

\begin{quote}
I would not go back and check. I would use these [source documents] to input but I would not go back and check\textsuperscript{4}. R3 also observed that ‘There is nothing [no protocol] to say you should go back [and check the inputted data using the computer console display]’\textsuperscript{5}.
\end{quote}

It should also be noted, that as explained in Chapter One, where a wedge is prescribed for a patient a diagrammatic representation should be shown on the Theraplan diagram. However, because of a scaling problem, although a the wedge had been prescribed for patient A it was not displayed diagrammatically on the paper treatment plan used daily for machine set up.
Thus, there was no representational reminder that a wedge was required for the correct delivery of the right lateral field.

Subsequently R4 carried out the first of the checks required on patient A’s treatment data but did not notice that the wedge that had been prescribed had not been recorded on the database. R4 could not remember any specifics regarding her check of patient A’s treatment data and when asked why the error might have occurred replied she had ‘No idea how I have missed it at all because I have missed it obviously’.

Patient A arrived at the department to commence her radiotherapy but the treatment position described in the Set-up Sheet could not be replicated by the radiographers on duty. This however is not an uncommon event and occurs for a variety of reasons, it did however require patient A to have her treatment parameters completely re-planned. As a result patient A could not be treated and the treatment data that had been input to the Linac B computer database by R3 relating to patient A was deleted.

The new Theraplan for patient A:

‘...did not come up until lunchtime and the patient came at 3 o’clock so it was worked out in the space of about an hour, which can have a bearing on why something went wrong’.

Having received the new Theraplan, which again did not have a diagrammatic representation of a wedge due to scaling problems, R4 created a new computer record on the Linac B computer database for patient A and inputted the new treatment parameters. The plan had been correctly computed using the Theraplan Plus Version 3.8 and the data was correctly transferred to patient A’s Treatment Card. However, R4 did not notice that the wedge prescribed for patient A had not been recorded on the database. Nor did she notice that some of the field data entries inputted were incorrect.

With respect to the radiographer tasked with the first inputting of a patients treatment data on to a Linac’s computer database similar to R3, R4 remarked:

‘When you do firsts on cards you tend to input the data and then that is classed as your check so you don’t actually physically check it again...[using the data display on the computer console].’

Once R4 had inputted patient A’s treatment data R5 carried out the first check of the inputted treatment data but did not notice that the wedge prescribed for patient A had not been recorded on the database and that some of the field data entries were incorrect. R5 was at a loss to explain why the errors had been missed during the checks that had been undertaken.
Patient A arrived on Linac B at approximately 3pm and radiographers R2 and R9 had begun the set up procedure when they discovered that the field size light projected on to patient A from the B Linac appeared to be incorrect. R9 immediately left the treatment room and informed R4 of the problem who then edited the field size in the Linac B computer database. R4 did not however undertake a check of all the treatment parameters for patient A, as there is no protocol that mandates such a check should be carried out\(^1\). As required prior to R4 entering the recalculated field sizes R5 carried out a second check on the edited field sizes. However, similarly to R4, R5 did not carry out a check on all patient A’s treatment parameters as there is no protocol requiring such an action.

Once the field size setting had been corrected and checked R9 returned to the treatment room were she and R2 completed setting patient A into the correct position for her radiotherapy treatment. Once they were both satisfied that patient A’s set up was correct they left the treatment room and went to the console area. It had been agreed that R2 would read the final checklist parameters and switch on the treatment beam. R9 would act as checker. However, as noted earlier, it was custom and practice that while the person energising the beam would read aloud the final checks both radiographers would check that the values shown on the monitor were in accordance with the verbal check. Thus, having carried out the final checks and convinced that all the checks were satisfactory R2 then switched on the treatment beam for the right lateral field.

As to why R9 did not perceive that a wedge should have been in the treatment beam she replied that ‘…as far as I was aware I checked it and it was right and I had seen it right\(^2\). R9 was baffled as to why the error could have occurred observing that radiographers ‘check the same stuff on every patient so why?’\(^3\). In response to a similar question R2 noted that:

> ‘As far as I was aware at that point [just prior to switching the treatment beam on] obviously everything was fine so I sort of went ahead and switched on the machine and unfortunately it was not right\(^4\).

R2 also observed that:

> ‘...sometimes because you are working under pressure you are obviously working at speed and the only thing is you check things and it is a very quick check some times…I suppose it is having a bit of trust in what previous people have done and you are sort of like just look. It is quick glances, you are probably concentrating more on other areas and you just miss other things\(^5\).

With regard to working pressure R9 stated:

> ‘Radiographers …put a lot of pressure on themselves and they feel it but at the end of the day we know what we have to do in
terms of our checks in order to give a correct treatment. Yes, there is always pressure but there at the same time you can’t compromise\textsuperscript{16}.

\textbf{....REDACTED....}

Patient A arrived at Linac B at approximately 2pm and R11 and R4 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R11 energised the treatment beam and R4 was the checker. With regard to the final checks just prior to energising the treatment beam R11 noted that:

‘I would have expected the person behind me also to be checking the monitor. I would say it verbally. She would listen to what I am saying and check it against both the card and the screen…If I am switching on I tend to look at the card first and then the screen\textsuperscript{17}.

Similarly, R4 stated that during the final checks that:

‘It is usually the person who is switching on that would verbalise it [the checks] but yes, you should both be looking at the information and checking the screen as well\textsuperscript{18}.

When R11 was asked if she could offer an explanation as to why the error had been made she replied:

‘All I can think is we just saw where it says “wedged out” and read “wedged in”. I don’t know. We have all tortured ourselves\textsuperscript{19}.

While R4 in response to the same question said ‘I have no idea. I really wish I did know but I have absolutely no idea\textsuperscript{20}.

Regarding the pressures of work R11 observed that, ‘…there is pressure. I don’t let that affect my working practice that is somebody else’s problem\textsuperscript{21}.

While R4 observed with respect to pressures of work and distractions that:

‘It is trying to get rid of those outside pressures and outside factors that distract you. It is not an excuse…it is difficult always to concentrate as well as you might have been doing if there was silence around you\textsuperscript{22}.

Prior to the administration of patient A’s treatment R9 carried out a third and much wider check on the source documentation but did not perceive that the wedge prescribed for the right lateral field had not been recorded in Linac B’s computer database. R9 was bewildered as to why the error had not been observed during the checking procedure\textsuperscript{23}.
Patient A arrived at Linac B at approximately 1.15pm and R4 and R13 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R4 energised the treatment beam and R13 was the checker. R4 repeated that she could not remember the individual treatments she was involved with patient A and did not understand how the error was made.

At the time of the serious adverse incident R13 was a junior member of staff. As R13 at the time of the Review had left the cancer centre and commenced work elsewhere the Review Panel decided not to call upon R13 to give evidence unless it was absolutely necessary. This proved to be the case.

Patient A arrived at Linac B at approximately 2.40pm and R14 and R12 undertook the administration of her radiotherapy treatment. Patient A’s Treatment Card shows that R14 energised the treatment beam and R12 was the checker.

Neither R14 nor R12 could remember the individual treatments they were involved with patient A nor explain why the error had occurred.

Patient A arrived at Linac B at approximately 12.50pm and R15 and R13 undertook the administration of her radiotherapy treatment. Patient A’s Treatment Card shows that R15 energised the treatment beam and R13 was the checker.

R15 could not remember the individual treatment of patient A nor explain why the error had occurred.

As noted above the Review Panel decided it was not necessary to interview R13.

Patient A arrived at Linac B at approximately 1pm and R13 and R16 undertook the administration of her radiotherapy treatment. Patient A’s Treatment Card shows that R13 energised the treatment beam and R16 was the checker.

As noted above the Review Panel decided it was not necessary to interview R13.

R16 stated that it was not her initials in the checkers box on the Treatment Card for the treatment that took place on this date but those of R15. However since the Review Panel had already extensively interviewed R15 it was decided not to recall the witness for further discussion.
Patient A arrived at Linac B at approximately 10.50am and R14 and an unknown radiographer (the checkers box on the patient Treatment Card had not been initialled) undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R14 energised the treatment beam and the unknown radiographer was the checker. R14 stated that she could not remember with whom she was working with at that time.

R14 could not remember the individual treatments she was involved with patient A nor explain why the error had occurred.

Patient A arrived at Linac A at approximately 1.10pm and R10 and R16 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R10 energised the treatment beam and R16 was the checker.

R10 noted that she and R16 normally worked on different Linac’s but on this occasion they had decided to merge their patients because both machines were running late and they wanted to keep waiting times to a minimum. As they had three radiographers on each Linac this arrangement allowed two radiographers from each Linac to go for lunch and the two who were left to carry on working until the others returned from their lunch break.

Neither R10 nor R16 could remember any specific details with regard to the treatment that they had provided to patient A nor explain why the error had occurred.

Patient A arrived at Linac B at approximately 3.35pm and R16 and R12 undertook the administration of her radiotherapy treatment. Patient A’s Treatment Card shows that R16 energised the treatment beam and R12 was the checker.

Neither R16 nor R12 could remember any specific details with regard to the treatment they had provided to patient A nor explain why the error had occurred.

Patient A arrived at Linac B at approximately 12.50pm and R15 and R13 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R15 energised the treatment beam and R13 was the checker.

R15 could not remember the individual treatment of patient A nor explain why
the error had occurred.
As noted above the Review Panel decided it was not necessary to interview R13.

.....REDACTED.....

Patient A arrived at Linac B at approximately 2.15pm and R15 and R13 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R15 energised the treatment beam and R13 was the checker.

R15 could not remember the individual treatment of patient A nor explain why the error had occurred.

As noted above the Review Panel decided it was not necessary to interview R13.

.....REDACTED.....

Patient A arrived at Linac B at approximately 2.15pm and R12 and R13 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R12 energised the treatment beam and R13 was the checker.

R12 could not remember the individual treatment of patient A nor explain why the error had occurred.

As noted above the Review Panel decided it was not necessary to interview R13.

.....REDACTED.....

Patient A arrived at Linac B at approximately 1pm and R16 and R13 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R16 energised the treatment beam and R13 was the checker.

R16 could not remember the individual treatment of patient A nor explain why the error had occurred.

As noted above the Review Panel decided it was not necessary to interview R13.

.....REDACTED.....

Patient A arrived at Linac C at approximately 4.20pm and R15 and R17 undertook the provision of her radiotherapy treatment. Patient A’s Treatment Card shows that R15 energised the treatment beam and R17 was the checker.
R15 nor R17 could not remember the individual treatment of patient A nor explain why the error had occurred.

REDACTED

R6 reported to the Review Panel that she and R 7 was originally scheduled to work on Linac D machine on this occasion however when they arrived for work the technicians were working on a fault and so Linac D could not be used for clinical work. In order to alleviate the waiting list for Linac D R6 and R7 requested that the maintenance check being carried out on Linac A be stopped and the machine returned to clinical use. This was done.

R6 noted that:

‘Basically, [R7] and I took it upon ourselves to sort everything that needed doing and I went and collected a selection of treatment cards from SLB [Linac B] which is the neighbour linear accelerator because it was easier then for getting patients out of the waiting room and things, selected however many patients. We then went to get this particular patient [patient A]’.

It is important to remember at this juncture that there were no patients scheduled to be treated on Linac A on this day and therefore as R6 noted in Chapter Two that ‘...on the day that [R7] and I treated her [patient A] there was only the two of us and we were pretty much in a nice quite space at that time’. Hence the interruptions, distractions, pressure of work and the attendant stresses that were typically present when treating patients on a Linac were absent.

Patient A arrived at Linac A R7 reported that she and R6:

‘...set her [patient A] up in the treatment room as usual, came outside, decided who was going to switch the machine on, decided I would and we did the normal checks on the treatment card’.

However, the treatment was not administered because upon carrying out the final checks it was found that the wedge prescribed for patient A had not been programmed into the Linac database. Both R6 and R7 were of the opinion that they found the error at the same time, i.e. because they were both checking patient A’s prescribed settings on the Treatment Card against those on Linac A’s monitor during the final checks.

Once the error had been identified R6 and R7 notified a superintendent radiographer who then rechecked their findings. Upon confirmation by the superintendent that the wedge prescribed for patient A had been missed from the list of treatment parameters recorded on the Linac computer database R7 stated that patient A was taken ‘...off the bed without treating her and she
went downstairs to see one of the consultants [C2] 

Where C2 explained the situation to her.

R6 and R7 also stated that the patient did not report or appear to present any adverse symptoms as a result of her radiotherapy treatment she had received. Indeed, it was also noted that patient A had been examined just prior to her arrival on Linac A by R18 a Specialist Radiographer trained to recognise the adverse affects of radiotherapy on a patients skin.

As noted earlier because the prescribed wedge was not in place patient A received approximately 2.5 times the prescribed radiotherapy dose of 40 Gray and is currently receiving remedial medical treatment for the overdose of radiotherapy she received.

Electronic data network transfer facilities

As noted in Chapter One, although the Theraplan system does not have the ability to transfer a patient’s treatment data electronically to the Linac’s computer database, the other treatment planning system (Helax) used at the cancer centre does. Indeed, an analysis of the Linac’s logbooks for the relevant period has revealed that the data for 72% of the radiotherapy treatments undertaken on Linac B and 73% on Linac D were transferred to the Linac’s computer database electronically.

Media coverage

During the interview with C2 and subsequently Patient A made it very clear that she did not want any publicity over the serious adverse incident as it would compromise her privacy. However, whilst every attempt was made by all those members of staff aware of patient A’s situation within the cancer centre to keep the information secure the media published outline details of the serious adverse incident on…..REDACTED….. Patient A was not named in the article however and her anonymity appears to have been preserved at the present time.

Observations

All the radiographers involved in this serious adverse incident acknowledge that the wedge prescribed for patient A was not recorded on the Linac database. However, they are all equally convinced that they carried out all the checks required by the protocols to their normal high standards and cannot understand why the error was not identified earlier than the fifteenth fraction. Evidence will be discussed in Chapter Four that appears to reveal a previously unidentified phenomenon in the creation of inadvertent accidents where checklist procedures are used. This apparently unrecognised mechanism has been named by the author as ‘Involuntary Automaticity’ and seems to account for both the errors that were made and the fact that those involved cannot understand why.
On both occasions that patient A’s treatment data was input to the Linac computer database no check was carried out by the radiographer concerned that they had input the data correctly. This was because there is no protocol that directs that such a check should be undertaken.

Similarly, following the changes to radiotherapy field sizes on the .....REDACTED..... neither the radiographer who made the change nor the radiographer who checked those field changes carried out a check of all patient A’s treatment parameters. The reason such a check was not undertaken was because there is no protocol that directs that such a check should be undertaken.

Due to a scaling problem the paper Theraplan used on a day-to-day basis for setting up patient A did not have a diagrammatic representation of the wedge that had been prescribed for patient A. Hence there was no additional visual reminder that a wedge was required for her treatment.

As reported in Chapter Two the radiographers were at the time of the serious adverse incident under pressures of work, distractions and interruption however they appear to believe that this did not or would not have affected their operational performance. There was however evidence to suggest that their confidence may not be well placed and this will be discussed briefly in Chapter Four.

The initials of one radiographer were confused with those of another on patient A’s Treatment Card.

The radiographer who acted as the checker for patient A’s treatment on .....REDACTED..... forgot to initial the Treatment Card to that effect.

When the wedge error was identified the radiographers concerned were not under any pressure to complete the task and there were no disruptions or interruptions.

Radiographers are of the opinion that they should both carry out the final visual checks prior to the treatment beam being energised. This is consistent with their belief, as noted in Chapter Two, that the accountability for treating a patient is shared rather than each radiographer being accountable solely for their own actions.

The treatment data for the majority of patients treated on Linac B and D was electronically transferred to the Linac computer database. Thus, very low treatment data error rates had been experienced by the all radiographers involved with patient A’s treatment. This could have created an unconscious expectation that the treatment data would be correct and this will be discussed in Chapter Four.

Although patient A expressed a wish that there should be no media coverage of her serious adverse incident it was eventually reported in the media. However the patient’s identity was not disclosed. It should be recognised
however that there are a plethora of ways in which the media could have found out about this incident. Therefore without incontrovertible proof to the contrary it should not be assumed that the information emanated from the cancer centre.
References

1 R3 transcript, page 67, line 44.
2 R3 transcript, page 71, line 31.
3 R3 transcript, page 71, line 19.
4 R3 transcript, page 77, line 37.
5 R3 transcript, page 84, line 20.
6 R4 transcript, page 89, line 23.
7 R4 transcript, page 90, line 18.
8 R4 transcript, page 95, line 40.
9 R4 transcript, page 93, line 37.
10 R5 transcript, page 114, line 39.
11 Radiotherapy Technique Protocols, RT3.Tec 3, Treatment Card Checks, Section 2.7’ 09/10/03 and 8.7, issued 01/10/04.
12 R9 transcript, page 6, line 6.
13 R9 transcript, page 6, line 19.
14 R2 transcript, page p.25, line 33.
15 R2 transcript, page 27, line 7.
16 R9 transcript, page 9, line 22.
17 R11 transcript, page 64, line 49.
18 R4 transcript, page 105, line 26.
19 R11 transcript, page 65, line 30.
20 R4 transcript, page 97, line 48.
22 R4 transcript, page 108, lines 24-34.
23 R9 transcript, page 6, line 6.
24 R16 transcript, page 133, line 12.
25 R14 transcript, page 72, line 43.
26 R10 transcript, page 99, line 5.
27 R6 transcript, page 28, line 55.
28 R6 transcript, page 40, line 18.
29 R7 transcript, page 49, line 5.
30 R6 transcript, page 29, line 15.
31 R7 transcript, page 49, line 16
32 R7 transcript, page 49, line 27.
33 R6 transcript, pages 34, line 1.
34 R18 transcript, page 112, line 51.
35 C1 transcript, page 149, line 4.
36 R8 personal communication, 11/04/05.
37 R18 transcript, page 149, line 37.
Chapter 4

Verbal double-checking protocols

Employing a verbal double-checking protocol is not unique to radiotherapy, for the procedure is widely used within the National Health Service and in other industries like aviation. The protocol is often referred to in the NHS as ‘witnessing’ and is undertaken in the expectation that if one person misses an error the other will detect it.

Ambiguous accountability

The British Committee for Standards in Haematology, Blood Transfusion Task Force, however argue that rather than reducing the possibility of errors by using two members of staff to carry out a check it may actually increase the risk of errors being made as, ‘Two members of staff may rely upon the other to be rigorous, resulting in neither giving the task their full attention’.

Similarly, Linden and Kaplan observe that:

‘Unless carefully configured to prevent it, in a system in which two people are responsible for the same task, neither person is truly responsible. Paradoxically, such safety procedures may provide less, rather than more assurance’.

Moreover, in a study undertaken by Krause et al it was reported that only a small benefit was found by requiring a second nurse to verify the medications that were being dispensed. The study, conducted over 46 weeks and 129,234 administered medications observed error rates for the administration of 1,000 medications by two nurses was 2.12, but for one nurse 2.98. However, while there is a statistically significant improvement using two nurses the error rate is still greater than 2 per 1,000 doses.

Furthermore, data contained in the Annual Report of the Serious Hazards of Transfusion 2001-2002 (SHOT) was analysed for the number of incidents of incorrect blood components that had been transfused where at least two members of staff had been involved in the verbal checking procedures. Of the 307 incidents reported to SHOT during the period 1996-2001, 238, i.e. 77% of the adverse events involved at least 2 members of staff carrying out identification checks.

The studies reported above demonstrate that failures of the verbal witnessing safety protocol occur in different healthcare settings. This raises the question of whether such failures are due to random chance events or if they could be due to inherent socio-psychological mechanisms that predispose people to make such errors. The latter of these two options is discussed below in relation to patient A’s serious adverse incident.
Conscious automaticity

The term ‘automaticity’ is a concept used in cognitive psychology and is generally described, as being the ‘...property of a process that takes place largely independent of conscious control and attention’\textsuperscript{5}. For example, learning to drive a car is for most people a laborious process. However when a person has practiced sufficiently their previous conscious and often awkward movements become replaced with efficient coordinated actions and the individual no longer needs to pay such close attention to the act of driving. At this point the drivers behaviour has become ‘automatized’. The driver is however consciously aware that they are engaged in such an activity.

Involuntary automaticity

Usually automaticity is discussed in terms of the benefits that it bestows on those who can reach such a level of skilful behaviour. Indeed, automaticity is usually associated with skilled performance and not with that of the novice. However several researchers have also observed there is a price to be paid for human beings having the aptitude to improve their performance in such a way\textsuperscript{6,7}. Barshi argues that:

‘Automaticity has, however, a cost that manifests itself in procedures that are highly routinized but require close attention, such as verbal checklists procedures. In such procedures, errors occur because the routine leads to automaticity’\textsuperscript{8}.

For example, Barshi notes that typically pilots when carrying out checks on their aircraft employ a challenge-response process. This is where the pilot not flying the aircraft (PFN) will read the items to be checked by the pilot flying the aircraft (PF) off a printed list. Having carried out the check required, the PF then verbally responds to the PNF with his or her findings. This could be as simple as repeating the name of the item that was to be checked and saying the word ‘checked’ or reading out aloud the actual information provided by a cockpit instrument. However, using such an identical checking procedure constantly it is argued can inadvertently lead to the process becoming more of a ritual where eventually ‘...the literal meaning of the message may be ignored’\textsuperscript{9}. Therefore, since such dysfunctional behaviour is not intended the automaticity routine that has been invoked, it can be argued, is both unconscious and involuntary.

The evidence reviewed suggest that such a situation is more likely to develop:

‘In cases in which the crew members know each other well and trust each other’s professionalism, or under time pressures and distractions, the PNF is especially un-likely to check the PF’s proper execution of the checked item, relying on the verbal response only...This reliance on the verbal exchange can easily lead to hazardous situations’\textsuperscript{10}. 

42
The dangers associated with automaticity are graphically illustrated by the example provided by Barshi. A Boeing 737 aircraft was coming in to land at Casper, Wyoming on 23 March 1983 and the aircrew were going through their routine pre-landing checklist. The Captain who was not flying the aircraft called out to the Co-pilot that he should lower the landing wheels. Shortly afterwards the Co-pilot verbally responded to the Captain that the landing wheels were now down. Thus, the subsequent wheels-up landing came as a considerable shock to all concerned.

With regard to the dangers of automaticity Green et al suggests that:

‘It is tempting for the pilot to regard a rapid dismissal of checklist items as indicative of his skill and familiarity with the aircraft, but, if checklists are dealt with in this automatic way, it is very easy for the pilot to see what he expects to see rather than what is there’\(^{11}\).

In the same way, the United States Federal Aviation Administration (FAA) also warns that the use of verbal safety checklist may on occasions cause crewmembers … to see what they expect to see rather than what is actually accomplished or indicated\(^{12}\).

Similarly, the International Atomic Energy Agency (IAEA) also note that radiotherapy accidents may occur on occasions because:

‘Wrong assumptions are made, leading to accidental exposures. This may be because the staff member makes the interpretation that matches his or her experience, expectation or convenience. Expectations are usually based on experience gained during normal operation of equipment or routine procedures’\(^{13}\).

While Olcott reinforces the view that it is imperative that aircrews do not unconsciously ritualise their aircraft checks when he notes that one of the conclusions made by the investigators of a fatal air crash was that, ‘The air carrier crew at LGA (New York La Guardia Airport) went through the motions of reading a checklist but responded without being effective’\(^{14}\).

Likewise in a study of radiotherapy accidents undertaken by French it was observed that:

‘…in a small number of situations, the system failed completely, the major errors went undetected despite independent verification checks at several points…[This may have occurred because] radiation therapists mechanically followed procedures, whereby verification [of the linear accelerator machine settings was] completed but not performed effectively’\(^{15}\).
It is also interesting to note in the context of the present review that French also reported in his study:

‘Five of the errors were due to using the wrong wedge or missing the wedge completely. Three of these resulted in large dose discrepancies and were directly linked to incorrect data entry.’

While the IAEA has observed that in one adverse incident the oncologist prescription was ‘…misread ten different times [and that] Checks by three members of staff failed to detect the setup mistake’.

Reason and Mycielska suggest that such human errors:

‘...are the price we pay for being able to carry out so many complex activities with only a small investment of conscious attention. They are the inevitable penalty of the necessary process of automatization.’

Thus, the evidence appears to suggest that where the same verbal checklist protocols are repeatedly undertaken the performance of those carrying out such a task can be adversely affected without them realising it.

**False hypothesis**

In his paper on ‘Ergonomic and Air Safety’ Rolf notes that research into the misleading influence that past experience can have with regard to the creation of accidents has been undertaken by Davis. The research carried out by Davis consisted of examining a number of aircraft and railway accidents in relation to a pattern of response that he termed the ‘False Hypothesis’. A human being he argued:

‘…sees the world in relation to his past experience. In consequence, what he perceives is partly determined by what he expects to see and on occasions, by what he would like the world to be. An individual, therefore, has expectations regarding what is likely to happen in a frequently encountered situation.’

Thus, when a person acts in a manner that follows an expected pattern of behaviour, rather than that actually required by the situation, then a false hypothesis situation has arisen. According to Davis people are most likely to be captured by a false hypothesis:

‘(a) When an expected event is very probable.

‘(b) When the operator is anxious.

‘(c) When the operator’s attention is being distracted.'
‘(d) During a period of reaction following a time of high stress.

‘(e) When a set pattern of interpretation and action has been held for a long time’.

It would seem therefore that the circumstances that can provoke individuals into producing a false hypothesis are similar in nature to those that provide an environment where involuntary automaticity may occur. Indeed, as discussed above, where adverse incidents have occurred through individuals being captured by involuntary automaticity those involved also appear to have generated a false hypothesis regarding the situation that they were attempting to manage. Therefore, it can be argued, that where circumstances exist that can promote involuntary automaticity then similarly there is also a potential for a false hypothesis to be generated.

Stress

There has been a great deal of research conducted on stress in healthcare settings which has revealed that all those who work in such environments are often subjected to excessive amounts. It is therefore of interest that Leape argues that:

‘Although it is often difficult to establish causal links between stress and specific accidents, there is little question that errors (both slips and mistakes) are increased under stress’.

In a similar manner Nguyen and Bibbings argue that:

‘It is accepted and proven that errors lead to accidents and that stress can lead to errors. It follows logically, therefore, that stress must also contribute to accident causation’.

Moreover, they suggest that the stress factors that increase the likelihood of an error occurring include, high workloads, distractions, interruptions, insufficient staffing levels, and fatigue. And while some ‘medical staff seem to deny the effect of stress and fatigue on performance’, as noted in Chapters Two and Three of this report, there appears to be a body of evidence to suggest the opposite. Thus, such factors should not be dismissed as they could also play a part in creating the right conditions for the adverse affects of involuntary automaticity to flourish.

Evidence of involuntary automaticity

As noted above, radiographers are highly skilled professionals working with complex technologies and, in some respects, work in an environment similar to that of commercial airline pilots. Thus, the mechanisms that create human errors in one group, it can be argued, are likely to have a similar affect in the other where circumstance are analogous. Indeed, the evidence discussed above, suggests that involuntary automaticity can adversely affect the
performance of both pilots and radiographers when they are performing operations that require the use of checklists.

Furthermore, stress, disruptions, interruptions and fatigue are often found to have played a role in providing the conditions for human error to flourish in both aviation and medicine. Indeed, the Annals of the International Commission on Radiological Protection (AICRP) note that the:

‘Preparation and delivery of treatment by radiotherapy technologists require a continuous and high level of concentration, which may be difficult to maintain when the workload is high. Measures to maintain concentration and awareness require a working environment where distractions are minimised…’.27

Therefore when such adverse physiological factors are present, as they were in this incident, they may also increase the risk that involuntary automaticity will affect verbal checklists and similar protocols.

In addition to the evidence presented regarding the use of verbal checklist within the Radiotherapy Department at the cancer centre evidence has also been presented that describes the turmoil endured by the radiographers involved in this serious adverse incident. The stresses they faced were created through the high workload, significant level of sick absence, continual overtime, a lack of continuity, disruptions and the complex case mix amongst other issues. These factors also appear to have been present when an adverse event at another hospital resulted in an overdose of radiation. And, while the chain of events leading to that accident were different to those at the Trust the working environment in the two radiotherapy departments appears to have been very similar in nature as noted in the interim report discussed below.

Remedial measures

Stringent conscious application of ones mind to the task in hand is one way to reduce the likelihood of unconscious checklist automaticity. However, it is suggested by the FAA that another way that aircrews can attempt to reduce the number of errors made when using verbal safety checklists is by:

‘Announcing the checklist item out loud (the challenge) stimulates the sense of hearing and helps focus attention on the task. The pilot-in-command responds by visually checking each item then actually touching (visual and tactile), operating, or setting the control or device and announcing (the response) the instrument reading or prescribed control position in question. The crewmember calling the challenge monitors and verifies the actions’.28

Additionally, in a study published in 2003 by Turner, Casbard and Murphy into the use of barcode patient identification technology as a means of improving
the safety of blood transfusions, it was found that:

‘The baseline audit revealed poor practice, particularly in patient identification. Significant improvements were found in the procedure for the administration of blood following the introduction of barcode patient identification, including an improvement from 11.8 to 100 percent in the correct verbal identification of patients (p ≤ 0.001)...’²⁹

Improvements were also found in a number of other important factors such as the number of patients correctly identified before blood samples were collected and the number of blood samples labelled correctly.

It has been reported in the aviation industry that one way in which checklist errors have been made is through a pilot calling out several items at once with the result that the other pilot responded in the same way. Such behaviour clearly undermines the whole concept of the challenge – response method. Thus, another way in which checklist errors can be minimised is through the persons reading out the checklist to call out each item separately and wait for the other person to respond to that request before moving on to the next item.

Adverse incidents

The Radiotherapy Department at the cancer centre has an adverse reporting system in place to record and if necessary, action any actual or potential adverse incidents that are identified. At the end of each month all the recorded treatment errors are reviewed and the synopsis produced is circulated by email. A hard copy of the synopsis is also posted on each Linac for the radiographers who do not have an E-mail account to read.

However, it would appear that radiographers do not receive any formal education regarding the identification of adverse incidents or how to deal with them either during their initial formal training or subsequently. The IAEA’s own research into the training of radiographers has shown ‘...that training generally addresses only normal situations and does not prepare radiotherapy staff for unusual situations, resulting in a lack of “safety culture”’. Similarly, ‘The International Commission on Radiological Protection’ (ICPR) notes with regard to the training of radiographers that:

‘In most cases, the training of professionals [Radiographers] had included only the “normal” circumstances likely to occur in radiotherapy, but did not consider the identifications of “unusual” situations. As a result, initiating events [of serious adverse incidents] were not detected and accidental exposure occurred’.

Furthermore, with regard to the availability of guidance should an adverse incident occur R1 stated that:
‘There is not a huge amount of information or literature out there shared informally through the radiotherapy networks… When we discovered the dose we had given to [patient A] we scouted around everywhere to see if there had been anything similar to know what to do, how to treat the patient more than anything else, and it was difficult finding information from anything that was vaguely similar.\(^{33}\)

R1 also noted at the time the serious adverse incident took place that she:

‘…felt quite abandoned actually. I did ring friends and colleagues but there was nobody who said, “Right, this is what you need to do with the staff, this is what you need to do with your systems and processes” which would have been useful.\(^{34}\)

The Review Panel then asked R1 if there had been any explicit guidelines or guidance in place to assist her in dealing with patient A’s serious adverse incident. R1 replied: ‘Well we got the IR(ME)R [Ionising Radiation Medical Exposure Regulations 2000] policy out and that was it, “Get on with it”.\(^{35}\)

With regard to publicly available information on radiotherapy overdoses C1 noted that in terms of managing patient A’s medical condition the plan was based on ‘…a similar but not identical incident that had happened in Poland…\(^{36}\).

Similarly the author of this report also found that there appears to be little in the way of public information on what factors can lead to a serious adverse incident occurring during the therapeutic use of ionising radiation. There also appears to be a dearth of information on how such untoward incidents might be prevented and if such an event should occur what remedial actions might be undertaken to improve the situation. One reason that such a situation exists however may be due to the fact noted by ICRP that:

‘While a number of serious and fatal radiotherapy accidents are reported, it is likely that many more have occurred but were either not recognised or reported to regulatory authorities or published in the literature’.\(^{37}\)

Likewise the study undertaken by French to investigate radiation therapy treatment errors he observed that in the literature search which he conducted that:

‘Most of the errors identified in the…studies and reports were related to medication administration. No data were reported concerning errors from the delivery of radiation therapy, although such errors are known to exist. It is not only certain that radiation therapy errors occur, but also that they have caused the death of patients or the public. However, no comprehensive numbers are available for the number of radiation therapy errors resulting in death\(^{38}\).
The NHS Litigation Authority (NHSLA) was however able to provide some limited data subject to conditions of very strict confidentiality. However, this is not to criticise the NHSLA for they were as were undoubtedly as helpful as circumstances permitted and the Review Panel are very grateful for their assistance in this matter.

The data provided by the NHSLA permitted a comparison to be made between the circumstances surrounding patient A’s serious adverse incident and those of the anonymised NHSLA adverse incidents. The analysis of the data revealed that patient A’s serious adverse incident had an aetiology similar to that revealed in the NHSLA data and which could easily be replicated in other radiotherapy departments if radiographers were not aware of these factors. Consequently, a short interim report (appendix 2) was submitted to the Medical Director of the Trust outlining the potential ramification of the findings. Subsequently, the Trust’s Medical Director informed the Chief Medical Officer for England and the Department of Health issued an ‘Alert’ warning of these findings to all Radiotherapy Departments in England (appendix 3).

In the search for information on radiotherapy treatment accidents the National Patient Safety Agency (NPSA) was also contacted but possessed no data on any adverse incidents that could be of assistance to the Review Panel. This was also the case with the Welsh Risk Pool. Both organisations however did respond to the request for data by the Review Panel. On the other hand Scotland’s ‘Clinical Negligence and Other Risks Scheme’ (CNORIS) was approached with the same request. CNORIS however did not respond despite repeated requests by the Chairman as to whether they were aware of any similar serious adverse incidents.

The Royal College of Radiologists and the Society and College of Radiographers were also contacted to ascertain if they had data on serious adverse incidents caused through patients accidentally receiving a significant overdose of therapeutic ionising radiation. Both institutions replied that they did not collect or hold such data.

A search for literature on adverse events caused by radiotherapy on the Internet produced a very small number of published papers and they are cited in this report where appropriate.

With regard to the serious adverse incident to patient A the Radiotherapy Department at the cancer centre appears to have had in place all of the quality management controls with regard to the safe practice of radiotherapy recommended by the ICRP and IAEA in their literature39. The only significant exceptions to the recommendations made by the ICRP and IAEA would appear to be the lack of a proactive safety assessments of the potential risks surrounding radiotherapy, emergency preparedness plans and the formal training and exercise of radiographers in likely adverse event scenarios.

It should be noted that the ICRP and IAEA literature cited above warns that shortages of staff, increases in patient workloads, disruptions and
interruptions can lead to an increase risk in errors and accidents. They also cite inattention by those involved as being a contributor to a number of the adverse incidents that they reviewed.

Education and training

As observed earlier, all radiographers have to successfully complete an exacting course of formal education and training (currently a BSc. honours degree) before being allowed to take part in the provision of radiotherapy for patients. Nevertheless regardless of their experience, before a radiographer is allowed to treat patients at the cancer centre they must also successfully complete the Radiotherapy Departments Induction Programme.

It should also be noted, as discussed above, that the protocols used by all members of the Radiotherapy Department at the cancer centre when administering radiotherapy to patients are the same and consequently ‘...regardless of the type of machine [Linac] the checks should be the same’[40]. All the radiographers interviewed confirmed this assertion.

However, with regard to training, as noted above, neither trainee radiographers nor those who are in post receive any formal teaching with regard to the kinds of adverse incidents that can occur in radiotherapy or how to deal with them if one should arise. The ICRP and IAEA however both recommend that radiographers should receive formal training with regard to such potential accidents. The IAEA observing that the ‘...dissemination of operational experience can avoid accidents elsewhere’[41].

Observations

Where two people are involved in healthcare verbal double-checking procedures, accountability for the role and activities undertaken by each person needs to be explicitly articulated. Otherwise ambiguity as to what each person is supposed to do may lead to neither of them actually carrying out the required checks.

There is evidence to suggest that while there are many advantages to human beings being able to automatise skilful behaviour there are occasions when this is not the case. The evidence also implies that where identical verbal-checking routines are used on a frequent basis they can be unconsciously ritualised and this can lead to checks being made without them being effective. It should therefore be noted that the final verbal-double checks carried out by all the radiographers involved in the treatment of patient A prior to the treatment beam being energised were identical.

The systems environment that appears to promote what has been termed ‘Involuntary Automaticity’ in this report are similar in nature to those that seem foster to the ‘False Hypothesis’ phenomenon identified by Davis. It is interesting therefore to note that a False Hypothesis appears to have been generated on each occasion that patient A was treated except on the last occasion when the system environment was substantially different from the
other treatments, i.e. there were no time pressures, disruptions or interruptions.

Thus, there is evidence from the fields of ergonomics and cognitive science, which suggests that it is possible for people to believe that they have input or checked data correctly when in fact they have not. Moreover, it can also be argued, that since this dysfunctional behaviour is an unconscious act those affected by Involuntary Automaticity would not be able to consciously recognise that they have behaved in such a way. Therefore it is to be expected that those who are captured by this phenomenon will not be able to explain why they did not detect an error that was present. As noted in Chapter Three all the radiographers involved in this serious adverse incident reported that they could not understand or explain how the error could have been missed.

Furthermore there appears to have been negligible recognition anywhere in the world that there are dangers associated with automaticity. Thus the practical ramifications of the costs of automaticity do not appear to have been widely disseminated and certainly not within the national or international healthcare sector. Consequently, there may be many cases where a serious adverse incident has taken place and members of the healthcare profession have been accused of ‘inattentiveness’ or ‘negligence’ but the conditions which foster involuntary automaticity or the creation of a false hypothesis were present in the system but not recognised for the danger that they posed. Thus raising the prospect of healthcare professionals having been blamed or found guilty of causing a serious adverse event that was not as a result of their negligence but because of the dysfunctional system environment in which they were working.

A body of evidence exists that suggests that stress can adversely affect the performance of healthcare professionals and increase the risk of errors and accidents occurring. Even though many healthcare professionals believe it does not. However, where such stress does exists it may unconsciously add to the likelihood of healthcare professionals being affected by involuntary automaticity or them creating a false hypothesis regarding the safety of the procedure that they are undertaking.

There does however appear to be remedial measures that can be implemented to reduce the likelihood of involuntary automaticity or a false hypothesis being generated. In particular the advice provided by the FAA with regard to pointing and touching the object that is the subject of a check. Or that of only calling one item on the checklist at time and waiting for the response to that request before the next item to be checked is called.

Radiographers’ do not appears to receive any formal education regarding likely serious adverse event scenarios either nationally or locally. The Radiotherapy Department at the cancer centre does however have its own adverse event reporting, recording and dissemination system. But does not have a radiotherapy serious adverse event emergency preparedness plan nor as a result hold exercises to prepare for such an eventuality.
Very little information seems to be collected or publicly shared on radiotherapy adverse events either nationally or internationally. Indeed, keeping such information confidential seems to take a higher priority than finding a way to use it to prevent similar accidents from taking place.

National guidelines also do not appear to exist that could inform and direct Radiotherapy Departments as to what remedial actions should be taken with regard to patient care if a serious adverse event should take place. Nor where authoritative information on such incidents can be found.

The empirical study of radiotherapy accidents undertaken by French, the interim report of this Review Panel and the example provided by the IAEA illustrate that there have been other serious adverse events that have occurred in what appear to be similar circumstance to those at the cancer centre. This suggests that the serious adverse event that occurred to patient A was not a unique incident and that had the circumstance surrounding these other events been widely disseminated it may have been prevented.

A paper discussing the phenomenon of involuntary automaticity has been submitted for publication in a peer-reviewed journal ‘Healthcare Services Management Research’.
References


4 Toft, B (June, 2004) Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, published by the Department of Health, section 7.34.


8 ibid, p.496.

9 ibid, p.496.

10 ibid, p. 497.


12 op cit Chapter 2, reference 44.


14 Barshi, I op cit, p.504.


16 ibid, p. 157.

17 International Atomic Energy Agency, op cit, p.34.


20 ibid, p.183.

21 ibid, p.183.


30 All the radiographers interviewed confirmed that they had received no training in the identification of adverse events or how to deal with them if they should occur.


33 R1 transcript, page 20, line 15 and line 34.
34 R2 transcript, page 20, line 42.
35 R1 transcript page 20, line 51.
36 C1 transcript page 148, line 42.
37 Valentin, J. op cit, page 9.
38 French, J. op cit, page 149.
39 See references 16 and 31 above.
40 R1 transcript, page 5, line 25.
41 IAEA, op cit, p.85.
Chapter 5

Conclusions and recommendations

The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to this serious adverse incident are noted below in plain text, while recommendations are shown in **bold italic**.

The recommendations made below are intended to address the range of issues revealed by the evidence presented to the Review Panel. However, the recommendations that have been made should not be considered to be a definitive set of actions that will guarantee the safety of patients who are administered radiotherapy under all circumstances. Medicine, technology and clinical management practices change and therefore given that no one can prespecify their own ignorance constant vigilance and a robust safety culture will always be required if such accidents are to be prevented in the future.

System Failures

The evidence presented to this Review Panel suggests that patient A’s serious adverse incident was caused by inadvertent human error due to a systems failure.

The specific conclusions and recommendations with regard to this serious adverse incident are detailed below.

Technical

All the treatment data produced by the Theraplan system has to be manually transferred to the computer database that controls the Linac’s because there is no direct electronic data network transfer facility. This provides an opportunity for inadvertent transcription errors to be made by the radiographers who have to input the patient’s treatment data.

**Recommendation 1**

*The current Theraplan system should be replaced as soon as possible with a treatment planning system that has the capability to transfer a patient’s complete set of treatment parameters directly to the Linac computer database via an electronic data network.*

A scaling problem on the machine used to plan patient A’s radiotherapy meant that the diagrammatic representation of the wedge that should have been visible on the paper Theraplan document was not present. Therefore there was no additional visual reminder that a wedge was required for patient A’s treatment.

**Recommendation 2**

*The scaling problem should be rectified as soon as possible. If this is*
not technically feasible then where wedges are required they should be
drawn on the Theraplan graphical output by hand. A final data
consistency check between the amended graphical and textual
hardcopy must then be carried out.

Radiotherapy department organisational culture

As discussed in Chapters Two, Three and Four there is evidence to suggest
that at the time of the serious adverse incident to patient A the radiographers
involved were working in organisational surroundings that unwittingly provided
an opportunity for them to be unconsciously influenced by involuntary
automaticity.

Recommendation 3

*Advice should be sought from the Intentional Medical and
Environmental Exposure Section of the Health Protection Agency,
Society and College of Radiographers and the Human Resources
Department at the Trust regarding the development and implementation
of an organisational change programme to reduce the opportunities for
involuntary automaticity to arise. The Chief Executive or a Member of
the Trust Board should sponsor this programme.*

Recommendation 4

*The circumstances that can lead to the phenomenon categorised in this
report as involuntary automaticity should be brought to the attention of
every radiographer in the Radiotherapy Department.*

Operational practices

Radiographers who input patients’ treatment data on to the Linac’s computer
database are likely to be subjected to interruptions and distractions and this
may be one of the reasons why R4 made the inadvertent transcription error
which led to patient A’s wedge being omitted from the treatment data entered
on to Linac B’s computer database.

Recommendation 5

*A separate room or space located in a quite environment away from
radiotherapy treatment areas should be allocated to the preparation of
Treatment Cards and the input of patient data on to the Linac computer
database. It should also be clearly indicated that the radiographers
undertaking such work must not be interrupted except in the case of an
emergency. This will help to prevent involuntary automaticity.*

Recommendation 6

*When a radiographer checks the patient treatment data, that has been
manually input on to the Linac computer database, the radiographer should not use the Vericord document produced by the Linac but read the data recorded in the various topic areas displayed on the Linac console monitor and check that it is the same as that recorded in the source documents. The radiographer concerned should do this by first touching or pointing to the data item to be checked on the console screen and then carry out the same action with respect to the item being checked against the source documentation. This will help to prevent involuntary automaticity.

R4 was under time pressures to finish the work required to put Patient A’s replanned Theraplan data on to the Linac B computer database before patient A arrived for treatment. This may in part have led to R4 making the inadvertent transcription error which omitted the right lateral wedge that had been prescribed as part of patients A’s treatment by C1.

Recommendation 7

Advice should be sought from the Intentional Medical and Environmental Exposure Section of the Health Protection Agency and the Society and College of Radiographers as to the optimum safe time required for the manual inputting of patient treatment data. In the intervening period no patient’s treatment data should be manually entered on to the Linac computer database without following the procedures recommended in 5 and 6 above.

R4 did not carry out a check on the treatment data she had input to the Linac B computer database regarding patient A as there was no protocol that required such an action.

Recommendation 8

It should be made mandatory that all radiographers who input patient treatment data on to the Linac computer database carry out a check as to the accuracy of their input in the manner described in recommendation 6.

When checking the data R4 had input to the Linac B computer database, regarding patient A’s treatment, R5 used the Vericord printout and other source documents. R5 did not however detect that the wedge prescribed for patient A’s treatment had inadvertently been omitted.

Recommendation 9

This concern is addressed by Recommendations 5 and 6 and will be met if those recommendations are implemented.

When the field data was discovered to be incorrect on the …..REDACTED….. although R4 recalculated the field data and edited Linac B’s computer database correctly she did not recheck all patient A’s treatment data as there
was no protocol that required such an action. Thus an opportunity to detect that the wedge prescribed for patient A and which had been inadvertently omitted was missed.

**Recommendation 10**

*Whenever a patient’s treatment data is found to be incorrect the radiographer who edits the Linac computer database should be required to check the accuracy of all the other treatment parameters as well in the manner described in recommendation 6.*

R5 rechecked the field data calculations and the edited input for patient A’s treatment by R4 on Linac B’s computer database. However, R5 did not recheck all patient A’s treatment data as there was no protocol that required such an action. Thus an opportunity to detect that the wedge prescribed for patient A and which had been inadvertently omitted was missed.

**Recommendation 11**

*Whenever a patient’s treatment data is found to be incorrect the radiographer who checks the edited version of the Linac computer database should be required to check the accuracy of all the other treatment parameters as well in the manner described in recommendation 6.*

On the final checks before energising the right lateral treatment beam on the ....REDACTED..... R2 and R9 did not detect that the wedge prescribed for patient A’s radiotherapy treatment had been inadvertently omitted. Thus, patient A was unintentionally given an overdose of ionising radiation.

**Recommendation 12**

*The centre should introducing ‘active’ witnessing rather than the ‘passive’ system currently in use as recommended by Toft*, i.e. each radiographer involved would take an active role in identifying the patients and their final treatment setting. Each radiographer would take it in turn to read out the patient’s details and the other person would confirm or refute them. Additionally, the radiographer reading out the data to be checked should only call one item at a time and wait for the checker to respond to that request before the next item to be checked is called. The checks should also be carried out as described in recommendation 6.*

On the ....REDACTED..... prior to the administration of patient A’s treatment R9 carried out a third check on all the source documentation and the Vericord print out from Linac B but did not perceive that the wedge prescribed for the right lateral field had not been recorded in Linac B’s computer database.
Recommendation 13

This concern is addressed by Recommendations 5 and 6 and will be met if those recommendations are implemented.

Neither R11 nor R4 noticed during the final checks carried out before energising the right lateral treatment beam that the wedge prescribed for patient A had been inadvertently omitted from patient A’s treatment data. Thus, patient A was unintentionally given an overdose of ionising radiation.

Recommendation 14

This concern is addressed by Recommendations 6 and 12 and will be met if those recommendations are implemented.

Patient A continued to receive a further 12 unintentional overdoses of ionising radiation from right lateral field treatment beam until the [REDACTED] when R7 and R6, during their final checks prior to energising the treatment beam, discovered that the wedge that had been prescribed by C1 for that field had been inadvertently omitted.

Recommendation 15

This concern is addressed by Recommendation 6 and 12 and will be met if those recommendations are implemented.

Recommendation 16

In so far as it is practical, organisational arrangements should be made so that the operating environment on each Linac, when patients are being treated, is as disruption and interruption free as possible.

The practice of running all the Linac’s to increase patient throughput meant that additional pressures were placed on the remaining Linac’s and their staff if a machine became unserviceable as patients were often transferred to other machines which had not been scheduled for the additional numbers. The additional work pressures this created would have favoured the capture of radiographers by involuntary automaticity.

Recommendation 17

There should always be a complete ‘back-up Linac so that if a Linac breaks down or requires servicing both patients and staff can be moved to the reserve machine.

The practice of over-booking patients with little or no redundancy in each days patient treatment list added to the already difficult operational problems faced by the radiographers in trying to ensure that each patient was kept waiting a short a time as possible. A system such as this favours the capture of radiographers by involuntary automaticity.
Recommendation 18

The practice of deliberate over booking of patients should cease immediately.

Swapping the Linac B and Linac D radiographers and patients added additional pressures to an already over stressed system. This favours the capture of radiographers by involuntary automaticity.

Recommendation 19

Whenever significant changes need to be made in the operational structure of the department and the scheduling of patients such changes should be made progressively and planned well in advance. However, since forward planning is not always possible the department should have an explicit rehearsed contingency and plan in place to help them manage such situations.

The paper Theraplan document is currently left in the Treatment Room although it contains all the Linac treatment data for the patient about to be irradiated. At the present time final check categories of ‘Energy’, ‘Wedge or Filter’ and ‘Monitor Units’ have to be transcribed on to the patients formal Treatment Prescription that are used for the final checks. This presents another opportunity for a transcription error to take place.

Recommendation 20

The paper Theraplan document should not be left in the Treatment Room but brought to the console and used by the radiographers for the final checks before energising the treatment beam.

The Linac Record and Verify system can introduce unintentional systematic errors even thought radiographers are taking great care. Particularly if the working environment in which the Linac is being operated favours the capture of radiographers by involuntary automaticity.

Recommendation 21

This should be brought to the attention of all radiographers and reminders given on a regular basis.

The current final verbal double-checks carried out are identical and this favours the capture of radiographers by involuntary automaticity.

Recommendation 22

This concern is addressed by Recommendations 6 and 12 will be met if those recommendations are implemented.
Protocols

There is no protocol that requires radiographers to ‘log on and log off’ each time they work on the Linac computer database. This means that the electronic audit trail of accountability is often broken.

Recommendation 23

An explicit protocol should be produced that requires all radiographers to “log on and log off” the Linac so that an electronic trail of accountability is maintained.

There is no explicit protocol specifying that random observations should be made of radiographers providing treatment to patients. Thus a potential opportunity to improve operational practices is being missed.

Recommendation 24

The departments Quality System should include an audit that ensures all radiographers are randomly observed during their work by a senior colleague to ascertain if operational practices might be improved.

There is no explicit specification of the activities and accountabilities of radiographers undertaking the provision of a patient's radiotherapy treatment. This may lead to a situation where unconsciously neither radiographer carried out the final checks before energising the treatment beam as thoroughly as them might otherwise.

Recommendation 25

Explicit protocols should be produced that specify the accountabilities of each radiographers undertaking the provision of a patient’s radiotherapy treatment.

There is no explicit protocol specifying that the initials of the person in the first box in the section entitled ‘Monitor units per fraction/time per fractions’ and categorised as ‘TRT BY’ on the patient’s Treatment Card must be the person who energised the treatment beam. And, that the initials in the adjacent box must be those of the person responsible for checking the console screen.

Recommendation 26

An explicit protocol should be produced that instructs the radiographers providing radiotherapy treatment to a patient that the person energising the treatment beam will initial in the first box in the section ‘Monitor units per fraction/time per fractions’ and categorised as ‘TRT BY’ on the patient’s Treatment Card. And, that the initials in the adjacent box must be those of the person responsible for checking the console screen. The protocol should also emphasis that ‘active witnessing’ means that
both the radiographers who carry out the final checks are legally accountable for the treatment beam delivered to the patient.

Internal training

There is no formal internal training regarding the identification of potential serious adverse incident or how radiographers should deal with one if it should occur.

Recommendation 27

Formal internal training concerning the identification of potential serious adverse incidents and how radiographers should respond if one should occur should be developed. Such training should be included in the Induction Training given to all new appointees to the Radiotherapy Department and undertaken by all radiographers once each year.

There does not appear to be an explicit and rehearsed crisis management protocol in place to deal with serious adverse incidents in the Radiotherapy Department.

Recommendation 28

An explicit crisis management protocol outlining the actions to be taken in the event of a serious adverse incident occurring in the Radiotherapy Department should be developed and implemented at the earliest opportunity. The actions described in the protocol should also be exercised at least twice each year with any other relevant departments.

National issues

Radiotherapy treatment planning systems that require a patients treatment plan to be manually transcribed on to a Linac computer database are inherently unsafe as there will always be the opportunity for a radiotherapist to make transcription errors that could lead to a serious adverse incident.

Recommendation 29

The practice of manual transcription of data and manual data entry of treatment parameters into a Linac computer database should be discontinued as soon as possible. All radiotherapy treatment planning systems should transfer a patient’s complete set of treatment parameters via an electronic data network to the Linac computer database.

There are appear to be no professional or regulatory guidelines for calculating the number of radiographers required in a radiotherapy department having regard to their workload and case mix.
Recommendation 30

The Society and College of Radiographers should, in consultation with the appropriate professional and regulatory bodies, consider guidelines about radiographers’ workloads and case mix.

There is no formal teaching of radiographers with regard to the identification of potential serious adverse incident or how to deal with one if it should occur.

Recommendation 31

The Society and College of Radiographers should, in consultation with the appropriate professional and regulatory bodies, develop an education programme to train radiographers how to identify potential serious adverse incidents and how to deal with one if it should occur.

There is no professional or regulatory guidance on where information might be obtained by a radiotherapy department that could help it manage a serious adverse incident.

Recommendation 32

The Society and College of Radiotherapists should, in consultation with the appropriate professional and regulatory bodies, develop a body of experts who can be contacted in confidence, if required, to provide advice on how to manage a serious adverse incident caused through the use of therapeutic ionising radiation.

There appears to be little in the way of publicly available information regarding serious adverse incidents caused through radiotherapy either nationally or internationally.

Recommendation 33

NPSA and Society and College of Radiotherapists, in consultation with the appropriate professional and regulatory bodies, nationally and internationally, should seek to develop a system that collates and disseminates information regarding serious adverse incident on a regular basis to all those involved in radiotherapy.

The NHS Litigation Authority possesses information on serious adverse incidents that could be valuable through preventing a recurrence of the same incident or provided guidance on how a particular incident could be managed to the benefit of patients but are constrained by issues of strict confidentiality.

Recommendation 34

The NHS Litigation Authority with the Department of Health should explore ways in which the information held on serious adverse incidents
could be made more available to healthcare professionals so as to improve patient safety.

The phenomenon identified in this report as Involuntary Automaticity does not appear to have been identified in the healthcare sector either nationally or internationally. This may have led to healthcare professionals being inappropriately ‘blamed’ for serious adverse incidents that were in fact driven by the system of work. Moreover the study by French, the findings of the interim report of this Review Panel and the serious adverse incident example provided by the IAEA suggests that patient A’s serious adverse incident is not unique and if the circumstances surrounding the previous incidents had been widely disseminated it may have been prevented.

Recommendation 35

The circumstances that appear to trigger Involuntary Automaticity should be brought to the attention of the national and international healthcare profession as soon as practicable.

Manufacturers of medical linear accelerators

The present system of electronic accountability relies on radiographers remembering to ‘log in and log off’ the machine they are operating. This has led to breaks in chain of accountability regarding the actions that have been undertaken by radiographers.

Recommendation 36

The manufacturers of medical linear accelerators should consider the integration of fingerprint scanner technology into their machines, as this would substantially improve the electronic chain of accountability.

References

Toft, B (June, 2004) Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, Department of Health, p.107.
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.....REDACTED.....

(Document includes information that could lead to identification of patient)
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.....REDACTED.....

(Document includes information that could lead to identification of patient)
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.....REDACTED.....

(Document includes information that could lead to identification of patient)
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.....REDACTED.....

(Photograph includes a number of individuals working at the Trust)
Plate 10 Initials of person energising treatment beam indicated by ‘X’
Appendix 1

INCIDENT DECISION TREE*
Work through the tree separately for each individual involved

Start Here

Deliberate Harm Test
Were the actions as intended?
- NO
  - Were adverse consequences intended?
    - NO
      - Deliberate Harm Test
    - YES
  - YES
    - Incapacity Test

Incapacity Test
Does there appear to be evidence of ill health or substance abuse?
- NO
  - Deliberate Harm Test
- YES
  - Foresight Test

Foresight Test
Did the individual depart from agreed protocols or safe procedures?
- NO
  - Substitution Test
- YES
  - Were the protocols and safe procedures available, workable, intelligible, correct and in routine use?
    - NO
      - Substitution Test
    - YES
      - Were there any deficiencies in training, experience or supervision?
        - NO
          - Foresight Test
        - YES
          - Were there any significant mitigating circumstances?
            - NO
              - Substitution Test
            - YES
              - System Failure

Substitution Test
Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances?
- NO
  - Foresight Test
- YES
  - System Failure

Consult NCAA or relevant regulatory body
Advising individual to consult Trade Union Representative
- Consider:
  - Suspension
  - Referral to police and disciplinary/regulatory body
  - Occupational Health referral

Highlight any System Failures identified

System Failure
Review system

* Based on James Beck's Culpability Model
Appendix 2

Dear ....REDACTED....

As you are aware the Review Panel sat on Monday and Tuesday of this week to take evidence from the members of staff involved with a serious adverse radiotherapy incident that has occurred at the Trust. Thus, I now have a far clearer picture of what occurred and the circumstances surrounding the incident. It is therefore now possible for me to state that at a surface level of analysis I am of the opinion that the incident which occurred at the Trust is not unique.

During my pre-review research I contacted ....REDACTED...., Managing Director of the NHS Litigation Authority (NHSLA), to ask if they had any information relating to adverse incidents that had occurred in radiotherapy departments. Subsequently, I received a list containing a very brief overview of a number of such incidents known to them. As three of the incidents appeared as if they might be of a similar nature to the one at the Trust I requested further details which they kindly supplied. Upon reading the reports that the NHSLA had sent me I found that two of the adverse incidents appeared to be in some respects comparable to those which had occurred at the Trust.

In the first of the NHSLA incidents, when the patient’s treatment data was input into the radiotherapy treatment machine a “wedge” that had been prescribed was left out. The staff checking the intended planned treatment and machine data input did not detect this error and a dose of radiation approximately 2.5 times the prescribed dose was administered to the patient.

In the report of the second NHSLA incident of interest, the adverse event resulted in an overdose of radiation, but was due to a different chain of events than those that had taken place at the Trust. However, the working environment reported to have been experienced by staff at the time of the adverse incident appeared to be similar in nature to that reported to the Trust following its adverse incident, i.e. a high workload, a significant level of sick absence, continual overtime, a lack of continuity and a complex case mix amongst a other issues.

Because of the observed similarities between the first case described above and the one that had occurred at the Trust I contacted ....REDACTED..... yesterday afternoon (.....REDACTED.....) and told him I had the following concerns. First of all, since there have now been two serious adverse radiotherapy incidents with what appears to be very similar patterns of events there could be more in the future. Indeed, there could be one taking place now. Secondly, if the information concerning the first incident had been anonymised and disseminated the accident at the Trust might not have occurred. Particularly, as one of the members of staff interviewed in the course of the Review noted that they tend concentrate on areas known to cause serious harm to patients, however, “wedges” had never been mentioned in that context. Thus, while there is a need to observe strict confidentiality regarding patients and Trusts involved in adverse incidents, which could result in litigation, some form of a mechanism is needed to ensure such important information is made available to those who could use it to improve patient safety. Indeed, the Annals of the International Commission on Radiological Protection (AICRP) note in one of the
case studies on radiotherapy accidents that because a particular adverse incident had been reported:

“A similar accident in another hospital was subsequently avoided because the medical physicist was aware of the first case and immediately recognised the problem. This emphasises the importance of incident reporting and dissemination of the lessons learned.” (Vol.30, No 3, 2000, p.27)

In fact during the course of our conversation …..REDACTED….. suggested that an alert to radiotherapy departments might be appropriate given the circumstances. However, while I agreed with his line of reasoning I informed …..REDACTED….. that the patient concerned is deeply troubled by the thought of the media finding out about her condition and becoming a news item. Thus, great care will have to be taken in the way such an alert is released.

Without going into the details from the evidence I received at the Review I would recommend that in the first instance radiographers who manually input and check the treatment data entered into a linear accelerator do so in a quiet and secluded environment where they cannot be disturbed. The AICRP stating that:

“Inattention can lead to...the selection or recording of wrong parameters. Preparation and delivery of treatment by radiotherapy technologists require a continuous and high level of concentration, which may be difficult to maintain when the workload is high. Measures to maintain concentration and awareness require a working environment where distractions are minimised…" (Vol.30, No 3, 2000, p.15)

Secondly, as noted above, radiographers treating a patient should not be interrupted in their work. Furthermore, when radiographers treating a patient carrying out their checks prior to energising the radiation beam I recommend that they read the data values from the monitor/console first and then check those data values against the patient’s “Treatment Card”. Not the other way around as appears to be the case at the present time. This is because it is the data values shown on the monitor/console that will actually be administered to a patient by the linear accelerator and consequently it is those data values that must be checked against the source document, i.e. a patient’s treatment card.

I have taken the liberty to produce this very brief report on my immediate findings, as the full report will take sometime to prepare and I believe these issues need to be urgently addressed.

Yours sincerely,

…..REDACTED…..

Chairman
Adverse Review Panel
Appendix 3

Safe Delivery of Radiotherapy Treatment

Reference:  DH ALERT 4181
Category:  For Action

Gateway Number: 4181
Safety Alert Broadcast System  issued: 19 November 2004

<table>
<thead>
<tr>
<th>Action required</th>
<th>See points 6 – 9 inclusive below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline ( for action complete )</td>
<td>23 December 2004</td>
</tr>
</tbody>
</table>

Issue

1. An incident has occurred during the delivery of a course of radiotherapy treatment, resulting in potentially significant adverse clinical consequences for the patient.

2. The incident occurred due to an error in the manual transposition of treatment machine parameters. These were entered into the linear accelerator record and verify system from a paper copy of the treatment plan.

3. Monitor units for a treatment beam using a 60° wedge were entered into the system but the wedge itself was not. Treatment was delivered without the wedge in the beam.

4. The error remained undetected for 93% of the treatment course. One of the factors contributing to this was that the wedge was not displayed diagrammatically on the paper treatment plan, used daily for machine set up. There was no visual reminder of the wedge required for correct delivery of that beam.

5. Following investigation, causative factors have been identified and the following recommendations are made:

   NHS Trusts are required to ensure that a suitable environment is provided for staff to concentrate fully on the task of data manipulation.

   Consideration should be given to the amount of time this high level of concentration can be sustained in any given period.

   NHS Trusts are required to review practice and procedures.
Prior to switching on the linear accelerator beam, delivery settings should be checked against defined primary information sources, which are comprehensive.

Whilst staff are actively delivering treatment they should be allowed to work uninterrupted.

**Action**

6. Review practice and procedure relating to data entry into linear accelerator record and verify systems (R&V).

7. Review and identify primary sources of information for checking data in R&V systems prior to treatment delivery.

8. Review provision of appropriate environment for data related tasks and at treatment console.

9. Take any necessary actions to address changes in procedure and practice to minimise the risk of this type of incident being repeated.

**Distribution**

10. FOR RESPONSE BY:

    Acute NHS Trusts,
    Ambulance Trusts,
    Care,
    Community NHS Trusts,
    Learning Disabilities,
    Mental Health and Learning Disabilities,
    Mental Health and Social Care,
    Mental Health Trusts,
    Primary Care Trusts,
    Specialist NHS Trusts

11. FOR ACTION BY:

    Medical Directors in Organisations Delivering Radiotherapy

12. For any queries about the content of this alert, please contact:

    .....REDACTED.....

    Department of Health
    Telephone: 020 7972 5122
The Safety Alert Broadcast System

13. From 26 April 2004 onwards, each English NHS Trust’s/PCT’s nominated Safety Alert Broadcast System (SABS) liaison officer is asked to acknowledge receipt of each alert sent via SABS by email, and to complete the electronic response form attached to each email on behalf of their organisation.

    Safety Alert Broadcast System - see
    [www.info.doh.gov.uk/sar/cmopatie.nsf](http://www.info.doh.gov.uk/sar/cmopatie.nsf)

14. For any problems in completing the process set out above, please email [safetyalerts@doh.gsi.gov.uk](mailto:safetyalerts@doh.gsi.gov.uk) or call the SABS technical helpdesk 020 7972 1500.

Department of Health
Patient Safety Team
November 2004