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Improving the safety of radiotherapy treatment delivery

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By

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Abstract

Errors during radiotherapy treatment can cause severe, and potentially fatal, patient harm. The final check immediately prior to treatment delivery, whereby two radiographers ensure that the dose about to be delivered corresponds with the prescription, is the last defence against error. The aim of this research was to increase understanding of this final treatment check and factors affecting error detection, in order to improve the safety of radiotherapy treatment delivery.

The research adopted a mixed methods approach, combining qualitative and experimental studies to investigate the interaction of factors affecting accuracy during the final treatment checks. The qualitative interviews and task analysis pointed to difficulties maintaining attention and variation in how these checks are conducted. The interface used to conduct the final treatment check was also recognised to have usability issues.

The laboratory-based experimental studies results indicated that a structured form of double checking, called challenge-response, is most effective at error detection, when compared to single or unstructured double checking. Furthermore, it was found that alternating the roles of challenger and responder, and the order parameters are checked in, significantly increases accuracy during repeated treatment checks.

The original contribution of this research was a detailed investigation of a previously understudied aspect of radiotherapy treatment. The results informed the design of an original, evidence and theoretical based two-person checking protocol for use during the final treatment check. Qualitative evaluation indicates that it would be well received as a standardised method of treatment checking. Furthermore, an alternative interface design has been proposed, specifically for use during the final treatment check. This was comparatively tested against the most frequently used software package within the UK and found to have a significant positive impact upon user's

accuracy. An additional output is a series of practice based recommendations to improve accuracy during repeated treatment checking.

This research has concluded that implementation of the practice recommendations, checking protocol and interface design should help maintain radiographers' attention during repeated final treatment checks, thereby preventing errors passing undetected. Future research into the radiotherapy interface design and implementation of the standardised final treatment check protocol have been identified.

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Dissemination as a result of work from this thesis

Invited speaker

- Gilbert, L. (2015) 'Radiotherapy Errors: Is involuntary automaticity an issue?' Society and College of Radiographers Annual Radiotherapy Conference, Bristol, 30 January – 1 February 2015

Conference presentations with full paper

- Dwyer, L., Moody, L., Wallace, L., Schlaghecken, F. (2014) 'Design of a Safer Radiotherapy Interface' in Yoxall, A. and Christer, K. (ed.) Proceedings of the 2nd European Conference on Design 4 Health. Held 3rd-5th July 2013 at Sheffield Hallam University. Sheffield: Sheffield Hallam University, 96-106

Oral presentations

- Dwyer, L., Moody, L., Wallace, L., Schlaghecken, F. (2013) 'Design of a Safer Radiotherapy Interface' Design4Health, Sheffield Hallam University, 3rd-5th July 2013

- Dwyer, L., Moody, L., Wallace, L., Schlaghecken, F. (2013) 'An Experimental Approach to Exploring Human Factors Issues Affecting Radiotherapy Safety' Institute of Ergonomics and Human Factors: Patient and Provider Safety Event, London, 25th November 2013

- Dwyer, L., Moody, L., Wallace, L. and Schlaghecken, F. (2013) 'Development of an evidence-based checking protocol to prevent errors in Radiotherapy treatment delivery' UK Society for Behavioural Medicine, Oxford University, 9th-10th December 2013.

Poster presentations

- Gilbert, L., Moody, L., Wallace, L. and Schlaghecken, F. (2015) 'Maintaining attention during repeated verification in radiotherapy treatment delivery' Ergonomics and Human Factors, Daventry, April 13th- 16th 2015

- Dwyer, L., Moody, L., Wallace, L. and Schlaghecken, F. (2012). 'Double Checking: Does it really work?' Making Health Care Safer, University of St Andrews, 25th-26th June 2012

- Dwyer, L., Moody, L., Wallace, L., Schlaghecken, F. (2013) 'Understanding Double Checking Errors in Radiotherapy Treatment Delivery' International Forum for Quality and Safety in Healthcare, London, April 17th-19th 2013

Abbreviations

BCU	Birmingham City University
BPS	British Psychological Society
DH	Department of Health
HTA	Hierarchical Task Analysis
IA	Involuntary Automaticity
NHS	National Health Service
NPSA	National Patient Safety Agency
NPT	Normalisation Process Theory
NRLS	National Reporting and Learning System
PDSA	Plan-Do-Study-Act model
RV system	Record and Verify System
SOP	Standardised Operating Procedures
SPSS	Statistical package for the Social Sciences
SSC	Surgical Safety Checklist
UHCW	University Hospital Coventry and Warwickshire NHS Trust
WHO	World Health Organisation

Glossary

Adverse event	In healthcare, this refers to an unintended or unexpected incident, resulting in patient harm.
Attention	Focussed awareness on available perceptual information.
Beam	The delivery of the radiotherapy treatment dose.
Beam modification	Accessories placed in the way of the radiotherapy beam to alter the amount of radiation reaching the body.
Challenge-response checking	A verbalised, structured form of double checking conducted by two people. One person acts as the challenger and reads values aloud, the other acts as the responder and verbally confirms if the value is correct or not. Often used in aviation.
DICOM mode	DICOM stands for Digital Imaging and Communications in Medicine and is a standard for storing and transmitting medical imaging data. This standard includes specific file formats and communications protocols between machines which can create or exchange DICOM format files of patient image and data. Alongside this, a record and verify system will usually be used to manage patient's treatment prescriptions on the linear accelerator machines as an additional safeguard. Yet, if there is a technology failure, the record and verify systems may be down which is referred to, by radiographers, as treating in DICOM mode. In these circumstances treatment verification against the source prescription must be reliable.

Double checking	When two people are responsible for conducting a check. Often used in healthcare.
Energy	One of the parameters prescribed on the patient's radiotherapy prescription. The value represents the amount of radiation energy absorbed.
Error	A generic term encompassing all acts which lead to a planned sequence of events not being executed as intended, leading to an undesirable outcome or significant potential for such an outcome.
Final treatment check	The last confirmation that the radiotherapy dose about to be delivered to a patient is correct. It happens immediately before the dose is delivered.
Fraction	Part of a patient's radiotherapy dose. Each patient has a radiotherapy prescription dose which consists of many different fractions, delivered on consecutive days.
Implementation	The planned process and systematic introduction of new intervention, innovations or practice changes of proven value with the aim that they become common practice.
Involuntary automaticity	The phenomena to describe when regularly repeated actions are conducted automatically without full attention paid to the stimuli. The person is unaware this has occurred.
Linear accelerator	The machine used to deliver the dose of radiation. Often referred to as linac for short.

Near miss	A potential error which was spotted and corrected before it caused harm to a patient.
Monitor units	One of the parameters which make up a patient's radiotherapy prescription. Monitor units are measured by ionisation chambers within the treatment head of the linear accelerator machine and give a measurement of the strength of the radiation beam delivered by the machine.
Prescription	The details of the radiation dose that it is intended the patient will receive.
Pre-treatment imaging and planning	This refers to the processes which occur prior to the patient receiving external beam radiation treatment. During this process a simulator machine takes X-rays of the body to determine the exact location and size of the tumour. Calculations are then conducted to determine the optimum dose and position to ensure maximum radiation reaches the tumour whilst minimising damage to healthy tissue. Ink marks may need to be made on the skin to help with positioning. This forms the patient's treatment prescription. Calculations and images must be checked for accuracy.
Record & Verify system	A software package installed on the linear accelerator machine. A patient's prescription is entered into the programme before treatment starts. Then prior to treatment the software then verifies that the correct treatment is about to be delivered, based on this initial entry.
Safety critical industries	Industries, such as nuclear power and aviation, which

	operate in a high risk domain in terms of safety.
Single checking	A check conducted by one person on their own.
Standardisation	The process of developing and implementing a set of processes or methods to be used in the same way across all departments, with the aim of reducing variation.
Standardised	A method or process which is identical and used the same way in all departments.
Switch on	The term given to the process of actually giving the radiation dose, actually pressing the button to deliver the beam.
Therapy radiographer	The healthcare professional responsible for the delivery of radiation, and patient care whilst undergoing radiotherapy treatment. Referred to as radiographer throughout this thesis.
Trapping errors	A term used to describe the detection of an error, before it causes harm.
Wedge	A specific type of radiation beam modification to optimise target dose distribution

1 Chapter 1 – Introduction

Patient safety is a major concern within healthcare. The World Health Organisation (WHO) has stated that unsafe care and avoidable errors result in *"significant mortality and morbidity throughout the world"* (World Health Organisation 2008: 3). In the UK iatrogenic harm can result in unnecessary patient harm, death, distress and increased cost to the NHS. The discipline has evolved over time and, with the publication of the Francis report in 2013, which exposed serious quality and safety concerns in the NHS, there is ever increasing public scrutiny on healthcare to improve (Francis 2013).

Radiotherapy is an area of healthcare which has a maturing patient safety culture following a series of high profile errors and publication of the *Radiotherapy Risk Profile* (WHO 2008). Approximately 125,000 patients undergo radiotherapy treatment in the UK annually (Department of Health 2012). It is estimated that errors, or near misses, occur in 1.9% of these treatment courses (Department of Health 2012). These errors may lead to either an overdose or an underdose, and may cause severe, and potentially fatal, harm. One mechanism put in place to increase safety in radiotherapy are treatment confirmation checks.

The radiotherapy treatment process consists of a number of stages. There are many checks of a patient's treatment built into this process, in order to minimise the likelihood of an error, or catch an error before it causes harm (Donaldson 2007). The final opportunity to detect an error is when two radiographers conduct the final check of a patient's treatment immediately prior to treatment delivery. During this final safety check the treatment dose, consisting of several parameters, are displayed on a screen. Radiographers must ensure, and confirm, that these values correspond exactly with those that were prescribed for the patient, by comparing the values on screen to the patient's paper prescription. This check is conducted by two radiographers, and should therefore be a double check (Donaldson 2007).

Double checking is employed in many other areas of healthcare, such as drug administration, to prevent or trap errors before they occur, thereby preventing patient harm (Shillito, Arfanis and Smith 2010). There is currently a debate in the literature as to whether single or double checking is more effective at preventing errors in healthcare. Double checking has been criticised for being ineffective and time consuming (Armitage 2009). Yet, there is little empirical evidence to support either method of checking with the majority of literature consisting of either opinion or retrospective analysis (Alsulami, Conroy and Choonara 2012). There has also been no research conducted on double checking in radiotherapy specifically. Consequently, there is currently limited evidence to support the best method of checking to be used during the final treatment check in radiotherapy.

Of the limited research into radiotherapy treatment checking safety, there is evidence to suggest that the final treatment check in radiotherapy is vulnerable to allowing errors to pass undetected resulting in potentially severe patient harm (Toft and Mascie-Taylor 2005). It has been hypothesised that this may be due to a failure in attention (Toft and Mascie-Taylor 2005). There are likely to be a number of contributory factors affecting the effectiveness of this final safety protocol. Therefore, this thesis will explore the final treatment checking process in depth, to analyse the factors underlying effectiveness. With this understanding, recommendations surrounding the final treatment checking process can be suggested to help ensure that the treatment check traps errors prior to treatment delivery, preventing patient harm.

1.1 Thesis aim and objectives

The aim of this research is to fully understand the process of the final treatment check immediately prior to radiotherapy treatment delivery in order to determine how the reliability might be improved to help ensure errors are detected and improve the safety of treatment delivery. The specific objectives are to:

1. Examine and review the checking process immediately prior to beam delivery and identify factors affecting the reliability of this process to detect errors
2. Experimentally test the impact on performance of different approaches to checking in a laboratory setting, to develop an empirical evidence base

3. Specify and design an evidence-based revised checking process for use immediately prior to beam delivery
4. Evaluate the revised process to determine user acceptance

1.2 Thesis content

The research is informed by a literature review. Literature relating to radiotherapy patient safety is presented in chapter 2. Through discussion of error rates in radiotherapy, this chapter provides the rationale for the focus on the final treatment check immediately prior to beam delivery.

Current understanding of errors in radiotherapy is reviewed in chapter 3. Theoretical models of error are applied to radiotherapy, alongside a discussion of the current literature on radiotherapy errors. This chapter argues that there is scope for increased understanding of checking errors and the final treatment check process.

Chapter 4 reviews the literature relating to double checking in healthcare, and the potential theories to explain double checking failure which have been presented to date. Chapter 4 concludes with a summary of all the literature review findings indicating that further empirical investigation is needed to understand the final treatment check in radiotherapy and why it may fail to detect errors.

Chapter 5 presents the methodology of the research contained in this thesis. It presents the research philosophy, structure of the thesis, and discusses issues of reliability, validity and ethics.

In response to the literature review, chapter 6 presents a task analysis of the final treatment checking process to explore the potential factors underlying checking accuracy. This is supported by the study presented in chapter 7, which consisted of semi-structured interviews with radiographers and student radiographers to understand their perceptions of how the final treatment check is conducted and potential reasons why it may not be effective at detecting errors.

The results of the interviews and task analysis were central in guiding the subsequent chapters. The main findings from the interviews suggested that there was variation in how the final treatment check was conducted both between and within departments and that a standardised protocol for the final treatment check was required and desired amongst radiographers. They also pointed to issues with the interface that may increase error. In chapter 8 two experimental, laboratory-based studies are described that explored different methods of checking to determine the most effective method of maintaining attention during repeated final treatment checks. The experimental studies employed a paradigm that involved a simulated radiotherapy checking task, designed to mimic the repetitiveness of the final treatment check in radiotherapy, albeit in shorter timeframes, see section 8.2. The first experimental study, in section 8.3, compared different methods of checking: single (one person) checking, unstructured two person checking and a structured form of double checking, called challenge-response checking. This was to explore the variation in current practice and provide evidence for the most effective method of checking to detect errors. The results of the experimental studies suggested that challenge-response checking is most effective at error detection, when compared to single or unstructured double checking. However, it was found that attention still lapsed during repeated challenge-response checking which has the potential for allowing errors to pass undetected. Therefore, the second study, in section 8.4, explored methods to maintain attention during repeated challenge-response checking. The results suggested that small changes to how the challenge-response check is conducted can help to maintain attention. These were regularly alternating the roles of challenger and responder, and varying the order parameters are checked in. It is thought that this improves attention through introducing variation and minimising routine.

In response to the findings in chapter 8, chapter 9 details the design and evaluation of a new two person final verbal safety protocol for use immediately prior to beam delivery. The verbal checking protocol incorporates the results from the experimental studies described above. Qualitative evaluation of this protocol was conducted through semi-structured group interviews with qualified and student radiographers. This revealed the strengths,

weaknesses, barriers to use and improvements to be made to the protocol, alongside consideration of implementation.

Following feedback from radiographers, chapter 10 considers the impact of the static interface used at the point of the final treatment check on error detection. The static interface displays the treatment parameters which are about to be delivered to the patient. It is these values which are compared against the patient's original prescription to ensure there are no discrepancies, and prevent erroneous treatment delivery. A study was undertaken to design and evaluate a proposed static interface to be used specifically for the final treatment check. This proposed interface was comparatively tested against the static interface from the most frequently used software package within the UK, MOSAIQ, and evaluated through semi-structured group interviews with qualified and student radiographers. The findings are translated into recommendations concerning future re-developments of radiotherapy software systems.

Chapter 11 is the concluding chapter. It discusses and draws together the research findings surrounding radiotherapy treatment checking safety. Future research directions are discussed along with observations surrounding the research process and results arising from it.

1.3 Original contributions of the research

This research has revealed a paucity of patient safety research specifically in relation to radiotherapy treatment checking. The thesis has addressed a very specific area of radiotherapy error prevention, the final treatment checking protocols used to 'trap' errors immediately prior to treatment administration. The approach adopted combines qualitative investigation and experimental studies to address the complex interaction of factors affecting checking accuracy. The thesis has made the following original contributions:

1. A detailed understanding of the final treatment checking process in radiotherapy and identification and analysis of factors contributing to effectiveness
2. The design of a unique experimental paradigm designed and employed to mimic the repetitiveness of radiotherapy treatment checking

3. An empirical evidence base to support the validity of challenge-response checking in radiotherapy
4. The development and evaluation of a new evidence and theoretical based verbal safety protocol for use immediately prior to treatment delivery in radiotherapy
5. Recommendations surrounding the design of the radiotherapy interface to improve treatment checking accuracy
6. Practice recommendations to improve detection of errors in patient's treatment during the final treatment check prior to treatment delivery

2 Chapter 2 – Patient Safety in Radiotherapy

This chapter will introduce the field of patient safety and the concept of adverse events. The chapter will then provide an overview of the radiotherapy treatment process and error rates within radiotherapy. Through discussion of error rates and patient safety considerations, the rationale for the focus of this thesis will be formed.

2.1 Patient Safety

Patient safety is the study of,

> *"the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare"* (Vincent 2006: 14).

As medicine has become more complex and advanced over the decades, it can also be said to have potentially become more risk-prone due to more opportunities for errors potentially resulting in iatrogenic harm (Vincent 2010). Patient safety is a multidisciplinary field, combining the theory and expertise from psychology, ergonomics, medicine and management, to research and prevent potential errors and subsequent patient harm.

Patient safety has always existed within healthcare, previously described within concepts of quality of healthcare, prior to the arrival of the term patient safety (Vincent 2010). Yet there is a distinction to be made between quality and safety. Quality refers to the gap between what should be done and what is done. Safety refers to the extent to which a patient is harmed during contact with healthcare providers or organisations (Vincent 2010). Therefore, it is recognised that the two terms are not interchangeable. Patient safety became a standalone priority across the world following the publication of key documents which highlighted that more needed to be done to prevent patients being harmed by the systems designed to improve their health. These key publications are discussed below in sections 2.1.1-2.1.6.

2.1.1 'To Err is Human'

The publication *To Err is Human: Building a Safer Healthcare System* was published in the United States of America (USA) in 2000 by the Institute of Medicine (Kohn, Corrigan and Donaldson 2000). It is widely cited as being the publication responsible for catapulting

patient safety to the top of healthcare agendas, as well as increasing public awareness about it (Vincent 2010). The publication included shocking statistics about the rate of iatrogenic harm. For instance it was stated that between 44,000 and 98,000 people die annually in USA hospitals as a result of medical errors. The key message from this publication, aside from the extent of iatrogenic harm, was that healthcare was at least 10 years behind other high-risk industries in terms of attention to, and a proactive approach to safety (Kohn, Corrigan and Donaldson 2000).

2.1.2 'An Organisation with a Memory'

An Organisation with a Memory was published in 2000 in the UK by the Department of Health, and was the British equivalent of *To Err is Human*. The publication reported that the NHS urgently needed to improve care so that patients were not being harmed by the system designed to treat them. It was also reported that the NHS did not appear to be learning from previous mistakes and errors (Department of Health 2001a).

2.1.3 'Building a Safer NHS'

Building a Safer NHS for Patients: Improving Medication Safety was published in the UK by the Department of Health in 2001 and detailed the plans for how to implement the necessary changes recognised in *An Organisation with a Memory*. It was noted in the publication that prior to 2000 there had been no systematic and focussed study on patient safety in the NHS. Poor safety rates in the NHS and the fact that healthcare lagged significantly behind other high risk industries such as nuclear power and aviation was recognised. It was also reported that efforts to improve safety in the NHS would be a long-term task requiring effort, commitment and strong leadership from healthcare professionals, due to the complex nature of healthcare (Department of Health 2001b)

2.1.4 Formation of the National Patient Safety Agency

In 2001 in the UK the National Patient Safety Agency (NPSA) was formed, partly in response to *An Organisation with a Memory*. This agency was designed to be a central focus point for targeting efforts at learning from mistakes and improving patient safety in the NHS. One of the outcomes of the formation of the NPSA was the creation of the National Reporting and Learning System (NRLS). The NRLS received feedback from, and provided guidance to healthcare organisations on safety issues. Importantly, in regards to learning from errors,

the NPSA, as a result of the NRLS was able to send alerts to all relevant departments in the UK when a preventable safety incident was recognised, with the aim of preventing the same error occurring twice (National Patient Safety Agency 2014). In 2012 the NPSA was disbanded, with the key functions and expertise transferred over to the NHS Commissioning Board Special Health Authority, to ensure patient safety considerations remained central to the organisation. Public Health England have since taken over responsibility for error monitoring.

2.1.5 Francis reports

A seminal public inquiry in the field of patient safety produced the two Francis reports into the failings at Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. The first inquiry revealed unacceptable levels of care and rates of incidents across the trust, which led to high levels of patient and relative suffering (Francis 2010). Alongside poor and unsafe care, the culture within the Trust was said to not be conducive to providing good care to patients, or a supportive working environment for staff. The report uncovered many reasons for the failings in care and a culture which accepted low standards of care. In addition, a series of serious systematic faults were uncovered which resulted in the failure to detect warning signs signalling poor quality care and compromised safety within the trust. Some of the factors believed to compromise patient safety were:

- Poor staff attitudes to patients, both lacking compassion and uncaring towards vulnerable patients
- Bullying and fear of adverse repercussions from whistle blowing amongst staff
- Lack of staff trust in management
- Low staff morale due to financial constraints and staff cuts
- A passive attitude towards change amongst senior staff
- Poor maintenance of professional standards across all staff grades
- Patients and families feedback was repeatedly not acted upon

The second Francis inquiry's remit was to reveal which organisations were responsible for the failings at Mid Staffordshire NHS Foundation Trust and make NHS wide recommendations to improve care (Francis 2013). This second Francis inquiry made 290 recommendations to be implemented in order to improve care and safety across the NHS

and to prevent a repeat of the failings at the Mid Staffordshire NHS Foundation Trust (Francis 2010). Above all the most prominent message the Francis report gave was that a fundamental culture change was required so that it is always the patients' welfare which drives a healthcare organisation, not targets. Hence, a major theme of the recommendations was increased seeking of patient feedback,

> *"While benchmarks and data-based assessments are important tools, these should not be allowed to detract attention from the needs and experiences of patients. Benchmarks, ratings and status may not always bring to light serious systemic failings."* (Francis 2010:24)

In response to the Francis report the government published *Hard Truths: The Journey to Putting Patients First* in 2013 which laid out what the government was going to do to implement the recommendations made by the Francis report (Department of Health 2013). These actions include:

- Every patient to know the name of the doctor in charge of their care
- Public access to each hospitals' safety levels
- Informing patients if they have suffered an adverse event
- Consulting with patients more about their care
- More feedback from patients sought by the Care Quality Commission
- A more transparent complaints process
- Nursing staff levels to be increased in hospitals
- Increased frequency of unannounced visits by the Care Quality Commission
- More support for NHS staff as whistle-blowers

Many of the actions published in *Hard Truths: The Journey to Putting Patients First* (Department of Health 2013) centred on improving and measuring quality and safety, alongside actions to help prevent adverse events in healthcare.

2.1.6 Berwick report

In response to the Francis report, the government approached Don Berwick to conduct a review into what needs to be done to "*make zero harm a reality*" in the NHS (Berwick 2013: 7). The resulting report, *A Promise to Learn-A Commitment to Act*, acknowledged the challenges faced by the NHS and set out many recommendations surrounding: transparency, a commitment to learning, patient feedback, abandonment of quantitative

targets and staff blame and a clear line of responsibility. The most important message from this report was that,

> *"The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end." (*Berwick 2013: 5)

Therefore, it is clear that patient safety developments and learning remain a priority in the NHS. As such a thorough understanding of all areas of healthcare is required in order to learn how to ensure a high standard of care throughout the NHS.

2.2 Adverse events

An adverse event is,

> *"an unintended injury caused by medical management rather than the disease process and which is sufficiently serious to lead to prolongation of hospitalisation or to permanent impairment or disability to the patient"* (Vincent 2010: 53).

Adverse events can arise from either the actions of an individual healthcare worker, or arise from the healthcare system. Adverse events can result a wide range of mistakes; misdiagnosis, omission of diagnosis or treatment, mistreatment or failure to intervene appropriately to prevent the disease process. The figures below taken from *An Organisation with a Memory* (Department of Health 2001a) illustrate the scale of adverse events in the NHS:

- Adverse events occur in around 10% of patient admissions or at a rate of an estimated 850,000 adverse events a year
- 400 people die or are seriously injured in adverse events involving medical devices every year
- Adverse events cost approximately £2 billion a year in additional hospital stays
- The NHS pays out around £400 million per annum on clinical negligence claims
- Hospital acquired infections, around 15% of which may be avoidable, are estimated to cost nearly £1 billion every year

From analysis of these adverse events, it was recognised that in some areas of medicine patterns of errors were occurring which could be prevented with specific targeted action, in order to reduce the risk of harm to patients in those areas. Therefore, the report *Building a*

Safer NHS was produced by the Department of Health in 2001 and set out national targets for reducing the rate of adverse events in four specific areas of healthcare (Department of Health 2001b):

- "Reduce to zero the number of patients dying or being paralysed by mal-administered spinal injections by the end of 2001
- Reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology which result in litigation by 2005
- Reduce by 40% the number of serious errors in the use of prescribed drugs by 2005
- Reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by 2002"

2.2.1 Never Events

These four key targeted areas of risk reduction can be seen to be a formative list of Never Events. Never Events are serious safety incidents which, given they are a known area of risk, should never happen (Vincent 2010). However, Never Events do still happen occasionally and are therefore used by organisations as a safety target. The first list of Never Events in the United Kingdom was drawn up by the National Quality Forum in 2004 and the list now consists of 25 Never Events, including:

- Surgery performed on the wrong body part or wrong patient
- Infant discharged to the wrong person
- Patient death or serious injury due to a medication error
- Retained instrument post-operation
- Inpatient suicide using non-collapsible rails

Incidents must meet the following criteria to be classed as a Never Event:

- The incident has potential for severe patient harm
- The incident has occurred in the past and is therefore a known source of risk
- There is existing guidance on how the event can be prevented
- The event is preventable if the guidance is implemented

From the information above it can be seen that radiotherapy does not feature in targeted areas for error reduction, or the list of Never Events. Within the patient safety field, there

has been little focus specifically on radiotherapy, despite the potential for severe patient harm if errors occur in this domain.

2.3 Patient Safety in Radiotherapy

> *"Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death"* (World Health Organisation 2008:2).

Radiotherapy is a clinically effective and cost efficient cancer treatment, accounting for just 5% of the national spend on cancer (Department of Health 2012). It is estimated that approximately 125,000 patients undergo radiotherapy treatment in the UK every year. Yet, as cancer is predominantly a disease of later life, that number is set to continue to rise due to an aging population (Department of Health 2012). Radiotherapy is the second most effective treatment for cancer, behind surgery. 40% of cancer survivors received radiotherapy as part of their treatment, and 16% of all cancer survivors cure can be attributed to radiotherapy alone (Department of Health 2012). However, as with all areas of healthcare there is a risk of error, that can devastating to the patients, their families and the healthcare professionals involved. A focus on this area is important as the delivery of therapeutic radiation has a high propensity for harm if errors occur.

2.3.1 Radiotherapy treatment process

The aim of radiotherapy is to target and maximise radiation to tumours in order to destroy cancer cells, whilst minimising damage to surrounding healthy cells. Hence the accuracy of the dose and placement of the radiation beam is vital to successful treatment. There are a number of stages in a patient's treatment which can be broadly divided into planning and delivery (Donaldson 2007). A patient's treatment is decided upon and planned by a multidisciplinary team of oncologists, medical physicists and radiographers in the planning stage. During the delivery stage the patient visits the radiotherapy department to receive their treatment. A patient's radiotherapy treatment is usually made up of a series of fractions (doses of radiation) given over consecutive days. The diagram in figure 2.1 summarises the stages of radiotherapy treatment.

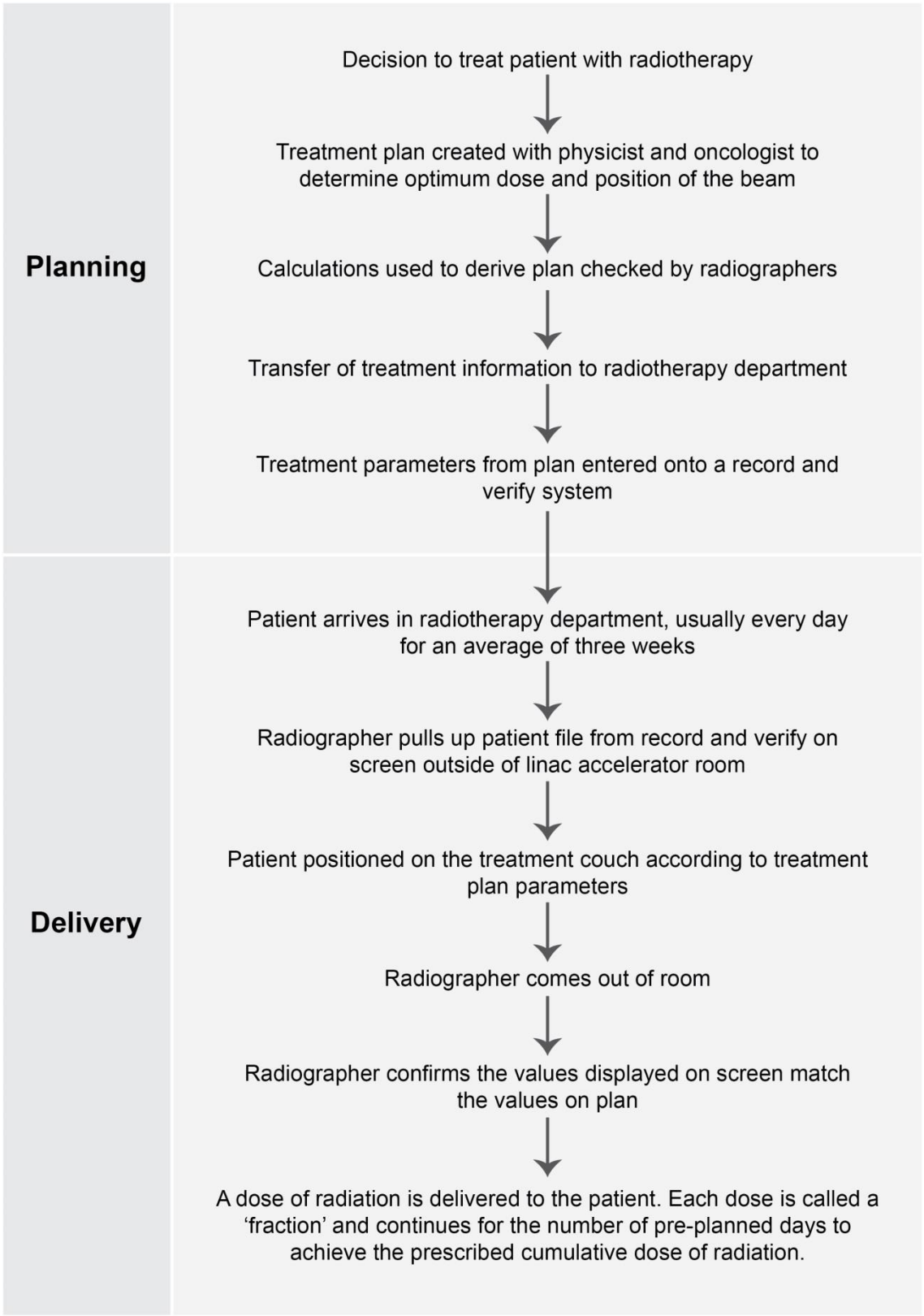


Figure 2.1: Overview of the radiotherapy treatment process, adapted from Donaldson (2007)

The radiation is administered by a machine called a linear accelerator. The linear accelerator interface displays the treatment parameters, including strength of radiation, area to be radiated and any beam accessories needed to modify the radiation beam, on a computer

screen both in the treatment room and an adjacent observation room. In the UK alone, there are over 200 linear accelerator machines which deliver approximately 4.5 million individual exposures each year (Department of Health 2007).

An error in radiotherapy can lead to either under dosing or overdosing, both of which can have considerable detrimental and potentially fatal effects on the patient (Donaldson 2007). An under dose can lead to inadequate tumour control, whereas an overdose can lead to burns, organ damage and death (Department of Health 2007). There have been a series of high profile incidents in recent years in the UK which are detailed below.

In 1991, at the North Staffordshire Royal Infirmary in England it was discovered that, following the introduction of new technology, radiographers erroneously believed that the machine did not make necessary adjustments to treatment doses. Hence, radiographers made additional unnecessary manual adjustments to every patient's dose. Consequently, all patients receiving treatment on this new machine received an under dose until the error was discovered 10 years later. This error is estimated to have affected one thousand patients (Department of Health 2007).

A serious error effecting one patient occurred in 2005 at the Cookridge Hospital in Leeds. A breast cancer patient received 2.5 times her prescribed dose due to an incorrectly programmed dose parameter. This went undetected, despite checks, for 14 consecutive treatment days. The patient survived the error but her doctors believe her life expectancy has been shortened as a result of the error (Toft 2005).

Errors can also lead to a fatal overdose of radiation. Lisa Norris, aged 15, was a victim of a fatal dose calculation error in 2006 at the Beatson Oncology Unit in Glasgow. Whilst undergoing treatment for a brain tumour, Lisa Norris received 158% of her prescribed radiation because radiographers erroneously believed the machine made the required adjustments to her dose. Consequently, dose adjustments were not made and 19 overdoses were given until the error was discovered (Department of Health 2007).

These high profile adverse events illustrate the negative impact of errors in radiotherapy. Following incidents in other countries and these in the UK, the World Health Organisation (WHO) published the *Radiotherapy Risk Profile*. This was a seminal document within radiotherapy and highlights vulnerabilities in the patient pathway, with a view to reducing or eliminating errors through analysis of previous adverse events and incidents. Other areas of healthcare conduct risk profiling as an activity to improve safety, but radiotherapy is currently the only healthcare domain to have a risk profile document published by the WHO. The document provides information on error rates and sources of errors. It also suggests interventions to increase patient safety including: ensuring adequate staffing levels, more use of checklists and increasing reporting of and learning from errors. Yet, detail on these interventions is limited thus far (World Health Organisation 2008).

In response to the imminent publication of the *Radiotherapy Risk profile*, the Department of Health (DH) in the UK published a document entitled *Towards Safer Radiotherapy* (Donaldson 2007)[1]. Recommendations were made in this document to increase patient safety in radiotherapy and prevent errors including:

- Development and promotion of a good safety culture in which staff are encouraged to question potentially unsafe working, and report errors and near misses
- Clear communication between all staff regardless of hierarchy
- Staffing levels appropriate to the number of patients being treated
- Working environments designed to prevent distractions

These recommendations, especially surrounding culture and reporting have been repeatedly echoed in many patient safety documents, illustrating a growing recognition of the importance of these factors in ameliorating patient risk across healthcare. One way to explore the importance of these factors and evaluate if the increased focus on culture and human factors is improving healthcare safety is to study patterns and rates of error.

[1] Towards Safer Radiotherapy is a document produced by a working party from Royal College of Radiologists, Society and College of Radiographers, the Institute of Physics and Engineering in Medicine, NPSA, Health Protection Agency and British Institute of Radiology which was designed to find practical and organisational changes to improve safety

2.3.2 Error rates in Radiotherapy

The WHO *Radiotherapy Risk Profile* reviewed literature in an attempt to calculate worldwide error rates (WHO 2008). In the document it is stated that many more errors may have occurred but passed undetected, or had not been reported. The WHO conducted a review of major radiotherapy incidents that led to radiation injury or death, in middle to high income countries in USA, Europe and Asia. This review suggested that between 1976- 2007, 3125 patients were reported to have been affected by an error leading to an adverse event in these countries. Some 1.4% (38) of these patients died as a result of the error.

The policy document, *Towards Safer Radiotherapy* (Donaldson 2007), provides error rates for the UK alone. It is estimated in the document that in the UK in the period May 2000 to August 2006, 181 incidents were reported, adversely affecting 338 patients. It has been estimated from this that incidents occur in 40 out of 100,000 treatment courses, giving an error rate of 0.04% (Donaldson 2007). Furthermore, out of these 40 errors it is estimated that 24 patients would suffer clinically adverse consequences (Donaldson 2007). Yet, these error rates are subject to the 'tip of the iceberg' effect, as recognised in healthcare as a whole, and may be higher.

2.3.3 Reporting of errors

> *"to err is human. To cover up is unforgiveable. To fail to learn is inexcusable"*
> (Donaldson 2004)

The above quotation is from the Chief Medical Officer of the Department of Health in 2004. As the above quote states, an additional way to help prevent errors is learning from previous errors. In order to learn from errors they must be reported alongside the circumstances surrounding the error, to increase understanding of where the weak defences in healthcare lie. Prior to 2000 there had been little systematic learning from previous errors in the NHS, partly due to the unsystematic method of recording errors (Vincent 2010). With the formation of the National Reporting and Learning System (NRLS), organisations in the UK were encouraged to report errors and near misses by uploading incident reports to the NRLS website, which were then categorised into error type and domain, and entered into a central database. Since its inception in 2003 until 2014 the

database has had over 4 million incident reports entered (National Patient Safety Agency 2014), illustrating more of a commitment to reporting and learning across the NHS.

However, it is widely recognised that reports of incidents suffer the 'tip of the iceberg effect', whereby in addition to the reported errors there are many more errors occurring and not being reported for reasons such as: fear of punishment, patient is unharmed or lack of awareness over what constitutes an error (Vincent 2010). Leape *et al.* (1991) states fear of punishment decreases reporting of errors. Consequently, Leape *et al.* (1991) found, from a large scale review of adverse events in the USA, that reporting rates increased if staff are offered immunity from punishment. Furthermore, analysis of incident reports detailing medication errors in a paediatric hospital in Glasgow submitted over a five year period between 1994 to 1999, showed the reporting rates increased when the form was changed to be less punitive and instead encouraged reflection from the healthcare worker involved in the error (Ross, Wallace and Paton 2000). From both studies, it may be concluded that if the culture surrounding reporting is altered to be less punitive, but more fair and open, reporting rates increase.

Prior to 2000 there was no legal requirement to report radiotherapy errors in the UK, unless they were attributed to equipment failure (Donaldson 2007), although it was customary for departments to record and investigate incidents locally. This lack of central standardised reporting system has made it difficult to compare error rates prior to 2000. In May 2000 Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) came into force in the UK. Under these regulations departments are required to immediately investigate any incidents resulting in a patient being *"exposed to ionising radiation to an extent much greater than intended"* (The Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000/1059: 4)). Unless this investigation can show *"beyond reasonable doubt"* that overexposure did not occur, departments must notify the appropriate authority and arrange for a detailed investigation into the circumstances surrounding the incident (The Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000/1059: 4)). The regulations state that the term *"much greater than intended"* should be interpreted as more than 10% of the whole dose or 20% more than intended in any given fraction. However, there is no requirement to report under dosing which could have just as detrimental effects (Donaldson 2007).

A study conducted by the NPSA suggests that the radiotherapy profession is increasingly committed to error reporting. The NPSA conducted a questionnaire study in order to understand reporting of errors and near misses to the NRLS. The NPSA sent email questionnaires to 56 radiotherapy department managers in the UK. There was a good response rate of 84% which the NPSA note reflects the occupations' dedication to improving safety (NPSA 2009). It was found that 42 of the 47 responders submitted incident reports in their departments to the NRLS, yet only 33 of these reported all incidents they were aware of. The remaining nine departments, only submitted reports of errors which they deemed to pose significant risk, or if there was severe harm as a result of the incident. This lack of reporting represents a potential missed opportunity for other departments to learn from near misses or less severe errors. All survey responders reported that they facilitate communication about recent errors and attempt to share lessons from errors with all staff in their trust, usually during staff meetings. Yet, the results showed there was very little dissemination about errors between other trusts. In sum, the survey showed that whilst the majority of radiotherapy departments report incidents to the NPSA and are committed to improving local reporting and learning from errors, there is minimal sharing of lessons learned between departments. This potentially allows similar errors to be repeated at different sites. This is known as isomorphism, whereby an incident in one organisational setting may be repeated in a similar setting, due to similar patterns of behaviour, unless lessons are shared from the original incident and acted upon in all similar settings (Toft and Reynolds 2005).

A more recent analysis of incidents reported to the NRLS has shown that the number of radiotherapy incidents being reported has significantly increased in the years between 2010 and 2013, from just 294 annually reported incidents to over 1500 incidents in 2013 (Robson, Clark and White 2014). The majority of these errors were either minor or near misses, with only a few major incidents reported. Furthermore, an analysis of radiotherapy errors by the Health Protection Agency (2012) has shown that the number of major incidents has reduced and the number of minor errors increased between 2009 and 2012. This increased level of error reporting is indicative of a maturing safety culture among radiographers. However,

more work is needed to continue the reduction in errors by sharing knowledge on errors and understanding the factors contributing to error.

There is evidence that the reporting and monitoring of errors has continued to increase significantly in recent years. Following the disbanding of the HPA, Public Health England have published biannual reports on radiotherapy errors since 2010, with a view to analysing error trends and disseminating error knowledge to radiotherapy departments in a timely manner via quarterly newsletters (Public Health England 2014). This is in response to the recommendations made in *Towards Safer Radiotherapy*. Departments are encouraged to report all errors, including minor incidents and near misses, rather than just errors which are reportable according to the Ionising Radiation Regulations criteria. The most recent analysis published in November 2014 was of errors during the period December 2011 to November 2013. During this period 7655 radiotherapy error reports were submitted (Public Health England 2014). For the first time data was also collected on the number of treatment courses delivered in the same time period. This data estimated that in this two year period 413,730 treatment courses were delivered, giving a rate of reported incidents of 1.9%. The majority of these reported incidents, 68.4%, were near misses with no patient impact. Some 28.6% were minor incidents which did not have clinically significant impact, as errors could be rectified by altering the remainder of the patient's treatment prescription. Of the remaining 3% of incident reports, only 1.7% of errors were reportable under the Ionising Radiation Regulations. Whilst this data suggests clinically significant adverse effects are rare, if they do occur, they can have severe and potentially fatal effects due to the nature of the treatment. Therefore, the document warns that the radiotherapy profession cannot become complacent about errors.

When comparing the figures above with the preceding two year period, it was observed that the number of reported incidents had increased by 130% (Public Health England 2014). This was noted to not be due to an increased risk in radiotherapy, but increased reporting, as there were fewer high level errors and an increase in minor incidents and near misses. This is believed to reflect the radiotherapy community's increasing commitment to reporting and learning from error. Indeed, the latest radiotherapy safety newsletter, published in February 2015, indicates that 88.1% of radiotherapy departments in the UK are

now regularly submitting error reports (Public Health England 2015). However, there is still variance in the swiftness of submitting reports, with a mean of 51 days between incident and error report submission. This increasing reporting is believed to reflect a maturing safety culture with radiotherapy.

2.3.4 Types of error

As radiotherapy is a complex process, in order to fully understand what is causing errors and adverse events, there is a need to know which part of the treatment process errors are originating from. The *Radiotherapy Risk Profile* (WHO 2008), alongside calculating error rates, also attempted to map where worldwide errors were occurring during the patient pathway. Of the 3125 errors between 1976-2007 in middle to high income countries in USA, Europe and Asia, 55% were attributed to errors in the planning stage. The remaining 45% of errors occurred during the delivery stage. These arose due to: the introduction of new technology or equipment (25%), during treatment delivery (10%), during information transfer (9%), or in multiple stages (1%).

Furthermore, the WHO *Radiotherapy Risk Profile* (2008) identified near misses and the stage from which they originated by reviewing published and unpublished literature from Australia, Canada, USA, UK and other European countries. From 1992 to 2007, 4616 near misses were identified. These errors were detected prior to treatment and did not harm the patient. The errors were due to planning (9%), incorrect transfer of info (38%) or arose during treatment delivery (18%). The remainder could not be attributed to one stage or were the result of errors at various stages.

From this analysis of errors it can be seen that many errors occur during the planning stage. The most recent available data available on UK errors, published by Public Health England as detailed in section 2.3.2, also suggests many errors occur during the planning stage. Of the 128 serious and clinically significant errors, 21.1% and 12.5% could be attributed to errors during pre-treatment imaging and planning respectively. However, 43% occurred during the delivery of treatment. When considering the reported near misses, it was found that the majority, 85.1%, were due to errors arising during the data entry phase.

At the planning stage radiographers are not involved and an understanding of these type of errors would require an understanding of diagnosis, decisions to treat and the complex physics calculations used to determine treatment plans. This is beyond the scope of this thesis which is focussed on investigating and preventing errors at the point of treatment delivery. Errors which originate from mistakes in the planning stage cannot be detected once they have passed into the delivery stage, as when comparing the treatment that is about to be delivered against the source treatment plan, it would appear correct.

Aside from those errors originating in the planning stages, it can be seen that the transfer of information and data entry is a vulnerable step in the patient process. Errors during treatment delivery may also be the result of erroneous data transfer or entry. There are many opportunities for human error to occur, as treatment data is transferred many times, from initial planning to entry into the treatment delivery machine, as can be seen in the flow diagram of the radiotherapy treatment process presented in figure 2.1. As Leunens *et al*. (1992) noted when discussing quality assurance in radiotherapy, *"garbage in equals garbage out"*. Therefore, the transfer of data is a critical safety step and the thorough checking of parameters immediately prior to beam delivery is essential to detect any errors before they cause harm. However, inadequate checking of treatment parameters has also been highlighted in the *Radiotherapy Risk Profile* as a risk with a high potential impact on the patient (WHO 2008).

2.3.5 The final treatment check

As shown in figure 2.1, there are a number of stages to the radiotherapy treatment process. Due to this complex nature of radiotherapy treatment, and the need for transfer of information, treatment checks are built in to every stage of the process in order to detect errors and prevent their impact. These are referred to as end of process checks. The most recent analysis of radiotherapy errors, detailed in section 2.3.2, revealed that in 17.9% of the incidents reported, errors were not detected during these end of process checks (Public Health England 2014). This was consistent with the figures from the prior biannual report which gave a figure of 19.4%. The most frequent failure (25%) of these end of pre-process checks were during the treatment unit process, when the radiation treatment is delivered.

This suggests that these end of process treatment checks, especially those occurring at the point of treatment delivery, are a poor defence against error.

The most important end of process treatment check is the final check conducted at the point of treatment delivery, immediately prior to beam switch on. This is the last check before radiation is given to the patient. Hence, it is the last opportunities to detect an error which may have occurred earlier in the delivery stage and prevent erroneous treatment delivery (Donaldson 2007). The safety role of the final treatment check was highlighted by an analysis of the first 1074 incident reports sent to the Radiation Oncology Safety Information System (ROSIS[2]) between 2003 and 2008. This analysis revealed that the majority of errors (754) were detected at the time of the patient's treatment, reinforcing the safety barrier which radiographers supply when checking and confirming treatment parameters (Cunningham *et al.* 2010). Some 43% of these errors were detected by the radiographer whilst at the treatment machine. Therefore, treatment checks immediately prior to beam administration are a vital defence against errors. However, it is also the safety check which has been identified as not being a strong defence against error in the latest error analysis by Public Health England, as detailed above.

2.3.6 Technological developments and the final treatment check

Radiotherapy technology has become increasingly sophisticated since the early 1990s. The field has moved from relying on manually inputting treatment parameters for every treatment, to more automated computer-controlled delivery (Fraass 2008). This increase in reliance on technology may lead radiographers to believe that the final treatment checks are now somewhat redundant. Many departments use record and verify systems (RV). These systems negate the need for radiographers to manually enter treatment parameters for every dose, with the aim of preventing data entry errors (Donaldson 2007). As illustrated in the treatment process presented in figure 2.1, prescribed treatment parameters are entered into the RV systems prior to the patient arriving in the department for their first radiotherapy treatment. The RV system wirelessly sends the patient's treatment data to the

[2] ROSIS is a voluntary reporting system for errors and near misses in Europe established in 2001 under the professional body "European Society of Therapeutic Radiology and Oncology" (ESTRO). It is not disbanded.

linear accelerator machines, which deliver the radiation, and verifies that the dose about to be delivered matches that which was originally entered into the system.

Comparative studies of pre and post implementation have shown that the introduction of RV systems have reduced errors in treatment delivery significantly (Fraass *et al*. 1998), and significantly increased efficacy in the radiotherapy department, reducing treatment time (Klein *et al.* 1998). However, these technological advances do not make the final manual treatment check redundant. It has been noted by Fraass (2008) that whilst technology has improved the treatment process it cannot replace human input. This is because technology may fail, data may have been incorrectly entered in the first instance, and RV systems do not prevent radiographers from opening up the incorrect patient file. Furthermore, not all departments have wireless networks to transfer data to the linear accelerator machines and may still rely on manual data entry immediately prior to treatment delivery (Baiotto *et al.* 2009). Therefore, Fraass (2008:4) warns that departments must ensure that *"human review quality assurance is not lost to automation".*

RV systems, whilst improving safety and efficiency by ensuring the same treatment parameters are set up for every treatment, may also introduce a different risk into the process. A warning is given in *Towards Safer Radiotherapy* that the implementation of guidelines for checking and confirmation of parameters prior to beam delivery is challenging, as radiographers believe the automatic system to be correct and hence the checks unnecessary (Donaldson 2007). However, a study which retrospectively analysed all treatments delivered for 1925 consecutive patients in the USA, found that 15% of treatment errors could be attributed to RV systems (Macklis, Meier and Weinhous 1998). Of the treatments involved in the analysis, there were 59 errors identified. The authors noted that many more errors had been prevented due to RV systems detecting an error prior to treatment delivery. Yet, nine of the errors were found to be directly related to the use of RV systems. In these incidents, it was found that patient's treatment parameters had been incorrectly entered into the RV system in the first instance, usually with a transposition of similar digits, which went undetected during the final treatment check. Hence, RV systems do not make treatment delivery infallible, as the systems are susceptible to human error. Therefore, the final treatment check, conducted by radiographers, must be robust.

Another study at a hospital in Utah, also suggested that RV systems do not make treatment delivery error proof and may play a contributory role in error. A retrospective analysis of 38 error reports from a one year period in one department was conducted. It was found that 23% of errors in this year were related to over-reliance on the RV software (Patton, Gaffney and Moeller 2003). It was suggested by the authors that these errors could have been prevented if radiographers had maintained vigilance during the final treatment check.

The risk of incorrectly entered parameters entered into RV systems has also been reported in Italy. Baiotto *et al. (*2009) reported the results of a study comparing source date with data entered in a RV system in one department. The source data was compared with the values which had been entered into the RV system. The checks were conducted weekly by the researcher for all treatments given to 7768 patients from 2000 to 2006. Discrepancies were found in 452 patient treatments. That means that for 5.8% of patients, treatment parameters had been entered incorrectly into the RV system and would have resulted in erroneous treatment delivery, if it was not for the manual check of treatment values. Therefore, whilst RV systems play a crucial role in ensuring accurate and correct treatment is delivered, radiographers should not rely on the RV system to be correct, but retain vigilance during the manual final treatment check.

Similar results have been found in the UK as well. Cunningham *et al.* (2010) reaffirmed the need for radiographers to remain vigilant as errors in treatment parameters were observed despite the presence of the RV system. Cunningham *et al.* (2010) conducted a review of the first 1074 incidents reported to ROSIS between 2003 and 2005. Some 50% of these incidents resulted in erroneous treatment delivery. Of these errors, only 258 were detected prior to the treatment delivery stage. Hence, the study by Cunningham *et al.* (2010) reinforces the notion that the final treatment check is the most important line of defence against error, as the majority of errors, 43%, were "*found at time of patient treatment"* (Cunningham *et al.* 2010:603).

All studies conducted to date which have analysed discrepancies between source data and RV data have had narrow samples of only one hospital. Yet, the similar occurrence of this

error suggests it is a universal problem. It is therefore suggested that RV systems do not remove the risk of error altogether but alter the type of potential errors; from random transcription errors when entering treatment parameters, to systematic errors resulting from overreliance on the technology. Furthermore, excessive confidence in RV systems could lead to patients receiving repeated erroneous treatment on consecutive days, if the error in input to RV systems continues to go undetected throughout treatment. Therefore, in order to minimise this radiographers must be supported to maintain attention and remain vigilant during the final treatment check immediately prior to treatment delivery, as it is argued that, this is a vital error defence, regardless of whether or not a RV system is used.

2.3.7 Beam modification errors

Beam modification accessories have been identified as a particularly vulnerable aspect of treatment. Beam modifications, such as a wedge or a bolus, are used to manipulate and target the amount of radiation reaching the body, and are planned as part of the patient's prescription (Donaldson 2007). The incident in Leeds, presented in section 2.3.1 was due to the incorrectly entered parameter of a patient's prescription, the status of a wedge, into the RV system. In this case it was prescribed to be in place, shown as IN on the prescription, but it was programmed as OUT. This went undetected for 14 fractions.

Wedge, and other beam modification mistakes, account for a large proportion of errors and hence demand a thorough check (Calandrino *et al*. 1997). Yeung *et al.* (2005) found that there were 252 incidents during patient set-up over a ten year period in just one cancer centre in Canada. However, the paper does not report the total number of treatments delivered in this period. The majority of these errors were beam shielding errors (48%) and three errors were related to wedge positioning.

In the past decade, in addition to the incident reported by Toft (2005), there has been another high profile error associated with beam accessories. In Brooklyn (USA) in 2007, a radiographer had mistakenly programmed the linear accelerator to wedge out instead of wedge in. Consequently the wedge was not there to modify the beam and the patient received a significant overdose which burnt a fatal hole in her chest (Bogdanich 2010).

These incidents and analysis of incidents suggest that not only is the final treatment check vital to ensure safety, but that the confirmation of the wedge status is especially vulnerable to error.

2.4 Chapter summary

This chapter has provided a brief overview and introduction to the field of patient safety, which is a relatively new but rapidly growing field, which aims to understand the causes of errors in healthcare, and methods to prevent them. This review has shown that errors in radiotherapy, whilst occurring in relatively small numbers compared to other areas of healthcare, have high impact with potentially devastating patient consequences. None of the Never Events currently published by NHS England and detailed in section 2.2.1 recognise patient safety incidents within the radiotherapy domain. Yet, an error resulting from a miss-programmed wedge or dose meet the criteria for a Never Event, as it is preventable, the error is known about and the error can result in major harm or death. Despite the potential severity of patient harm resulting from error, the quality and scope of patient safety research within radiotherapy, especially in regards to treatment checking, is limited. Yet, there does appear to be a maturing safety culture within radiotherapy.

The review has demonstrated that errors can occur at many stages of the radiotherapy treatment process, but that data transfer is a particularly vulnerable stage of the treatment process. It is not clear the number of errors occurring in radiotherapy, but what is clear, is that the final treatment check of parameters immediately prior to beam switch on, is the final opportunity to detect an error and prevent patient harm. Whilst technology, such as record and verify systems, have been introduced to address some of the risk, these do not entirely eliminate the risk. Therefore, this thesis will explore the role of the final treatment check.

The next chapter will explore this final treatment check in more detail, and through application of theoretical error models, begin to build an understanding of why this check may fail to detect treatment errors.

3 Chapter 3: Applying error theory to the final treatment check

In this chapter theories of error propagation will be applied to the final treatment check immediately prior to treatment delivery, in order to help understand the factors influencing the effectiveness of the final treatment check to detect errors. As discussed in section 2.3.5, the final treatment check immediately prior to treatment delivery is the last opportunity to ensure that the radiation the patient is about to receive corresponds exactly with the patient's prescription. This check is carried out immediately prior to treatment delivery whilst the patient is positioned on the treatment couch, by two radiographers working together (Donaldson 2007). If errors go undetected at this stage, it may result in a patient receiving a potentially fatal overdose of radiation. As the final defence against error in this domain is a human defence, efforts must be made to consider how the human interacts with the wider system. Reason's theory of human error will be presented, before applying it to the final treatment check in radiotherapy.

3.1 Human error theory

3.1.1 Human factors and defence against error

As the final defence against error in this domain is a human defence, efforts must be made to consider and optimise how the human interacts with the wider system, therefore a human factors approach to error is valuable. When systems and processes are evaluated with a consideration of human factors, potential human errors can be pro-actively designed out of the process or system (Vincent 2010). Human factors applies psychological and ergonomics theory, principles and methods to the design of technology, devices or systems. This approach is increasingly being adopted to improve healthcare safety.

The clinical human factors group was set up 2007 in the UK by Martin Bromiley in response to losing his wife to an avoidable error during routine surgery. The aim of the independent campaign group is to embed the study and application of human factors within healthcare, and increase the understanding of the role that human factors play in the safety, quality and efficiency of healthcare. Their manifesto published in December 2012 notes three areas in which the increased application of human factors, aside from the design of improved systems, technology or devices, can significantly improve patient safety: human factors

education and training for health professionals and healthcare managers, building high reliability organisations and mandatory independent investigation of errors (Clinical Human Factors Group 2012).

Awareness of human factors within radiotherapy appears to be growing, evidenced by published investigations of errors and the publication of *Towards Safer Radiotherapy* and other papers exploring reasons underlying radiotherapy errors, for instance, Portaluri *et al.* (2010), Akroyd, Caison and Adams (2002) and French (2004). These are discussed in more detail in section 3.2.1. However, radiotherapy appears to lag behind other healthcare domains and it has been recognised that the application of a more thorough human factors approach to radiotherapy delivery could improve safety (Chan *et al.* 2010). Therefore, in order to understand how the final treatment check may be improved it is important to consider the role of the person within the wider system.

3.1.2 Systems and person-centred approach to errors

There are two main approaches to error in the literature and in practice. Reason (2000) makes the distinction between a systems approach to understanding error and a person-centred approach. The person-centred approach implies that errors are the 'fault' of an individual, without considering the impact of the systems in place or other contributory factors to error, such as the environment. Therefore, a person centred approach to error implies that it is healthcare staff at the 'sharp end' of healthcare who are responsible for any unsafe acts or errors. A consequence of this approach is that organisations which blame an individual, rather than assessing the situations surrounding an error, forfeit the opportunity to learn from the error and potentially prevent future similar errors. Furthermore, this approach to error leads to potentially unfair blaming of staff with no organisational responsibility taken for an error.

A systems approach recognises that humans are prone to error and that errors are triggered by faults in the system. Errors may be trigged by, for instance: the organisational culture, process of working, work design or workplace design. The systems approach allows a proactive response to safety, in which the system is analysed, errors anticipated and the design of the system then altered to prevent errors.

3.1.3 'Swiss cheese model'

Reason's (2000) accident causation model uses the analogy of Swiss cheese to illustrate this system approach to error. This is probably the most widely cited model in patient safety, and therefore is used here to analyse radiotherapy errors. This model, presented in figure 3.1, describes error formation; how active failures, latent failures and human error combine to cause an error.

Figure 3.1: Reason's (2000) Swiss Cheese model of accident causation

The model illustrates that hazards are ever present, yet there are many defences built into a system to prevent errors occurring. Reason likened the layers of defence to Swiss cheese. Each slice of cheese represents a defence, which should, in an ideal world, be impenetrable by a hazard.

These defences may be embedded in technology, for instance alarms or forcing functions in computer systems. Conversely, defences may rely on input from humans, for instance in checking or following established procedures. Yet, if defences are weak, illustrated by a hole in the cheese, errors may occur. If a hazard escapes detection at one defence, or slice of cheese, it can still be picked up, and thereby an error prevented, at the next layer of defence. Yet, if the holes in the defences align, an accident trajectory is created.

When this model is applied to radiotherapy, it can been seen that each end of process check acts as a layer of Swiss cheese, or a defence against error. The final treatment check prior to beam switch on acts as the final slice of cheese, the final defence against error. If errors have passed undetected during the earlier lines of defence in the system, they must be detected at the final treatment check to avoid an error occurring. Therefore, in order to improve the safety of treatment checks, either the final check, or previous defences must be strengthened. It has already been recognised, based on analysis of error rates, as discussed in section 2.3.5, that the final treatment check is a weak error defence. The factors underlying this weakness need to be understood in order to strengthen the defence.

3.1.4 Active and latent factors

The 'holes' in the layers of defence, illustrated in Reason's 'Swiss cheese model', could be due to either active or latent conditions, which are fluid yet ever present in the system. The distinction between the two is discussed below.

Latent factors are often factors which have lain dormant within a system for a length of time until, when combined with an active failure, can contribute to error. Latent conditions create situations which can easily provoke an error, for instance, short staffing leading to fatigue in staff, or medical wards designed with no quiet environment for staff to check patient medication. Latent conditions can also be managerial decisions which weaken defences in the system, for instance deciding to forgo daily quality assurance tests on equipment or muting safety alarms on wards. These latent conditions are more easily identifiable than active conditions as they are always present, observable and predictable. Therefore, a proactive approach, rather than reactive, to safety could theoretically be taken to identify and remove, or design out, these potentially error inducing latent conditions prior to an error occurring. Conversely, a reactive approach to patient safety may involve conducting an error analysis, subsequent to an error to identify these latent conditions. However, these latent conditions are often embedded into the healthcare organisation and may require culture change to alter perceptions to remove (Vincent 2010). Some previous research into radiotherapy has identified potential latent factors believed to contribute to error, such as: lack of training, staffing levels and working environment (Donaldson 2007). These are discussed in more detail in section 3.2.1.

In comparison to latent conditions, an active failure can be referred to as the 'unsafe acts' of individuals, which lead to an action not being carried out as intended (Reason 2000). These are less predictable and influenced by individual factors.

3.1.5 Types of active failures

The final defence against error in radiotherapy is a human defence; two radiographers conducting a check of treatment details to confirm they are correct. As humans are fallible they must be supported to be a strong final defence, or earlier defences built stronger to compensate. Due to the frequency of a defence against error requiring human input in many safety critical industries, human error is often reported as the cause of an accident. Yet, an understanding of the term reveals that simple human error is a vague description. Reason (2000), one of the popular theorists of human error, suggests that errors can be differentiated as faults in either memory, perception or attention. Reason (2000) has also presented categorisation of types and levels of human error. It is recognised that there are other theories of human error, such as Norman's slips and lapses (1988) and Rasmussen's skill-based, rule-based and knowledge-based errors (1983). Whilst both of these error theories consider the setting in which the error occurred, both are considered too vague to fully explain error in complex domains. Norman's hybrid classification does not fully expand upon the cognitive processing underlying error. Whereas, Rasmussen's SRK model does not differentiate the underlying levels of complexity underlying cognitive processing. Reason's theory of error is considered more comprehensive as it combines and builds upon both of these theories, in order to explain errors occurring in highly complex environments. As such this error model is discussed in reference to radiotherapy errors.

Reason (2000) has defined slips and lapses, the lowest level of error, as failures of action. Slips are a skill-based failure and can be described as failing to complete an action as intended and is often due to attention failing. Lapses however, result in the same phenotype of error, a skill-based failure, but are due to memory lapsing. Both slips and lapses most frequently occur during regularly repeated actions which are prone to automatic performance, and the cause of the memory or attention lapse can usually be assigned to a distraction.

Unlike errors occurring from a skill-based failure, Reason defined mistakes as a failure in knowledge. Mistakes are a higher level error than a slip or a lapse, where an action has gone the way it was intended but the planning for the action was incorrect. Mistakes can be either rule-based or knowledge-based. A rule-based mistake occurs when the wrong rule has been applied to an action, for instance treating a patient for a heart attack when they are suffering an anxiety attack. A knowledge based mistake occurs commonly during a novel situation when there is no knowledge of how to plan an action correctly, for instance, a patient has symptoms the doctor is not familiar with and is therefore treated for the incorrect condition.

Another high level error is a violation, which is an intentional deviation from known rules or procedures. An important distinction is that unlike slips, lapses and mistakes, violations are intentional rather than unconscious errors. Violations do not necessarily mean the person was intending to do harm, they may have been forced to commit a violation by the latent conditions in a system. For instance, if a nurse was forced to cut corners when checking a patient's medication records due to time pressure resulting from staff shortages.

The combination of how latent failures, active failures and human error can combine is presented in figure 3.2, which is an expanded illustration of the Swiss cheese model adapted from (Reason 1997) and summarises the information presented in the previous sections.

Figure 3.2: Accident causation model adapted from Reason (1997)

Reason's error model is applicable to all high risk industries, which have complex systems requiring human input. Vincent, Taylor- Adams and Stanhope (1998) expanded upon Reason's model by adapting it to healthcare. Table 3.1 presents a list of error and violation producing conditions in healthcare delivery which have been categorised into factor types. The authors note this framework provides a conceptual basis for guiding the understanding of all possible contributory factors for errors when investigating and analysing incidents. These provide a useful framework for investigating errors during the final treatment check in radiotherapy. This is because each factor can be analysed in more detail to determine if that factor has an impact upon the final treatment check. This allows research to be focussed on the most relevant factors.

Table 3.1: Contributory factors effecting safe healthcare (Vincent *et al*. 1998)

3.2 Applying error theory to radiotherapy

The models detailed above are useful to apply within the context of radiotherapy delivery in order to understand how the final treatment check could be strengthened to help increase the likelihood of error detection. As there is limited existing literature on the final treatment check, literature was sought surrounding errors in radiotherapy generally. This is because the latent and error producing conditions would be applicable to all errors in this healthcare domain.

A search of the existing literature on errors in radiotherapy was conducted using the databases EBSCO, Science Direct and SCOPUS, and combinations of the search terms

'radiotherapy' 'safety', 'error' and 'human factors', alongside published reports such as *Radiotherapy Risk Profile* and *Towards Safer Radiotherapy*. In order to identify key human factors issues and build an understanding of error in radiotherapy, the results of this search were classified into latent failures, error and violation producing conditions, and active failures, as in figure 3.2. These are discussed below.

3.2.1 Latent factors

Towards Safer Radiotherapy (Donaldson 2007) identified a number of latent factors, present in radiotherapy departments and believed to contribute to radiotherapy incidents:

- Lack of training, competence and experience. This includes a lack of specific local training when staff move between departments which is pertinent considering the range of equipment and local protocols in use
- Poor design and documentation of procedures
- Overreliance on automated systems. This can impair staff expertise if the automated systems negate the need to exercise their skills
- Hierarchical departmental structure and culture. These can prevent junior staff from speaking out about failure to comply with protocols
- Staffing and skills level
- Changes to process. Changes to processes must be monitored as any change may make old processes redundant. If this is the case, continuing with redundant processes will divert resources away from safety critical steps with potential risky effects

3.2.1.1 Culture

Culture is often cited as a major factor contributing to quality and safe delivery of healthcare. For instance, it is quoted as a major contributory factor in the failings at Mid Staffordshire NHS Foundation Trust (Francis 2010). It is a widely held belief that culture change combined with structural and procedural change in the NHS will lead to improved and safer healthcare (Vincent 2010). Yet, it is argued that the link between culture and healthcare improvement lacks explicit evidence, as culture is hard to define and there are many sub-cultures with local barriers preventing widespread culture change. Scott *et al.* (2003) therefore argue that universal culture transformation within the NHS would be a challenging, complex and uncertain endeavour. Therefore, they argue that it is perhaps best

to focus on improvement in individual NHS departments or professions, rather than the entire NHS, such is the approach taken in this thesis.

A subset of culture is an organisation's safety culture, or safety climate. Safety climate refers to the way staff in an organisation think about patient safety, and how safety is implemented through processes in the organisation (Vincent 2010). This can be measured in various ways using numerous evaluated tools, such as the Safety Attitudes Questionnaire and Safety Climate Survey (The Health Foundation 2011). Within radiotherapy, little work has been focussed on safety culture, or safety climate, despite the large influence culture is known to have on safety. Yet, the increased reporting of errors as detailed in section 2.3.3, may well represent an increasing safety culture within radiotherapy.

Another measure of safety culture can be adherence to, or compliance with, safety protocols. Simons *et al*. (2010) found, by video-taping two teams of radiographers in one department in the Netherlands for 56 treatment deliveries, that compliance with safety guidelines in radiotherapy was not consistent. Across 18 safety processes such as observing patients during treatment and verbally confirming patient ID, compliance to guidelines ranged from 2% to 100% with an average of 59% compliance. They concluded that compliance was higher if guidelines were detailed and accompanied by an explanation as to why they should be used. This research did not include compliance rates with double checking treatment details, yet suggests research must measure adherence alongside staff understanding of the safety reasons behind checking protocols to increase adherence. However, the methodology of this study can be considered weak as there was a small sample size of treatments observed with the sample drawn from a narrow population of one department.

The paucity of safety culture research within radiotherapy, especially surrounding treatment checking, represents the need for an increased focus on patient safety and treatment checking within radiotherapy. This research adds to this by creating the building blocks of a robust environment to support safety in one specific area of radiotherapy treatment delivery. Yet, there is a need to move beyond a tick box approach and have all the systems

in place to manage identified risks. Only then can radiographers be more actively involved in safety and alert to all possible errors.

3.2.2 Error producing conditions

The literature revealed a number of factors, present in the environment or radiographer's work design, which are believed to contribute to the risk of error.

3.2.2.1 Fatigue

Towards Safer Radiotherapy identified the risk of fatigue and stress in radiographers. This was recognised as especially relevant when data checking, hence it was recommended that staff take regular breaks during this task and regularly alternate tasks (Donaldson 2007). One of the few empirical studies investigating radiotherapy patient safety provides support to many of the factors identified in *Towards Safer Radiotherapy*. Portaluri *et al.* (2010) conducted a human factors analysis of incidents over a five year period in a radiotherapy department in Italy. It was found that there were recurrent factors underlying the majority of incidents: attention failures, distracted/overconfident behaviour, loss of situational awareness and mental fatigue. Consequently, the authors recognised the need to alter departmental protocols in order to improve attention and reduce fatigue. The department therefore implemented a protocol to ensure radiographers alternated job roles during a shift, to prevent long periods of sustained attention on one task. However, this has not become a required standard worldwide in the profession, suggesting more work is needed to implement findings from research.

There has been more empirical support to the notion that radiographers can easily be affected by work fatigue. Akroyd, Caison and Adams (2002) found, in a study of radiographers in the USA that they are often multi-tasking during their duties due to supervision and training of new staff and students. Additionally, the authors found that radiographers are under pressure to work quickly, which, when combined with the emotional demands of working with cancer patients, leads to a high level of burnout amongst radiographers (Akroyd, Caison and Adams 2002). Hence, the radiographer's job can be demanding and stressful, however, this study was conducted in the USA, and the results may not be generalisable to this country.

A qualitative investigation of stressors and coping mechanisms in qualified radiographers (n=8) of varying grades working in one NHS trust in East Anglia in the UK was undertaken (French 2004). Analysis of the interviews found that there are several categories of stressor reported by radiographers: personal performance, patient contact, working environment (including pressure due to machine breakdowns), communication, management, professional behaviour and departmental working. The most frequently cited coping mechanisms were social support and escape-avoidance. This paper also claims to have uncovered a new stressor amongst radiographers, the *'potential to make errors'* (French 2004:13). Radiographers were very aware that the treatment had potential for harm and that despite there being processes in place, errors could still occur (French 2004). Therefore, it is believed that radiographers will benefit from any process which can reassure them that their work is being made safer. However, it is recognised that this study had a small sample size and was conducted at one site only, and therefore results may not be generalisable to all radiographers nationwide.

3.2.2.2 Time pressure

The time pressure to deliver treatments has been recognised in the literature. An audit of practice in 32 departments in the UK in 2004 found that 75% of departments allocated only ten minutes to treat each patient, with the remaining departments allocating a maximum of 15 minutes per patient. Departments treated on average 40 patients per day with some departments treating over 50 patients on an average of three linear accelerator machines (Stratford *et al*. 2006). In reference to the earlier process diagram in figure 2.1, this means radiographers have 10 minutes to collect the patient, align them correctly on the treatment couch, verify the treatment parameters and deliver the radiation. Some patients may have more than one treatment field which means the alignment and final treatment check must happen multiple times. Hence, radiographers may be under pressure to conduct the final treatment checks quickly.

3.2.2.3 Equipment design

Chan *et al*. (2012) conducted a work flow analysis of the interface on the linear accelerator used by radiographers to deliver radiotherapy. The research suggested the interface design is not optimal to support human performance in this task. A re-designed interface with more consideration of human factors was demonstrated to support users and prevented

errors from occurring, as well as being more time effective. More detail on this study will be presented in chapter 10 which considers the role of the interface design.

3.2.3 Active failures

These factors have not been as represented in the existing literature, which is more focused on the radiotherapy system and environment, rather than the radiographers working within the system. The investigation by Toft into the wedge error in Leeds, detailed in section 2.3.1., suggested that errors may be due to failures in radiographer's attention. During the investigation into the error it was found that it was only on the 15th day of treatment, when the patient was treated on another linear accelerator machine in a much quieter location that the error was detected (Toft 2005). Toft and Mascie-Taylor (2005) believed this error to be due to a phenomenon called involuntary automaticity (IA). IA occurs when a regularly repeated action becomes second-nature and as such is conducted without attention (Toft and Mascie-Taylor 2005). If IA occurs during checking, errors can pass undetected. As the process of the final treatment checks, comparing the linear accelerator screen to the prescription, are identical on every occasion, they may quickly become vulnerable to IA. Toft and Mascie-Taylor (2005) also note that IA is more likely to occur during pressurised situations and in a noisy environment.

3.3 Chapter summary

The final treatment check immediately prior to beam delivery is the final defence, in Reason's error model, against errors which may have occurred earlier in the treatment process. This final treatment check conducted by two radiographers, of four parameters relating to patient's dose, is vulnerable to error, as humans are fallible.

In order to reduce risk either the prior layers of defence need to be strengthened, or the human needs to be supported to conduct a robust final treatment check. To do this a thorough understanding of the active and latent factors present in the very specific system of study is needed. This review has demonstrated limited previous research into the latent factors and error producing conditions in radiotherapy treatment checking. Additionally, there is little empirical research in this area with the majority of literature consisting of qualitative research or retrospective reviews. This indicates a need for research into the conditions surrounding treatment error in radiotherapy.

This review has indicated even less existing research on the potential active failures surrounding the final treatment check. Therefore, the following chapter will explore the final treatment checking task in more detail, in order to understand how active failures may influence the effectiveness of the final check at detecting errors. Due to the paucity of research around treatment checking in radiotherapy, the chapter will review and discuss existing literature surrounding double checking within healthcare and factors potentially underlying double checking failures. Literature from other industries will also be drawn upon to explore how checking may be improved in the radiotherapy context.

4 Chapter 4 – Checking failures

The previous chapter identified latent conditions potentially contributing to ineffective final treatment checks and concluded that further research is required to understand the active failures surrounding why the final check may fail to detect errors it is designed to trap. The final treatment check is the final defence against error (Reason 2000). Therefore, this chapter will focus on the checking task in order to understand how it could be improved to aid error detection.

The final treatment check should be conducted by two radiographers as a double check, according to radiotherapy guidelines (Donaldson 2007). Therefore, this chapter will review the existing literature surrounding double checking. Double checking is frequently used throughout healthcare with the aim of catching errors before they cause harm to a patient. Double checking is defined as check completed by two people independently, both of whom have equal responsibility to ensure that details are correct. Conversely, single checking is conducted by just one person. Checking sometimes involves checking of calculations used to arrive at a dose. Radiotherapy, at the point of the final treatment check prior to treatment delivery, does not require calculations, but simple confirmation that the treatment parameters on screen correspond exactly with those on the patient's paper prescription (Donaldson 2007). Due to the paucity of research on checking within radiotherapy, double checking research across other areas of healthcare will also be considered, in addition to literature from other safety critical industries.

The chapter will also consider the importance and role of other patient safety concepts, such as standardisation, implementation and sustainability of safety initiatives.

4.1 Existing checking recommendations

There are currently no standardised published guidelines on how to conduct the final treatment checks in radiotherapy. This is despite the Royal College of Radiographers stating that they are *"seeking to improve checking procedures"* following the death of Lisa Norris (Royal College of Radiologists 2006:1). Furthermore, the Department of Health issued an alert to all radiotherapy departments on 19th November 2004 following the Toft (2005)

report into an incident, to inform sites to review their procedures for checking of the wedge position. This alert stated that departments must ensure that their checking procedure immediately prior to beam delivery elicits an active response, in order to combat involuntary automaticity, whilst also ensuring there is *"a suitable work environment*" and that "*staff should be allowed to work uninterrupted when checking*". However, there is little precise detail provided on how to check, and no evidence of departments' adherence to this alert.

The final treatment check immediately prior to beam delivery was recognised as a risk in the *Radiotherapy Risk Profile* and the solution provided to prevent errors passing undetected was the use of independent checking of treatment parameters (WHO 2008). However, once again, there is no description of how to do this provided. The document *Towards Safer Radiotherapy* goes into more detail on checking and advises on the need for detailed protocols stating:

> *"The fine details of checks and verification procedures and how they are performed are critical in ensuring they are effective and have the greatest chance of detecting an error"* (Donaldson 2007:6).

The document states which parameters must be checked prior to switch on:

> *"Prior to turning on key parameters of monitor units, beam energy and beam modifications should be verified by both staff using source documentation and active verification".* (Donaldson: 44).

The document states that active verification must elicit verbal input from both staff and be conducted in a quiet distraction free environment. The guide also recognises the need for detailed protocols which make staff responsibilities and accountability clear:

> *"Procedures to verify data should be active, eliciting a specific detailed response rather than a passive reaction in which case the answer "yes" might suffice….Active procedures can help to overcome the problem of involuntary automaticity, where one perceives what one is expecting rather than what is actually present"* (Donaldson:35)

The document *Towards Safer Radiotherapy* also states that data checking is a tiring task requiring immense concentration that can quickly result in fatigue. Hence, it is recommended that staff involved in these tasks take frequent breaks and alternate checking with other tasks. It is also recognised that double checking is resource intensive yet *"is a*

minimum standard to avoid errors from Involuntary Automaticity" (Donaldson 2007: 39). However, involuntary automaticity (IA) is equally as likely to happen between two people. Therefore, despite recognition of the need for precise details in checking protocols no guidance is given on how to verify the treatment parameters aside from ensuring there is an active response from each checker rather than just agreement. However, technological advances, such as the record and verify system, have made the final treatment check increasingly passive, because radiographers are no longer required to manually input treatment parameters prior to beam switch on, and rely on the RV system to be infallible, as discussed in section 2.3.6. As such, a new, evidence-based method of conducting this final check is required.

4.2 Single or double checking debate

In order to understand how the final check could be improved, the literature on checking was considered. Shillito, Arfanis and Smith (2010) conducted a literature review into double checking in healthcare with the aim of increasing understanding of the role of double checking in healthcare safety. The review confirmed that double checking is used extensively in healthcare. Double checks are conducted at multiple points in a patient's journey through the healthcare system, from background checks on equipment and procedures through to identity checks and pre-procedure checks. Some of these double checks will have standardised practice guidelines for performing the checks, whereas others are less officially enforced. Shillito, Arfanis and Smith (2010) suggest double checking is under studied due to its apparent and presumed simplicity and suggest a number of research directions to improve the practice of double checking. Of particular note was the need to find methods to overcome involuntary automaticity when checking and the need for empirical research comparing the effectiveness of single and double checking in order to provide evidence-based practice recommendations. As there is controversy in the literature as to whether single or double checking is more effective in healthcare settings, there is currently no concrete evidence base to support the implementation of either checking policy in radiotherapy.

Through a post hoc review of intravenous drug administration errors in anaesthesia from 1978 to 2002, Jensen *et al*. (2004) concluded that if a two person double check of the

medicine prior to administration had been conducted, 58% of the errors could have been prevented. However, this conclusion was based on post-hoc consideration and judgment by experts, rather than an experimental study and hence could be argued to be opinion rather than fact based. Nonetheless, the authors concluded that the double checking of drugs prior to administration is the most effective measure to prevent erroneous intravenous medicine administration in anaesthesia (Jensen *et al.* 2004).

Another retrospective study demonstrated double checking to be effective at reducing medication errors in pharmacy. A retrospective document review of medication errors over a five year period between 1994 and 1999 was conducted at the Royal Hospital for Sick Children in Glasgow, one of the largest paediatric teaching hospitals in the UK. It was found that 195 errors were reported during this period. The authors calculated this equated to one error per 662 patient admissions, or one error per 1976 patient bed days. Pharmacy errors accounted for 20% of all errors. Midway through the period in focus the pharmacy checking policy was changed; from 1996 it was policy to double check all drugs prior to dispensing. The authors found that this reduced error rates in pharmacy dispensing from 9.8 per year to six per year. However, from analysing error reports it was found that 67% of the pharmacy errors over the five year period occurred despite two people double checking (Ross, Wallace and Paton 2000). Therefore, this suggests that double checking can prevent some, but not all, medication errors.

It has been suggested that double checking does not prevent all errors and there is doubt surrounding the effectiveness of double checking over single checking. For blood transfusions it is accepted as best practice that blood products be double checked immediately before transfusion, yet, it has been acknowledged that more research is needed to confirm the effectiveness of double checking over single checking (Bradbury and Cruickshank 2000). One reason for this doubt over the efficacy of double checking is that it may lead to a diffusion of responsibility whereby each checker relies on the other checker to apply their full attention. As Linden and Kaplan (1994) note,

> *"not only does the passive check have significant potential for distraction, multiple responsibility itself does not necessarily enhance human performance. Unless carefully configured to prevent it, in a system in which two people are responsible for the same task, neither person is truly responsible"* (Linden and Kaplan 1994:175)

Therefore, a recommendation was made by the British Committee for Standards in Haematology in 1999 stating that it is more effective for a single registered nurse or doctor to conduct the check prior to transfusion. However, very few hospitals have implemented a one-person check policy, perhaps due to a lack of supporting evidence (Watson *et al*. 2008). Consequently, Watson *et al.* (2008) undertook a systematic review of the literature surrounding blood transfusion checking and found that no randomised controlled trial has been conducted to support either single or double checking in either blood transfusions, or any other healthcare field (Watson *et al.* 2008).

In addition to divided opinions on effectiveness, arguments have been put forward in regards to the economic implications of double checking. It has been suggested that double checking requires more time and is more staff intensive than single checking. Kruse *et al*. (1992) conducted a randomised cross-over study across two wards of a geriatric assessment and rehabilitation unit at a hospital in Australia. For the study period of 23 weeks one ward employed single checking and the other double checking, this was then reversed for the second study period, also of 23 weeks. During the study periods an independent researcher audited the patient's medication charts and drug error reports. It was found that the error rate was 2.98 errors per 1000 medications administered when single checking. This was significantly higher than the 2.12 errors per 1000 medications administered when double checking. This suggests double checking prevented a significant number of medication errors. However, the researchers also conducted a time and motion study for one week during the study period, which involved counting the number of medications administered and the time taken to do so. From this it was found that double checking required an extra 17.1 hours per 1000 medications administered compared to single checking. The authors calculated that this time was equivalent to having another nurse working 40 hours per week for 55 weeks. Therefore, despite double checking significantly lowering the number of medication errors the authors concluded that a clinical recommendation to double check was dubious considering the extra time and money it required. This finding resonates with the views of Leape (2000 cited in Armitage 2007) who states that double checking is a sacred cow which saps time and is ineffective. Additionally, Leape asserts that frequent

double checks run the risk of becoming an ineffective ritualistic chant (Leape 2000 cited in Armitage 2007).

Jarman, Jacobs and Zielinski (2002) conducted a descriptive research design to examine the impact of a change from nurses double checking to single checking prior to medication administration at a hospital in Australia. The researchers measured reported errors in all adult inpatient departments, the emergency department, operating theatres and birthing suites for seven months following the change to single checking. It was concluded that double checking did not have any significant safety benefits over single checking because there was no difference in the number of errors reported. Furthermore, a visual analogue questionnaire with 15 items related to medication checking was administered to a convenience sample of 129 registered nurses from the studied wards. Results of the questionnaire suggested that nurses preferred single checking because it freed up time which could be spent on patient care, increased their autonomy and flexibility and made the nurses feel more confident, accountable and responsible for their actions.

Research has also suggested that this preference for single checking is more pronounced if staff receive adequate training in how to check effectively. O'Connell *et al.* (2007) evaluated nurses' perceptions of single checking pre and post education sessions surrounding single checking. The education sessions consisted of outlining changes to checking policy, assessments of the nurses' competencies to administer medication and all attendees were provided with a resource manual containing the written checking policy and a self-assessment checklist for single checking. A questionnaire assessing attitudes to single checking were completed by 129 nurses pre and post attendance at the educational sessions. Analysis of the questionnaires suggested that after attending the education sessions nurses had a more favourable view of single checking. Results of this study also suggested that the education session increased nurses' confidence to administer medicines correctly, encouraged nurses to pay more attention during checking, and afforded nurses more responsibility and accountability. Furthermore, nurses reported believing that single checking occupies less time than double checking and that the nurses would welcome this. This research suggests that good understanding of checking procedures facilitates effective practice.

Dickinson *et al*. (2010) sought to understand paediatric nurses understanding of double checking and both facilitators and barriers to conducting double checks. Three focus groups were conducted with a total of 19 paediatric nurses recruited from one hospital in New Zealand. The focus groups were analysed using thematic analysis. Four themes were found; independent checking is best practice, variability in the process of double-checking, environmental influences such as competing priorities and interruptions, and attitudinal influences such as a false sense of security when double checking. The research also found that there was poor understanding about what double checking is and that more clarity was needed on how to double check. This research also identified that workload, distractions, automaticity and deference to authority were detrimental to effective double checking.

Armitage (2007) attempted to understand why double checking may be ineffective. Firstly, a random sample of 191 drug error reports from a large city based teaching hospital were content analysed. This confirmed that double checking was a frequent safety process across the hospital, especially in nursing. The analysis also revealed that double checking errors occurred, yet the author notes that these were only clear cut in 12 cases. It was found that the error reports where a double checking failure occurred were very brief and the error reports did not seek to investigate why the double checking failed by examining the checking process, instead the authors suggest that individuals were blamed for the error. The author therefore asserts that more research is needed to understand why errors may occur. Armitage (2007) also conducted semi-structured interviews about double checking with 40 multidisciplinary healthcare professionals including doctors, nurses, pharmacists and pharmacy technicians from the same hospital. The results of these interviews suggested that double checking was an inconsistent process. The authors believe that as double checking is used across disciplines, it requires a solution which can be suited to all disciplines. Qualitative analysis of the interview revealed four reasons as to why double checking may fail. Staff believed deference to authority was a risk as staff may feel staff more senior to them must be correct and feel unable to question a senior. Reduction of responsibility was also perceived to be a risk, both through over reliance on the other checker and the social nature of checking leading to informality and diminished responsibility. Auto-processing was cited by participants as a reason for ineffective double

checks, with checks repeated regularly but with little active input from both checkers, especially if the drugs being checked were routine and frequently administered. The final weakness of double checking suggested in this research was lack of time. Even staff who spoke of themselves as advocates of double checking felt it was hard to find the time to be able to double check effectively. Armitage (2007) therefore concludes that double checking may contribute to error as staff trust it to be effective, yet there are many reasons why it may fail. Therefore, greater understanding of the risks of double checking are needed through increased psychological research into the process, in order to ensure that checking is conducted optimally.

A recent literature review into double checking in healthcare has concluded that there is insufficient evidence on which the use of double checking can be justified. Alsulami, Conroy and Choonara (2012) conducted a search for literature search for articles related to double checking in healthcare. Some 16 articles were found to meet the inclusion criteria of assessing or discussing double checking of drug calculation, dispensing or administration. Of the 16 articles, two articles were literature reviews, and nine were qualitative-assessing views and perceptions of healthcare staff. These have been reviewed in this chapter. Only three articles employed quantitative methods to compare the effectiveness of single and double checking. However, one of these was a retrospective analysis (Ross, Wallace and Paton 2000) and therefore not a direct comparison. Another revealed very small numbers of errors when single or double checking (Kruse *et al.* 1992). Only one study, described below, directly compares methods of checking (Evley *et al.* 2010). Therefore, Alsulami, Conroy and Choonara (2012) concluded that clinical trials are required in order to provide evidence that double checking prevents errors.

A small number of studies have compared the difference between single and double checking. Evley *et al*. (2010) has conducted one of the only comparative studies on methods of checking. Following a review into adverse incidents which suggested 58% of errors in anaesthesia could be prevented with double checking, the authors suggested that there was a lack of evidence on the efficacy of double checking. Therefore, Evley *et al.* (2010) conducted a feasibility study which compared two methods of confirming drugs; barcodes and double checking. No error or near error rates were recorded, rather this study sought to

evaluate the feasibility of introducing double checking or barcode confirmation into practice. Seven NHS trusts participated in a study period of three months. Five trusts employed a second person check and two employed barcode technology to confirm drugs administered during anaesthesia. Independent observers visited each site to observe both methodologies. For those sites with barcode technology, barcodes were attached to each drug vial. When drawn up the vial could be scanned with a hand held scanner by the anaesthetist and an electronic system provided a visual and audible drug confirmation. For those sites using two people confirmation the authors created a double checking flowchart which made the role of each checker explicit (see figure 4.1). The flowchart ensures both people checking have an active involvement in the checking process. The checking process follows a challenge-response format which will be described in more detail in the section 4.5, when discussing checking methods in aviation.

Figure 4.1: Anaesthesia drug double checking process flowchart (Evley *et al.* 2010)

After the study period four focus groups were conducted with participants and observers from the seven sites. Qualitative analysis revealed benefits, disadvantages and practicalities

associated with both methods of checking. Both methods of checking were perceived to increase safety and potentially prevent drug errors. Double checking was seen as enhancing patient safety whilst not requiring any additional equipment. However, the practice of double checking did not always fit into working patterns, as a second checker was not always available when it was needed. Consequently, the protocol was adapted by users to fit their workflow, for instance by checking multiple drugs at once. Also it was noted than in an emergency situation double checking was abandoned. Some participants also refused to take on the role of the second checker as they felt it delayed administration. Conversely, the barcode technology was believed to require less time, and impinged less on working practices. As such the author's concluded that the electronic system was preferred as it fitted better into existing workflow. However, there were design faults with the technology, such as being able to scan multiple drug barcodes simultaneously. Additionally there were teething technical problems such as integration of existing technology and missing drugs from the database. Evley *et al.* (2010) note that both methods of checking when introduced increased participants' perception of the importance of checking, although some staff were reluctant about the need for double checking due to errors being rare. Hence, the authors conclude that barcode confirmation was more feasible in the anaesthetic environment, but only if technological integration was preferred and feasible. They also note that second person confirmation was effective but would require cultural change for it to be successfully implemented.

Barcode technology has also been advocated in blood transfusions. Due to the high risk associated with erroneous blood transfusions, the NPSA issued an alert entitled "Right Patient, Right Blood" which directs organisations to establish the feasibility of introducing barcodes or other electronic patient identification. The John Radcliffe Hospital in Oxford uses barcodes at all stages of a patient's transfusion journey which is described as an unquestionable success (Murphy *et al.* 2009), as correct patient identification rose to 100% after implementation of barcode technology. However, they noted that is likely to have been in part due to a clearer, simplified procedure delivered alongside education. Askeland *et al.* (2008) calculated that with the use of barcodes transfusion errors would only happen once in every 100 months on average, making it approximately three times safer than manual checks.

Barcode technology has also been considered in pharmacy to improve safety. Poon *et al.* (2006) found that errors and potential adverse events significantly decreased after implementation of a barcode assisted system. The use of barcode technology appears to be a possible alternative to two people checking. However, within radiotherapy, the purpose of the final treatment check is to ensure values which have been manually entered into a computer system match those prescribed for the patient. In order to use barcode technology these values would have to be entered onto another computer system, therefore the use of barcode technology would still require a manual check of values entered into a computer system.

As this review of existing literature has demonstrated, there is a divide in the literature as to whether single or double checking is more effective at detecting, and thereby preventing, errors. Furthermore, there has been little research into why double checking may fail to detect an error. Consequently, more research is needed to conclude which method of checking is most effective, in order to apply this knowledge to the final treatment check in radiotherapy.

4.3 Causes of checking failures

Several root cause analyses have identified that a double check of medicines could have prevented a medical error, for instance, Toft's (2007) review of an erroneously administered injection of heparin. However, following Toft's (2007) review Sir Liam Donaldson expressed his concerns that a double check may actually increase the risk of errors due to involuntary automaticity and reduction of responsibility. Donaldson also notes that double checking is a complex area, with little evidence on the benefits. Anderson and Webster (2001) also note that checking in any form can never be 100% effective because humans are not 100% reliable.

According to Reason's (1990) classifications of human error, a double check not detecting an error is an active failure which can be divided into slips and lapses, due to disruptions in memory or attention respectively. As discussed in section 3.2.3, there is limited literature to identify active failures during the final treatment check in radiotherapy, yet there are

existing reports in the literature surrounding attention failures during checking in healthcare more generally.

4.3.1 Attention failures during checking

Existing literature suggests that double checking can become a ritualistic task, conducted without attention if repeated regularly. Double checking has been labelled a "double checking chant" and Leape (2000 cited in Armitage 2007) notes that it saps time and is ineffective. Barshi and Healey (1993) conducted an experimental study and found evidence to suggest that checklists are susceptible to automaticity. The study is grounded in aviation where checklists are used for safety purposes. Hence, if checklists are susceptible to automaticity, they can be potentially dangerous. Barshi and Healey (1993) provide an excellent rationale for their study into automaticity in checklists; previous research has focussed on the benefits of automaticity and ignored the risks of automaticity. The design used to investigate ritualisation and automaticity in checklists was original and simple. The authors asked participants to proof-read a number of multiplication sums, which the authors argue simulates the five stages in checklists: call, action, visual verification and response. Participants were timed as to how long it took to complete the proof-read of all the multiplication sums. After practice, the decrease in time spent completing the proof-reading of multiplication sums suggested automaticity occurred, as automaticity is associated with high speed responding. However, after several repetitions of these set of sums, participants failed to notice errors in completed multiplication sums. Therefore, the authors showed that the same stimuli presented in the same order leads to automation, wherein performance becomes quicker but errors can pass undetected. This suggests automaticity will occur quickly under identical conditions, such as the final treatment check in radiotherapy;

> *"Habit diminishes the conscious attention with which our acts are performed"* William James (1890 cited in Reason 2000:114)

Barshi and Healy (1993), in the same study into checklist automaticity, suggested that automaticity can be prevented in repeated checking by varying the order of operations or stimulus and placing alerts in the material. When the order of the sums was varied, less errors were missed, which the authors theorised was due to preventing automaticity. Furthermore, when participants had alerts placed in the set of sums, this resulted in more

errors being detected, which was theorised to be due to the interruption of automaticity. The finding that varying the order of items and placing alerts into the checklist resulted in significantly higher error detection can possibly be applied to healthcare checklists.

Toft and Mascie- Taylor (2005) conducted the only existing research into double checking errors in radiotherapy specifically. They suggest that double checking in radiotherapy is prone to, what they call, involuntary automaticity. Automaticity is not a new concept. Automaticity is generally a positive and useful phenomenon, as it means that regularly repeated actions, such as walking, can be performed without conscious consideration. This allows attention to be diverted to other, more productive, higher-level processes. The process of automation is when the nervous system actively adjusts to accommodate its own processing. Frequently occurring processes become 'hard-wired' into the system, so that that can run on their own, or autonomously, without the need for constant consideration and monitoring. Neuroimaging studies have been able to map the neuroplasticity mechanisms which underlie this autonomic motor skill learning (Dayan and Cohen 2011). This motor learning and automation is clearly beneficial, until a regularly repeated action requires conscious attention, such as the final treatment check. The danger of IA is that one is not aware when it is occurring. This makes it a dangerous phenomenon in healthcare, because errors can easily pass undetected if the check is conducted autonomously, yet healthcare staff believe they have conducted a thorough double check. As IA is an unconscious and unintentional phenomenon, IA has been suggested as a legal defence for healthcare professionals against accusations of negligence in cases of adverse medication events (Toft and Gooderham 2009). The authors note that if a healthcare professional has previously reported to their line manger that their working conditions are placing them at risk of forcing an error, be it noise, workload or stress, and these conditions are not addressed, then the healthcare professional should not be held accountable if an error does then occur.

In addition to the literature suggesting that attention factors underlie checking failures, further factors have been identified to affect checking accuracy in healthcare.

4.3.2 Deference to authority

Armitage's (2007) qualitative study, detailed in section 4.2, reveals deference to authority as a cause of errors in healthcare. This research suggested that errors may be perceived by junior staff but that they disregard their perception as wrong if their senior disagrees. Griffiths (2009) writes that the health service is one of the most hierarchical organisations but these hierarchies are dangerous when it comes to double checking and need to be removed.

4.3.3 Diffusion of responsibility

Armitage's (2007) study also suggests that when double checking individual responsibility becomes diluted which leads to complacency. Hence, double checking can be considered a safety risk as staff may not take full responsibility for ensuring they conduct an effective check.

4.3.4 Perceived workload

Schell (2004) asked participants to complete a visual search task and memory tasks either before or after an error detection task, simulated in a pharmacy context. The authors found that when participants completed the tasks before the error task they performed better in the accuracy checking task. The authors note that tasks thought to cognitively demanding had a 'mobilization' effect on error detection, whereby the pre-tasks increased arousal which led to higher perceptual and cognitive readiness. The authors state that if this finding is replicated it could have important implications when applied to checking, as the results suggest that a cognitive or visual task can act as a 'warm up' to improve error detection.

4.4 What can be learnt from other industries

Despite definitive research related to checking efficacy in healthcare, lessons on checking can be learned from other high risk industries, such as aviation. Both healthcare and aviation are safety critical industries involving highly trained individuals working in teams and transfer of knowledge from the aviation industry to healthcare is advocated (Armitage 2007).

The aviation industry has been the subject of intensive research into human error, and the industry has used checklists to help ensure errors are prevented since the 1930s. A checklist is a simple tool to aid effective and error-free working, especially processes which require

complex human interaction. Gawande (2011), author of the checklist manifesto, is an advocate of the effectiveness of a simple checklist to support humans to perform optimally. He notes that aviation checklists were introduced after WWII because flying had become much more complex and there was so much for pilots to remember. A significant number of aviation crashes can be traced back to a failure to complete a checklist properly (Gawande 2011). Field studies of flight deck checklists, interviews and analysis of accidents have revealed a number of common checklist mistakes, resulting from early aviation checklists not benefitting from human factors input (Degani and Weiner 1990). These mistakes include; not reading checklist items aloud, calling items from memory, responding quickly to checklist items without actually verifying, and chunking items together. Hence, significant work has been focussed on improving the effectiveness of checklists.

Checklists can be said to have a dual purpose; both as a memory aid and generator or co-ordinator of tasks. Degani and Weiner (1990) note all checklists follow the same format:

1. Reading or hearing a checklist item
2. Accomplishing that item, either by verification or executing that task
3. Responding to the outcome of the action

Following a review of aviation checklists, Degani and Weiner (1993) recommended the following checklist features: placing safety critical items at the beginning of the checklist, employing the user's tactile sense and keeping items in a logical order. Additionally, the sterile cockpit rule is advocated whereby there is silence during critical safety phases. Furthermore, aviation checklists employ a challenge- response method, whereby one person reads out an item and the other checks it and responds. The work in aviation suggests that a well-designed checklist which elicits an active challenge- response call successfully improves safety (Degani and Weiner 1990).

However, there is argument that the comparison between aviation and healthcare is too simplistic. There may be too many variables in medicine compared to aviation. It could also be argued that authority gradients are much more salient in healthcare, compared to aviation. Despite the potential differences between the domains, the principles of good checklist design will be retained and applied to the radiotherapy domain. However, there is

a need to understand the requirements of the users in the specific domain, which can only be achieved through new empirical research.

4.5 Healthcare checklists

A systematic review of 20 articles on the impact of healthcare checklists on team factors, found that checklists have also been demonstrated to improve team work, communication and inter-disciplinary working in healthcare (Russ *et al.* 2013). The design of aviation checklists was used to inspire the development of the surgical safety checklist (Weiser *et al.* 2010). The surgical safety checklist (SSC) is perhaps the most notable checklist in use in healthcare. The SSC was introduced in 2008, with the view to increase consistency of care in the operating theatre, to minimise the frequency of surgical adverse events. The checklist is comprised of three stages, 'sign-in', 'time-out' and 'sign-out'. These are carried out when the patient arrives in the operating room, prior to incision and following completion of the procedure respectively. The principle of the checklist is for all operating staff to be present when the checklist is conducted, and to create an environment in which all staff feel able to speak out about any potential errors or expected difficulties. A landmark publication in 2009, comparing pre- and post- implementation, reported that implementation of the SSC reduced mortality rates from 1.5% to 0.8% (Haynes, Weiser, Berry *et al*. 2009). Use of the SSC in all operating theatres is currently recommended through national guidance in the United Kingdom, but the decision for use lies at the individual Trust level. However, a recent report published following an investigation into 11 incidents of retained foreign objects post-operatively at Sheffield Teaching Hospitals NHS Foundation Trust in a 38 month period, recommends that this guidance to follow the SSC becomes national policy, and thus mandatory in the UK (Toft 2014).

An observational study of 294 operations across five hospital sites, demonstrated that the compliance rate of performing the SSC correctly is not optimal (Pickering *et al*. 2013). The study found that the 'sign out' stage of the SSC is often not conducted, suggesting that it does not fit the workflow of surgical teams. A qualitative investigation on the barriers and facilitators to use of the SSC revealed some interesting findings surround healthcare staff's perceptions of the SSC (Russ *et al.* 2015). Results of the semi-structured interviews in this study suggested that there was initial variation on how the SSC was conducted both within

and between hospitals. A number of facilitators to SSC adherence were found including; integration with existing protocols, strong leadership skills from the person leading the checklist, senior clinician buy-in, feedback on the impact of the SSC and support from management. Additionally, a number of barriers to use were discovered, including; patient perceptions, scepticism of the evidence base, additional time implications, lack of local modification and duplication of existing safety procedures. These barriers must be considered in the design of any new treatment checking protocols.

4.6 Standardisation of checking

Towards Safer Radiotherapy provides the guideline that two radiographers conduct the final treatment check and be recognised as the responsible operators (Donaldson 2007). Employers are required to maintain a list of operators entitled to "switch on", meaning press the button which administers the radiation beam, and to provide precise protocols specifying their responsibilities and accountabilities. However, as discussed in section 4.1 there is no standard checking protocol, leaving the final treatment check open to local interpretation. Therefore, if a new checklist protocol was to be implemented, it would require a standardised method of working at the point of the final treatment check which is currently novel in radiotherapy

Standardisation is common elsewhere in healthcare, with the aim of preventing variation in practice, and ensuring everyone is working to the best practice. Standardisation is thought to reduce the risk of error, as well as increasing efficiency by reducing complexity:

> *"one of the most powerful means of preventing errors of all kinds is to standardise processes"* (Institute of medicine 2000:190).

This is because when processes are standardised trained healthcare workers can easily move to a different department or hospital, and immediately be capable of working to best practice. However, healthcare lags significantly behind other safety critical industries in terms of standardisation. For instance, in aviation any trained pilot can fly a Boeing 747 for any airline, yet it is unlikely that any qualified surgeon can schedule, prep and perform an operation in any hospital (Leotsakos *et al*. 2014). A reason for this lag may be because it is believed that achieving standardisation in healthcare is challenging. Standardisation improves safety, but standardisation is often difficult to develop and implement due to the

complexity, diversity and changing nature of healthcare and the NHS. Another reason may be the prevailing person-centred approach to error which removes responsibility for error from the system design (Runciman *et al.* 2008).

Standardisation within healthcare is currently the subject of a body of research by the WHO. This body of research focuses on three standardised operating procedures (SOP): correct surgery, medication reconciliation and concentrated inject-able medicines. Implementing these SOPs into practice in five hospitals around the world, followed by evaluation of adherence to the SOPs, will provide insight into the feasibility of standardisation and associated behaviour management needs in healthcare (Leotsakos *et al.* 2014). The results are expected over the next few years.

What is currently clear is that radiotherapy currently lags behind other healthcare domains in terms of standardisation, and that standardisation of error-prone processes, such as the final treatment check, may reduce risk.

4.7 Implementation science

In order to achieve standardisation of the final treatment check, new ways of working would need to be introduced, yet implementing change is challenging. Implementation science, sometimes referred to as improvement science, is the term given to the relatively new multidisciplinary field concerned with evaluating the best methods of closing the gap between what is consider best practice and what is done in practice (May 2013).

In healthcare, the evidence based practice approach is the underlying approach to quality standards. Yet, gaps often exist between what healthcare professionals know they should be doing to deliver quality healthcare and what is actually done (Haines 1998). In fact it has been estimated that successful implementation rates for quality improvement projects (QI) are under 50% (Alexander 2008). The gaps between knowledge and practice, and low implementation rates, could be attributed to the challenges associated with implementation of QI initiatives. QI innovations include clinical breakthroughs, protocols or interventions which are developed but then may not realise the patient benefit they were designed for due to failed implementation attempts. There are numerous documented reasons for

implementation failure: the intervention not being of proven effectiveness in practice, lack of evidence of cost or resource benefits, resistance, and culture in the target setting (Ham, Kipping and McLeod 2003). It could be said therefore, that change in healthcare is an iterative process between science and practice- one needs to inform the other reciprocally to produce effective change.

A QI initiative failing to be integrated into practice may be because of the way it was introduced. There are many theories surrounding the best way to implement quality improvement initiatives successfully, to describe these all is beyond the scope of this thesis. These theories draw upon multiple discipline fields, such as: psychology, health behaviour change, economics and management. It is clear there is a need for reviewing and refining the many theories of implementation into a single, complete and simplified general theory of implementation (May 2013). The main components that each current theory draws upon are presented in table 3.2. Each theory of implementation is likely to feature one or more of these components, which are taken from Grohl, Wensing and Eccles (2013).

Table 4.1: Approaches aimed at implementation (Grohl *et al*. 2013)

There is currently little evidence of which theoretical approach to implementation is more successful. A systematic review of 235 studies which had reported to have used theory to inform evaluations of implementation concluded that there is often little, or poor quality, justification for the use of a chosen theory (Davies, Walker and Grimshaw 2010). Therefore, the authors argued that there needs to be greater and more explicit use of theory in implementation in order to increase understanding of what works, and what does not work, in healthcare implementation.

Not only is there poor use of theory in implementation approaches, but each local specific improvement intervention may require a different balance of the components described above to ensure successful implementation. There is little guidance on how to determine the best match for each local situation (Proctor, Powell and McMillen 2013). Furthermore, with each local situation there are specific determinants of change, or barriers and enablers, which can influence the effectiveness of change in a negative or positive way respectively. These determinants of change can either be; related to the innovation that is implemented, the motivations or beliefs of the individuals expected to adopt it, the setting in which they act, or the structure of the healthcare organisation. To avoid unexpected challenges in implementation users must be considered and placed at the centre of the QI initiative design, process of implementation and continued evaluation of the innovation (Proctor, Powell and McMillen 2013). Therefore, any design of a QI initiative must involve a detailed analysis of barriers, enablers and the situation into which it is intended to be deployed, in order to optimise the design and determine the best method of implementation to ensure every chance of success.

The engagement and involvement of health care professionals in the design of improvement interventions can be crucial to success. In order for an intervention to be implemented, it requires behaviour change from the healthcare staff. Behaviour change can be challenging, but is more effective if based on psychological theories of behaviour change (Cane, O'Connor and Michie 2012). A review of 235 implementation studies showed that only a small minority explicitly used behaviour change principles in the design of the implementation (Davies, Walker and Grimshaw 2010). There are a plethora of behaviour change theories and, as such, the Theoretical Domains Framework (TDF) was designed to simplify and improve accessibility to behaviour change theory for healthcare researchers when designing interventions (Michie *et al*. 2005). This framework was developed with input from health service researchers, psychologists and health psychologists. Some 33 theories and 128 key theoretical constructs related to behaviour change were simplified into one single framework to assess behavioural problems and inform intervention design. This synthesis also resulted in exemplar questions for use in interviews or focus groups to allow assessment of theoretical implementation problems. TDF has been successfully employed by researchers to explain implementation problems and inform implementation

interventions. For example, Dyson, Lawton, Jackson and Cheater (2013) conducted a study of the barriers and enablers related to hand hygiene amongst healthcare professionals using TDF. The use of TDF was also demonstrated by Taylor *et al*. (2013) who combined user feedback and theory in the successful implementation of evidence based guidelines to reduce the risk of feeding into misplaced nasogastric tubes. The authors therefore demonstrate that it is possible, and preferable, to combine theory and co-design approaches when designing strategies for implementing patient safety initiatives.

Alongside consideration of a new innovations users, the role of the middle manager has recently been argued to be very important to the implementation process, yet currently poorly understood and utilised (Birken, Lee and Weiner 2012). The authors argue that middle managers can be utilised to bridge the gap and mediate between frontline staff and top managers, and "sell" new innovations to staff. A tool to measure implementation leadership has been developed (Aarons, Ehrhart and Farahnak 2014). The implementation leadership scale (ILS) is a 12-item scale which aims to assess to what extent a person scores on four dimensions of successful implementation leadership: proactive, knowledgeable, supportive and perseverant. After pilot testing on 459 mental health professionals from 93 outpatient departments in California, USA, the scale was reported to have high internal consistency, reliability and validity. The authors argue that the scale can be used, not only to strategically appoint staff to managerial positions during an implementation process, but to comparatively assess implementation leadership in order to increase the understanding of leadership as a predictor of successful implementation.

Even when well implemented it is documented that initiatives may fail to be sustained (Ham, Kipping and McLeod 2003). The NHS Institute for Innovation and Improvement designed a Sustainability Model to assist healthcare providers to identify and address issues which may affect innovation sustainability (Maher, Gustafson and Evans 2010). This tool can also be used prior to implementation to assess the likelihood of adherence to, and sustainability of, a new innovation before resources are invested into implementing it. The tool consists of ten factors affecting sustainability which are presented in table 3.3.

Table 4.2: Factors likely to contribute to initiative sustainability

Domain	Factor
Process	Benefits beyond helping patients
Process	Credibility of the benefits
Process	Adaptability of improved process
Process	Effectiveness of the system to monitor progress
Staff	Staff involvement and training to sustain the process
Staff	Staff attitudes towards sustaining the change
Staff	Senior leadership engagement
Staff	Clinical lead engagement
Organisation	Fit with the organisations strategic aims and culture
Organisation	Infrastructure for sustainability

These items were derived from a review of healthcare management literature alongside consultation with clinicians and health care experts. Each factor can be scored by staff and the scores for each domain amalgamated in order to assess which areas require focus in order to increase the likelihood of sustainability (Maher, Gustafson and Evans 2010). Therefore, because these concepts can be measured, future research could use these as tools before and during patient safety QI implementation.

In response to the recognised need for theory to inform implementation to a greater extent, Normalisation Process Theory (NPT) was developed (May *et al*. 2009). NPT focuses on the process of an intervention becoming normal practice through three stages; implementation (bringing a new process into practice), to embedding (the new process becomes routinely incorporated into practice) to integration (the new process is reproduced and sustained) (May *et al.* 2009). This theory helps researchers and clinicians to evaluate implementation of, and continued adherence to, new interventions or technologies by analysing the factors which inhibit and facilitate success. There has been a recent growing interest in applying NPT to healthcare interventions, and it is recognised that the theory is flexible and its use in shaping implementation processes is continually evolving (McEvoy *et al.* 2014). Alongside the theoretical application to help guide intervention design and process implementation, the NPT provides a toolkit to be used with clinicians to further understand likely barriers and facilitators (May *et al.* 2010).

The large existing literature on implementation suggests that whilst radiotherapy may benefit from more standardisation, implementing this change will need to be carefully considered to ensure adherence and sustainability. It is also clear that in the design of any new radiotherapy safety initiative, radiographers must be involved in the design, and the initiative must be derived from a firm evidence base. Therefore, user involvement and evidence-based requirements will remain central to the development of any initiative arising from this research.

4.8 Chapter summary

This review has highlighted that double checking is used in many areas of healthcare, yet there is a debate on the efficacy of double checking over single checking. However, this debate is not underpinned by a large body of empirical research. The majority of research into double checking in healthcare consists of retrospective analysis or viewpoints, not empirical or comparative research. There is very little research focussed specifically on double checking in radiotherapy, with the majority of research focussed on either nursing practice or anaesthesia. This means a critical safety defence is not currently evidence based, therefore this must be a research priority.

In order to provide an evidence base, more human factors analysis is required in order to understand the factors contributing to human error during checking in radiotherapy. Existing literature on double checking has suggested some solutions to preventing errors passing undetected, especially when consulting the literature in the aviation field, for instance, checklists to lessen cognitive demands, challenge-response verbal checking and 'sterile' environments. Previous research in aviation and healthcare appears to have focused on the role of attention during repeated double checking, and suggests that attention failures, specifically involuntary automaticity, could be a major cause of error detection failures. Therefore, research must investigate methods to combat attention failures during repeated double checking.

The preceding three chapters have provided a review of the existing literature on patient safety, radiotherapy and double checking. From this is can be concluded that more research is needed to provide evidence for the effectiveness of double checking in radiotherapy and

understand the factors which impact on error detection during the final treatment check. A summary of the key findings from the literature review are provided below:

- Errors in radiotherapy have the potential to cause severe or fatal patient harm.
- The final defence against errors in radiotherapy is a treatment check conducted by radiographers, during which values on the linear accelerator are confirmed as corresponding to the patients' paper prescription.
- There is limited existing guidance on how to conduct this final treatment check.
- Double checking is advised, but this is prone to error itself.
- There is limited research on the factors surrounding errors during checking in radiotherapy.
- There is limited evidence to support the use of double checking over single checking.
- There are recommendations from aviation and other areas of healthcare which can be embedded into improving the final treatment check in radiotherapy.

Building on this literature review, the next section of the thesis details the empirical work undertaken to further develop the knowledge on the final treatment check in radiotherapy and how the safety of this process can be improved. The research objectives of the empirical work are to:

1. Examine and review the checking process immediately prior to beam delivery and identify factors affecting the reliability of this process to detect errors
2. Experimentally test the impact on performance of different approaches to checking in a laboratory setting, to develop an empirical evidence base
3. Specify and design an evidence-based revised checking process for use immediately prior to beam delivery
4. Evaluate the revised process to determine user acceptance

The following chapter provides an overview of the methodology used to meet these research objectives, and maps the content and structure of the thesis.

5 Chapter 5- Methodology

This chapter discusses the research methodology adopted in this thesis. The aim of the research was to understand the process and efficacy of the final treatment check in radiotherapy treatment, in order to improve the safety of this process. This research has adopted an interdisciplinary, mixed methods approach in order to meet the research aims. This chapter explains the guiding methodological approach taken. The overall structure of the thesis is then provided, where the research methodologies are mapped against the research objectives. A discussion of reliability, validity and ethical considerations then follows. As each empirical chapter employs a different method, further operational method detail will be provided within each empirical chapter in order to aid the flow and clarity of the thesis.

5.1 Mixed-methods approach

This thesis has employed a mixed-methods, multi-disciplinary approach in order to understand the final treatment check process in radiotherapy treatment delivery and how it may be improved to increase safety. This mixed-methods approach fits within the pragmatic approach to research (Creswell and Plano Clark 2007). This approach allows the researcher the freedom to adopt research methods from either qualitative or quantitative research, depending on which is best suited to meeting the research objective, without being constrained by philosophical debates on the knowledge gained by these research approaches (Creswell and Plano Clark 2007). Each research method used is analysed in the appropriate manner, but it is recognised that both qualitative and quantitative methods are complementary, and can be used to inform the other. As well as allowing flexibility in the research, this approach is also considered to provide valid results, as it allows for a higher level of data, methodological and theory triangulation (Creswell and Plano Clark 2007), which increases validity. As such this approach is believed to have struck the right balance between empirical and naturalistic research:

> *"without naturalistic facts, experimental work may become narrow and blind: but without experimental research the naturalistic approach runs the danger of being shallow and uncertain"* (Baars 1980:15)

5.1.1 Patient safety approach

Patient safety is an applied science, which combines theory with improvement initiatives, yet there is no single unified research framework within the field (Pronovost *et al*. 2009). The purpose of patient safety research is to reduce the risks and hazards within healthcare which could lead to clinical harm. Battles and Lilford (2003) attempted to provide an overview and conceptual framework for patient safety research, and note that the aim of the discipline is achieved with a three step process:

1. Identification of risks and hazards
2. Design, implementation and evaluation
3. Ensuring safe practice and a safe environment continue

It is recognised that each stage requires different research methods. Each healthcare domain demands the utilisation of different research methods, therefore no single research method can be used for all patient safety research (Battles and Lilford 2003). Three main research methods are typically used within patient safety to identity risks and hazards; archival data analysis, observation and process mapping. The most commonly used method in patient safety research is retrospective analysis of error from incident reports, and other archival data, or through root cause analysis (Pronovost *et al.* 2009). This method is inherent to the issues surrounding reporting, as well as being time intensive due to the necessity of incident data collection (Battles and Lilford 2003).

Due to the reactive nature of archival error analysis, Pronovost *et al.* (2009) advocate prospective analysis of the weaknesses in the system. This can be conducted through observation of the systems in action, in order to understand the associated social and operational factors. Yet, as Battles and Lilford (2003) note, a patient safety incident may not occur during this period of observation. Process mapping is also increasingly being used to understand the weak points in a system, after being used successfully in other high risk industries. A further method which is gaining popularity, but not commonly used due to limited resources, is that of simulation studies (Pronovost *et al*. 2009). These are considered effective as they can map a process and observe errors, in a safe environment, whilst allowing manipulation of factors and analysis of the resulting outcome.

Small-scale patient safety initiatives often follow a Plan-Do-Study-Act model (PDSA). This involves planning the target for improvement and change is then trialled on a small, specific scale. This small scale change is then evaluated by comparing pre and post implementation data, before the cycle is either repeated again or implementation on a wider scale is decided upon (Langley, Nolan, Nolan, Norman and Provost 2009). This allows a structured method to study iterative development of QI initiatives. However, it has been argued that not all studies adopting this method do so in a consistent manner, with many studies not fully adopting the key principles leading to limited learning and adaptation between each cycle (Taylor *et al.* 2013). This potentially means the PSDA model is not used optimally to improve patient safety.

From this discussion it is concluded that a range of research methods are suitable in patient safety research, yet all have their own strengths and weaknesses. Therefore, a mixed methods approach is advocated in patient safety research, to ensure that the appropriate method is used to explore the specific healthcare domain (Battles and Lilford 2003). This thesis has included methods advocated in patient safety research, such as: observation, interviews and laboratory based simulation. A PDSA model has not been adopted as it was not possible to implement a new treatment checking protocol into a department's practice due to ethics. Furthermore, it is argued that there should be a process of iterative development in a simulated setting, involving user feedback, prior to the implementation of a QI in a real life setting. This minimises the potential for any unexpected negative consequences of the QI initiative. Yet, it is recognised that the PDSA model is valuable as the next step following simulation-based study when implementing a new QI initiative across an organisation.

5.2 Thesis structure

Table 5.1 displays which research methods have been used to address each research objective. As each empirical chapter employs a different method, further method detail will be provided within each empirical chapter in order to aid flow and clarity. Each chapter will provide the rationale for the study, detailed method, results and discussion of results along with a critique of the method used in that study. Figure 5.1 provides an overview of the thesis and illustrates key findings from each stage of the research process and how these

then informed either the next stage of the research process, and/or a resulting practice recommendation.

Table 5.1: Overview of thesis content and relation to research aims

Research Objective	Methods	Chapters
Examine and review the checking process immediately prior to beam delivery and identify factors affecting the reliability of this process to detect errors	• Literature review • Task analysis • Exploratory semi-structured interviews	2, 3, 4, 6 & 7
Experimentally test the impact on performance of different approaches to checking in a laboratory setting, to develop an empirical evidence base	• Laboratory based experiments	8
Specify and design an evidence-based revised checking process for use immediately prior to beam delivery	• Protocol and interface design	9 & 10
Evaluate the revised process to determine user acceptance	• Semi-structured interviews	9 & 10

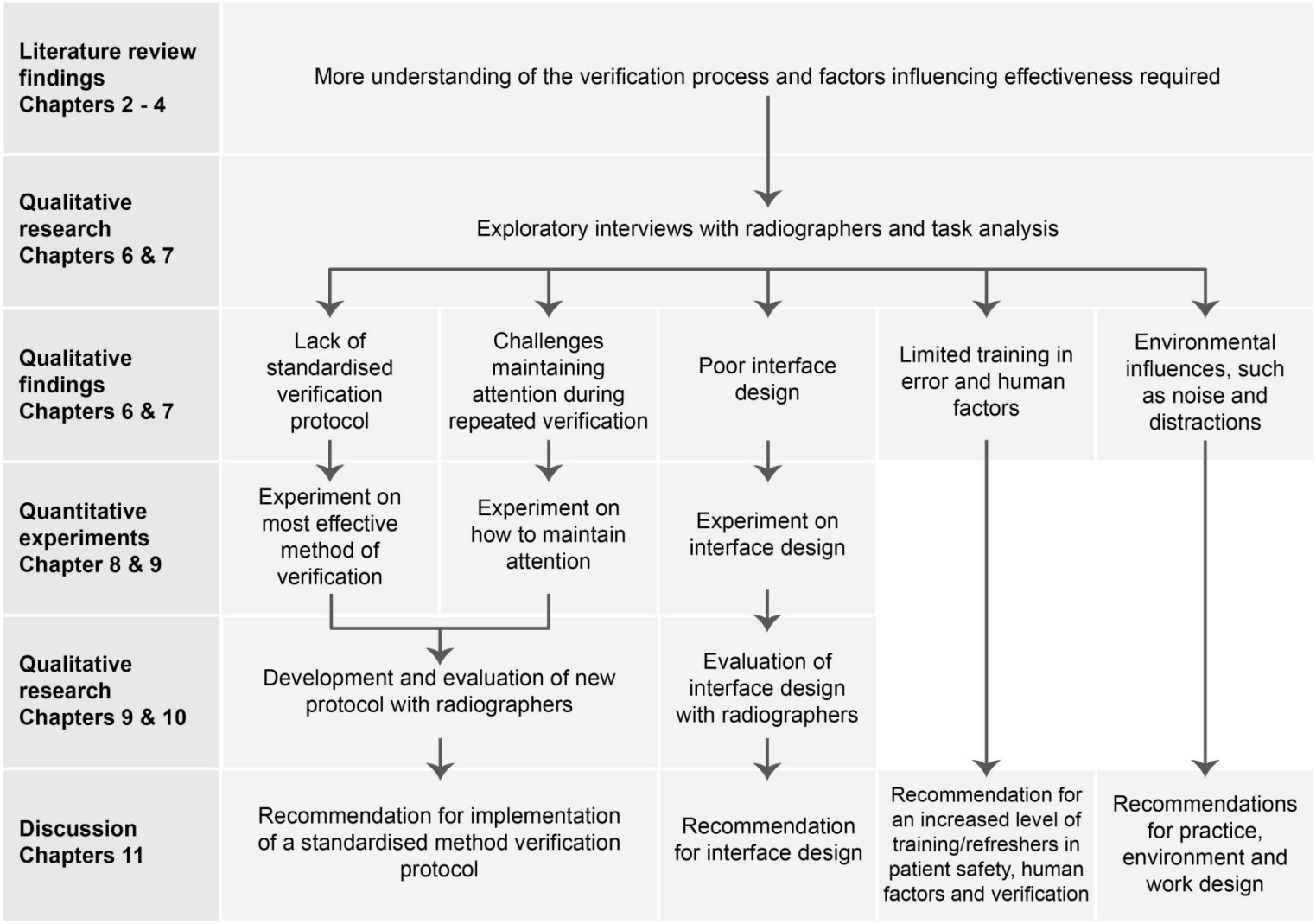


Figure 5.1: Overview of thesis

5.3 Qualitative methodology

The thesis both starts and ends with qualitative methodology, as shown in figure 5.1. Qualitative research is useful for gaining an understanding of a research topic, evaluation and aiding continued development, because participants are able to express their perceptions and beliefs which allows the researcher to understand their viewpoint (Coolican 2004).

A qualitative approach is beneficial as an introduction to the topic, because as the literature review has demonstrated, checking within radiotherapy is currently an understudied topic. This qualitative approach was adopted at the start of the body of research to conduct observations and interviews which provided descriptive data and informed the later avenues of research, as shown in figure 5.1. A qualitative approach was also adopted as an evaluation tool to explore staff views on the new verbal checking protocol and proposed interface developed.

5.3.1 Semi-structured interviews

Semi-structured interviews were employed to evaluate the resulting protocol and proposed interface design. The use of semi-structured interviews allowed for interesting points raised by participants to be followed up on by the researcher. This flexible approach ensured the participants were able to adequately express their views, yet the interview allowed collection of the required data (Coolican 2004). This is why semi-structured interviews were chosen over closed or open interviews.

5.3.2 Qualitative analysis

Thematic analysis (TA) was chosen to analyse the data collected using the semi-structured interviews, as this was an exploratory topic and thematic analysis allows identification and exploration of patterns across the data. TA is less interpretative than other qualitative methods such as Interpretative Phenomenological Analysis (IPA), but this was ideal considering the exploratory nature of this research (Braun and Clarke 2006). This research was designed to collect staff views rather than develop an understanding of their personal experience and perspective on their job for which IPA

would have been better suited. Thematic analysis is a relatively new method of analysis, coined in the 1970s (Braun and Clarke 2006). The aim of TA is to identify and analyse patterns and can be used with smaller data sets. TA is a recursive and flexible process, hence the researcher can go back and change codes or themes to better describe the data. Although TA is flexible it is important to follow an established methodology. The process followed here is mapped against the stages described by Braun and Clarke (2006) which consists of the six steps detailed below. A second coder was involved in the analysis, in order to minimise subjectivity.

5.3.2.1 Stage 1- Familiarisation with the data

This was done both through transcription and re-reading of transcripts. During this stage initial thoughts about patterns arising were noted. This proved to be very useful for getting to know the data. As Bird (2005) notes, transcription is a key stage and not just functional because interpretation also begins at this stage.

5.3.2.2 Stage 2- Initial codes

Anything relevant to the research question was coded in this stage. Each transcript was coded individually. Each code thus became a piece of data. A second independent coder also coded a sample of the transcripts to check the reliability of coding, and codes were compared for agreement.

5.3.2.3 Stage 3- Searching for themes

All codes were then collated and, due to the high number of codes, these were grouped into similar categories. This allowed for a more manageable number of categories from which meaningful patterns relevant to the research question could be seen. The next stage was the start of analysis- grouping codes into meaningful themes.

Similar codes were grouped together with themes constructed from them. Then thought was given to the use of over-arching themes and sub-themes. At this stage the second coder read all transcripts and reviewed the use of categories and themes and a discussion was had surrounding the placement and formation of themes to minimise subjectivity.

5.3.2.4 Stage 4- Reviewing themes

During this stage themes were reviewed and refined. As TA is a dynamic, recursive process codes and themes can be changed and altered. The themes were reviewed, some were split and others combined. Some themes were discarded due to lack of data to support them. It was ensured that every theme had been repeated more than once and that themes emerged from across data so that each interview was not treated as a separate data set. This continued until the researcher and second coder were confident that the themes 'told the story' of the data.

5.3.2.5 Stage 5- Defining and naming themes

Each theme was named and described. It was important that the description captured the participants' views and essence of that theme succinctly and accurately.

5.3.2.6 Stage 6- Writing up

The themes were written up using quotes weaved amongst the theme's description. It was ensured that this writing up of themes was not just a narrative but an answer to the research question.

5.4 Quantitative methodology

A quantitative experimental approach was adopted to comparatively evaluate different methods of checking and the impact of the interface design in a laboratory setting. This allowed the research to follow up the main findings from the initial qualitative interviews, as shown in figure 5.1. The use of quantitative techniques allows for numerical data to be gathered and analysed, which can be used as evidence for effectiveness or to test hypotheses (Coolican 2004). According to Karl Popper's theory of falsification, a theory must be testable and found to be supported, or not supported, through empirical study (Popper 1959). Previous research into radiotherapy errors passing undetected during the final treatment safety check has been theorised to be due to involuntary automaticity (Toft and Mascie-Taylor 2005). Therefore, in order for this theory to be valid it needed to be falsifiable, and a laboratory study allowed this. Furthermore, evidence to support effectiveness was also

vital when developing a new treatment checking protocol to ensure it was evidence-based.

The laboratory based experimental research in this thesis employed a paradigm designed to mimic the repetitiveness of the final treatment check in radiotherapy. This simulated experimental approach is useful as it allows for the variables of interest to be isolated, away from the confounding variables present in a real life scenario. It also allows for these variables to be studied in a much shorter timescale. Errors in real life settings are infrequent and unpredictable, therefore it is argued that it is of value to simulate errors in a laboratory setting in order to allow efficient and measurable assessment of the impact of different variables. Errors can also cause patient harm, therefore a simulated setting is required to measure the impact of variables on error occurrence so as not to cause potential harm to patients. The method is described in detail in section 8.2 to ensure transparency about how the experiments were run and to ensure they can be replicated. The participant instructions were standardised for all participants to ensure all participants received the same instructions so as not to influence their performance. However, it is recognised that there are potential limitations when applying laboratory findings to the real world.

5.4.1 Use of lay participants

The participants who took part in the laboratory based experiments in this body of research were undergraduate students at Coventry University and not trained in radiotherapy. Lay participants were recruited for two reasons. Firstly, there was a greater level of accessibility to lay participants. As the experiments were lengthy, it was not possible to recruit radiographers into the experiment. This is because taking them away from the department, in pairs, for upwards of 45 minutes at a time would have had negative resource, and therefore safety, impacts on the department. Participation at the end of a shift was also not considered methodologically sound, due to fatigue. Secondly, the actual process of the final treatment check is a simple task, which requires no specific training in radiotherapy. That said, the participants in the experimental studies were given a brief explanation of radiotherapy and what the

experimental paradigm was mimicking, in order to place the task they were being asked to do in context. Hence, it is argued that the use of lay participants does not affect the validity of the results.

5.5 User centred design

User centred design is a design philosophy which ensures that end-users remain central during the design process, by collecting their views, requirements, limitations and goals which are then considered in the design. User centred design is an iterative process, during which end-user feedback is continually sought between each draft of a design in order to aid further development (Garrett 2010, Norman and Draper 1986). As the users requirements are embedded into the design from the start of the process, this is believed to improve the usability and acceptance of the end product (Johnson, Johnson and Zhang 2005).

This design philosophy has been adopted in this thesis, in a number of ways:

- Drawing up user requirements through interviews
- Mapping the activity through task analysis
- Design of a protocol and interface features
- Design evaluation with end-users of both the protocol and interface design

As shown in figure 5.1, qualitative interviews with users informed the research directions, and the resulting outcomes were also evaluated with end users. This user-centred approach has informed the design of a useable and effective checking protocol for use immediately prior to radiotherapy treatment delivery and interface design recommendations.

5.6 Reliability and validity

Research results must be valid and reliable before generalisation can be made. This thesis has employed a range of methods from both qualitative and quantitative approaches: task analysis, interviews and laboratory based experiments. The process

of triangulation was used to ensure that the results gained were valid, as Webb, Campbell, Schwartz and Sechrest (1966:3) note:

> *"Once a proposition has been confirmed by two or more independent measurement processes, the uncertainty of its interpretation is greatly reduced."*

Validity is how well the research measures what it intended to measure (Coolican 2004). Reliability refers to the accuracy of the research measures or designs, and to what extent they are dependable and consistent (Coolican 2004). There are many forms of both reliability and validity which need to be considered throughout all stages of the research process. A discussion of the main concepts in regards to this thesis are discussed below.

5.6.1 Sampling

All participants in this thesis were self-selected which could have impacted upon the validity of the results. When recruiting for the interview studies, the invitation to participate was extended to a whole department, or training year group, yet participants put themselves forward to participate. As such, it is likely that the participant sample consisted of those radiographers and student radiographers who were interested in the subject and who possibly had stronger opinions on the subject matter than others who did not volunteer to participate.

It is recognised that the sample in the interview studies was narrow, as qualified participants came from one of two departments and student radiographers from one education establishment. The exploratory interviews were conducted with radiographers from one department and the evaluation interviews were conducted with radiographers from another department. This was not believed to have had an impact on the findings for two reasons. Firstly, the majority of participants spoke of having either trained or worked at a different department to the one they were working in when interviewed, and hence drew upon their experiences in all departments when interviewed. Consequently, the interview data provided was informed from participant's experiences in a range of departments, other than just the

department the interviews were conducted in. Secondly, the attitudes of staff regarding safety and the final treatment check, and subsequent themes emerging from the analysis were similar between the exploratory and evaluative interviews despite participants coming from different departments. This suggests that the views of radiographers are similar across departments. The views of student radiographer participants were also similar and in keeping with the views of qualified radiographers. Student radiographers had been on placement in a number of departments in the region and as each student radiographer had been on placement in at least two departments, this adds validity to the results found.

The participant samples in the experiment studies were also self-selected, as they were all undergraduate psychology students at Coventry University and recruited via the university's online experiment management system, SONA. Students receive credits for time spent participating in research, and are required to collect a certain number of credits during the academic year. However, they have the option of signing up to many studies on SONA, and receive the credits regardless of whether they choose to withdraw or not, so there is no issue of bribery. This is similar to many schemes in other universities. As students need a set level of credits, it is likely that those students volunteering to participate towards the beginning of the academic year were conscientious students, which may have impacted results. However, participants took part in the experimental studies across the time span of academic years, thus random allocation to experimental condition is believed to have diluted any impact of personality traits on results. Hence, validity of results has not been affected.

5.6.2 Research design

The validity of the interview findings began with ensuring the interview schedule contained valid questions which would elicit useful and meaningful data. The interview schedule was derived from both the literature review, task analysis and the research aims. The interviews followed a flexible emergent design. That meant that if a participant brought up any points which proved interesting in regards to the research aims these were added to the interview schedule for subsequent participants. Data

collection continued until data saturation was reached. This is the point at which participants were not providing new insights or findings. This suggests the participant sample was adequate to represent all views from the organisations involved.

When conducting research on a potentially sensitive topic such as patient safety, there is always the risk that participants may not be entirely truthful. This risk was minimised during the interview by it being made clear to the participants that the researcher was an independent outsider who was not affiliated to the hospital or university they were working in. Furthermore, participants were assured that the data they provided would remain anonymous and confidential. It is believed that with these conditions in place, participants in this research were honest throughout the interviews.

At each stage of the research the results and direction of the research were discussed with a qualified radiographer to ensure that the research direction was both valuable and that the research procedure was reliable. This was especially pertinent when designing the experimental laboratory paradigm, as it needed to be an accurate mimic of the final treatment check process.

5.6.3 Analysis

The researcher was not blind to the research aims, objectives and previous findings, because this was a PhD study and the researcher was responsible for all aspects of the research. Although not intentional, this may have influenced the findings, especially qualitative investigation which is inherently subject to some degree of subjectivity. A number of precautions were taken to limit any researcher bias, and resulting reliability issues.

The interviews were all conducted by the same researcher to ensure consistency in the interviewing approach. Care was taken to ensure that leading questions were not used. The reliability of the data gained from the interviews was assisted by the researcher employing active listening techniques during the interviews. That is, the researcher regularly paraphrased and repeated back what the participant had said and

sought agreement from the participant that the summary accurately represented their views. Furthermore, a sample of interview transcripts were reviewed by an independent person to ensure the scrutiny of the questioning technique.

An issue with the reliability of results gained from qualitative analysis is that of subjective and researcher bias. This issue was tackled with the use of a second coder who coded a sample of the transcripts. Inter-rater reliability was ensured through a discussion and subsequent agreement of the codes and themes arising from the analysis. Furthermore, it was ensured that every theme could be recognised in a number of interviews and not isolated to one participant in order to ensure the results were a true representation of participants' views. The issue of subjectivity and validity in the task analysis was addressed, and believed to be minimised, by consulting radiographers to ensure what was depicted in the produced task analysis was an accurate representation of what happens.

5.7 Ethical considerations

All research was conducted in accordance with the British Psychological Society (BPS) code of ethical conduct. Each stage of the research was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee. Additional permission was sought and gained from Birmingham City University, Research and Development at University Hospital Coventry and Warwickshire and Research and Development at Northampton General Hospital before conducting evaluation interviews with qualified and student radiographers.

5.7.1 Patient safety ethical considerations

A number of additional ethical issues needed to be considered during this research. Patient safety can be a sensitive topic, and as such, healthcare proffessionals may have been unwilling to talk about these issues. Therefore, throughout the research process participants were assured that the researcher was independent to their workplace or university, and that the information they gave would remain anonymous. The researcher was aware, and participants informed, that if participants gave information

which exposed an immediate risk to patient safety, this would have been reported to the appropriate department manager immediately, whilst respecting participants anonymity. No such event occurred during the research process, and participants appeared willing to talk about patient safety.

The only exclusion criteria for participation in this research was that participants must not be under investigation for a patient safety incident. This is so that this research did not interfere with any on-going investigation, and no confidential details about such an incident or investigation was given during the interviews.

Patient confidentiality was retained during observations in radiotherapy departments. The researcher did not have direct contact with any patients, and all observations took place outside of the treatment room. No patient details were recorded at any time.

5.7.2 Informed consent

Prior to participation in research all participants were invited to read an information sheet which described the research aims, what was involved, and their right to withdraw. Participants were also assured that their data would remain anonymous and confidential. After reading this participants were always given the opportunity to ask the researcher any questions before they signed and dated a consent form. The consent form for the exploratory interviews can be seen in appendix 4. The consent forms were similar for all studies, with the study title changed.

5.7.3 Debrief

Immediately following their participation participants were both verbally debriefed and handed a debrief sheet. The debrief contained information about the study aims, previous related research and the researcher's contact details. Participants were given the option to withdraw their data up to two weeks after participation by quoting their unique participant number. No participants withdrew their data at any point.

5.7.4 Confidentiality

All data remained anonymous through the use of alphanumerical participant codes. The only place these codes correlated with a participant's name was on the consent forms. The consent forms were stored separately from any data in a locked filling cabinet.

5.7.5 Data storage

All data was stored confidentially and securely in accordance with data protection laws. Consent forms were stored separately from any data in a locked filling cabinet. Hard copies of experimental data were stored in a locked office, with digital files of results stored on a password protected computer. Data from interviews needed to be processed and stored with extra care to comply with data protection laws. Electronic recordings were stored on a password protected computer until transcribed and then deleted. Hard copies of transcripts were stored in a locked filing cabinet with digital transcripts stored on a password protected computer. The transcripts were only identifiable through the use of alphanumeric participant codes.

5.8 Chapter summary

This chapter has provided an overview of the methodology adopted in this body of research. It is believed that the use of mixed-methods has allowed the research objectives to be met whilst retaining reliability and validity in the research process.

6 Chapter 6- Study 1: Understanding the Final Treatment Check in Radiotherapy

Building on from the literature review, this chapter seeks to understand and map the patient pathway and the process of checking immediately prior to beam delivery in detail, based on current practice. One of the objectives of the thesis was to examine and understand the nature of radiotherapy verification in order to improve safety and increase the likelihood of identifying errors before they have an opportunity to cause patient harm. It was aimed to map the patient pathway in order to place the final treatment check, which this thesis is focussing on, into context and to produce a framework to guide the empirical work and subsequent final treatment check protocol design.

6.1 Method

A hierarchical task analysis (HTA) was produced in order to contextualise and explore the final treatment check. HTA is a method used widely in the field of human factors, which provides a framework to map, examine and model an activity. HTA represents a task in increasing levels of detail, in order to analyse potentially vulnerable parts of a process, at the lowest levels of an activity (Shepherd 2001). As Drury, Paramore, Van Cott, Grey, and Corlett (1987: 371) note a task analysis,

> *"Describes and analyses the performance demands made on the human element of a system. By concentrating on the human element in the system, it can compare these task demands with the known human capabilities"*

Evidence of an existing HTA for radiotherapy treatment checking has not been found, and is therefore a worthwhile endeavour to understand potential vulnerabilities, and areas for improvement, in the process.

In order to produce a task analysis a detailed understanding of the patient pathway in radiotherapy and the final treatment check process was sought through various methods:

- Over three days the delivery of treatment to 12 patients by six pairs of radiographers was observed at University Hospital Coventry and Warwickshire (UHCW) NHS Trust. The radiographers observed were of varying grades, and hence experience
- At a later date a further period of observation of treatment being delivered to patients was conducted at Northampton General Hospital
- Review of documentation, specifically *Towards Safer Radiotherapy* and the *Radiotherapy Risk Profile* in order to map the theoretical stages of treatment
- The above sources of data were collated together and cross referenced to break down the process
- The process was mapped using hierarchical task analysis (HTA)
- It was then verified with qualified and student radiographers in interviews, detailed in section 7.2.

Ethical approval for the observations was granted by the Faculty of Health and Life Sciences at Coventry University, and the R&D departments at UHCW NHS Trust and Northampton General Hospital. Confirmation of these approvals can be seen in appendix 1 and 2 respectively. The observations were conducted according to BPS ethical code of conduct and no patient details were recorded.

6.2 Results

6.2.1 The patient pathway

The diagram presented in figure 6.1 below maps the patient pathway through radiotherapy treatment. Steps 1-4 are completed prior to the patient arriving for their first dose of radiation. Steps 5-7 are repeated over a series of days, sometimes more than once in a treatment session. Table 6.1 gives a brief explanation of what happens at each of these stages, along with professional responsibility, derived from the literature. It is believed that these treatment stages are consistent across hospitals.

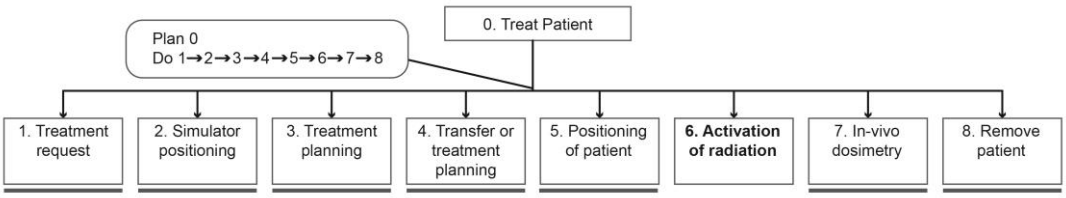


Figure 6.1: Task analysis of patient pathway

Errors can occur at many stages of the patient treatment process. It is important to note that the final treatment check will not prevent any errors which have occurred prior to stage 3 of the treatment process. This is because these errors would be errors associated with diagnosis, or treatment planning. Exploration of these types of errors are beyond the scope of this thesis due to the complex nature of treatment planning and clinical decision making in radiotherapy.

As discussed in section 2.3.4, stage 4 is vulnerable to error as this is the stage at which patients' treatment information is uploaded onto the computers responsible for delivering the dose, for example due to transcription mistakes and technology failures. Errors are also possible at stage 5 or 6 as staff could pull up the incorrect patient file. It is these types of errors which the final treatment check immediately prior to treatment delivery should detect in order to prevent harm. The final treatment check prior to treatment delivery occurs during stage 6, activation of radiation; this is the treatment stage upon which this thesis is focussed.

Table 6.1: Description of each stage in patient pathway

	Stage	Description	Profession responsible
1	Treatment request	A decision is made to treat the patient with radiotherapy. Treatment plan decisions are made and the patient is booked in for treatment.	Clinical oncologist
2	Simulator positioning	Patient attends radiotherapy department to receive CT/MRI scans to locate position of tumour and fit immobilisation devices if required.	Clinical oncologist, radiographer
3	Treatment planning	Images from scanning are combined and treatment dose and treatment parameters are calculated and checked. This includes energy, monitor units, bed position and beam accessories (these are used to target the radiation beam). These parameters are entered onto the patients' paper prescription.	Clinical oncologist, physicist, radiographer
4	Transfer of treatment parameters onto radiation delivery device	All treatment parameters and patient details are entered onto the radiation delivery device in the radiotherapy department, usually through a record and verify programme. This programme negates the need for treatment parameters to be entered prior to every treatment.	Radiographer
5	Positioning of patient	When the patient arrives for treatment, their file is pulled up on the computer. The patient is then collected from the waiting room, their identity checked and they are positioned on the bed in the precise location detailed on their paper prescription and on the computer system.	Radiographer
6	Activation of radiation	The radiographer leaves the room where the radiation machine is located and returns to the nearby computer console. They check the parameters the machine is about to deliver, which are displayed on screen, match those on the patients paper prescription before turning on the beam. A patients' treatment usually consists of many daily administrations of radiation and spans up to three weeks. The patient will attend for treatment every day during their treatment. Each administration of radiation is called a fraction and often more than one fraction will be given each day. Each fraction requires the dose parameters to be checked, although not all fractions require re-positioning of the patient. Therefore, this step is repeated at least once a day, and in many cases, more than once at a time.	Radiographer
7	In-vivo dosimetry	This measures the radiation dose received given after the patient's first dose to ensure the dose administered was correct. It is not universally practised.	Radiographer

6.2.2 Activation of radiotherapy process

During stage 6, the activation of radiation, is when the final treatment check prior to treatment delivery is undertaken. As earlier highlighted this is the final opportunity for an error in the treatment values entered into the radiotherapy machine to be detected, before it causes patient harm. This check, if done correctly and efficiently, should detect earlier errors in the treatment process to prevent erroneous treatment administration. Through observation of actual treatment a clearer understanding has been gained in how this treatment is given by radiographers and enabled a mapping of the individual task element. Building on this, figure 6.2 details the task analysis of the steps taken to activate the radiation.

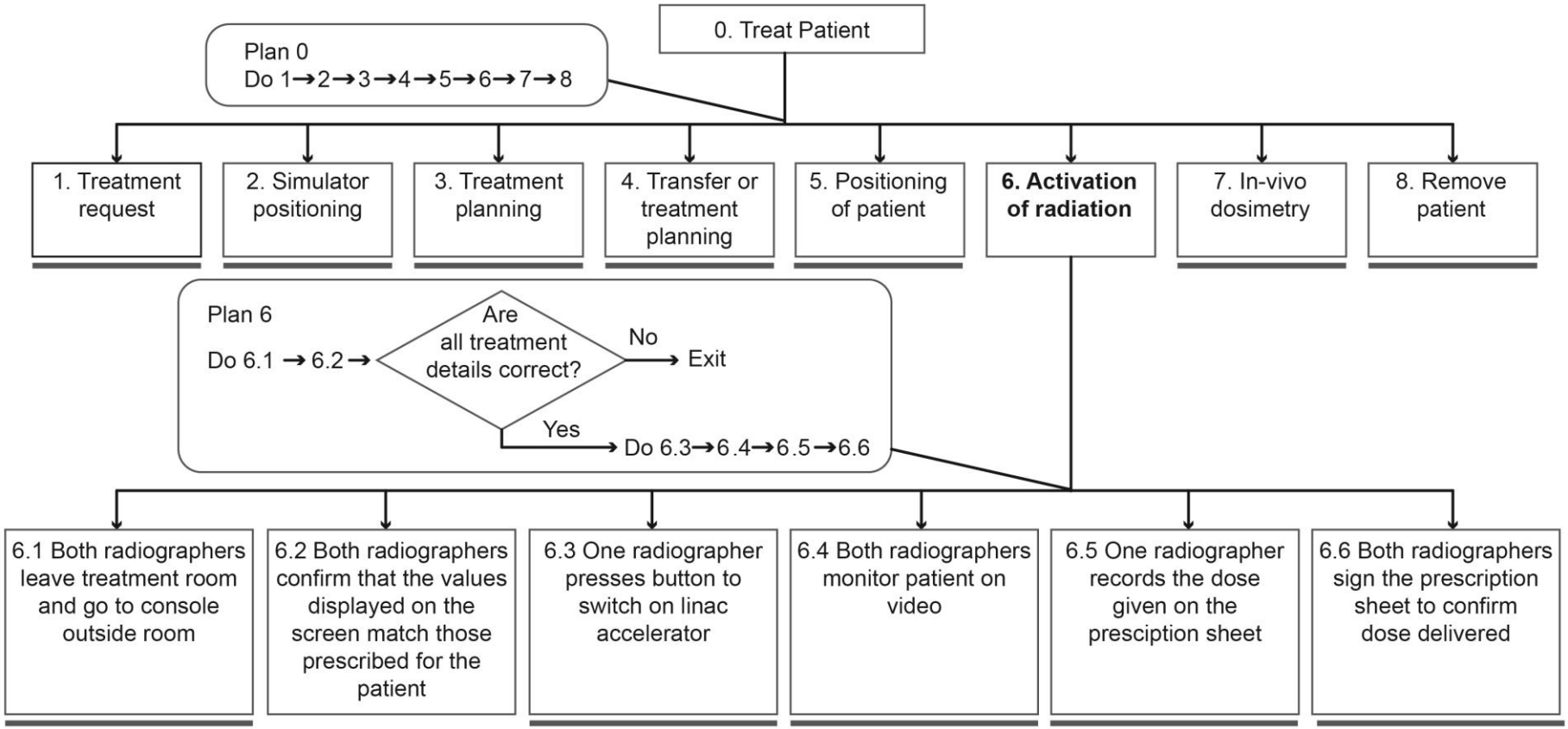


Figure 6.2: Task analysis of activation of radiation

6.2.3 Variation in the final treatment check process

As detailed on the diagram above, step 6.2.1 is when the final treatment check before treatment delivery is undertaken. From the review of documentation, detailed in section 6.1, this process cannot currently be mapped to a published protocol. The observations, also detailed in section 6.1, suggested that there is variability during this stage, both between and within radiotherapy departments. It is believed this variability is due to a lack of standardised treatment checking protocol.

As recommended in *Towards Safer Radiotherapy* four parameters should be checked and confirmed during the final treatment check: energy, monitor units, wedge monitor units, and wedge position. The documentation review and observations revealed three methods of checking. The first two versions are how it is believed radiographers currently conduct this final treatment check, based on the results from the observations. The first version describes the process when both staff look at the linear accelerator interface and the paper prescription with no verbal interaction. One pair of radiographers, in one department were observed to complete the final treatment check in this way. The interview results, detailed in section 7.2, suggested that many radiographers complete the final check in this way, across many departments. This suggests this method of checking is common place across departments. The second method of conducting the final treatment check which was observed, is when radiographers do conduct a verbalised check, but 'chunk' all the parameters together. Across both departments observed, the majority of radiographers completed the final treatment check in this way. The interview results, detailed in section 7.2, also confirmed that this is a common place method of current checking.

The third version is a challenge-response check, with an active repeat back of treatment parameters. As discussed in section 4.4, challenge-response checking was identified in the literature review as being an effective method of checking, which, due to its safety merits, is employed by the aviation industry (Degani and Weiser 1990). This method of checking has also been recommended in *Towards Safer*

Radiotherapy, although not in a high level of detail. The document simply states that treatment checks should be:

> *"active with a verbal response from the second checker"* (Donaldson 2007).

Therefore, this method of checking is currently proposed as best practice. During the observation period, no radiographers were seen to follow this method of checking. Although two pairs at one hospital were seen to conduct a challenge-response check without the active repeat back.

The observations suggested variation in the method of checking used for the final treatment. It appeared that not everyone in the same department were checking the same way as each other, and there was no standardised approach between departments. Active challenge- response checking appears to be used less often than no verbalised or 'chunked' checking. The interviews, described in the following section, confirm this finding. Detailed below are the three step-by-step versions of the final treatment check stage, where these four parameters are verified: no verbal checking, 'chunked' checking, and active challenge-response checking. Following each version of the final treatment check is a review of the potential weaknesses of the check which may lead to a failure to detect errors, based upon theories of psychological processes. This allows comparison of the human elements requirements with human capabilities, in order to understand weaknesses and areas of improvement within the final treatment check process.

6.2.3.1 No verbal checking

The observations, and interviews described in the following chapter, revealed that some radiographers do not call out the parameters verbally when conducting the final treatment check. This method of current checking is detailed in figure 6.3. This contravenes the guidance presented in *Towards Safer Radiotherapy*.

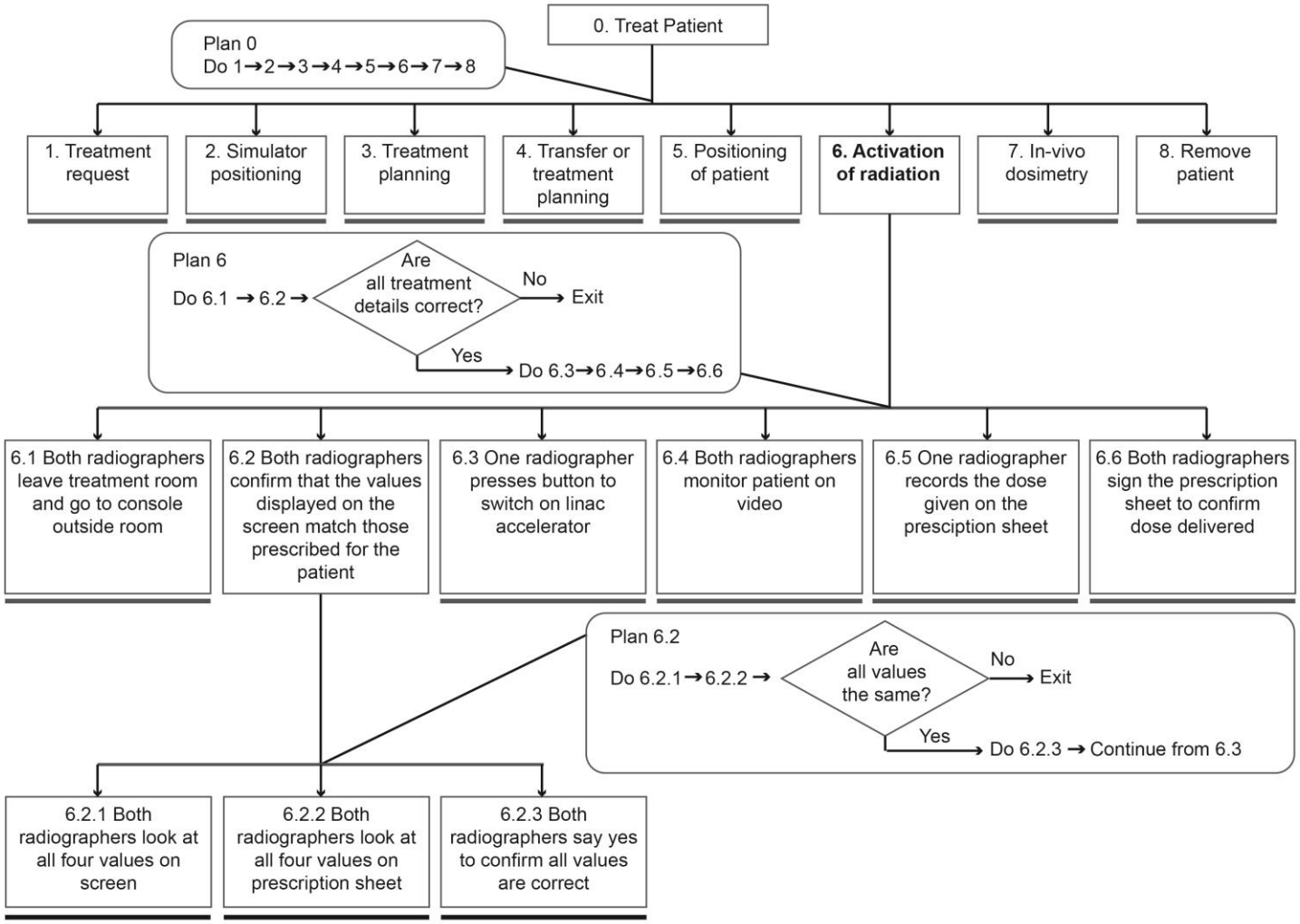


Figure 6.3: Task analysis of non-verbal checking

There a number of reasons why this method of checking is vulnerable to errors passing undetected. Firstly, there may be an over-reliance on the other radiographer during the check which may lead to neither radiographer taking full responsibility for conducting a thorough check. Second, as the checking process is not verbalised, neither radiographer can be sure that the other has checked the parameters. This also makes the check vulnerable to deference to authority. This would be especially pertinent if a junior radiographer is delivering treatment with a senior radiographer. The interviews, in section 7.2, also detail this vulnerability.

A further phenomenon this method of checking is vulnerable to is 'see what you expect to see' (expectancy bias). This is a well-established notion in psychology that suggests various cognitive biases can influence perception:

> *"Whilst part of what we perceive comes through our senses from the object before is, another part (and it may be the larger part) always comes out of our own mind"* (James cited in Curry, Meyer and McKenney 2006).

Of note within the final treatment check in radiotherapy is the role of the cognitive bias, expectancy. Perception is malleable. The perceptual set theory of perception defines perception as an active process based upon inferences, interpretation and selection (Allport 1955). According to this theory of perception, previous experience, context or motivation (Balcetis and Dunning 2006), can influence what is perceived. If expectancy effects occur, radiographers may perceive the value which they expect to be there, based on experience or knowledge of the patient, not what is actually there. Therefore, it is important to minimise the effects of expectancy bias by ensuring that radiographers look at the linear accelerator machine first, and check that against the prescription. This is so that the expectancy of seeing what was written on the prescription does not influence the perception of the values which are about to be delivered by the machine.

The phenomena of 'see what you expect to see' was also noted by Degani and Weiner (1990) in their review of aviation checklist use. They noted that after repeated checklist use, pilots would create a 'mental model' of the task which speeds up the checklist process, to the detriment of accuracy. It was noted that this

occurred much more quickly if the checklist was conducted in unfavourable physical and psychological conditions such as with a heavy workload or noisy environment.

6.2.3.2 'Chunked' checking

This method of checking is illustrated in figure 6.4. The observations revealed that radiographers often did not verify parameters one-by-one. Instead, all four parameters were often called out as one. The interviews, detailed in the following chapter, also suggested that this method of checking is commonplace across departments.

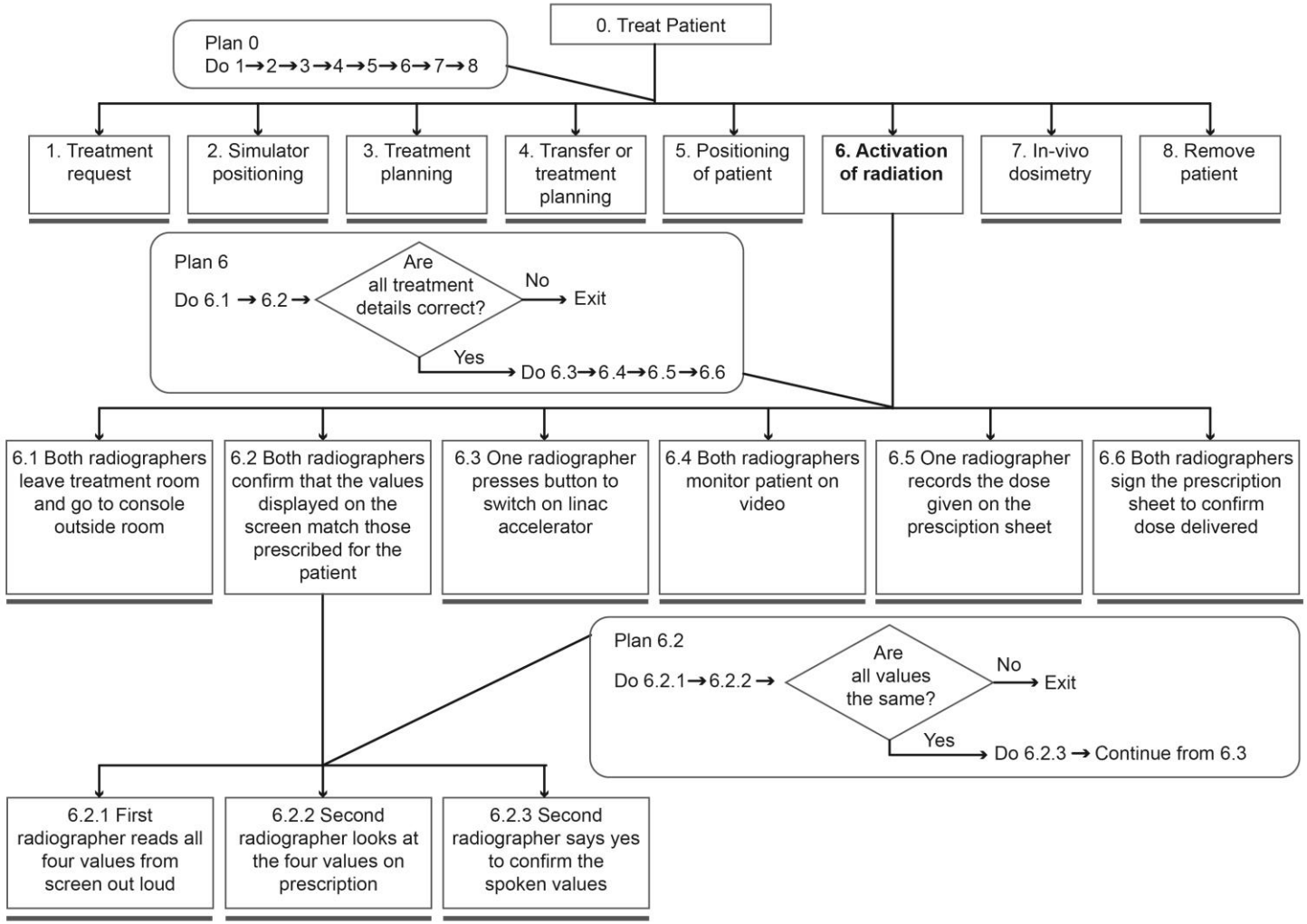


Figure 6.4: Task analysis of 'chunked' checking

This habit of 'chunking' checklist items together was also observed by Degani and Weiner (1990) in their review of aviation checklist use. Whilst this method of checking is verbal, there are a number of vulnerabilities of this method associated with memory and attention. This method of checking places a high cognitive load on the radiographer listening to the parameters being called out, which could lead to errors from a few theoretical perspectives. Firstly, this high cognitive load may lead to a failure of memory. The parameters to be verified must be held in the short term memory of the radiographer listening, in order to confirm they correspond with the parameters written on the prescription. The dominant models of memory suggest that the capacity of short term memory is very limited, limited to around five to nine items (Miller 1956, Reitman 1974 and Atkinson and Shiffrin 1968). As each parameter consists of multiple digits, this means the later parameters may displace the earlier parameters. This vulnerability to short term memory decay is also increased if there are distractions.

The listing of parameters and high short term memory load may also have a negative consequence on attention. The phenomenon of inattentional blindness is thought to result from limited mental attention (Green 2004). Visual perception is reduced to a narrow field of focus when the brain is attending to another stimuli, which results in a lack of awareness for the stimuli presented in an unattended part of the field. There is a distinction between looking at a stimuli and attending to it. Todd, Fougnie and Marois (2005) found that an increase on visual short term memory load impaired the activity of the right temporoparietal junction which, in turn, prevented participants from perceiving a novel, unexpected stimuli. Hence, it can be inferred that increased visual load leads to inattentional blindness. This is of relevance to radiographers who are presented with a large amount of visual stimuli at the time of the final treatment check. Furthermore, there is a newer, related concept of inattentional deafness. The concept presented by Macdonald and Lavie (2011) suggests that stimuli may not be heard accurately when there is a high visual load. This can be applied to the final treatment check as, if the person responding to the call is looking at the screen or prescription, and hence exposed to a high visual load, they may not hear the value being called correctly.

Finally, due to a number of parameters being verbally called out in a list, it is possible that the second radiographer may be looking at the written parameters whilst listening. If this is the case, there is a possibility of errors due to cross modal attention. When audio and visual events happen simultaneously they can integrate. It has been suggested that this is not automatic and can be prevented by retaining a high level of attention (Koelewijn, Bronkhorst and Theeuwes 2010). This has implications in radiotherapy because if radiographers are looking at visual information when the values are perceived audibly (read out by the other radiographer), there is the possibility for these two stimuli to integrate and for radiographers to erroneously perceive to have heard the value which they were reading. In order to prevent this attention must be maintained at a high level.

6.2.3.3 Active challenge-response checking

This is the 'active' checking method recommended as current best practice in *Towards Safer Radiotherapy*. This document states that active checking is sufficient to overcome involuntary automaticity and is defined as;

> *"Verifying should be active and elicit a specific detailed response rather than a "yes"* (Donaldson 2007: 35)

This method is detailed in figure 6.5. Within this method of checking there are two chances at error detection as each checker hears the other announce the value. This method of checking is known as challenge-response and, as discussed in section 4.4, is widely used within aviation due to its safety benefits. This method of checking was not seen during the observations and no participants reported this method being used in their department during the interviews presented in the following chapter. Radiographers where observed using this method without the active repeat back infrequently during the observations. As such, it is believed that this method of checking is not currently common practice across radiotherapy departments.

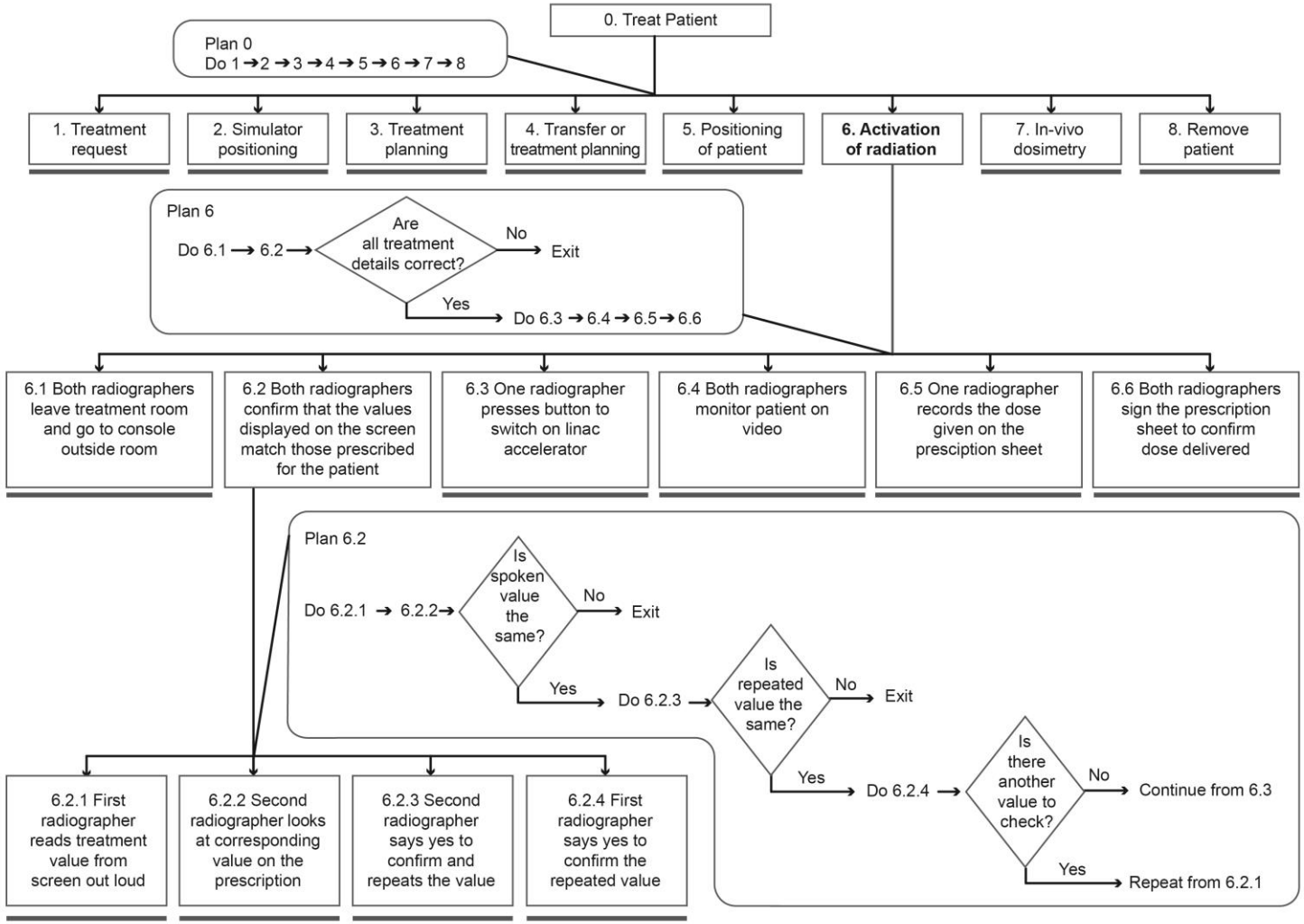


Figure 6.5: Task analysis of current best practice checking

This method of checking is verbal, and there is less cognitive load placed on the radiographer listening and responding to the parameters, as they are verified one by one. However, as the literature review and observations have indicated the final treatment check is regularly repeated and therefore vulnerable to involuntary automaticity. By definition involuntary automaticity is when a regularly repeated behaviour is conducted on autopilot without the need for conscious attention (Toft and Mascie-Taylor 2005). This is clearly beneficial for certain behaviours, yet when conducting safety critical tasks, attention needs to be maintained. In these circumstances, involuntary automaticity would be considered a failure of attention. However, attention has three parts; orientating, executive control and alerting (Bonnefond *et al.* 2010). Even a momentary lapse in attention can result in a lack of endogenous behavioural control which could easily lead to a catastrophic error. In radiotherapy sustained attention is required to detect infrequent and often minor errors, which meets the definition of vigilance, as defined by Wickens (1992:605):

> *"Vigilance is a state of readiness to detect and respond to certain specified small changes occurring at random time intervals in the environment"*

Sustained vigilance over a long period of time can lead to work fatigue which in turn leads to errors. This phenomenon of vigilance decrement has been demonstrated in many studies. The issue of sustained vigilance was first investigated by Mackworth (1950) who asked participants to watch a clock and detect when the second hand missed a beat. It was found that performance started to deteriorate after 30 minutes, and more missed seconds went undetected as time went on. The majority of vigilance research has been conducted within signal detection, during which attention must be focussed upon a single stimuli. Radiotherapy is a little different in that radiographers must detect errors, but this vigilance task is punctuated by other tasks. However, the findings from attention and vigilance research should be considered in respect to radiotherapy, for example through regular breaks, or change of task, to break up monotony and help prevent fatigue and vigilance decrement.

There is a debate in literature as to what causes vigilance decrement. Various theories have been suggested, such as: Arousal Theory (Frankman and Adams 1962)

and Resource Theory (Hancock and Warm 1989). The Arousal Theory draws upon the 'inverted-U' model of arousal attributed to Yerkes and Dodson (1908). According to this model, arousal increases an individual's level of task performance up to a point, beyond which performance decreases. Performance decrement therefore either results from under-arousal or over-arousal resulting from stimulation from the task. Easterbrooke's cue-utilisation hypothesis (1959) also adopts this model of performance, stating that an individual's level of emotion mediates the perception of visual and auditory cues. According to this theory, an individual's stress levels may also mediate task performance.

A modern theory of attention adapts this inverted U shaped model to attention. The overload and underload theory of attention also represents attention as an inverted 'U' shaped graph, with an optimal level of arousal on performance, above which and below which, attention drops off. It has been theorised from a meta-analytic review of the neural mechanisms of vigilant attention that vigilance or attentional decrements may be more likely if a task is repetitive and simple (Langer and Eickhoff 2013). This phenomenon of underload is also thought to be more likely if there is a high level of automation in the system, which reduces human input further (Young and Stanton 2002[a]).

In regards to the process of the final treatment check, it is suggested, and further supported by the findings from the interviews (see section 7.3), that attention may fail due to underload. The final treatment check task is repetitive, simple and staff may feel bored when conducting repeated final treatment checks. It is not believed that radiographers suffer from cognitive fatigue as a result of overload because the final treatment check task itself is not cognitively demanding. Therefore, there is a need to prevent underload during repeated final treatment checks, perhaps by making the task fractionally more difficult to increase arousal. Less research has been conducted on underload, as compared to overload (Pattyn *et al.* 2008), even less on repetitive tasks which are punctuated by other tasks. However, research has suggested that the addition of a secondary task can improve performance during

monotonous tasks. For instance, asking drivers to answer trivia questions has been shown to alleviate driver fatigue during monotonous driving (Gershon *et al.* 2009).

Automation of systems (such as R&V) are in some senses considered beneficial as they reduce operator work load. However, this automation may be detrimental if the task is already simple, as it could lead to underload which can be just as detrimental as overload. The Mallleable Attentional Resources Theory (Young and Stanton 2002[b]) states that attentional capacity shrinks in line with demand. Therefore, automation systems, arguably, reduce the cognitive demand required of humans in the system. A further danger with computer operated systems requiring human input is the challenge associated with knowing when and how to switch between user and computer control (Bainbridge 1983). Within radiotherapy this can be compared to the introduction of R&V systems, which check patient's treatment parameters, which may lead radiographers to believe that the final treatment check is unnecessary. Therefore, it is ironic that the introduction of computer systems, such as R&V systems, designed to increase reliability may have actually made humans more prone to error.

6.3 Chapter discussion

This chapter has presented a HTA for the final treatment checking process prior to beam delivery in radiotherapy. This has been formed by combining observations with published radiotherapy guidance. The task analysis has mapped the patient pathway in order to contextualise the importance of the final treatment check prior to beam delivery. There was variation found in how the final treatment check was conducted. This variation was unexpected, but is believed to be due to there being no standardised, published protocol for this process.

This HTA has detailed three different methods of final treatment checking, non-verbal, chunked and challenge-response. Each of these methods has been reviewed for effectiveness based on theory and literature. This highlights that the methods of checking currently believed to be in use are not effective at detecting erroneous treatment parameters. The evidence suggests that the best method is challenge-

response checking as both radiographers have an equal and active involvement, making it a more robust verification.

It is recognised that the development of this HTA may have been vulnerable to researcher bias as the observations were conducted by the researcher alone. As the observations were overt, there is a possibility that the radiographers may have exhibited demand characteristics and deviated from their usual behaviour during the period of observation. However, these biases are believed to have been minimised by the triangulation of the observation data with the published literature and guidance from *Towards Safer Radiotherapy*. The HTA as an initial model will be further validated and built upon through the interviews conducted with qualified and student radiographers, which are presented in the next chapter. The different methods of checking, alongside radiographers' views and experience of error and checking accuracy will also be explored. This will then allow for initial recommendations surrounding the design of a safety protocol for use immediately prior to beam delivery to be made.

7 Chapter 7- Study 2: Exploring current practice and the experiences of qualified and student radiographers

The literature review suggested that more research is needed into the efficacy of the final treatment check in radiotherapy and the factors contributing to its efficacy. Chapter 6 explored different methods of checking which appear to be in use based on observations and literature. This chapter details exploratory interviews conducted with qualified and student radiographers which aimed to explore radiographers' views and experiences of how the final treatment check was conducted currently, why errors may pass undetected and how it might be improved. Participants' views on wider patient safety issues were also sought. The interviews also aimed to verify the content of the HTA, presented in the previous chapter.

7.1 Method

Exploratory interviews were undertaken to further understand the process of the final treatment check and perceptions of wider patient safety issues within radiotherapy, as they are considered valuable for accessing end-users perceptions and opinions as discussed in section 5.5.

7.1.1 Design

Semi-structured interviews were chosen because they allow a flexible interview schedule to be followed. This interview schedule covered the topics necessary for the research question whilst allowing the researcher to follow up on any interesting points raised by the participants.

7.1.2 Participants

Qualified radiographers were approached to take part in this research to enable an understanding of the situation on the ground, from those practising in the field. It was intended that the participants would represent a range of experience and views. Therefore, student radiographers were also approached as they were at the beginning of their career and may have a different viewpoint from qualified radiographers. Students in their final year of training were approached as they were

believed to provide a range of experiences as they had been on placement in various different hospitals across the region. Teaching staff from the university were also recruited to provide views on training and academic aspects.

Participants were recruited via opportunity sampling. An email invitation was sent to potential participants who were asked to contact the researcher to arrange a convenient time for interview if they were interested in taking part. All radiographers from University Hospital Coventry and Warwickshire (UHCW) NHS Trust and all third year student radiographers from Birmingham City University's (BCU) radiography department were invited. These locations were chosen as they were local to the researcher. The only exclusion criterion for this study was that participants must not be under investigation for a patient safety incident. Recruitment continued until data saturation was reached, this was the point at which participants provided no new data.

Six qualified therapy radiographers were recruited from UHCW NHS Trust radiotherapy department. Nine student radiographers in their final year of training were recruited from BCU. Two academic teaching staff from the same university were recruited (who were still practising clinically). This group was believed to represent a range of experience and views. A summary of participant experience is provided in table 7.1.

Table 7.1: Exploratory interviews participant experience

Grade	Number of participants
Band 5 radiographer	1
Band 7 radiographer	5
Academic teaching staff	2
Third year student radiographer	9

7.1.3 Procedure

The interviews took place in a quiet room, away from any distractions in which the researcher was able to conduct the interview one to one. Interviews at BCU took place in a teaching room on campus. Interviews at UHCW NHS Trust took place in a

private office. Interviews lasted between 30-60 minutes. The interviews were voice recorded to allow the production of a verbatim transcript and to allow the researcher to focus on what the participant was saying and ask probing questions. These interviews were transcribed verbatim by the researcher and the transcripts used for analysis.

7.1.3.1 Interview schedule

All interviews were conducted following the same interview schedule which can be seen in appendix 5. A description of the interview content is presented in table 7.2.

Table 7.2: Content of exploratory interview questions

Question number	Content Description
1-2	**Demographics** • Initial demographic questions to allow comparison of participant responses in the analysis.
3-7	**Patient Safety** • Experience of patient safety and patient safety incidents. • Patient safety awareness amongst staff • Common errors or weak points in the radiotherapy process.
8-14	**Checking** • Checking and verification in daily practice • Checking methods and perceptions of effectiveness • Factors that contribute to checking effectiveness
15-20	**Improving verification** • Potential improvements to the final treatment check

Questions were developed to build upon the findings of the literature review. As attention and deference to authority had been suggested as potential reasons underlying checking efficacy in the literature review, these were specifically included in the interview schedule. Questions were also guided by the observations conducted in departments, and detailed in section 6.2. Throughout data collection the questions followed a flexible emergent design- that is, if an unexpected topic arose during an interview it was added to the schedule for subsequent interviews. This allowed for the addition of some interview theme questions such as the impact of technology.

7.1.4 Ethics

This study was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee and approved by UHCW NHS Trust's Research and Development department. Approval was also sought and gained from BCU. Confirmation of these approvals can be seen in appendix 1, 2 and 3 respectively. The interviews were conducted according to BPS ethical code of conduct.

7.1.5 Analysis

Thematic analysis (TA) was chosen as this was an exploratory topic and thematic analysis allows identification and exploration of patterns across the data, as discussed in section 5.3.2. The analysis process detailed in section 5.3.2 was followed. Examples of coding, and a table of themes, sub-themes and codes can be found in appendix 6 and 7.

7.2 Results

Participants gave many reasons as to why double checking may fail to detect errors. Thematic analysis of the interviews led to these reasons being clustered into seven themes to potentially explain why the final treatment check checks may fail to detect errors. These were; lack of standardised protocol, lack of training in patient safety and treatment checking, difficulty maintaining attention, working environment, interface design and authority structures and team culture. These are discussed in turn.

7.2.1 Lack of standardised protocol

A prominent theme to emerge was the lack of standardised protocol when conducting final treatment checks both between departments and within the same departments. This was of particular concern to student radiographers. Some students were unaware of any protocol for the final treatment check in their department:

> *"I'm not aware of a set protocol, everyone seems to know what it is that they're for and you just do it whatever way, as long as you've done it I think it doesn't matter how you've done it" Third year student radiographer*

There was also some debate over whether single or double checking was more effective. Some participants believed single checking made them more responsible

for their actions, yet the majority viewpoint was that double checking provided reassurance that the checks are thorough. Respondents reported that, all but one department, conducted double checks, but there was variation in how these were conducted. Five students reported that their departments conducted unstructured double checks whereby no values were read out and verified, instead both staff members looked at both the screen and prescription together and signalled agreement:

> "*Two members of staff will kind of look at the sheet, look at the screen and they'll just go "happy?" and then one will say "happy" and they'll just switch on". Third year student radiographer*

Participants believed that an unstructured check could allow responsibility to be passed to the other checker as there are no clearly defined roles. For this reason students reported they would have to be even more vigilant to compensate for others. Another concern for students when staff used this unstructured method of checking was that they were done too quickly, with staff seemingly only glancing at the screen. Students were in agreement that this unstructured method of checking was potentially unsafe:

> "*I would definitely be uncomfortable being treated by them!" Third year student radiographer*

A challenge-response method was believed to be safer by students and qualified radiographers as both radiographers know the other is checking. It was suggested that the verbal callout was effective as it engaged more senses. Participants were unanimous in their appreciation for a standardised protocol. They believed this would be especially beneficial if they have been away from practice and ease the transition period when moving to a new department:

> *"Sometimes you come back into department after ages and think "Oh what do I check?" It would help with a set way or set order to check it in and not everyone just doing it their own way" Third year student radiographer*

Participants suggested a "*gold standard verification protocol*" would not only improve safety but also emphasise the importance of the final treatment checks. However, participants warned that this may be met with resistance from senior staff who were used to their way of working. As such it was stressed that the protocol

should be evidence-based and must strike a balance between time and effectiveness:

> *"If someone tells you to do something and you don't know why, people won't pay attention. You've got to provide the support- why you're doing it and what benefit it has. Otherwise there's no point changing it" Third year student radiographer*

7.2.2 Lack of training in patient safety and verification

A lack of training both around patient safety and specifically about how to conduct the final treatment checks was reported by both qualified and student radiographers. Students reported not having been taught how to do a final treatment check and reasoned this was due to the perception that the checks were simple to do and hence overlooked. Participants were very aware of the dangers and responsibilities associated with their job:

> "You know you can't take back a dose that you've given somebody and mistakes can be catastrophic". *Third year student radiographer*

However, it was apparent that this 'fear factor' can wane after qualification and that safety reminders were needed to maintain it:

> *"*I guess you get more and more confident you perhaps lose that element of fear factor to get it right" *Third year student radiographer*

A suggested reminder was knowledge about errors and near misses. Aside from hearing of errors from colleagues no specific patient safety training was reportedly given. The majority of participants were unable to explain exactly what patient safety was, referring only to procedures for manual handling and ensuring their own safety was maintained through wearing lead vests to block radiation. Training is delivered mainly whilst students are on placement, yet there is variation in the quantity and approach to training:

> "We don't actually have an actual lesson over it all, anything like that. We just go into department and you kind of rely on the senior on the room to explain things to you {…..} That's why different students know a bit more and some people know a bit less because it really depends who's on the room with you and of they bother going over it" *Third year student radiographer*

Students reported that they would appreciate more error training, to understand how errors may occur and increase their safety awareness. It was suggested this is

delivered through case studies to maintain interest. Furthermore, both students and qualified staff noted that, not only is there no specific patient safety training but that there is no discussion on the course about variation in local protocols. Both students and senior staff expressed that this would be beneficial as discussion of protocol variation would not only prepare students for working elsewhere but also stimulate critical thinking and understanding of why things are done the way they are:

> *"I think being able to go to other departments and see how they go about their checking would help with that level of "ok, yes", so they can make their own judgement then as to what is appropriate" Academic teaching staff*

7.2.3 Difficulty maintaining attention

Attention was a major theme, with sub-themes of boredom due to the repetitive nature of the job, a sense of number overload, fatigue, assuming the treatment is already correct and overreliance on technology all possibly leading to inattention. Both staff and students acknowledged that the job, especially newly qualified roles, can be perceived as repetitive and boring. They believed this monotony could lead to lapses in concentration:

> *"If you do it every day then obviously it gets a little bit mundane and perhaps people don't pay as much attention to it." Band 7 radiographer*

Participants noted that they had personal responsibility to maintain attention, and to look past the numbers and observe the person being treated. Yet it was also noted that the high concentration demands easily leads to fatigue.

Participants reported that often treatment machines treat only one anatomical region to increase productivity. However, when treatment machines treated a variety of anatomical regions participants reported that it alleviated the monotony and staff became more engaged:

> *"when there are different things you do go "yippee!" Band 7 radiographer*

Staff also reported being less engaged during the mid-stage of a patient treatment as it is presumed that all details are correct because the treatment has been checked multiple times and any changes will be alerted to staff by the system. Participants were aware that although these checks may appear redundant, mid treatment is a

vulnerable stage of treatment because they are expecting certain values to be read and hence may hear only what they expected to hear:

> *"Sometimes you hear what you're expecting to hear. Especially if the patient's been on treatment for several weeks you think, well it's been checked that many times, you're not expecting a problem. So perhaps you're less likely to pick it up". Band 7 radiographer*

It was believed that this risk could be alleviated by having a new staff member join the team, as "*a fresh pair of eyes*" who was considered to be more vigilant.

It also emerged that the job is very number-orientated, which requires concentration and has detrimental effects on attention:

> "You're just getting numbers thrown at you all day long and while you're in the room setting the patient up you're looking at all the numbers. You come out the room and you've got all the number there and you're recording the numbers. So you do thirty, forty times a day, every day. Yeah it would all become a blur". *Third year student radiographer*

Due to this repetition of checks participants observed that the checks could easily become automated, or "*second nature*". Participants reported that they believed this automated checking was increased by relying on technology. Technology promotes inattention as the computer is believed to be correct and hence checking redundant:

> "If the computer threw up some little bit of info that was wrong, would you notice?" *Third year student radiographer*

This increase in computer responsibility was illustrated by a divide between the younger generation of radiographers who had never worked without R&V systems and those who had. The former were apprehensive to work without R&V and refused to manually enter parameters when technology failed. Although R&V systems were unanimously considered safer, participants believed that manual input of data was a much more active process which ensured attention levels were maintained. This led some participants to suggest an interface which mimicked manual data entry by requiring parameters to be typed in and checked for correspondence:

> *"If you had to physically type it in and it has to correspond then that would make a difference, keep you more on your toes." Third year student radiographer*

Maintaining attention is clearly challenging, however, participants noted that it was their personal responsibility to maintain attention, but also the role of the senior radiographer on duty to ensure staff had adequate breaks. A suggestion to maintain attention was switching roles; both tasks and role of challenger and responder during final treatment checks:

> "Where I train they do take it in turns to alternate switch on. I think that is quite important and it does break up the monotony a bit" *Third year student radiographer*

Another suggestion to maintain attention was the use of alerts, calling out something unexpected as a 'test' to ensure staff are not just signalling agreement to every value:

> *"It's completely wrong but it would be nice now and again to have a little something thrown in where you think, hang on, that's not right!" Band 7 radiographer*

7.2.4 Working environment

The working environment was perceived to have an impact of checking efficacy with atmosphere, distraction and workloads varying. Whilst primarily for patient benefit, the issue of music was mentioned as having both a positive and negative effect on concentration and hence checking efficacy- either making the staff more engaged or distracting staff. Participants reported there are many distractions around the machines; phones ringing, colleagues talking, patient enquiries and other staff interrupting, with distractions from fellow staff mentioned more frequently:

> *"If you've got a patient in the waiting room who's suddenly poorly or fits or something then you'll be distracted. Similarly somebody coming in saying "do you want some chocolates?" Academic teaching staff*

Aside from distractions, radiographers are under pressure to treat patients quickly due to machine breakdowns, sick patients, and to reduce waiting times:

> "In my department we're always in a rush. There's always a queue. Patients are always moaning" *Third year student radiographer*

These factors, especially machine breakdowns, where reported to increase the workload on remaining functioning machines, and have a negative impact upon the working environment for staff. Heavy workloads were reported to increases stress which participants suggested can lead to concentration lapses and potential errors:

> *"I* think the more chaotic things are the more potential there is for someone just not registering that someone's said 131 instead of 113." *Third year student radiographer*

7.2.5 Interface design

Participants reported that the interface used for the final treatment check was not user friendly. The information was too densely presented; as a result information cannot be easily extracted. Participants suggested the interface would benefit from an improved layout, increased font size, more use of colour and highlighting of key information:

> "when you first look at it, you think, "oh my god!" It's just a bank of numbers". *Third year student radiographer*

Additionally, participants believed that active engagement with the interface, for example active data entry, this would help to prevent errors.

7.2.6 Authority structures and team culture

Issues of authority arose frequently, both in regards to participants feeling able to speak up to a senior radiographer, and the senior radiographer setting the team culture. Participants reported that there was variation in attitudes amongst colleagues in terms of the importance of the final treatment check. Some staff placed more importance on the final treatment check than others:

> *"But I know some people don't see it as important and I wondered if that's because they've never been involved in an error." Academic teaching staff*

It was also noted that the composition of the team working on each machine changes frequently which results in the team culture subtly changing each time. All participants asserted that they would not defer to authority, and would be willing to question current practice and speak out about errors. However, they reported that they felt others would be less willing, which is something challenging to address:

"some of the newer, less confident individuals may well say, I can't question here. So that is something that we would discourage but it's difficult to stop" Band 7 radiographer

7.3 Chapter Discussion

Chapter 4 highlighted that there is lack a research on checking practise and effectiveness in radiotherapy. Here that has been addressed by exploring the use of double checking in practise and the perception of effectiveness in radiotherapy specifically. The aim of this study was to explore how the final treatment check was currently conducted and gather radiographers' views on how final treatment check could be improved to be more effective at error detection.

7.3.1 Current practice

The interviews revealed how the participants currently conduct the final treatment check immediately prior to beam switch on. The interviews indicated that radiographers employ differing methods of checking, both within and between departments. The methods of checking discussed in the interviews supports the findings from the task analysis presented in section 6.3. There was little knowledge of any existing protocols for the final treatment check which undoubtedly contributes to this variation. The majority of participants reported that no verbal call out was performed during the final treatment check. As indicated in the task analysis in section 6.3, and literature reviewed in section 6.3.3, a verbal method of checking is considered more effective at error detection. Without this, the check may not be carried out independently, as one radiographer may rely on the other to check.

Section 4.1 discussed the guidelines for two radiographers to be responsible for switching on. These interviews indicated that sometimes the final treatment checks are conducted by one radiographer only, violating these published guidelines. The literature in chapter 4, highlighted the debate surrounding single or double checking. Here participants' views on this issue were explored. The effectiveness of double checking over single checking was debated by many participants who all agreed that double checking was more effective and accurate. This contradicts previous research which reported medical staff preferred single checking (Jarman, Jacobs and Zielinksi 2002). Although the previous research was not situated in a radiotherapy context, in

this present research staff appreciated the verbal call out and felt reassured by using it, as the final treatment check was not rushed through when verbalised.

The findings of these interviews point to the need for a standardised safety protocol for the final treatment check. Participants reported that this would reduce variation in final treatment checks, and ensure all radiographers were conducting a verbal check which was preferred as it was perceived to have safety benefits. A need for a written policy on double checking has been suggested before from other healthcare domains (Dickinson *et al*. 2010) and this research also suggests a clearly defined final treatment check policy is required. Previous research within the patient safety field, suggests that standardisation of procedures helps to prevent errors, as discussed in section 4.6

7.3.2 Performance shaping factors

The lack of a standardised method of final treatment checking was the main reason cited for errors passing undetected. Yet, other potential reasons were given by participants as to why the final treatment check may fail to detect treatment errors.

The issue of automatic responding when double checking had previously been recognised in healthcare broadly (Armitage 2009) and radiotherapy specifically (Toft 2005, Toft and Gooderham 2009) and was also supported by participants' perception in this study. Participants were very aware that because the final treatment checks were repeated regularly they were susceptible being conducted on "auto-pilot". This reflects Leape's view that double checking can become a "ritualistic chant" (Armitage 2007). Maintaining attention and interest, to prevent involuntary automaticity, is challenging in radiotherapy as the checks are repeated regularly. The interviews revealed that the radiographer's role is sometimes repetitive and monotonous. The job requires concentration which, when combined with the need for accuracy, can be demanding, as discussed in the task analysis in section 6.3.3. The danger of conducting final treatment checks on auto-pilot was highlighted by the radiographers who recognised that errors were more likely to occur during the middle to end of a patient's treatment, when radiographers were familiar with what

the treatment parameters should be. Furthermore, the interviews suggested that it is common practice for each linear accelerator to treat one particular anatomical area. As such, during a shift radiographers will treat the same anatomical area. This is of consequence for the 'see what you expect to see' phenomena, as the parameters will be similar for each anatomical region, for example the monitor units for breast treatments will be similar for all breast treatments.

A further issue identified in the interviews as affecting the accuracy of the final treatment check, and related to attention is boredom. Boredom can be defined as:

> "*thrawted engagement of attention*" or "*inability to maintain attention*" (Cheyne *et al*. 2009:580)

It is well known that a monotonous task or a task requiring sustained vigilance can lead to boredom (Grandjean 2009). Boredom can be defined as an experience in a situation with too few stimuli which leads to a decrease in central nervous system activity, and decrease in alertness. This has clear implications for the final treatment check in radiotherapy where alertness is important to detect errors. There is known to be individual differences in how prone people are to boredom. Factors known to increase likelihood of boredom include: fatigue, low motivation or interest, high level of education, knowledge and ability, and extrovert characteristics (Grandjean 2009). Factors known to decrease boredom vulnerability include: continuation of learning and job contentedness (Grandjean 2009). Baschera and Grandjean (1979) conducted a study in which participants were asked to complete a monotonous task, picking nails. This task was dull and repetitive and quickly led to boredom. Boredom was measured through subjective ratings and physiological measures. When the difficulty of the task was increased, boredom decreased. However, this only happened up to a point, there was an inverted U relationship, in that beyond a point of difficulty boredom increased once more. The findings of this research can be applied to the final treatment check task, perhaps by fractionally increasing the difficulty of the task in order to alleviate boredom.

As demonstrated in the above interviews, and task analysis from the previous chapter, there are many factors which could induce errors during the final treatment check immediately prior to beam delivery. There is currently variation in the way these treatment checks are currently conducted, yet all current methods of checking are vulnerable to allowing errors to pass undetected. Table 7.3 summarises the performance shaping factors that have been identified through interviews and task analysis, and supported by existing psychological literature. These factors are argued to potentially impact on the effectiveness of the final treatment checks.

Table 7.3: Performance shaping factors during the final treatment check

Factor	Observations	Interviews	Potential error/impact of performance	Possible solution
Over-reliance on the other checker		✓	Diffusion of responsibility	Verbal check with clearly defined roles requiring equal input
Looking at the value on the prescription sheet before looking at the screen	✓		'See what you expect to see'	Look at screen first
Parameters to be verified combined together	✓	✓	High cognitive load/demand on memory	Verify one parameter at a time
Responder looking at screen when the parameters are announced	✓		Cross modal attention Inattentional deafness	Responder to not look at screen whilst parameters are announced
High authority gradient between the checkers		✓	Deference to authority	Culture change
Noisy environment/distractions	✓	✓	Diffused concentration	Checking to be done in a quiet environment
Patient in the middle of treatment		✓	'See what you expect to see'	Maintain vigilance
Boredom		✓	Loss of vigilance	Introduce variation

The task analysis, interviews, and related review of literature have suggested that a challenge-response check is likely to be more effective as it reduces the vulnerability to some of these error inducing factors. Yet, this method of checking is still vulnerable to allowing errors to pass undetected due to fatigue, attention deficits, boredom and involuntary automaticity. These factors are all interlinked and in order to reduce the impact of these factors there is a need to increase the cognitive demand and active engagement in the task, according to the attentional theory of underload. Some strategies such as role rotation, and treating different anatomical areas on each machine were suggested by participants. These can potentially go some way to mitigating the damaging nature of involuntary automaticity, as they break up the monotony. These will be explored experimentally later in chapter 8.

7.3.3 Latent factors influencing accuracy of the final treatment check

Alongside these performance shaping factors, a number of latent factors have been identified surrounding the final treatment check. Thorough investigation into the impact of these factors is beyond the scope of this thesis, however, these factors have been translated into preliminary practice based recommendations, as detailed in table 7.4.

The team structure and culture was suggested to contribute to failures during the final treatment checks with possible deference to authority and differing team perceptions on the importance of verification. This supports findings by Armitage (2009) that deference to authority and reduction of responsibility during two person checking can potentially contribute to ineffective checking. As presented in the literature review, Armitage (2009) reported that double checking was often not conducted due to lack of time. Time also featured in this research as participants felt they had to rush the final treatment check due to time pressure from machine breakdowns or urgency to treat patients. Although time pressure did not prevent double checking from being undertaken, it is clear that if the process is rushed or takes too long to complete, it may not be undertaken properly. This must be considered in the design of any new treatment checking protocol. The similarity of the results arising from Armitage's study with doctors and nurses, and the interviews

described here with radiographers, suggest that double checking errors are not domain specific and the perceived risk factors for error are similar to other healthcare domains. Therefore, any developed checking protocol can potentially be transferrable to other areas of healthcare.

There also appeared to be a lack of understanding around what patient safety is, and what the term encompasses. This may be due to the lack of training dedicated specifically to patient safety and errors, as suggested by participants in these interviews. Furthermore, students in this research were not aware of the process involved in error reporting. This may also be linked to the paucity of patient safety curriculum content. This may also be due to local variation in error reporting policies and differences in the induction processes for students. These processes were clearer to the qualified radiographers in a department. As well as the need for standardised processes and training, increased profile of patient safety in radiotherapy would be beneficial and contribute to an increasing awareness of safety culture.

The interviews revealed that there is perhaps a slightly lax attitude towards the final treatment check in qualified radiographers, which may be linked to the lack of training in, and awareness from staff about, patient safety. Fraass (2008) noted that record and verify systems may lead to staff not checking thoroughly. This is reflected in this research as staff believed the technology to be infallible. Furthermore, qualified radiographers reported that they frequently knew what the treatment parameters were going to be before they were called out. Hence, they were more "blasé" about checking mid-treatment as they believed treatment parameters could not have been changed and must be correct. Training dedicated to how errors propagate earlier on in the patients' treatment pathway may help reinforce the importance of the final treatment check. Participants also suggested that a new protocol could provide a tool for a cultural shift in the appreciation of safety and the final treatment check. Hence, a new protocol may be the first step to changing the culture surrounding the perception of the importance of the final treatment check.

The interface used to verify was also reported to impede effective checking of treatment parameters. Participants reported a sense of “number overload” which impacts upon attention, alongside the use of small font sizes on the information they need to conduct the final treatment check and having to search for these required values. This issue is explored further in chapter 10 through consideration of the interface design.

7.3.4 Practice recommendations

This research has identified a number of active failures, latent failures and error producing conditions surrounding the final treatment check in radiotherapy which pose a potential safety risk. These are detailed in figure 7.1, which is an adapted version of Reason’s model of accident causation (Reason 1997), applied to final treatment check in radiotherapy.

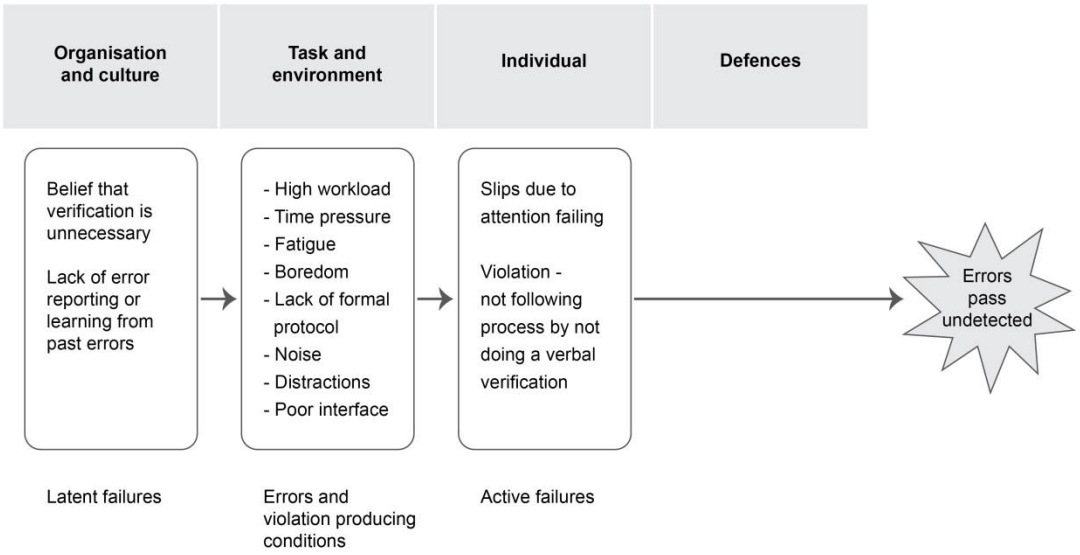


Figure 7.1: Adaption of Reason’s error model to show factors which impact upon effective checking

Table 7.4 makes some preliminary practice based recommendations to potentially address these risks.

Table 7.4: Practice recommendations

Risk	Explanation	Recommendation
Belief that verification is unnecessary	• The interviews suggested that radiographers may believe the final treatment checks are unnecessary. Yet, a final manual verification is necessary regardless of whether a RV system is used or not. • May lead to either rushing the final treatment check or conducting it without vigilance. • May increase with experience, as newly qualified radiographers are safety conscious and aware of making mistakes.	• Qualified radiographers to undergo regular refresher training surrounding patient safety and the importance of the final treatment check.
Lack of learning from previous mistakes	• Literature review suggested error reporting and learning is continuing to improve • Increased reporting and learning may increase radiographers' perception of the importance of final treatment checks.	• Continuation of reporting errors and near misses associated with the final treatment check • Sharing of lessons learned from previous errors within and between departments.
Lack of training	• The interviews suggested patient safety and human factors education is missing from the curriculum of student radiographers. • Increased training may lead to more awareness of own working practices and what supports error prevention. • May also lead to radiographers taking more responsibility for the final treatment checks	• Increased embedding of human factors and patient safety into education.
High workload	• The interviews suggested radiotherapy departments treat increasing numbers of patients, which increases stress	• Review radiographer's workload and departmental staffing levels

Time pressure	• The interviews revealed radiographers are under pressure to treat patients quickly, so rush the final treatment checks • This directly impacts on the efficacy of the final treatment check • The stress which accompanies time pressure makes attention more likely to lapse.	• More time allocated to treating each patient, subject to resource limitations. • Fair culture- radiographers not blamed for mistakes when working under pressure. • The final treatment check to become a protected task, with an adequate length of time allocated to it. • Regular audits to ensure the final treatment check is not skipped.
Fatigue	• It has been recognised in *Towards Safer Radiotherapy* that checking can be tiring and result in fatigue. • Treatment delivery is a repetitive task, increasing risk of fatigue	• Radiographers to take frequent breaks. • Radiographers to rotate round different tasks throughout their shift such as; treatment delivery, inputting data into RV systems, patient advice, patient follow ups.
Boredom	• The interviews suggested radiotherapy can be a repetitive job. • Many departments dedicate one linear accelerator machine to each anatomical treatment region, in order to streamline the treatment process. • This increases the repetitiveness of treatment delivery. • The parameter values are similar when treating the same anatomical region, increasing the chance of involuntary automaticity occurring.	• Departments should not assign treatment machines to anatomical regions, but ensure treatment teams treat a variety of patients throughout the shift.
Lack of protocol	• The interviews and task analysis suggested there is a high level of variation in how radiographers conduct the final treatment check immediately prior to beam delivery.	• A standardised checking protocol to be employed immediately prior to beam delivery • Audits to measure adherence
Noise	• The interviews and observations suggested the area surrounding the treatment console is often crowded, and	• A limit enforced on the number of staff in the area surrounding the console

	noisy.	• This area should be reserved for treatment only, with other areas provided for radiographers conducting tasks not directly relating to delivering treatment. • When departments undergo renovations it is suggested that thought is giving to sound proofing the area where final treatment checks are conducted.
Distractions	• The interviews and observations suggested there are many distractions from colleagues, patients and phones, in the area surrounding the treatment console.	• Whilst final treatment checks are being conducted, the surrounding environment is silent • The encouragement of a culture in which all staff respect the need for silence. • Phones and patient enquiries re-routed to another area of the department which is not so safety critical.
Diffusion of responsibility	• The interviews and the literature suggested when there are two checkers, one may rely on the other to maintain vigilance during a check	• A verbal challenge-response check, as per the protocol produced.
Deference to authority	• The interviews and the literature suggested radiographers may defer to their senior and not speak out either about an error they believe is present	• An open culture to be encouraged, to enable radiographers to speak out, regardless of hierarchy.
Poor interface design	• The interviews and experiments suggested the design of the interface may impede effective checking due to; small font size, number overload, inability to quickly perceive required values	• The usability of the software to be reviewed, with a view to taking a user-centre approach to design.
Involuntary automaticity	• The interviews, literature and experiments suggest this is likely to occurs as the final checking task is repeated regularly, in the same way, allowing the behaviour to be conducted without attention.	• The final treatment checking process needs to be varied with repetition minimised. The protocol developed here to be adopted in all departments.

7.3.5 Limitations

Any form of qualitative analysis could be argued to be subjective. In order to ensure valid and reliable results were gained the interview schedule was informed by the research aims and literature, active listening techniques were used by the researcher and a second-coder was involved in the analysis, as discussed in section 5.6.3.

The participant sample for the interviews consisted of varying grades of therapy radiographers, reflecting a range of experiences. A potential limitation of this research is that participants included qualified radiographers from only one department. This was partially addressed through the participation of students trained at a number of different hospitals in the region and there were no noticeable differences in viewpoints between them. It is recognised that the interviews used a small sample size, which, whilst normal in qualitative research, may limit the generalisability of the results.

7.4 Chapter conclusion

The interviews in this study, in combination with a review of existing literature and the task analysis, have allowed the variability in how the final treatment checks are currently conducted to be understood. This research has demonstrated that the current methods of checking during the final treatment check are highly vulnerable to errors passing undetected. Whilst the challenge-response method of checking, as recommended in *Towards Safer Radiotherapy*, may minimise some error inducing factors, it remains vulnerable to the issue of involuntary automaticity. The attentional theory of underload, discussed in section 6.3.3, suggests the effects of involuntary automaticity could be reduced by increasing cognitive demand during the repeated final treatment checks. Some methods to maintain attention have been suggested by participants in interviews which will need empirical investigation. Participants reported that any checking protocol would have to be evidence-based. Currently there exists little experimental evidence to support the use of challenge-response checking over double, or even single person, checking.

Following the findings detailed in this chapter and the previous chapter, a series of practice based recommendations have been made with the aim of improving the safety surrounding the final treatment check in radiotherapy, detailed in table 7.4. A significant finding was the need for a standardised method of conducting the final double check to reduce variability and cognitive load, thereby increasing safety. Therefore, the following chapters will explore the creation of a new standardised protocol which will attempt to incorporate methods to maintain attention when conducting the final treatment checks, as detailed in figure 5.1. Table 7.5 provides the requirements for a checking protocol for use immediately prior to beam delivery, which have been extracted from the research presented in this chapter, the task analysis and the literature review.

Table 7.5: Summary of requirements for checking protocol

Checking protocol requirements	**Source**
Verifies energy, monitor units, wedge monitor units and wedge position	*Towards Safer Radiotherapy*
Standardised	Interviews, literature review
Challenge-response	Interviews and task analysis, literature review
Evidence based	Interviews, literature review
Time efficient	Interviews
Maintains attention	Interviews and task analysis
Involves two radiographers	Interviews and task analysis, *Towards Safer Radiotherapy*
Verbalised	Interviews and task analysis, *Towards Safer Radiotherapy*
Vary anatomical region being treated	Interviews
Role rotation	Interviews

These protocol requirements will be taken through to the next stage of the thesis. As the protocol needed to be evidence based and there was little empirical evidence to support either single or double checking, empirical investigation into the most effective method of checking, to form the basis of a checking protocol was needed. This experimental process is detailed in the following chapter.

8 Chapter 8 - Study 3: Experimental exploration of checking methods

Chapter 7 concluded that the development and use of a standardised checking protocol immediately prior to beam delivery would have safety benefits in radiotherapy. Table 7.5 summarises the requirements of a checking protocol drawn from the research findings described so far. This current chapter presents the method and results of two experimental studies which explore and evaluate the protocol requirements identified, with the aim of investigating the most effective method of checking and future design of a checking protocol. The first experiment engages with the debate surrounding single and double checking. The second experiment investigates methods of maintaining attention during repeated final treatment checks. Recommendations are produced that guide the design of a checking protocol for use immediately prior to beam delivery, and will be applied in chapter 9.

8.1 Method

Most of the research on double checking in healthcare consists of qualitative studies, retrospective incident reviews or expert opinion, as discussed in chapter 4. Here, an experimental approach is taken to systematically explore checking effectiveness. As discussed in section 5.4, use of laboratory-based studies to recreate and test scenarios are useful within patient safety research in order to provide an empirical evidence base.

8.2 The experimental paradigm

An experimental paradigm was designed to mimic the process of the final treatment check in radiotherapy, as identified in the task analysis in chapter 6, but in a laboratory, controlled environment. Based on the assumption that automaticity is one of the main sources of checking errors, as discussed in section 4.3.1, the objective of the experimental design was to induce automaticity within the limited time span of a laboratory experiment. The task involved repeated presentation of information on screen that required comparison with information presented on paper (as per the final treatment check task described in section 2.3.5). The

information was of the same type as the information that radiographers encounter in the real life final treatment safety check. Both experiments presented in this chapter used this paradigm, which is detailed below.

8.2.1 Setting

The experimental paradigm was run in a quiet room, free from distractions, so that there were no confounding variables from noise.

8.2.2 Equipment

The focus of this research was on the process of the final safety check of treatment before treatment delivery. It was decided to isolate this particular task and remove surrounding environmental distractors. The only equipment present was therefore the screen image which displayed the treatment values and the paper prescription with the treatment values on. An iPad was used to display the radiotherapy interface. A direct replica of the interface of the record and verify system, MOSAIQ, was recreated. This system was reported by the majority of the exploratory interview participants to be in use in their departments.

The interface was static, that is a screen shot, rather than a system that required input from the user. A series of screen shots were developed that represented a treatment for a patient with prostate cancer. The decision was made to not vary the anatomical area being targeted, as the interviews revealed this is typical of what happens in the radiotherapy department where each linear accelerator machine is used for one specific anatomical area. Seventy variations were developed that had differing values for each parameter and these values were altered for every trial using Adobe Photoshop, so that the static image of the interface remained intact and identical for every trial. An example screen can be seen in figure 8.1.

Each screen had a corresponding paper prescription which was based upon those used in a radiotherapy department. Seventy iterations of these paper prescriptions were filled out by hand, scanned and printed by the researcher. Figure 8.2 shows an example prescription sheet.

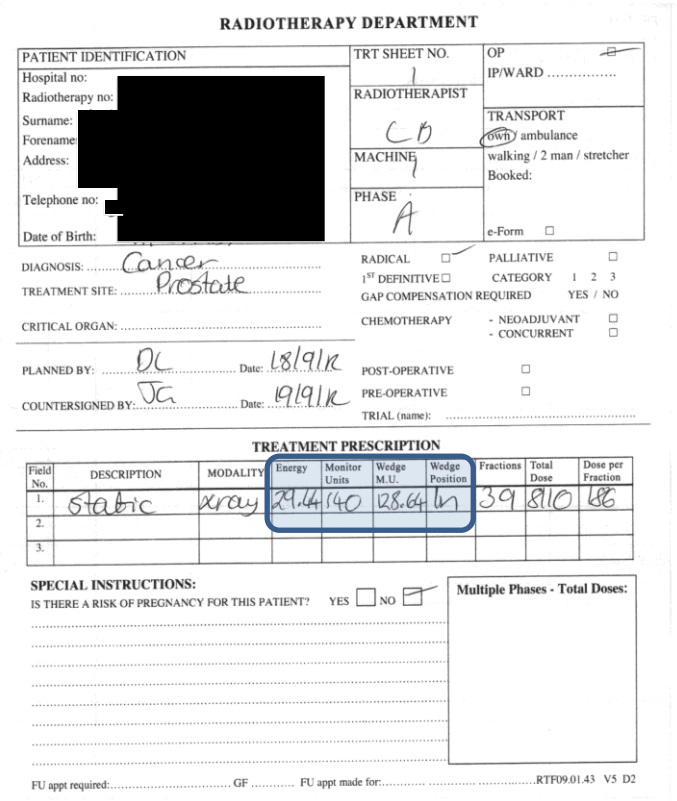
8.2.3 Task

This paradigm was designed to mimic radiotherapy practice, in terms of multiple final treatment checks, punctuated by either collecting a patient or arranging them on the bed, but with much shorter timeframes than in clinical practice. The aim was to make the experiment boring and tedious in order to induce involuntary automaticity. This paradigm allowed for errors to be planted within the materials and the impact of the different methods of checking on error detection measured.

The task required participants to conduct a number of screen-to-paper prescription checks to ensure there was no discrepancy between the values displayed on the screen, and those written on the prescription. Participants were asked to check that the energy value, monitor units, wedge monitor units and wedge status on screen were correct according to the paper prescription. The wedge status always read either 'in' or 'out'. The monitor units and energy were numerical values ranging from 100 to 999. These values are highlighted on an example screen and paper prescription in figures 8.1 and 8.2.

Participants were seated in front of the iPad and asked to swipe the screen once to reveal the first set of values. Next to the iPad were a pile of paper prescriptions in the order that they were needed to be checked. After verifying the first pair of materials, participants were asked to sign the prescription sheet if there were no discrepancies between the screen values and paper prescription for any of the parameters they were required to check, and place the prescription sheet to one side. If there was a discrepancy, participants were told not to sign the prescription sheet. Participants were then required to stand up and walk a few steps over to a table on the other side of the room to complete a distractor task (see below). Upon completion of this task they returned to their seat in front of the iPad and swiped the screen to reveal the next screen. This process was repeated for the duration of the experiment.

All participants were given a standardised briefing on the experiment and the final treatment checks in radiotherapy, followed by standardised instructions on how to complete the task. These instructions can be found in appendix 9.



RADIOTHERAPY DEPARTMENT

PATIENT IDENTIFICATION

Hospital no:
Radiotherapy no:
Surname:
Forename:
Address:
Telephone no:
Date of Birth:

TRT SHEET NO. 1
OP
IP/WARD
RADIOTHERAPIST CD
TRANSPORT (own) ambulance / walking / 2 man / stretcher / Booked:
MACHINE 1
PHASE A
e-Form

DIAGNOSIS: Cancer
TREATMENT SITE: Prostate
CRITICAL ORGAN:
RADICAL ☐ PALLIATIVE ☐
1ST DEFINITIVE ☐ CATEGORY 1 2 3
GAP COMPENSATION REQUIRED YES / NO
CHEMOTHERAPY - NEOADJUVANT ☐ - CONCURRENT ☐
PLANNED BY: DL Date: 18/9/12
COUNTERSIGNED BY: JG Date: 19/9/12
POST-OPERATIVE ☐
PRE-OPERATIVE ☐
TRIAL (name):

TREATMENT PRESCRIPTION

Field No.	DESCRIPTION	MODALITY	Energy	Monitor Units	Wedge M.U.	Wedge Position	Fractions	Total Dose	Dose per Fraction
1.	Stabic	xray	29.44	140	128.04	In	39	8110	186
2.									
3.									

SPECIAL INSTRUCTIONS:
IS THERE A RISK OF PREGNANCY FOR THIS PATIENT? YES ☐ NO ☐

Multiple Phases - Total Doses:

FU appt required:..... GF ..... FU appt made for:..... .....RTF09.01.43 V5 D2

Figure 8.1: Example prescription sheet

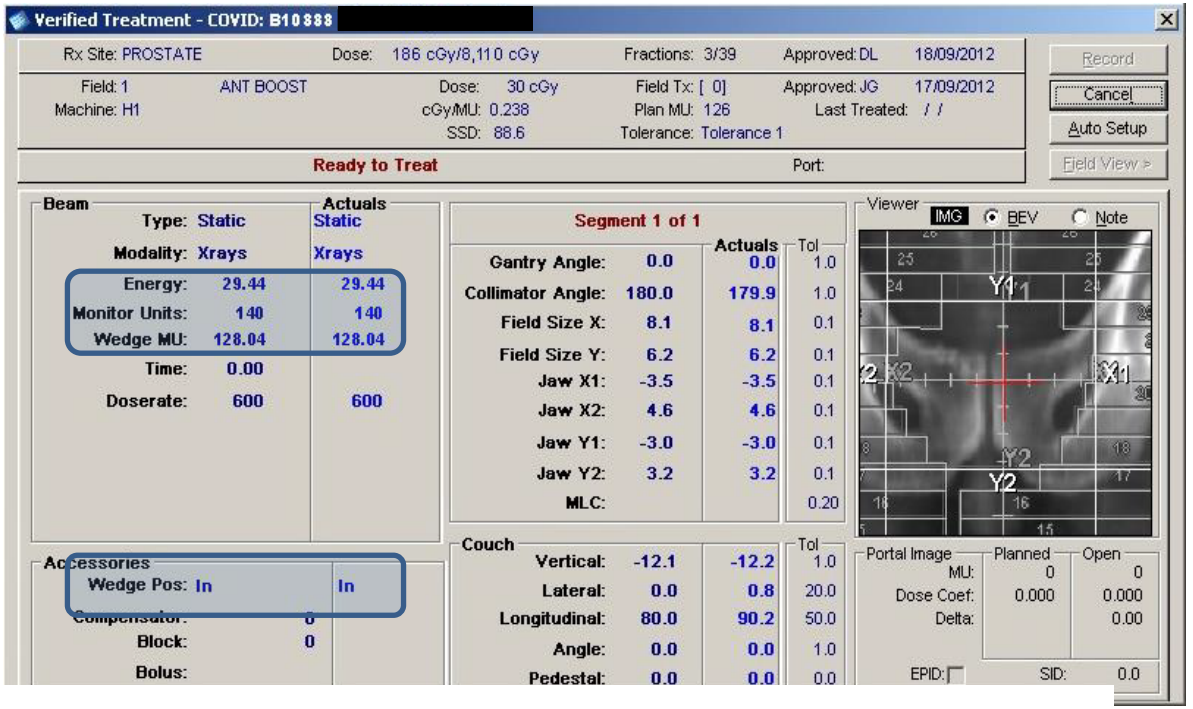


Figure 8.2: Example MOSAIQ interface

8.2.4 The distractor task

Between each screen-to-paper check, participants were asked to complete a non-cognitively demanding task. This task was designed to mirror the break between checks that radiographers get when undertaking other duties between treatments, such as collecting a patient or arranging them on the treatment bed. The distractor task in the experiment was the un-stacking of Russian dolls, and placing them in a prescribed height order, before re-stacking the dolls. Participants walked to an adjacent room and arranged the five dolls in the order displayed on a height order plan. The plans altered each time. This task was chosen as it is not cognitively demanding and forces participants to stand up and do a physical task, as in radiotherapy. Figure 8.3 shows an example Russian Doll plan.

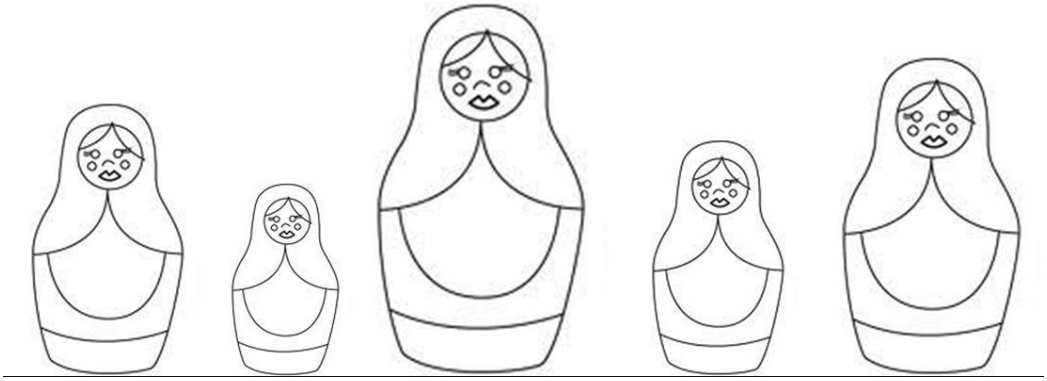


Figure 8.3: An example Russian Doll plan

8.2.5 Participant motivation and time pressure

As this experiment was likely to be perceived as repetitive and tedious, it was vital that participant's motivation was maintained. Participants were told that there would be between zero and five errors randomly planted within the checks in order to ensure they took the task seriously. Also, to encourage motivation participants were told they had to complete a minimum of 60 checks within 45 minutes, but for any checks they completed above this they would receive a reward. The reward was in the form of wrapped sweets which they were invited to choose from a selection. This also placed time-pressure upon the participants, which mimics radiotherapy. To ensure participants had the motivation to do the checks well they were told that for every error missed and every false alarm they would receive a penalty. The penalty was the removal of two sweets from their total earned. This

motivation is vital so that the check is not meaningless but has consequence, as in radiotherapy. Klein (2001) found evidence through a database error detection task that expectations of error rate and performance based incentives increased error detection. Esterman, Reagan, Liu, Turner and DeGutis (2014) have since published a paper suggesting that performance on a sustained attention task is maintained if participants are rewarded either with monetary or early completion rewards. Yet, these rewards do not have an impact on performance decrement over time. This suggests that performance on a sustained attention task is affected by both motivational lapses and cognitive resource depletion, yet the former can be overcome with rewards. Hence, it can be assumed that by using such a reward system in the current paradigm participants' motivation and performance was increased without affecting performance decrements over time, that is, without interfering with the effect of involuntary automaticity, that these experiments were designed to address.

8.2.6 Pilot testing

Pilot testing was conducted, using 12 psychology students accessed through the university's SONA system, to assess if the directions given to the participants were clear and allowed the paradigm to be followed. Participants were randomly assigned to an experimental condition based on order of presentation and took part in the paradigm as detailed above for 45 minutes. Four participants took part alone, two pairs of participants did double checking and two pairs of participants did challenge-response checking. After completion they were invited to comment on the task ease, the clarity of task instructions, and the use of sweets as a motivator. Participants commented that the task instructions were clear, and the sweets motivated them to act quickly but thoroughly, however they found the checking task was too easy. Subsequent analysis of the results from pilot testing revealed that using numbers without decimals resulted in a ceiling effect, with all participants but one detecting all errors, regardless of experimental condition. Therefore, the decision was made to increase task difficulty by including decimal places in the materials. Results also showed that all participants in all experimental conditions were able to complete 60 checks of materials within 45 minutes, with no more than 70 completed. Hence, it was decided that 60 trials were the optimal number of trials required for 45 minutes of testing, with a maximum of 70 trials provided.

8.3 Experiment 1: Comparison of checking methods

8.3.1 Rationale

The research discussed in chapter 4 demonstrated that opinion is divided in the literature as to whether single or double checking is more effective at error detection. The interviews presented in chapter 7 suggested that radiographers themselves consider challenge-response checking to be more reliable than non-verbalised or single checking. This is supported by research from other domains such as aviation, as discussed in section 6.3.3. The experimental research described here aims to inform that debate.

This experiment aimed to directly compare the effectiveness of single checking, non-verbalised double checking and challenge-response checking. These three methods of checking were chosen as they are the three ways of checking which are used in radiotherapy departments currently, as discussed in chapter 6 and 7. It was important to empirically investigate the effectiveness of these checking methods, to provide evidence for best practice, as it was identified that compliance with a new protocol increases when supported by evidence. The decision was made to investigate challenge-response checking when the values are not chunked together, as the task analysis had already identified the risks when chunking values together.

One specific factor affecting checking reliability, as discussed in section 6.3.3, and 7.3.3, is involuntary automaticity. Research has suggested that repeated actions can become habitual and this issue has already been identified as an issue in the final treatment checks in radiotherapy (Toft and Mascie-Taylor 2005). This was supported by the interview findings in chapter 7, and will also be explored here.

8.3.2 Hypotheses

It was hypothesised that:

- Challenge-response checking would be more effective at detecting errors than both unstructured double checking and single checking, in line with the findings described in the task analysis
- The errors placed towards the end of the experiment will be missed more often than the early planted errors due to involuntary automaticity

- When conducting challenge-response checking, participants reading the values from the screen will have a lower accuracy score than participants reading the values from the prescription sheet, as the interface was discussed in the exploratory interviews as not being user friendly.

8.3.3 Method

8.3.3.1 Design

This experiment employed a between groups design, with participants allocated to one of three experimental conditions:

1. single checking
2. non-verbal double checking
3. challenge-response checking.

The independent variable was the method of checking used and the dependent variables were the number of errors, false alarms and accuracy.

8.3.3.2 Participants

Participants were undergraduate psychology students at Coventry University, recruited via opportunity sampling. Participants responded to a call for participants on the university's online experiment management system and received course credits for participating. The only inclusion criteria were that the participants must have normal or adjusted to normal eyesight. Participants were excluded if they had taken part in the pilot study, as this may have introduced practice effects. Sixty participants were recruited and allocated to one of the three conditions based on order of presentation. There were 20 participants in the single-check condition, and 20 paired participants in each double-check condition. Table 8.1 describes each of the three conditions.

Table 8.1: Checking methods experimental conditions

	Condition	**Description**	**Number of participants**
1	Challenge-response checking	One participant is assigned the challenger and reads the values from screen. The other checks these against the paper plan and responds.	20 pairs
2	Unstructured double checking	Two participants are asked to check together but not told how to check	20 pairs
3	Single checking	Participant checks alone	20 individuals

8.3.3.3 Materials

There were 70 different interface displays presented on an iPad with 70 corresponding paper prescription plans, one pair of materials constituted one trial. These were displayed in the same order for every participant. A set of Russian dolls consisting of five stackable dolls were used with 70 laminated sheets with differing height arrangements of these dolls.

8.3.3.4 Planted errors

Four errors were planted, in four different pairs of materials (a pair was a corresponding paper prescription and screen). There was one wedge error, one monitor units error, one wedge monitor units error, and one energy error. When an error was planted the value displayed on screen differed from that displayed on the paper prescription. The errors were minor, for instance a wrong digit or erroneous decimal place. Figures 8.1 and 8.2 displayed an example trial with an error planted in the wedge monitor unit (wedge MU) parameter. Errors were planted on trial 10, 17, 55 and 60. The errors towards the end of the experiment provided an opportunity for involuntary automaticity to have built up.

8.3.3.5 Procedure

Participants were invited to read the participant information sheet and sign the consent form. The procedure was then explained to them, to ensure consistency this was read from the same participant instructions presented in appendix 9.

If participants were in the single checking condition they checked the parameters by themselves (i.e. compared the paper prescription to the values displayed on the screen and indicated if they matched). If they were in the double checking condition, both participants checked the parameters, but did not verbalise the check. If in the challenge-response condition, one participant was assigned the challenger and the other the responder. The challenger read the values from the screen one by one, and waited for the responder to confirm and repeat the value back before moving onto the next value. All participants completed the distractor task. Appendix 9 details the verbal instructions given to participants on the checking task for each experimental condition.

Participants were provided with two practise trials (two checks to conduct) to ensure they understood the task. After ensuring participants did not have any questions, participants

completed the experiment as per the description of the paradigm. Throughout the experiment the researcher was seated in the corner of the room so that participants did not feel as though they were being observed.

8.3.3.6 Data recording

In all three conditions and for each trial, a signed paper prescription indicated that participants deemed the trial "correct", an unsigned prescription sheet indicated that they deemed the trial "erroneous". After the experiment, participants' responses were coded as detailed in table 8.2.

Table 8.2: Categorisation of trial responses

Trial code	Description
Hit	Signed sheet on a correct trial
Correct rejection	Unsigned sheet on an error trial
Miss	Signed sheet on an error trial
False alarm	Unsigned sheet on a correct trial

Additionally, a record sheet was used by the researcher in the challenge-response condition which listed what the challenger and responder should be saying (it listed the on-screen values the challenger should be reading for each trial, and if it was a trial with a planted error). The researcher circled if either the challenger or responder made a mistake (i.e. if the challenger announces a value incorrectly or responder responds incorrectly). This allowed for identification of where errors occurred and whether they were the fault of the challenger or responder.

8.3.3.7 Data metrics

Performance in each condition was measured in the following ways based on the data collected from the signed prescription sheets and response sheet:

- Missed errors- a discrepancy between the screen and paper prescription was missed
- False alarms- participants thought there was a discrepancy when there was not
- Accuracy- the percentage of correct trials (combining hits and correct rejections)
- Challenger accuracy- the percentage of mistakes the challenger made when reading out values (Challenge-response condition only)

- Responder accuracy- the percentage of mistakes the responder made when deciding if there was an error or not (Challenge-response condition only)

Percentages were used for missed errors and false alarms, as participants would complete a varied number of trials over the minimum required, based on how quickly they completed each trial.

8.3.3.8 Ethics

This study was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee, see appendix 10. The research was conducted according to BPS ethical code of conduct.

8.3.4 Results

The data for each participant or pair of participants were entered into SPSS and aggregated according to experimental condition. SPPS was used to conduct the descriptive and inferential statistics on the data.

8.3.4.1 Effect of checking condition on error rates

Comparison of the three conditions, based on missed errors and false alarms, suggests that there is variance in how effective each method of checking is. Figure 8.4 displays the mean percentage of errors detected and mean percentage of false alarms broken down by condition. It can be seen that those in the challenge-response condition missed the least percentage of errors. Those single checking missed the highest percentage of errors. The means (and standard deviations) are displayed in Table 8.3.

Table 8.3: Mean percentage errors missed, false alarms and accuracy per condition

Condition	Mean % errors missed (SD)	Mean % false alarms (SD)	Mean % accuracy (SD)
Single (n=20)	25.00 (6.85)	1.56 (0.72)	96.95 (0.8)
Double (n=20)	20.00 (3.44)	1.39 (0.73)	97.49 (0.73)
Challenge-response (n=20)	3.75 (2.74)	1.65 (0.47)	98.20 (0.45)

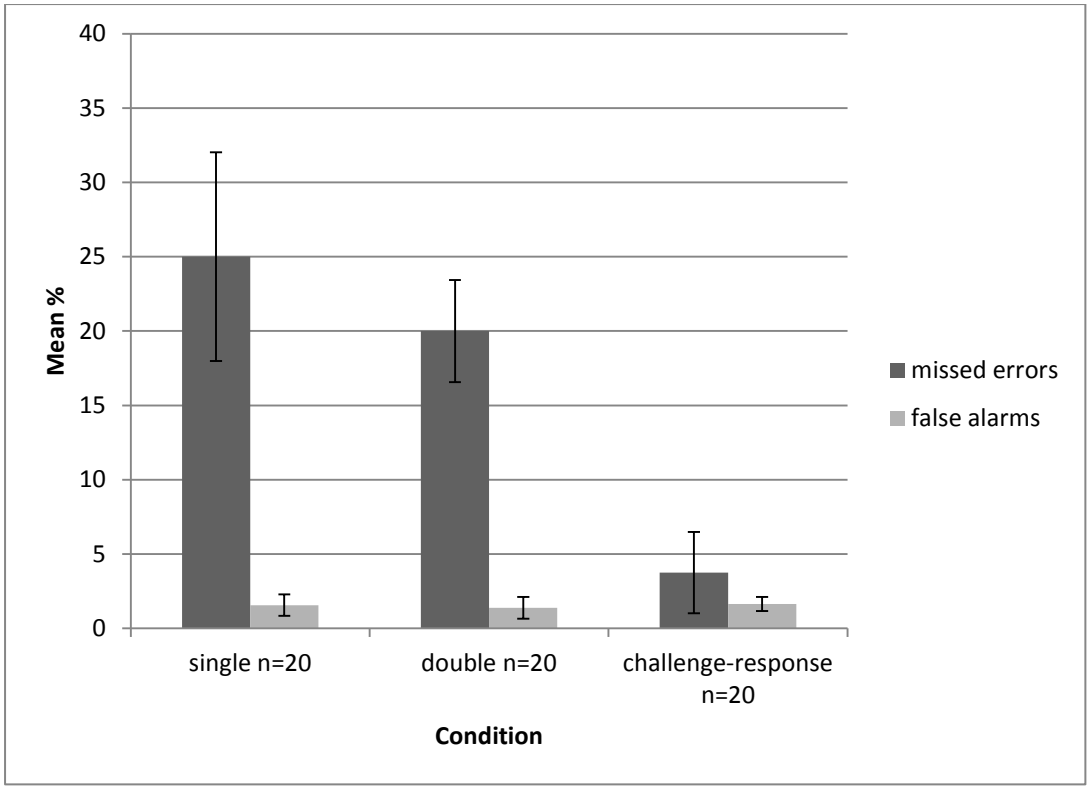


Figure 8.4: Graph displaying percentage of misses and false alarms per condition

As the data met parametric assumptions, one-way ANOVAs were conducted to assess if the differences between the checking conditions were significant.

No significant differences were found between checking conditions in the number of false alarms, $F(2,57) = 0.42$, $p = .959$.

In contrast, the number of errors missed differed significantly between conditions, $F(2, 57) = 5.393$, $p = .007$. Post-hoc Tukey tests confirmed the difference to be both between single checking and challenge-response checking, and unstructured double checking and challenge-response checking. There was no significant difference between single checking and unstructured double checking. Therefore, the first hypothesis is supported, challenge-response checking resulted in significantly less planted errors passing undetected.

However, overall accuracy did not differ between the three conditions, $F(2,57) = .833$, $p = .440$.

8.3.4.2 The effect of involuntary automaticity

To investigate the second hypothesis, that errors towards the end of the experiment are more likely to be missed due to involuntary automaticity, the number of participants missing each error was analysed by checking condition. Figure 8.5 shows that the final planted error was missed more often than the prior three errors. Importantly, although this trend was very clear in the single and the double checking condition, it was absent in the C-R checking condition.

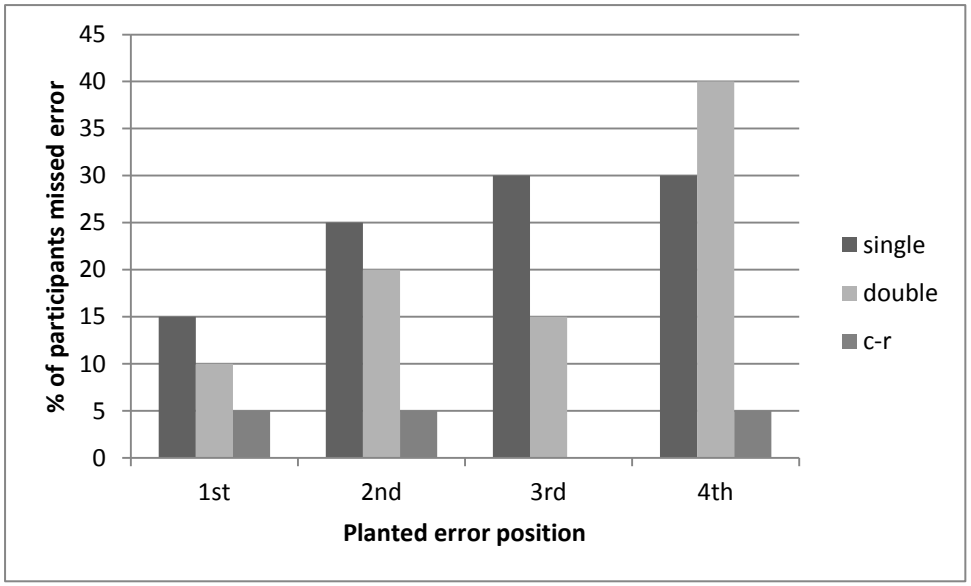


Figure 8.5: Graph to show the percentage of participants in each condition who missed the error

This provides evidence for involuntary automaticity occurring and supports the second hypothesis. It also suggests that involuntary automaticity was prevented, or at least prevented from affecting performance, in the C-R group, lending support to this method of checking being most effective.

8.3.4.3 Differences between challenger and responder role accuracy

The accuracy of challengers and responders in the challenge-response checking condition were also compared. This score was obtained by calculating the number of times the participants said a value or responded incorrectly. This included instances where they went back to correct what they originally said. These scores were then converted into a percentage accuracy score. Figure 8.6 shows that participants in the role of the challenger displayed a lower percentage accuracy than the responder.

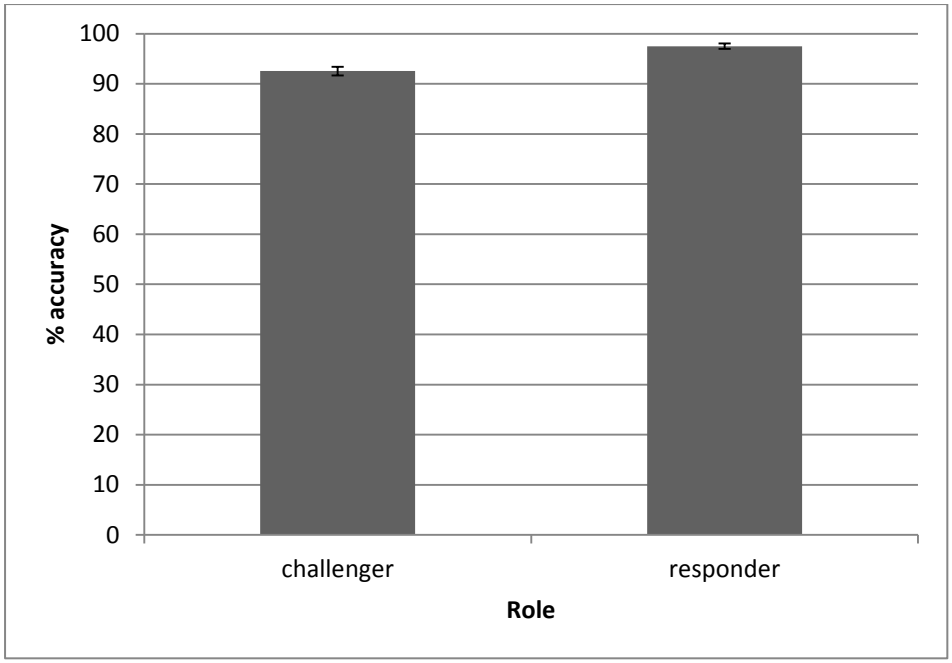


Figure 8.6: Difference between challenger and responder accuracy

An independent t-test showed that this difference was significant, t(38)= 4.985 *p* <.001. This suggests that errors, false alarms and near misses were more likely to be due to the challenger making a mistake in reading the values from the screen, and not the responder. Participants reading the values out loud from the screen made more mistakes than those confirming the values on the prescription sheet, this supports the third hypothesis.

8.3.5 Comparison of checking methods discussion

The results have shown that, in this experiment, single checking was least effective at error detection and challenge-response checking was most effective. This may be because during challenge-response checking both participants have a clearly defined role and are therefore unable to avoid taking responsibility for completing the check. Accuracy was also higher in the double checking condition and lowest in the single checking condition, although the difference was not significant. All the groups' percentage accuracies were around 97% meaning the majority of trials were completed correctly.

However, if this percentage is translated into patient treatments it becomes unacceptable. A 97% accuracy rate would mean that three in every 100 fractions are potentially delivered incorrectly. Furthermore, it makes the difference between single checking accuracy and challenge-response checking accuracy appear clinically important, as the 0.38% difference in this experiment relates to nearly four fractions in every 1000. Despite the challenge-

response method of checking resulting in less errors passing undetected and higher accuracy, it is worth noting that errors still went undetected and accuracy was only 98.2% in this condition. This suggests that, in a laboratory setting, there is still scope to improve the efficacy of challenge-response checking.

It has been suggested that the final treatment checks in radiotherapy are prone to involuntary automaticity (Toft and Mascie- Taylor 2005). This experiment lends support to this theory, as the final error in the materials, after almost 45 minutes of checking, was missed more frequently than earlier errors. An unexpected result was that the third error was most likely to be spotted. This went against the involuntary automaticity hypothesis as the third error was planted on trial 55, after 38 correct trials had occurred, allowing automatic responding a chance to build. However, error three was a wedge error so perhaps participants just found the wedge error easier to spot than numerical errors. The final error was a wrong digit in the monitor units and hence harder to spot. This automatic responding seemed to lessen when participants were challenge-response checking, lending more support to using this method of checking. Perhaps this prevention of involuntary automaticity was the underlying reason for the challenge-response checking group having a higher accuracy score.

This experiment provided support to the notion of involuntary automaticity occurring during repeated checking. However, as challenge-response checking seemed to lessen the effect of involuntary automaticity this does not seem to support the views of Armitage (2009) who stated that double checking is reduced to an ineffective ritualistic chant. The findings challenge research which calls for single checking in medicine (Jarman, Jacobs and Zielinski 2002). As challenge-response checking is a form of double checking, the results seem to support the notion that double is more effective than single checking, at least in a laboratory setting. Furthermore, unstructured double checking was better than single checking. This experiment has provided empirical evidence to further encourage the debate surrounding single and double checking.

The finding that there was a significant difference in accuracy of the two checkers during a challenge-response checking suggests that research needs to further explore the challenger

role during checking, and support them through a protocol to do an effective check. It was found that the challengers displayed a significantly lower accuracy rate than the responders. This suggests the challengers' attention lapsed more often than the responders. Hence, any further improvements to the method of checking should consider ways to support the challenger.

There are limitations to the transferability of these results. The experiment only lasted for 45 minutes. Further research is needed therefore to determine the direct applicability if these results to radiotherapy and different healthcare settings.

8.4 Experiment 2: Maintaining attention during repeated checking

8.4.1 Rationale

The first experiment established that challenge-response checking was the most reliable method to detect errors. However, this type of check did not totally prevent errors, so it was decided to take this a stage further by considering how to prevent involuntary automaticity during repeated challenge-response checking.

This also builds upon the literature and the interview findings that highlight the risk presented by involuntary automaticity. In particular, the challengers in the previous experiment were found to be prone to mistakes when reading the values aloud from the screen. Therefore, the aim of this experiment was to explore ways that attention can be improved during repeated final treatment checks in order to reduce the risk of involuntary automaticity.

8.4.2 Maintaining attention

From the task analysis conducted in chapter 6, it seems that errors passing undetected during final treatment checks could be due to underload, because the checking task is not cognitive demanding. Therefore, it is argued that there may be a need to increase cognitive demand slightly in order to help maintain attention, whilst ensuring the cognitive load is not too much to induce overload, which would be equally as detrimental to safety. A number of potential mechanisms to maintain attention, thereby mitigating the risk of involuntary automaticity, were drawn from the aviation, attention and checklist design literature

presented in chapter 4, in addition to mechanisms suggested by participants in the exploratory interviews. These are presented in table 8.4.

Table 8.4: Potential mechanisms to maintain attention

Mechanism	Explanation	How identified
Involve the kinaesthetic sense	• Radiographers point at values whilst reading them to engage additional sense • Suggested by Degani and Weiser (1990), pointing to checklist items combines muscle memory with mental sequencing • May not be well received by radiographers, and not followed	• Literature
Random or changing order of the parameters	• Barshi and Healy (1993) suggest varying the order that stimuli were presented in, slowed down performance, but increased accuracy • Reading the parameters out in the same order each time adds to the routineness of the final treatment check	• Literature • Interviews
Pre-engaging task prior to the final treatment check	• Schell (2004) found that a cognitively demanding task completed prior to a checking task increased error detection • Time implications	• Literature
Different responses to each parameter call out	• This would be less routine, if the required response was ever-changing response • May appear irrelevant • Time implications • Could not be built easily into practice	• Interviews
Simultaneous task	• Used in driving simulation tasks • Gershon *et al.* (2009) found that asking drivers trivia questions during monotonous driving reduced driver errors	• Literature
Switching roles of challenger and responder	• Variation introduced if the two radiographers were to switch roles. Less routine	• Interviews

The number of potential methods to maintain attention which are able to be integrated into a safety checking protocol are limited, as the solutions also need to be feasible and practical to work into practice. There must be a clear rationale for inclusion and the radiographers must feel they are able to easily integrate it into their practice without it requiring extra time or appearing irrelevant.

As table 8.4 highlights, the majority of potential solutions are not feasible for implementation. Furthermore, anything introduced to maintain attention and overcome involuntary automaticity (such as use of the kinaesthetic sense by pointing to parameters) could become automatic itself over time. Therefore, a method which continually changes and minimises routine is likely to be most effective. As such, the chosen mechanisms to maintain attention to be tested are:

- Varying the order of the parameters to be verified
- Switching the roles of challenger and responder regularly

These methods to maintain attention during repeated final treatment checks will be investigated in the following experiment.

8.4.3 Experimental design decisions

The above mechanisms were chosen for two reasons. First, because they were suggested by radiographers themselves during the exploratory interviews. Second, because they are practical and can be done in practice. It was decided to switch roles every 15 minutes because this length of time was deemed sufficient to prevent involuntary automaticity from building up.

This second experiment will also address some potential methodological limitations of the previous checking methods experiment, as discussed below. The previous experiment suggested challenge-response checking was most effective at detecting errors. As the previous experimental method worked well to mimic final treatment checks in radiotherapy it was used again for this study but with improvements to address some of the limitations of the previous study. The length of the experiment was doubled from 45 minutes to 90 minutes and the number of errors increased from four to six. This also meant the materials

were doubled from 60 pairs of materials to check, to 120. This increase in time spent verifying is more representative of the real life scenario.

A potential limitation of the previous experiment was the type and placement of errors. All participants were required to spot the same errors in the same order. The fourth and final error was an incorrect decimal place. The third error, which was spotted more frequently than the final error, was a wedge error. Therefore, as the percentage of participants detecting the final error towards the end of the experiment was lower this may be because the final error was harder to spot, rather than a suggestion of involuntary automaticity. There are four parameters which must be verified: energy, monitor units, wedge monitor units and wedge position. Aside from wedge position, which is either 'in' or 'out', the other parameters are all number values and hence errors will be similar, either an erroneous decimal place or digit. Therefore, errors can be defined as either a word error or a numerical error. As the wedge parameter was the only word error, it was an unique error which always occurred in the same position in the experiment. As such, it is not possible to infer whether it was its uniqueness or position which leads to the relatively high detection rate.

Therefore, this experiment varied the placement of these two different error types to ensure that the conclusions from the experiment surrounding involuntary automaticity are defendable. All errors were presented in the same error trials (i.e. the same point in the experiment for all participants), but within each experimental condition, the ordering of error type varied, in order to minimise the effects of error type on performance. The errors were presented during trials 45, 66, 89, 92, 109 and 120. There were two wedge errors, two energy errors and two errors in monitor units. As there were six planted errors this means 15 combinations of where the planted word errors are. Each experimental condition has 15 participant pairs, and hence the order of materials is used once in each condition. Only the placement of the one word error needs to vary as the number errors are all similar. This then allows for an analysis of the accuracy for detecting each planted error and whether this accuracy was affected by which type of error was planted.

8.4.4 Hypotheses

It was hypothesised that:

- Switching the roles of challenger and responder will result in greater checking accuracy than simple challenge-response checking
- Varying the order of the checked parameters will result in greater checking accuracy than simple challenge-response checking
- Combining these two factors into challenge-response checking will result in the greatest accuracy.

8.4.5 Method

8.4.5.1 Design

All participants undertook challenge-response checking in pairs, and a between subjects factorial design was employed with participants allocated to one of four conditions:

1. challenge-response
2. challenge-response with role rotation
3. challenge-response with varying the order of parameters
4. challenge-response with varying the order and switching roles.

This factorial design allowed the interaction between varying the order of parameters and rotating roles to be investigated. The independent variable was the method of challenge-response checking used, and the dependent variables were the performance, measured by: percentage errors missed, percentage false alarms and measures of accuracy (as detailed in section 8.4.3.6).

8.4.5.2 Participants

Participants were undergraduate psychology students at Coventry University and were recruited via opportunity sampling. Participants responded to a call for participants on the university's online experiment management system and received course credits for participating. The only inclusion criteria were that the participants must have normal or adjusted to normal eyesight. Participants were excluded if they had taken part in one of the other experiments run as part of this thesis, as this may have introduced practice effects. 120 participants were recruited in pairs and allocated to one of the four conditions based on

order of presentation. There were 15 paired participants in each of the four conditions. Table 8.5 describes each of the three conditions.

Table 8.5: Checking methods experimental conditions

	Condition	Description	Number of participants
1	Challenge-response (C-R)	Simple challenge-response as described previously	15 pairs
2	C-R with role rotation	Roles of challenger and responder swapped every 15 minutes	15 pairs
3	C-R with varying the order	Parameters read out in a different order every time	15 pairs
4	C-R with role rotation and varying the order (both)	Roles of challenger and responder swapped every 15 minutes and parameters read out in a different order every time	15 pairs

8.4.5.3 Materials

There were 140 different screens displayed on an iPad with 140 corresponding paper prescription plans, one pair of materials (one paper prescription and one screen for comparison) constituted one trial. These were displayed in the same order for every participant. An example of these materials can be seen in figure 8.1 and 8.2. A set of Russian dolls consisting of five stackable dolls were used with 140 laminated sheets with differing height arrangements of these dolls.

8.4.5.4 Planted errors

Six errors were planted, in six different pairs of materials. There were two wedge errors, two monitor units error, and two energy errors. When an error was planted the value displayed on screen differed from that displayed on the paper prescription. The errors were minor, for instance a wrong digit. Errors were planted in trials 45, 66, 89, 92, 109 and 120. The errors towards the end of the experiment provided an opportunity for involuntary automaticity to have built up.

8.4.5.5 Procedure

Participants were invited to read the participant information sheet and sign the consent form. The procedure was then explained to them, to ensure standardisation the participant instructions in appendix 9 were used to instruct the participants. All participants completed

a challenge-response check, as in the previous experiment. If in the 'role rotation' condition, participants were told to switch roles every 15 minutes. They were then prompted by the researcher to switch roles every 15 minutes. If in the 'varying order' condition participants were told to vary the order they verified the parameters for every trial. The researcher monitored this and provided a reminder if it was needed. If in the 'both' condition, participants did both of the above. Appendix 9 details what was said to participants when instructing them on how to check the materials, depending on the experimental condition they were in.

Participants were provided with two pairs of materials to check as a trial run in order to check they understood the task. Participants then took part in the experiment as per the description detailed in section 8.2. However, the length of time spent checking was doubled to 90 minutes, and the number of materials also doubled. Participants were told that they had to complete a minimum of 120 checks within 90 minutes, but that for any checks they completed above this, they would receive a reward. Participants were told there were five errors within the materials. Although there were six errors, this prevented participants who may have performed well to remain vigilant for the final error. Throughout the experiment the researcher was in the corner of the room so that participants did not feel as though they were being observed.

8.4.5.6 Data recording

A record sheet was used by the researcher which listed what the challenger and responder should be saying (it listed the on-screen values the challenger should be reading for each trial, and if it is a trial with a planted error). The researcher circled if either the challenger or responder made a mistake (i.e. if the challenger announces a value incorrectly or responder responds incorrectly). This allowed for identification of where errors occurred and whether they were the fault of the challenger or responder. There was also a column for the researcher to indicate if a participant corrected what they originally said. Participants were also voice recorded to check for accuracy in the researcher's data recording.

8.4.5.7 Data metrics

Errors missed and false alarms were recorded, to allow calculation of percentage accuracy across all trials. Performance on each trial was categorised as described in table 8.6.

These types of trial category responses were combined to provide an overall accuracy rate for challengers and responders separately. Furthermore, as what participants said was being recorded, instances when participants made a mistake but then corrected themselves before the next trial were also recorded. These instances were combined to give a percentage accuracy score including corrections. These have been included as they still indicate a lapse of attention and in real life situations where the check is conducted so quickly, the beam may have been switched on before the mistake was realised.

The categorisation of trial responses was used to calculate accuracy, challenger accuracy, challenger accuracy including corrections, responder accuracy, responder accuracy including corrections, as detailed in table 8.6. Percentages were used for errors and false alarms, as participants would complete a varied number of trials over the minimum required.

Table 8.5: Data metrics

Trial category	Participant response on the trial	Accuracy contribution by checking role
Challenger miss	Error was missed due to challenger miss-reading	Challenger accuracy
Challenger false alarm	False alarm due to challenger miss-reading	Challenger accuracy
Challenger near miss	Challenger miss-reads but corrects themselves on an error trial	Challenger accuracy including corrections
Challenger near false alarm	Challenger miss-reads but corrects themselves on a non-error trial	Challenger accuracy including corrections
Triple error	Challenger miss-reads but responder does not notice on an error trial	Challenger accuracy and responder accuracy
Double error	Challenger miss-reads but responder does not notice on a non-error trial	Challenger accuracy and responder accuracy
Responder miss	Responder says there is no error incorrectly	Responder accuracy
Responder false alarm	Responder says there is an error incorrectly	Responder accuracy
Responder near miss	Responder says yes incorrectly but then corrects themselves on an error trial	Responder accuracy including corrections
Responder near false alarm	Responder says no incorrectly but then corrects themselves on a non-error trial	Responder accuracy including corrections

8.4.5.8 Ethics

This study was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee, see appendix 11. Due to the length and repetitive nature of this study, participants were given a £5 voucher upon completion of the study. Participants would have received this voucher even if they had withdrawn during the study, as it was considered a thank you and not an incentive. The research was conducted according to BPS ethical code of conduct.

8.4.6 Results

The metrics for each pair of participants was entered into SPSS and aggregated according to experimental condition. SPPS was used to conduct the descriptive and inferential statistics on the data.

8.4.6.1 Effect of condition on accuracy

The mean percentage of errors missed across all experimental conditions was fairly low. It is worth noting that, as seen in table 8.7, the percentage of errors missed in all conditions was higher than the missed error rates in the previous experiment. It is thought this is due to the increased number of errors and the much longer time spent checking.

Table 8.6: Descriptive statistics for each condition

Condition	Mean % errors missed (SD)	Mean % false alarms (SD)	Mean % accuracy (SD)	Mean % accuracy with correction (SD)
All participants	10.27 (15.67)	1.24 (1.21)	98.36 (1.39)	92.16 (1.13)
C-R	10.00 (13.8)	2.1 (1.8)	97.55 (1.77)	88.80 (4.42)
C-R with role rotation	6.66 (8.45)	1.19 (0.73)	98.56 (.89)	92.01 (2.97)
C-R with varying order	15.55 (23.11)	1.18 (.79)	98.17 (1.49)	92.20 (3.95)
C-R with both	8.89 (13.89)	0.47 (.57)	99.17 (.72)	95.63 (1.67)

As table 8.7 and figure 8.7 shows, participants missed a greater percentage of planted errors when varying the order of values.

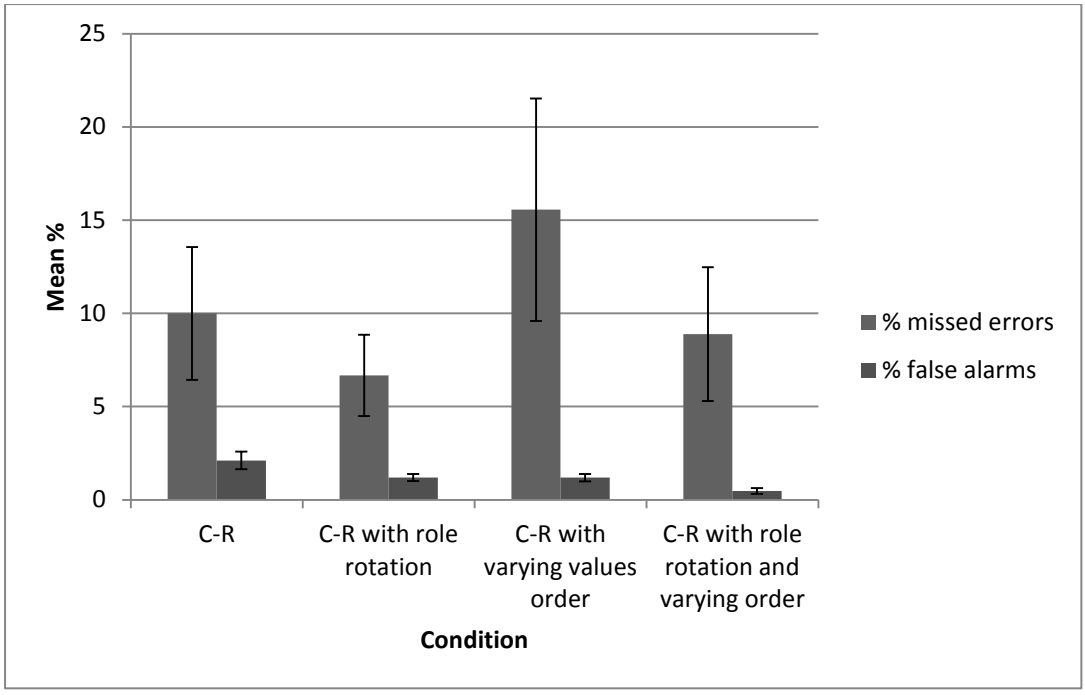


Figure 8.7: Mean percentage errors and false alarms across conditions

There were differences between groups on how accurate they were when reading the values and responding correctly. As table 8.7 shows accuracy was higher when participants rotated roles and varied the order of parameters. The difference was more pronounced when including instances where participants made a mistake but corrected themselves before the next trial. This is shown in figure 8.8.

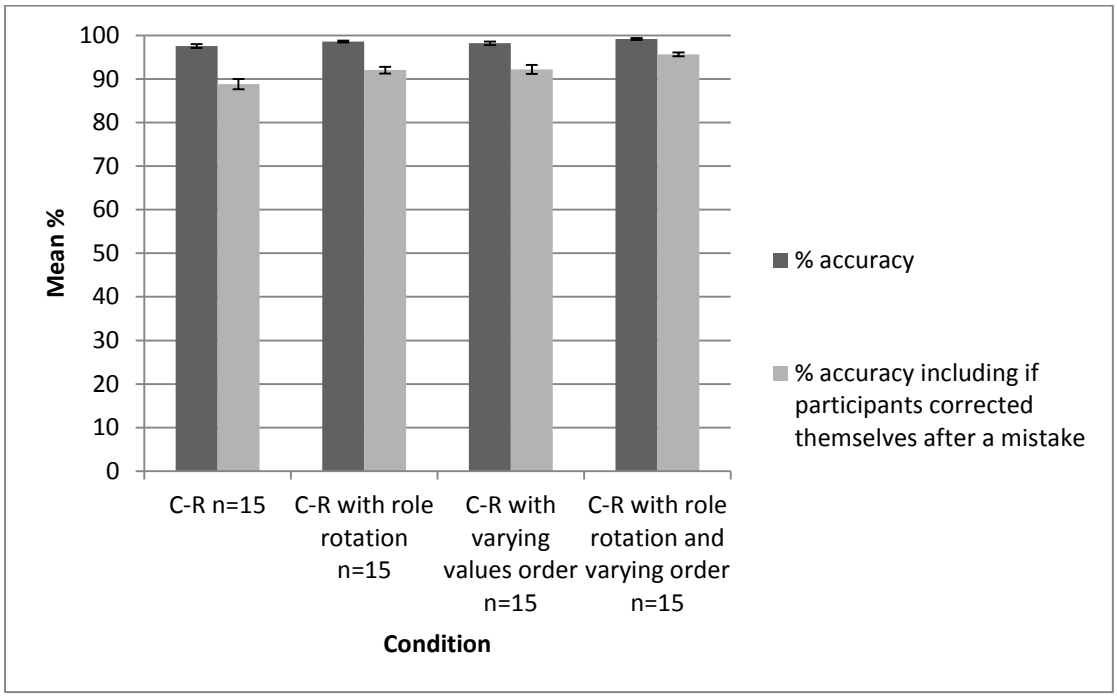


Figure 8.8: Mean accuracy of each condition

The accuracy of both challengers and responders was higher when participants rotated roles and varied the order of parameters. The difference was also more pronounced when including instances where participants made a mistake but corrected themselves before the next trial, as shown in figure 8.9.

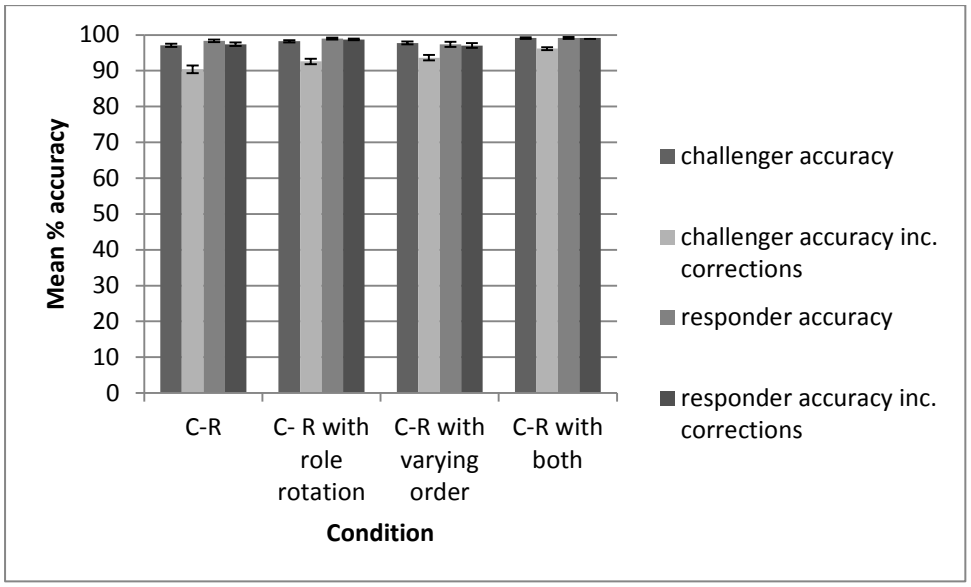


Figure 8.9: Challenger and responder accuracy across conditions

As there were two factors under investigation, varying the order and rotating roles, each with two levels, either present or not present, a 2x2 MANOVA was conducted. A MANOVA was chosen as there were multiple dependent variables: percentage errors missed, percentage false alarms and measures of accuracy, as detailed in section 8.4.3.6. The data for all dependent variables displayed an unacceptable level of skew, with no homogeneity of variance, as demonstrated by a significant Levene's test. Therefore, the data were transformed in order to meet the parametric assumptions needed to conduct a MANOVA (Tabachnick and Fidell 2007 and Howell 2007). The data for the 'miss' and 'false alarm' dependent variables displayed severe positive skew and had some zero values so the command LG10(x+C) was used, where C= 1 so that the smallest value was 1. The remaining dependent variables displayed severe negative skew so the command LG10(K-x) was used where K= the highest value plus 1.

Once transformed all data met parametric assumptions allowing a safe MANOVA to be conducted. In order to avoid a type I error, alpha was adjusted to 0.00625, as there were 8 dependent variables (0.05 divided by 8, Coolican 2004). Only the dependent variables displaying a probability value of less than this alpha value were accepted as significant. The full MANOVA results can be seen in table 8.8.

The MANOVA showed a significant main effect of 'role rotation' on 'percentage accuracy with corrections', $F(1,56)= 16.34$, $p<0.001$, 'false alarms', $F(1,56)= 8.13$, $p = 0.006$, 'challenger accuracy with corrections', $F(1,56)= 8.13$, $p=0.006$, 'responder accuracy with corrections', $F(1,56)=13.25$, $p=0.001$, and 'challenger accuracy', $F(1,56)= 19.88$, $p<0.001$. This shows that when participants conducted a challenge response with role rotation, their accuracy with corrections, challenger accuracy with corrections, and responder accuracy with corrections were increased, yet the number of false alarms were decreased.

The MANOVA showed a significant main effect of 'varying order' on 'accuracy with corrections', $F(1,56)= 20.62$, $p<0.001$, 'false alarms', $F(1,56)= 8.63$, $p=0.005$, and 'challenger accuracy with corrections', $F(1,56)= 23.81$, $p<0.001$. This shows that when participants conducted a challenge response with varying the order, their accuracy with corrections and challenger accuracy with corrections, were increased, yet the number of false alarms were decreased.

Table 8.7: MANOVA results

	Dependent variable	**F**	***p* value**
Role rotation	Percentage accuracy	7.41	0.009
	Percentage accuracy with corrections	**16.34**	**<0.001**
	Percentage miss	0.31	0.58
	Percentage false alarm	**8.13**	**0.006**
	Challenger accuracy with corrections	**11.12**	**0.002**
	Responder accuracy with corrections	**13.25**	**0.001**
	Challenger accuracy	**19.88**	**<0.001**
	Responder accuracy	7.44	0.008
Varying order	Percentage accuracy	4.04	0.049
	Percentage accuracy with corrections	**20.62**	**<0.001**
	Percentage miss	0.01	0.921
	Percentage false alarm	**8.63**	**0.005**
	Challenger accuracy with corrections	**23.81**	**<0.001**
	Responder accuracy with corrections	0.25	0.618
	Challenger accuracy	9.97	0.007
	Responder accuracy	0.22	0.641
Role rotation * varying order	Percentage accuracy	0.13	0.716
	Percentage accuracy with corrections	1.38	0.245
	Percentage miss	0.01	0.945
	Percentage false alarm	0.44	0.510
	Challenger accuracy with corrections	1.51	0.225
	Responder accuracy with corrections	1.03	0.314
	Challenger accuracy	1.75	0.191
	Responder accuracy	1.46	0.232

8.4.6.2 Differences between challengers and responder accuracy

The previous experiment showed a difference between the accuracy of challengers and responders during challenge-response checking, with challengers' accuracy being

significantly lower than responders' accuracy. Table 8.9 displays the accuracy of challengers and responders in this second experiment.

Table 8.8: Challenger and responder accuracy across conditions

Condition	Challenger % accuracy (SD)	Challenger % accuracy with corrections (SD)	Responder % accuracy (SD)	Responder % accuracy with corrections (SD)
All participants	98.10 (1.56)	93.20 (3.65)	98.48 (1.85)	98.08 (1.95)
C-R	97.12 (1.75)	90.39 (4.21)	98.35 (1.57)	97.39 (1.94)
C-R with role rotation	98.23 (1.24)	92.59 (2.80)	98.99 (1.0)	98.75 (2.9)
C-R with varying order	97.74 (1.51)	93.64 (3.01)	97.40 (2.79)	97.05 (2.66)
C-R with both	99.31 (0.81)	96.17 (1.6)	99.16 (1.05)	99.11 (1.02)

As figure 8.10 shows, the difference between challenger and responder accuracy was also present in this experiment. As data was not normally distributed, and therefore did not meet parametric assumptions, a Mann-Whitney *U* test was used to test this difference for significance. The Mann-Whitney *U* test showed that the difference between challenger and responder accuracy was not significant, U=1439, *p*= 0.56. However, the difference between challenger and responder accuracy including corrections, was significant, U= 298, *p*=<0.001. This suggests that challenger's accuracy, when including corrections, was significantly lower than responders when looking at all experimental conditions in aggregate.

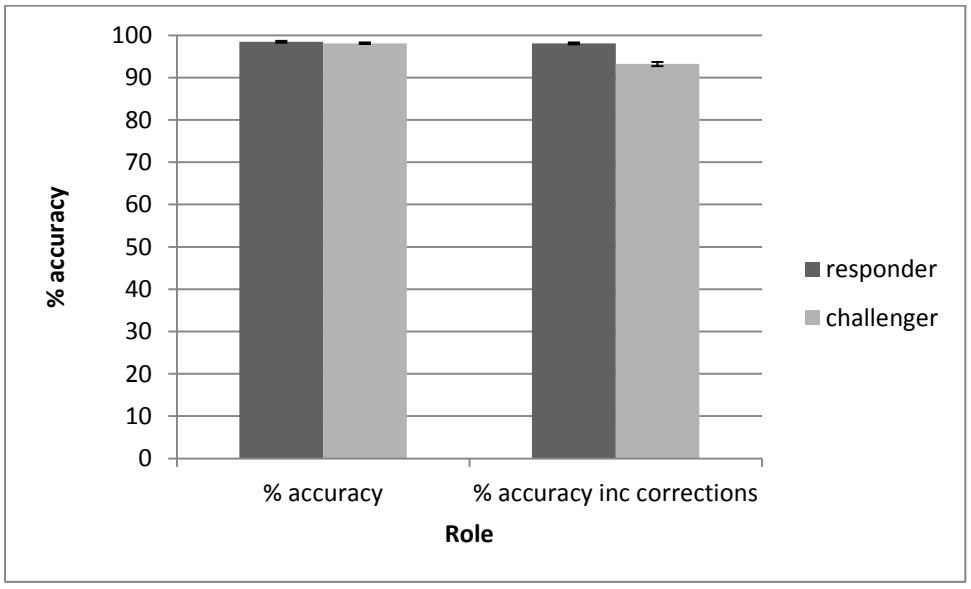


Figure 8.10: Challenger and responder accuracy

As can be seen in the earlier figure, challenger accuracy when including corrections, was lower across all four conditions, than responder accuracy. Table 8.10 displays the results of Mann Whitney *U* tests which show that this difference was significant across all four experiment conditions. This suggests that no matter what method of checking was used, the challengers' accuracy including corrections was significantly lower than responders' accuracy with corrections.

Table 8.9: Mann-Whitney *U* test to compare differences in role accuracy

Condition	Comparison	U	P
C-R	Accuracy	66.5	0.056
	Accuracy with correction	**4**	**<0.001**
C-R with role rotation	Accuracy	71	0.089
	Accuracy with correction	**1**	**<0.001**
C-R with varying order	Accuracy	102.5	0.683
	Accuracy with correction	**32**	**<0.001**
C-R with both	Accuracy	102	0.683
	Accuracy with correction	**12.5**	**<0.001**

8.4.6.3 The effect of involuntary automaticity

This experiment also demonstrated an effect of involuntary automaticity. The final planted error on trial 120, towards the end of the experiment, was missed more frequently than any of the other errors. This effect was present whether the error was a numerical error or wedge error, as displayed in figure 8.11. Although this was more pronounced when the error was numerical parameter, suggesting it is harder to spot a numerical error. As such the second hypothesis was partially supported.

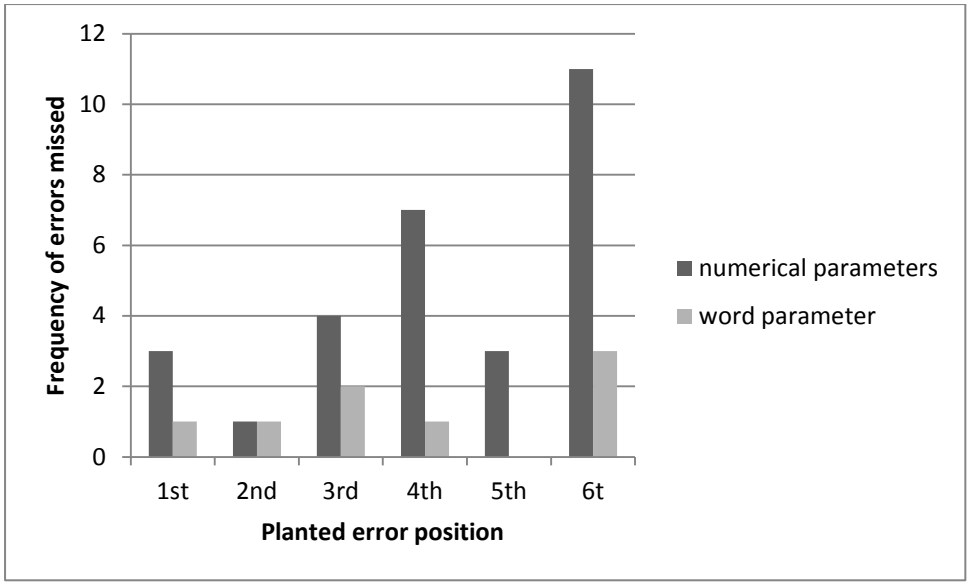


Figure 8.11: Error placement and frequency of error missed

Figure 8.12 displays an analysis of the error position and error detection in each condition. It can be seen that the final error was detected more frequently when participants were asked to rotate roles, and use both methods. Therefore, these methods appear to minimise the effect of involuntary automaticity.

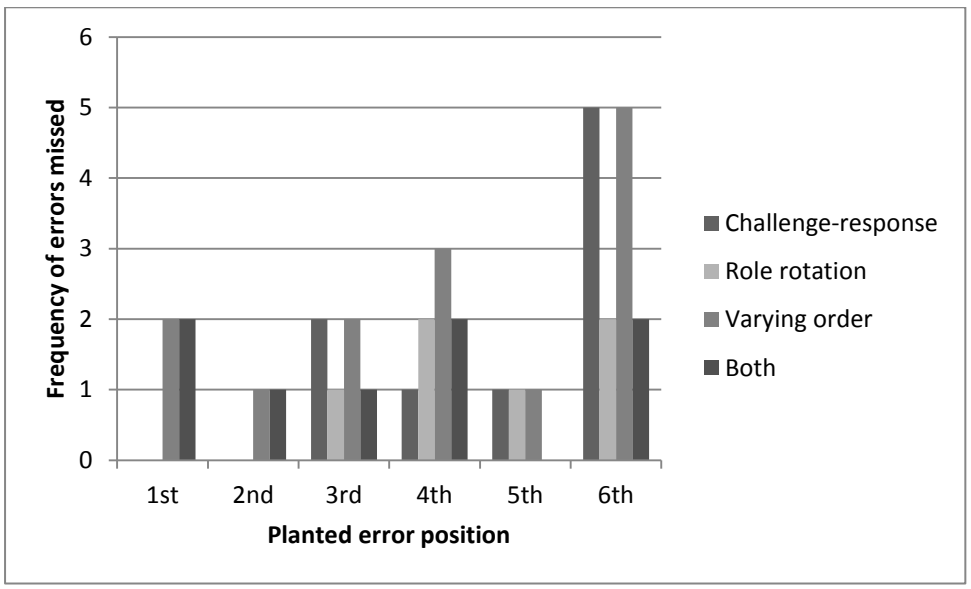


Figure 8.12: Missed errors by experimental condition

8.4.7 Maintaining attention discussion

The experiment investigating methods to maintain attention during repeated challenge-response checking adopted the same methodology as the first checking methods experiment but with improvements. The length of time spent checking was doubled in order

to increase the reliability of results, as it was more like the final treatment checks in radiotherapy departments which are done for long periods of time. The types of planted errors (numerical or wedge errors) were also varied in order to ensure that it was the time placement of the error, rather than the error type, which made it more likely to be missed. It is believed that this allows conclusions surrounding involuntary automaticity during repeated final treatment checks to be valid.

8.4.7.1 Effect of method on accuracy

There was no significant difference between checking methods on percentage of errors missed. This is believed to be because challenge-response checking is an effective method of error detection. The focus of this experiment was on measuring attention, indicated by accuracy rates. It was observed that both 'varying the order of parameters' and 'rotating roles' on their own led to a significantly increased accuracy score. This suggests that either method helps to maintain accuracy. As accuracy was higher, it is assumed that attention was maintained to a higher extent, resulting in fewer attention lapses. It is theorised that this is because these methods of checking required slightly more cognitive demand, as participants had to be focussed on either altering the order of parameters every time or rotating roles, thus the phenomena of underload did not occur. The parameters being varied also introduced variation into repeated final treatment checks, preventing routine. The switching of roles of challenger and responder every 15 minutes also prevented routine and ensured each checker did not become susceptible to involuntary automaticity in their role.

8.4.7.2 Comparison of role accuracy

As with the previous experiment, the challenger's accuracy rate was lower than the responders. This difference was present even when switching roles and varying the order of parameters. It is argued that this may be the interface design which is making it difficult to read the values correctly and therefore forcing the errors. Varying the order in which the parameters were read significantly improved challenger's accuracy. Therefore, this should be explored further to utilise potential safety benefits.

8.4.7.3 Involuntary Automaticity effect

The results suggested that involuntary automaticity does occur doing repeated final treatment checks as the final error was missed more frequently than the other errors, regardless of whether it was a numerical value or a wedge error. When an error went undetected this suggests attention failed, and involuntary automaticity is one interpretation of this. This effect appears to have been reduced when participants were asked to switch roles and vary the order of parameters, suggesting that these methods help to prevent involuntary automaticity from occurring.

8.5 Chapter discussion

This chapter has sought to explore experimentally the effectiveness of different methods of final treatment checking through laboratory based experimental studies. A novel experiment was devised to simulate some of the demands of checking in radiotherapy. It combined understanding of radiotherapy with the literature on checking and attention. The experimental design sought to determine the effectiveness of different methods of checking and the potential for involuntary automaticity during repeated final treatment checks. It also explored ways attention can be maintained during repeated final treatment checks, to minimise the likelihood of attention lapsing and involuntary automaticity occurring.

The chapter results have suggested that there is a difference in error detection and accuracy across different checking methods. Evidence has been provided to suggest that more errors are detected when a challenge-response method of checking is employed, compared to single or double (non-verbal) checking. Furthermore, the experiments have suggested that attention is still vulnerable to lapses during repeated challenge-response checking, but that changes to the way a challenge-response check is conducted can limit these attentional lapses, thereby improving checking accuracy. These changes are switching the roles of challenger and responder every 15 minutes, and varying the order the required parameters are checked in.

These methods were demonstrated in a laboratory setting to increase the accuracy of checking. The results are believed to be because the challenge-response forces both checkers to remain active during the final treatment check due to clearly defined roles. The

introduction of switching roles and varying the order is believed to prevent attention lapsing as it places slightly more cognitive demand upon checkers. These findings can potentially be incorporated into a checking protocol, in order to optimise error detection during the final treatment check in radiotherapy. This will be explored in the following chapter.

The results of these experiments also suggest that the materials used in radiotherapy departments would benefit from a re-design in order to support users to check treatment details effectively. This is because the results suggested that during repeated challenge-response checking the accuracy was mostly affected by the attention of the challenger when reading the values from the screen. This effect was also present even when participants switched roles of challenger and responder. This finding mirrors the views of qualified and student radiographers who, as discussed in section 7.3.5, reported that their software systems' interface is not user-friendly at the point of the final treatment check, and could be utilised further to help engage users and prevent involuntary automaticity. Therefore, these results suggest that research on the design of the interface used to conduct the final treatment check could be beneficial. This will be further explored in chapter 10.

8.5.1 Critical evaluation of experimental method

This experiment successfully employed a novel paradigm designed to mimic radiotherapy in order to investigate and compare the efficacy of several checking methods. Although the paradigm was designed to mimic radiotherapy the process was still not fully reflective of real life. Foremost, there was no danger of causing harm due to ineffective checking which is ever present when delivering radiation. Also, the number of errors planted was highly artificial because errors at the final treatment check are rare. This is because the frequency of planted errors needed to be high in order to compare the effect of checking methods. Participants only checked for a maximum of 90 minutes, whereas in real life this is done for hours. Furthermore, the time between each final treatment check is likely to be much longer in radiotherapy departments.

The values used in the experiment for the numerical parameters were also artificial. This was done to reduce the ceiling effects observed in the pilot study of the paradigm, and to compensate for the experiment being much less pressurised than real radiotherapy checks.

An important point to note here is that monitor units are often similar and staff quickly become accustomed to what the values for each parameter should be, although this would have additional consequences for automatic reading in real life settings.

It could be argued that the use of lay participants is a limitation of these experiments as they are not trained in radiotherapy treatment delivery. This may have meant they were not checking as conscientiously as would happen in real life due to their being no human danger from erroneous approval of treatment parameters. However, as detailed in section 5.4.1 this is not believed to be an issue as participants were briefed on radiotherapy treatment delivery prior to the study commencing, students were also provided with an incentive to check thoroughly in these studies, in the form of sweets. The use of lay participants has been further discussed and justified in sections 5.4.1 and 5.6.1.

Independent groups were used in both experiments in order to prevent either fatigue or practice effects in participants. All participants were assigned to the experimental conditions based on order of presentation, to help minimise individual differences in the experimental conditions. Despite the possible limitations of this experiment, it is believed that this novel approach to exploring patient safety provided interesting results that would warrant further exploration of the findings in a more realistic setting. This further exploration would help ensure that the results observed can be transferred and applied to real life scenarios.

8.6 Chapter conclusion

This chapter has concluded that, in this experimental context, challenge-response is the most effective method of checking to detect errors. Rotating roles and varying values during repeated treatment checks also helps to maintain attention, thereby limiting errors from passing undetected during repeated final treatment checks.

Results from this chapter will be taken forward in chapter 9 and used to inform the design of a new checking protocol for use immediately prior to beam delivery, as detailed in figure 5.1. The protocol will then be evaluated qualitatively with radiographers.

The second conclusion to be drawn from this chapter, and the interviews in chapter 7, is that the design of the interface needs to be further considered to ensure that the design is optimal in supporting the user when conducting a challenge-response check. This is because the results in this chapter suggested that challenger's accuracy was significantly poorer than responders. Chapter 10 builds on these findings and presents the design and evaluation of a new static interface design for use during the final radiotherapy treatment safety check.

9 Chapter 9 – Study 4: The development and evaluation of a checking protocol

The results of the literature review, exploratory interviews and task analysis (chapters 2-7), suggested that there is currently variation in how the final treatment check prior to treatment delivery is conducted. The exploratory interviews (chapter 7) suggested that radiographers would value a standardised checking protocol which details an evidence-based and effective method of checking. To inform the design of this protocol, laboratory experiments in chapter 8 explored the most reliable method of checking to detect errors in a simulated checking task. It determined that a challenge-response check, with parameters checked one by one would be beneficial. The experiments also suggested that changes to the checking process, regularly switching the roles of challenger and responder and varying the order in which the four parameters are checked, can help to maintain attention on the task. This new knowledge will therefore be applied to the evidence based protocol design in this chapter.

Standardised checking protocols are available in other areas of healthcare, for instance the surgical safety checklist, and other safety critical industries such as aviation. The work in aviation suggests that a well-designed checklist which elicits an active challenge-response check improves safety (Degani and Weiser 1993). However, rather than directly transferring an existing checklist from one of these domains, it is argued it is valuable to apply learning from other domains, but develop a domain specific protocol that maps directly to the context and domain specific requirements. This will increase the likelihood that it will work effectively when integrated into practice.

The research described in this chapter aimed to embed the findings derived from earlier chapters and apply these to the development of a protocol to assist radiographers maintain attention during repeated final treatment checks, and hence prevent involuntary automaticity and errors potentially passing undetected. The research also sought to evaluate this protocol with the end users.

9.1 Development of the checking protocol

This checking protocol seeks to provide a standardised work instruction, to minimise variation in how the final treatment check is conducted.

9.1.1 Method

Requirements for the development of the protocol were informed by:

1. The literature review
2. The HTA in chapter 6, see section 6.3
3. The exploratory interviews in chapter 7, see table 7.5
4. Results from the experimental findings in chapter 8

The requirements were compiled (see section 7.4) and used to inform the development of the protocol. Once the protocol design had been drafted, a radiographer was consulted to ensure that the content of the protocol was sufficient and in keeping with what needed to be done at the point of the final treatment check.

9.1.2 Emerging requirements

As a result of the above methods, the following requirements emerged regarding the purpose of the checking protocol:

- Communicate to radiographers exactly what treatment parameters need to be checked and how to check them effectively
- Provide a standardised operating procedure to minimise variation in how the final treatment check is conducted
- Minimise variation on checking practice both within and between radiotherapy departments
- Provide a short checklist, in which both users of the checklist can ensure they have checked all required parameters prior to beam switch on
- Focus radiographers' attention and therefore increase the likelihood of error detection during repeated final treatment checks

In addition to the purpose indicated above, a number of required features of the protocol have emerged from the methods detailed in section 9.3.1. Table 9.1 details these requirements, alongside an explanation and the evidence supporting the feature.

Table 9.1: Requirements of the checking protocol

Requirement	Explanation	Supporting evidence
Inclusion of only energy, monitor units, wedge monitor units and wedge position	These are the parameters which must be verified at this point in treatment	Literature- *Towards Safer Radiotherapy* (Donaldson 2007)
Verbal checking	Considered to be more effective	Task analysis Literature review- *Towards Safer Radiotherapy* (Donaldson 2007) Interview findings
Challenge-response format	Considered to be more effective	Task analysis Literature review- Degani and Wesier (1993) Interview findings Experimental findings in chapter 8
Vary the order of parameters for each final treatment check	Helps to maintain attention by minimising repetition and introducing variation	Experimental findings in chapter 8
Switch roles of challenger and responder	Helps to maintain attention by minimising repetition and introducing variation Role switching every 15 minutes is suggested as this should mean they are switching roles between every patient.	Experimental findings in chapter 8
One parameter checked at a time	Prevents 'chunking', which places too much demand upon memory	Task analysis, section 6.3.3
Active repeat back of value	Prevents responder just saying yes, helping ensure active checking. Also provides a second chance at error detection for each parameter, as both checkers hear the value and say the value.	Task analysis, section 6.3.3
Told to listen	Makes explicit that both radiographers must remain involved in the check	Interview findings
Read from screen	The machine is giving the dose, therefore the value should be read from the machine and not the prescription	Task analysis, section 6.3.3

Requirement	Explanation	Supporting evidence
Check against prescription sheet	This is the source documentation and what the dose should be verified against	Literature- *Towards Safer Radiotherapy* (Donaldson 2007)
Explanation of why it is important to swap roles and vary the order of parameters	A reminder of the safety reasons for this is intended to increase adherence.	Literature review – Simons *et al.* (2010)
Fits current workflow	This was found to help compliance in the SSC	Literature review – Evley *et al.* (2010) Interview findings
Time efficient	If it takes too much time it will not be followed	Interview findings
Not forcing the user to rely on memory	Principle from good aviation checklist design	Literature review- Degani and Wesier (1993)
Critical items placed at the beginning	Principle from good aviation checklist design	Literature review- Degani and Wesier (1993)
Items presented in a logical order	Principle from good aviation checklist design	Literature review- Degani and Wesier (1993)
Silence during critical safety phases	Principle from good aviation checklist design	Literature review- Degani and Wesier (1993)
Use of ‘ standard phraseology’	Principle from good aviation checklist design to formalises the process and provides a distinction from other communication.	Literature review- Degani and Wesier (1993)
The roles of both challenger and responder made explicit	Principle from good aviation checklist design as distinct roles in a checklist co-ordinate actions and communication.	Literature review- Degani and Wesier (1993)
Written protocol	To provide more detail and a brief explanation of why it is important to swap roles and vary the order of the parameters, because compliance increased if the reasons explained	Literature review – Simons *et al.* (2010) Interviews
Diagram to provide a visual reminder	Shown to be effective at explaining double checking in anaesthesia.	Literature review- Evley *et al*. (2010), see figure 4.1.

9.1.3 The protocol

The requirements detailed in table 9.1, were developed into a protocol. The written form is shown in figure 9.1, and the diagrammatic in figure 9.2.

Protocol for the final treatment check in radiotherapy

Immediately prior to beam delivery, having set-up the patient up on the bed, **two qualified radiographers** are required to ensure that the parameters displayed on the linear accelerator machine screen correspond exactly with those which were prescribed by the patient. To do this the **values on screen must be checked against the patient's original prescription**. The parameters which must be checked are **energy, monitor units, wedge monitor units** and **wedge position.**

The two radiographers must conduct an active check by following this method:

- The first checker reads a parameter value aloud from the screen
- The second checker waits to hear the value and then looks at the prescription and confirms this is correct, then repeats aloud the energy value from the prescription
- The first checker waits to hear the value and confirms it is correct by looking again at the screen
- This process is repeated for the remaining parameters
- Only when all four parameters have been verified this way can the beam be switched on

- For any subsequent beams, or for the following patient to be treated, the verification is to be repeated in the same way, but the order in which the parameters are checked must be altered. Radiographers must ensure they **continually vary the order in which the four parameters are checked.**
- Radiographers must ensure that they **regularly alternate the roles of first checker and second checker**. Role rotation for every patient is ideal, with a maximum of 15 minutes to pass before a role rotation.
- **Varying the order of parameters and alternating roles is vital to ensure involuntary automaticity during the final treatment checks does not occur. Involuntary automaticity makes the final treatment check vulnerable to error.**

Figure 9.1: Text protocol for final treatment check

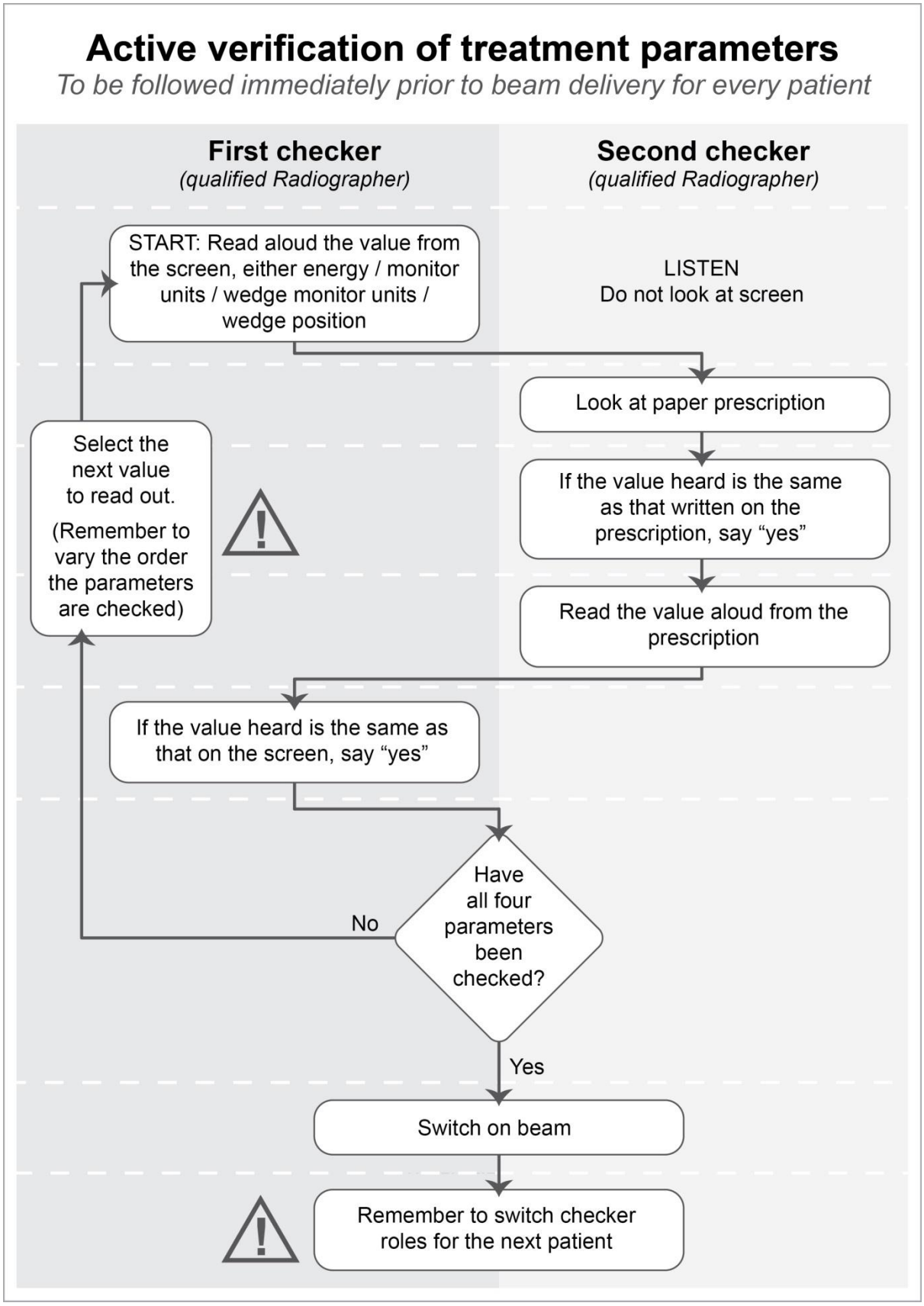


Figure 9.2: Diagram protocol for final treatment check

9.2 Evaluation of the final treatment check protocol

In order to evaluate the effectiveness, strengths, and weaknesses of this new protocol, group interviews were conducted with qualified and student radiographers. The aim of this study was to evaluate the usability and potential effectiveness of the new protocol by understanding qualified and student radiographers' views of the protocol's strengths, weaknesses, benefits, effectiveness, and possible improvements to be made.

9.2.1 Method

A qualitative approach to the evaluation of the protocol was taken as it was important to gather the views of the potential end users of the protocol, so that they could feedback into the development of the protocol, as discussed in section 5.5. Furthermore, the protocol could not be put in place 'live', due to ethical considerations surrounding service delivery in the NHS.

9.2.1.1 Design

Semi structured group interviews were used to conduct the evaluation, so that participants had an opportunity to use the protocol by verifying example treatment details in pairs. Additionally, group interviews provided an opportunity for participants to stimulate discussion amongst themselves, thereby providing richer data.

9.2.1.2 Participants

Participants were recruited via opportunity sampling. An email invitation was sent to potential participants who were asked to contact the researcher to arrange a convenient time for interview if they were interested in taking part. All radiographers from Northampton General Hospital and all second and third year student radiographers from Birmingham City University's radiography department were invited. Student radiographers were chosen has they were believed to provide a range of experiences as they had been on placement in various different hospitals across the region. These locations were chosen as they were local to the researcher. The only exclusion criterion for this study was that participants must not be under investigation for a patient safety incident. Recruitment continued until data saturation was reached- this was the point at which participants gave no new data.

Sixteen qualified therapy radiographers were recruited from Northampton General Hospital's radiotherapy department. Twelve student radiographers were recruited from Birmingham City University. This group was believed to represent a range of experience and views. Details of participant experience are provided in table 9.2.

Table 9.2: Evaluative interviews participant experience

Grade	Number of participants
Band 5 radiographer	4
Band 6 radiographer	4
Band 7 radiographer	4
Band 8 radiographer	2
Second year student radiographer	5
Third year student radiographer	7

9.2.1.3 Procedure

Participants took part in interviews in small groups of two or three. One participant took part alone. In this instance the researcher worked through the final treatment check protocol with the participant. The number of participants per interview was dictated by staffing levels on the department at Northampton General Hospital, it was always ensured that participation did not have a negative impact on staffing in the department. The interviews took place in a quiet room, away from any distractions. At the start of the interview participants were invited to read the protocol and trial it in pairs in order to allow them to become familiar with the checking detailed. After all participants said they understood the protocol and had no more questions, a semi-structured approach was used to conduct the interviews.

The length of the interviews ranged from 15-55 minutes. The interviews were audio recorded to produce a verbatim transcript and to allow the researcher to focus on what the participant was saying and ask probing questions. These interviews were transcribed verbatim by the researcher and the transcripts used for analysis.

9.2.1.4 Interview schedule

The semi-structured approached allowed a flexible interview scheduled to be used which covered the topics necessary for the research question, whilst allowing the researcher to follow up on any interesting points raised by the participants. The interview questions were designed to elicit responses which would allow exploration of the strengths, weaknesses, likely effectiveness, implementation, barriers to use and design of the protocol.

Questions were designed based on the previous research, and informed by the research aims. Questions about the implementation of the new protocol were derived from the factors surrounding SOP implementation identified in the literature review. Throughout data collection the questions followed a flexible emergent design- that is, if an unexpected topic arose during an interview it was added to the schedule for subsequent interviews. All interviews were conducted following the same interview schedule which can be seen in appendix 14. A summary of the interview content is presented in table 9.3.

Table 9.3: Content of evaluative interview questions

Question number	Content Description
1	**Demographics** • Initial demographic questions to allow comparison of participant responses in the analysis
2-9	**Design of the protocol** • Were both version of the protocol clear? • Were roles of both checkers explicit in both versions of protocol? • Was the diagrammatic representation of the protocol clearly communicated and easily understood? • What was liked and disliked? • Any improvements to be made
10-15	**Using the protocol** • How effective would the protocol be at error detection? • Would it help maintain attention during repeated final treatment checks? • Comparison of this protocol with current practice
16-22	**Implementing the protocol** • Would the participants use the protocol? • Their perception of others adopting this new protocol • Barriers to usage

9.2.1.5 Data analysis

As these were exploratory interviews, thematic analysis (TA) was chosen as it allows identification and exploration of patterns across the data (Braun and Clarke 2006). The analysis process detailed in section 5.3.2 was followed. Examples of coding and a table of codes, themes and sub-themes can be found in appendix 15 and 16.

9.2.1.6 Ethics

The research protocol was approved by Coventry University Faculty of Health and Life Sciences Ethics Committee and permission sought from Birmingham City University and Northampton General Hospital's Research and Development department. Approvals can be seen in appendix 12, 13 and 14 respectively. The interviews were conducted according to BPS ethical code of conduct.

9.2.2 Results

Participants were largely positive about the protocol, both in terms of likely error trapping through use and likely adherence to the protocol. Alongside discussion of the strengths, benefits and implementation of the protocol, a few improvements were also suggested, mainly the design of the treatment systems to work in tandem with the protocol. Thematic analysis of the interviews led to these results being clustered into six themes. These were: challenge-response method valued, preference for the process illustrated on a diagram, implementation of new protocol, error prevention, secondary benefits and design improvements. These will be discussed in turn.

9.2.2.1 Challenge-response method valued

A challenge-response method of checking treatment details was widely valued. Participants believed that this structured method of checking was safer, and more likely to detect errors because it was more active due to its verbal nature, during which a "yes" or "no" would not suffice:

> *"Having been on an audit, I'd have to say this method is better, because I am far from convinced, even though you remind people to actively engage in the check, it happens. There's almost a ritualistic calling out of numbers, and then a yes" Band 8 radiographer*

Participants recognised that if the final treatment check was done in this way it would mean that both checkers were forced to remain focussed on the task. Furthermore, the verbalised

nature of the check means that both radiographers were aware if the other was paying attention, forcing both to remain on task rather than leaving the responsibility of verification to the other radiographer:

> *"At the moment you don't actually have to listen. They just wait for someone to stop talking and do their bit of talking. Whereas if you've got to mirror the order that the person that has told it to you, you've got to find them in the right order." Band 5 radiographer*

Feedback on how the final treatment check procedure was laid out on the protocol was positive with participants appreciating that both of the checker roles were clearly defined. Student radiographers especially reported appreciating the clearly defined roles of both the challenger and responder. They felt that it helped with their training, as they could follow what the qualified staff were doing when observing and knew what to do when they were switching on the treatment beam. The absence of any ambiguity was appreciated as it allowed student radiographers to be clear on what they were expected to do at this point in the patient's treatment.

Whilst feedback on this structured method of checking, with a repeat back and parameters checked one at a time was positive, it was also noted that there would be time implications to its adoption. Some participants thought this active call back would take too much time, and negatively impact on treatment times. It was believed that reading and verifying the parameters individually would especially take too much time and may lead radiographers to revert back to checking them all together. Conversely, some participants argued that it was worth spending a few extra seconds if it prevented even one error:

> *"It would probably only increase a patient's treatment time by a minute, if you've got 40 patients a day, that's 40 minutes at the end of the day. On the other hand, if it could prevent even a single error…." Third year student radiographer*

Some participants reported a positive benefit of the check taking extra time. They felt that if it took longer to do the final treatment check it would slow the process down, which would be of benefit, as it is normally rushed. Therefore, extra time would allow them to pay more attention and think about the check.

9.2.2.2 Preference for the checking process illustrated on a diagram

Whilst feedback on both the written and diagrammatic protocol were positive, all participants preferred the protocol presented on a diagram, as opposed to the written prose, as it was perceived to be clearer, quicker to read and easier to digest. It was recognised by participants that the diagram was very different to other work instructions in their departments, which were almost without exception, written:

> *"Even at a cursory glance at the diagram would be very straight forward. The alternate protocol description is like the million others I've seen and I would have to sit down and really scrutinise it for it to go in." Third year student radiographer*

Due to the clarity and simplicity of the diagram, participants did not perceive reading the diagram to be an arduous task. In contrast, many participants reported that the written protocol was not appealing and they would struggle to find the time whilst in the department to read, or remind themselves of, the protocol if it existed only in prose form. It was reported that this difference in the protocol design would capture their attention and assist in the successful implementation of the protocol:

> *"There's something about it which just draws your attention to it, you know. If it's just right there in front of you, maybe it's the colours on the diagram but it does drag your attention more than this paper. You tend to push these written things to the side." Third year radiographer*

Some participants drew parallels with the infection control posters around the department, due to the visual nature of the diagram, which had been successful in changing the ways staff and patients approached hand-washing. A further benefit of the diagram protocol recognised by participants was that it is visual and hence suited to being displayed on a wall. Participants suggested that this diagram could be positioned on a wall next to the treatment console in order to act as a constant reminder on final treatment check best practice:

> *"It would be ideal to have on a wall, because you can just glance at it." Band 8 radiographer*

It was believed that the step-by-step nature of the diagram would allow staff to remind themselves of the final treatment check process. This would help during the implementation stage and particularly when staff returned to therapy treatment from leave or working elsewhere in the department, without having to go and consult the written departmental policies and procedures. Participants also believed the visual nature would help them to

remember the process, whereas they sometimes struggled to recall other departmental protocols. A further perceived benefit of the diagram being present near the treatment machines was when training student radiographers. As senior staff could then, not only tell them what to do, but students can see what to do and understand it for themselves, whilst at the same time ensuring staff are doing it properly. This method of training is currently lacking in radiotherapy:

> *"Student training is very much based on the principle of monkey see, monkey do." Band 8 radiographer*

All student radiographers reported that they would like being able to view the protocol at the same time as listening to the check being done by staff when they were observing. Furthermore, all qualified staff reported that it would be easier to refer student radiographers to a nearby diagram when explaining how and why to conduct the final treatment check.

Whilst the diagrammatic version of the protocol was preferred, all participants acknowledged that the optimal effect of the new protocol would come with the written and diagrammatic protocol versions being used together. The written protocol contains the reasons why staff should vary the order and swap roles, whereas the diagram highlights these points and provides a prompt with exclamation marks. Participants universally agreed that the explanation of why, whilst simple, would help bolster adherence to the protocol:

> *"The written protocol explains what we need to do and then how to do it, and there's things in bold, but the diagram is a short and sweet version." Band 6 radiographer*

All participants came to the conclusion that both versions of the protocol should be used; the written included in departmental policies and procedures which have to be read and signed off by all staff during induction and annually, then the diagram positioned as a constant visual reminder near the treatment console.

9.2.2.3 Implementation of a new protocol

Participants were not only positive about the content, reasons underlying and design of the protocol, but they also gave largely positive feedback surrounding the feasibility of the implementation of the new protocol. A standardised method of conducting the final treatment check was universally appreciated. It was recognised that there was no existing

standard method of conducting this final treatment check prior to beam switch on and that this part of the treatment was open to local departmental interpretation:

> *"It's a significant step forward to have something formally set out and standardised." Band 8 radiographer*

Standardisation of this process was believed by all participants to be an improvement over current procedures. It was recognised that standardisation of processes was absent in all areas of radiotherapy with departments writing their own protocols and procedures. It was reported again that there was variation in how the final treatment check was conducted across departments:

> *"Where I'm on placement, I've seen it done on different units, I've seen it done different ways, but the more common method would be the "have you checked it?" "yes" "alright then, press go". Rather than making a sort of effort." Third year student radiographer*

Participants reported that implementing this protocol as a standard protocol across all departments would emphasise the importance of the final treatment check and would ensure all radiographers were working to best practice. It was also believed to assist when staff and students moved department and allow for an easier transition period:

> *"Yeah it brings in that uniformity in radiotherapy which we lack really. Most departments they have their own way of doing things but it would be ideal knowing that whether you're working at one department, or go to another department, their method of verification is quite the same regardless of which software they use, you still know what roles you have in double checking. I think that would be ideal." Second year student radiographer*

For some participants this method of checking was similar to current departmental practise. Whereas some participants recognised that the final treatment check was often not done as a double check, or as a verbalised check, in departments they had worked in or visited. Nearly all participants who verified in a similar way, using a two person verbal check, recognised that their current method of checking did not include the second verbal repeat back, or double confirmation. All participants who expanded on how they checked currently reported that they did not vary the order of parameters to be checked. Some participants reported that they did vary the roles of 'challenger' and 'responder', yet this was not a regular occurrence and they often did not do it consciously or because of departmental protocol:

"Staff would switch roles depending on how sits down in the chair first, rather than, any sort of conscious effort on their part." Third year student radiographer

As the protocol would not require a radical change in practise it was suggested that only a gentle introduction of the new protocol would be needed to ensure it was followed. It was suggested by many participants that the new protocol should be introduced during lunchtime seminars with small group training sessions during which staff are explained the reasoning behind the new protocol and given a chance to practice using it before it went 'live':

"I think too much, with protocols, new protocols. It's just been here's a paper, read it. You know. I think it needs to be fully introduced and why." Third year student radiographer

It was strongly suggested that the protocol would require the full support of seniors and technical leads in the department to ensure others embraced the new protocol:

"It depends how it was enforced by the technical leads. The technical leads are very well respected and they're kind of separate to the staff base, as they should be, they write the policy, a lot of the protocol, as well as approving it. So if they took it seriously it would trickle down even if there was some resistance" Third year student radiographer

Trial periods were suggested by many participants as being a useful way to incorporate staff feedback into the implementation and support willingness to adhere. It was also suggested that regular, internal, informal audits would be beneficial to ensure the protocol was being adhered to and ensure its longevity:

"It'd be, we adopt it, we write into procedure, we'd run very short training sessions with staff, just literally running through the protocol with a couple of members of staff, each one, take them off two at a time, run them through the protocol and off you go, you're off and running." Band 8 radiographer

Other participants suggested that the protocol would need higher support from the Department of Health if it was to be standardised successfully across all departments:

"If it needs to be rolled out, then it's got to come from the government, it's got to be made mandatory rather than something that different radiotherapy managers can pick and choose from. If you're going to roll it out and say this is worthwhile doing it's got to come from the top, Department of Health, this is what you're doing and it's been proven to work. I think if it's come from the government as well it would really enforce how important it is because it is important. Some people just blurt it out and

they're more concerned with getting through the patients rather than treating them." Band 7 radiographer

The majority of participants indicated that they would be willing to embrace and follow the new protocol as they could envisage the safety benefits. However, it was noted that there may be some resistance from experienced staff:

"If you gave some people this in gold, they still wouldn't follow it would they! We've always got that group of people who just want to do what they've always done. But I think the majority would follow it." Third year student radiographer

The potential resistance was believed to be due to the change in habits that adherence to the protocol would require. It was recognised that following this protocol would get easier with time. This is primarily because it would become more 'second-nature' to check each parameter individually with an active repeat back. Although, if this would lead to the same issues of involuntary automaticity the protocol seeks to avoid, would remain to be tested by further research. Furthermore, the adoption of the protocol was expected, by participants, to become easier with time, as the numbers of student radiographers who could be trained in this way of verifying increases, and they progress through the qualified grades, they would be in positions to train the next generation of radiographers, thereby creating a cultural evolution in final treatment checking:

"Once you get it ingrained in your students and then they become radiographers then you're starting to build that process up right from the ground level" Band 7 radiographer

Whilst the future adoption of the protocol seems promising, it was also acknowledged that adoption is not a linear process, as staff may revert to checking all parameters together, as it would be quicker. Participants spoke a little about the potential for application of this protocol to other areas of cancer treatment where there are double checks in place as a safety measure, such as radiotherapy pre-treatment imaging and planning, and chemotherapy drug administration.

9.2.2.4 Error prevention

All participants believed that this structured method of checking, with role rotation and varying the order of parameters, would help to detect any errors during the final treatment check immediately prior to treatment delivery. Participants believed that rotating the roles

of 'challenger' and 'responder' would act as a *"speed bump to automation"* and help to maintain attention during repeated final treatment checks, especially when patients had long treatments consisting of many treatment fractions. This was believed to be because the addition of varying the order and switching roles forces them to think just a little bit more about what they are doing:

> *"You have 30, 40 patients a day, if you're just the second checker throughout, you're bound to know the order, and might end up saying yeah, yeah. If you're changing back and forth, starting with one thing, finishing with another, that would keep you on your toes" Second year student radiographer*

As positive as the feedback was from the participants about the protocol preventing errors, it was recognised that this protocol could not address some issues associated with checking errors: a lack of human factors training, time pressure, distractions, design of the treatment areas and authority gradients. Time pressure and staffing levels were recognised by many participants as impacting negatively upon effectiveness of the final treatment check. Participants reported that there is an increased throughput of patients in radiotherapy departments, which is having a negative impact on the amount of treatment time dedicated to treat each patient. This may, in turn, have an impact on how stringently the final treatment check, and other protocols, are followed:

> *"I'm in my second year and even since I started training it's becoming more noticeably busy and waiting lists are going up and up and that's had an impact on the treatment units I've been on where it's much busier, you've got less catch up slots as well so it's easier for you to fall behind, so I think that's when corners start getting cut." Second year student radiographer*

A further negative impact on the final treatment check accuracy, which participants noted would be easier to change than time pressure, is distractions. Participants noted that no matter how good a protocol was, it could not prevent the staff who are checking from being distracted by colleagues, other professional staff, patients and patient families. Whilst the NHS department in which these interviews with qualified radiographers were conducted in had recently tried limiting the number of phone calls being routed to the treatment consoles, it was recognised that there was still too much noise and distractions in the same area as the final treatment checks are conducted:

"I think if you want to reduce the number of errors, if there are a number of errors, I think you need more focus and more time to do it and less distractions." Band 5 radiographer

The issue of distractions is closely related to the design of the department, which some senior radiographers also noted had a negative impact on the final treatment check. Some senior radiographers reported that the area around the treatment console was too crowded and that some work which was being done there could be located elsewhere to minimise disturbances:

"It does invite that whole question about actually how to structure the work on the unit. You've got 4, sometimes 5, staff on that unit, no matter how small or how big that space is. Is 4 or 5 actually healthy or should they be on activities elsewhere in the department? Which again that's another thing which comes down to resources and availability of space." Band 8 radiographer

These participants also suggested that ensuring that the area around the console was a quiet, protected and perhaps screened off area, would improve their concentration during final treatment check:

"You kind of almost need a screen behind where you're switching on, to separate the rest of the control area where conversations are happening and need to be happening" Band 5 radiographer

A further issue which all participants noted was a challenge to eradicate, was deference to authority. Whilst it was recognised that the detailed protocol with clearly defined roles may go some way to preventing this, junior staff may still feel uncomfortable questioning a senior:

"That's actually one of the key safety measures isn't it, because always the risk is that people will defer to the senior person and the senior person is just as prone to making a mistake as anyone else is." Band 8 radiographer

A further issue that senior radiographers felt needed to be addressed to ensure effective checking was human factors and patient safety training for both student and qualified radiographers. The senior radiographers who spoke about this believed that if staff and students had more of an understanding around error propagation and causation they would be more willing to alter their own and other's work behaviours and embrace safety measures more actively:

"I think it all comes back to the training culture as well, planting human factors in the training which I think is lacking at the moment." Band 7 radiographer

Student radiographers also noted areas in which they felt their training had been lacking. They reported feeling like they were *"thrown in at the deep end"* when going out on placement, and that they would like an opportunity to practice clinical skills in a non-threatening environment at their university before going on placement. This checking protocol was identified as an ideal aspect of clinical practice which could be introduced at university:

"We don't have anything much related to practical inside our university, we do the academic, but yes, we know we need to go out there practically, but it's not like a nurse where you have a clinical setting and they learn before they go in. They throw you out there, everything's new, you're learning everything" Second year student radiographer

9.2.2.5 Secondary benefits of introduction of the protocol

Many participants believed that this protocol had some additional benefits above error prevention including: increasing awareness of the importance of the final treatment check, improving team work and increasing staff confidence. The greatest benefit to individuals reported was the positive improvement this would make when student radiographers begin their training, as the protocol would serve as a useful introduction to this particular aspect of patient treatment. Many participants believed this protocol would benefit all staff, on an individual level, as having it positioned nearby would increase confidence to speak up if another member of staff was deviating from the protocol. Some participants, especially student radiographers, also recognised that having the protocol forcing them to speak would increase confidence, especially as it was so simple they could not get it wrong:

"Especially if you're a newly qualified band 5 working with a high band 7, it would help break the ice as such and help us to not feel as small." Second year student radiographer

The protocol was also reported to have some team benefits; improving working relationships between staff and improving team working. Participants also believed that having a formal and visible final treatment checking protocol may have the secondary benefit of increasing, not only radiographer's perceptions of the importance of the final treatment check, but also support staff and staff from other professions. It was believed

that this may prevent these other staff from distracting them when verifying, and increase their understanding on the need for silence during the final treatment check.

9.2.2.6 Design improvements

Whilst feedback on the protocol was largely positive, some improvements were suggested by participants. Firstly, participants wanted the software to support and assist them in varying the order of parameters. Participants believed that varying the order of the four checked parameters every time would be too difficult to do and that they would forget the order they had done previously. Some believed having to remember to vary the order may take their focus away from the patient or from checking effectively. Some participants were also concerned that one parameter may get forgotten:

> *"I do think where it says that they should vary the order in which the four parameters are checked may create errors. Because I think people may forget which ones they have checked." Third year student radiographer*

Consequently, participants suggested that they would like support to vary the order of parameters. It was noted that paper prompts would not be ideal as there was already too much paper around. Instead software prompts were preferred, perhaps in the form of tick boxes on screen next to each parameter which were ticked as they were checked. However, some participants noted that this may lead to the final treatment check being reduced to a tick box exercise. An alternative solution suggested, and supported by participants, was the software randomly varying the order of the four parameters for them, so that for each fraction the parameters were presented in a different order. Participants believed this would force them to read them out in a different order, hence following the protocol without having to focus on remembering to vary the order. Participants believed this would still retain the advantage that they would read them out in a different order, forcing the second checker to remain alert, but they would not have the focus taken away from the patient and the act of checking:

> *"I think that would help the keeping it up and keeping it random, because I'm not very good at random! I settle into a pattern if I can. Yeah if it comes up in a different order then you read it out in a different order." Band 5 radiographer*

Another suggestion was that the software could prompt staff to swap roles, perhaps with the background colour of the interface changing every 15 minutes to signal a role rotation had to take place:

> *"That might be the prompt that you need to change the role. "It's a different colour this time we need to change roles." Band 6 radiographer*

Some participants whose department swapped roles informally noted this may be quicker as sometimes staff forget whether they should be swapping roles or not:

> *"I think some kind of prompt is needed, because a lot of time we have two radiographers, who walk out the room and once goes "you switch on" and the other "no you do it", and that can take a minute!" Second year student radiographer*

Participants also suggested some valuable additions to the protocol. Some noted that it would be useful to have all parameters which are going to be checked denoted at the top of the diagram, as it is on the written protocol. A further possible addition was an additional check of the patient details, name, date of birth, fraction number and anatomical area being treated. Many participants noted this would be a good introductory check before launching into the check of the treatment numbers. Furthermore, this would be especially beneficial if they were treating in DICOM mode, which is when there is a software fault and there is consequently no safety net of a record and verify system. It was noted that this would reduce the 'distance' between them and the patient, as they would be referring to them by name rather than a series of numbers:

> *"Yes, because one of our big sins, is that we do tend to talk about the prostate or the lung, rather than Mr Smith and Mrs Jones." Band 8 radiographer*

9.3 Chapter Discussion

This chapter has presented the development and qualitative evaluation of a standardised 'best practice' checking protocol for use immediately prior to treatment delivery. This protocol has been developed from a sound evidence base and presented in both written form and diagram form to aid understanding. The aim of the protocol development was to produce a standardised operating procedure which would minimise variation and help to maintain radiographers' attention during repeated final treatment checks. The standardised checking protocol was well received by qualified radiographers and student radiographers

who perceived it to have safety benefits. Radiographers also perceived the protocol to help maintain attention through minimising routine.

9.3.1 Protocol strengths

The interview findings suggested there is much strength to this protocol. As with the preceding research, discussed in chapter 6 and 7, it was found that there is currently variation in how the final treatment checks are done, both across and within departments, which appeared to lead to some confusion amongst students around how to conduct this final treatment check. Consequently, this standardised protocol would help to reduce this confusion and ensure all staff are conducting the final treatment check according to best practice. It appeared that the method of checking described in the protocol is similar to current methods of checking in some instances, but with the addition of switching roles and varying order, which are sometimes done but informally. Therefore, this protocol has the benefit of sharpening current practise, yet not being radically different from current practice in some departments, which may make it easier to implement in these departments. However, it is acknowledged that this similarity may mean staff revert to their current way of checking and therefore the protocol should be implemented alongside considerations of how to maintain adherence.

The research presented in chapter 7, suggested that a new standardised method of conducting the final treatment check was needed in order to aid understanding on how to conduct an effective check and emphasise the importance of the final treatment check. Student radiographers believed this protocol would help aid their understanding of why and how the final treatment check should be conducted. Furthermore, standardisation of the protocol across the profession was considered a benefit when staff move between departments and to ensure all departments follow best practice.

In this evaluation, some participants revealed that they had wanted to do a challenge-response check but did not feel able to if others do not feel it is necessary. The presence of a formalised standardised protocol would help to ensure a consistent approach and highlight the importance of the final treatment check, which could wane after qualification. This research confirmed findings in the previous interviews, discussed in chapter 7, that there is

variation in the conduct of final treatment checks and highlighted a variety of factors that affect effectiveness, i.e. environment, distractions and hierarchy.

Participants believed the protocol would help maintain attention and increase the likelihood of error detection prior to treatment, by interrupting this final treatment check becoming a ritualistic chant. This supports the findings from the experimental, laboratory-based study in chapter 8. In the interviews in chapter 7, radiographers suggested switching roles to maintain attention. Experimental work supported this approach and here the implementation of this approach was regarded as effective and feasible during clinical practice.

Varying the order and remembering to switch roles may place slightly more cognitive demand on participants, preventing their levels of attention from dropping. However, it was suggested here, and supported by the experimental findings in chapter 8, that requiring each checker to vary the order of parameters would be challenging. Therefore, radiographers may need support varying the order of parameters, and the interface varying the order for them could be the solution.

The feedback on the protocol was mostly positive in terms of trapping errors, focusing attention, student training and standardisation. However, no matter how good a protocol is there are additional factors which can negatively impact on error detection such as; distractions, education, authority gradients and workplace design. Therefore, in order for this protocol to be successful these issues also need to be targeted at the point of, or prior to implementation.

9.3.2 Barriers to use

Evaluation of the protocol suggested a few potential weaknesses in the protocol. It was recognised that it would be easy for staff to slip back into old habits where parameters are not checked individually or there is no active repeat back. Hence, there is a need for regular audits alongside education around why this method of checking is necessary to maintain patient safety.

The lapsing into old habits is likely at times due to time constraints and pressure. Radiotherapy departments are under increasing strain; this new checking approach may take a few seconds longer than current practice. However, the impact of this will depend on how the final treatment checks are currently undertaken. In departments where there is no verbal checking immediately prior to treatment delivery, staff may be more likely to not follow the protocol due to the increased time required. Herein lies a paradox, in that it is during these pressured times that errors are more likely to occur, but that a process put in place to prevent errors is likely to be cut in order to save time.

In order to overcome potential cutting of corners to save time, staff would need to be convinced on the protocol's potential to detect errors, thereby preventing potential patient harm. Following these interviews it is recognised that despite the majority of radiographers being willing to adopt this method of checking, there is likely to be resistance from some staff, particularly more senior radiographers. Hence, there may be a need for simultaneous initiatives to alter cultural perceptions around the importance of this final treatment check alongside implementation of the protocol.

9.3.3 Improvements

Two improvements to the protocol were suggested by participants. It is recommended that the following amendments are made to the protocol:

- All parameters to be checked are listed at the top of the diagram
- Additional patient identity, and anatomy to be treated, to be added at the start of the final treatment check
- Design software to prompt staff to vary the order of parameters
- Design software to prompt staff to regularly swap roles of challenger and responder

9.3.4 Implementation

This research also provided insight into the best method of implementing this new protocol. Altering staff perceptions around the final treatment check may be challenging, therefore a

progressive introduction is required. The interviews suggested that a directive approach, such as giving staff a lengthy protocol or work instruction, may not result in adoption, especially if they do not believe in the reason why it is necessary. This fits with the models of implementation reviewed in section 4.7. Therefore, an explanation of why this protocol is being introduced is required from the outset. It was suggested by some participants that the best method of introduction and long-term adherence to the protocol would be to introduce it and audit adherence informally. Introducing the checking protocol could be done either during lunchtime seminars or small group training. This could be followed by a trial period with an opportunity for radiographers to give feedback, alongside internal audits with results fed back to radiographers. It was suggested that it is important also to have buy-in from senior staff to ensure adherence. This is also in line with implementation theory, reviewed in section 4.7. However, some senior radiographers recognised that perhaps more support from the Department of Health would be needed to ensure standardisation across all departments. Otherwise the protocol may be implemented inconsistently, particularly if it is allowed to be voluntary and open to interpretation by individual departmental managers. These barriers and facilitators to use were similar to those uncovered by Russ *et al*. (2015) when interviewing healthcare staff about the implementation of the surgical safety checklist, who also found resistance from senior staff was the main barrier to implementation. The methods to aid implementation suggested by participants in these interviews were also similar to those identified by Russ *et al.* (2015) such as education, strong leadership and accountability.

9.3.5 Study limitations

This evaluation provides an early evaluation of the protocol, and suggests an initial acceptance of it by the target user group. As qualitative research is vulnerable to subjectivity, the interview schedule was informed by the research aims and literature, active listening techniques were used by the researcher and a second coder was involved in the analysis to ensure validity and reliability, as discussed in section 5.6.

A limitation of the protocol evaluation is that a limited number of qualified radiographers were included from only one department. However, this was partially addressed through

the participation of student radiographers trained at a number of different hospitals in the region and there were no noticeable differences in viewpoints between them. The current evaluation only involved direct users. The inclusion of the viewpoints of other stakeholders, such as departmental managers and patients would also be important, especially as the protocol was determined to take more time to conduct than current practice.

A further potential limitation is that the checking protocol evaluated is similar to what is already done in the NHS department from which the qualified radiographers were recruited in this study. This might affect feedback on the protocol should it be more widely evaluated. Future work will explore the wider acceptability of the protocol. The department from which the qualified radiographers were recruited, was reported by the participants to be quite "*safety conscious*" and the interviews revealed they were willing to embrace change. This may have impacted upon the results given, as the protocol will seem familiar to the group's working processes, and therefore more acceptable, than to a group that currently employ a very different method of checking. However, the effect was minimised by the inclusion of student radiographers, none of whom were in placement at this NHS hospital, yet their results mirrored that of the qualified radiographers. Furthermore, many of the participants had worked at other departments and drew upon their experiences elsewhere.

The aim of this study was to use the feedback to make recommendations about further development, rather than be conclusive, in which case a range of subjective views from participants of different experience levels are important. Further evaluation following implementation of the protocol would be needed to assess more robustly the views of radiographers, and the effectiveness of the protocol to maintain attention during repeated final treatment checks.

9.3.6 Further research

A number of areas of further research have emerged. Firstly, the evaluation of the protocol design was only subjective, and only sought the views of the end users. Therefore, before implementation, an assessment of the readability of the protocol needs to be assessed, along with the use of colour, typeface and layout to ensure it adheres to optimal usability. Furthermore, an objective comparison study into the effectiveness of this protocol over

current practice would be valuable. Due to the variation and lapses in reporting and lack of firm error rates in the past it would be challenging to compare pre-implementation error rates with post-implementation error rates. Therefore, this could be conducted in a simulated laboratory setting as in chapter 8. This evidence may help to convince those who are reluctant to adopt this protocol. Alongside an evaluation of the effectiveness of the protocol in reducing errors, there is an opportunity to conduct an improvement science study into the optimal method of implementation to sustain adherence to a new checking protocol in radiotherapy.

Second, there is a need to ascertain if the new protocol does take much longer to do, as this may have time and resource implications. It should only be a few extra seconds but it depends on how thoroughly the checks are done currently as to how much extra time it would take. This may vary both between and within departments due to the variation in how the checks are done currently. Evidence supporting the additional time may help convince reluctant staff or departments to follow the new protocol, if it is shown that the extra time required is not significant.

Finally, it is important that the protocol sits within context of the wider task, system and related software. A systems approach is needed to consider the interlinking role of the radiographer, the software, the prescription sheet and the environment, to ensure they work together to be conducive to effective checking. An integrated human factors approach to address the environmental and work design issues would be of value in this domain. Implementation of human factors training for staff would also be beneficial to increase awareness and understanding of the impact of variables on their own work performance. One element of the system, the interface is discussed in more depth in chapter 10.

9.4 Chapter conclusion

This chapter has brought together the research reported in earlier chapters in the form of requirements for a standardised checking protocol for use immediately prior to treatment delivery. In response to these requirements a draft protocol in both written and

diagrammatic form has been developed. This has been evaluated by exploring qualified radiographers' and student radiographers' views of the new protocol.

The feedback on the new, standardised protocol was positive and encouraging. It is believed that this more active checking method would help to maintain attention, thereby increasing the likelihood of detecting errors before treatment is administered. As a result of these findings it can be concluded that the implementation of this standardised checking protocol across radiotherapy departments could be beneficial for patient safety.

The successful implementation of this protocol is likely to be influenced by how departments currently verify and hence there may be variation in adoption. It is envisaged that implementation will be easier in those departments with a good safety culture and which employ verbal checks already, and more difficult in those departments which allow variation in checking, with perhaps only single or two person checking conducted silently. The gap between this protocol and current practice in these latter instances is much greater. Hence, these departments may require more support when implementing this protocol.

Alongside implementation of this protocol, the results suggest there are other ways to improve the effectiveness of the final treatment check. Formal practice-based recommendations, including distraction free environments, specific patient safety and human factors training and addressing issues of authority structures would be of benefit as presented in table 7.4. Additionally, it is argued that the software could be further developed to support the final treatment check. The role of the interface is further explored in chapter 10.

10 Chapter 10 – Study 5: Improving checking through interface design

The research presented in this chapter builds on the earlier findings that the design of the interface may affect the efficacy of the final treatment check. This was suggested through the interviews in chapter 7 and further supported by the experimental findings in chapter 8. The results of the experiment suggested that participants made more mistakes when retrieving and reading values from the screen, than responding to the call out. This suggests that consideration of the design of the interface, specifically in respect to the final treatment check, would be worthwhile. The research thus far has directed the design of a new standardised checking protocol but it is also important to consider the role of technology in causing and trapping errors. A human factors systems approach advocates the exploration of human interaction with all elements of a system. Therefore, the aim of the research described in this chapter is to consider the role of the interface in terms of checking accuracy. The chapter details the re-design of the current interface used to conduct the final treatment check, and the results of comparative testing of the current and proposed interface. The broader implications of the interface design are then discussed.

10.1 Rationale for a new interface design

As detailed in the radiotherapy treatment delivery process, see figure 2.1, during the final treatment check, radiographers are required to check that the values displayed on the linear accelerator interface correspond with the patient's paper prescription. There are currently three software programmes in use in the UK, the most common of which is MOSAIQ, designed by Elekta, and used by the majority of the participants interviewed during this research. An image of the interface used during the final treatment check can be seen in figure 10.1. Chan *et al*. (2010) conducted a workflow analysis of the radiotherapy process in one department in Canada and, through a heuristic evaluation of the software in use (MOSAIQ), showed that the software did not adequately fit workflow or support the final treatment check process. The software was found to have poor usability as users had to click onto multiple different screens to see all the required information. The authors used Zhang *et al*. (2003) heuristic evaluation method. This method combines the two predominant interface heuristics models, Nielson's 10 interface heuristics and Shneiderman's eight golden rules for good interface design, with a consideration of patient

safety to create a heuristic evaluation to be used in the safety evaluation of medical software. Zhang's 14 heuristics are displayed below in table 10.1. To complete a heuristic evaluation experts 'walk through' the system and identify any elements which violate the heuristics. Results are then triangulated with a number of evaluators to ensure reliability. Zhang *et al.* (2003) argues that this method, which has been used extensively to test websites and software, can effectively be used to test the safety of medical devices with low costs.

Table 10.1: Zhang's user heuristics for medical systems (Zhang 2003: 25-26)

Heuristic	**Description**
Consistency	Users should not have to wonder whether different words, situations or actions mean the same thing. Standards and conventions in product design should be used.
Visibility	Users should be informed about what is going on with the system through appropriate feedback and display of information
Match	The image of the system perceived by users should match the model the users have of the system
Minimalist	Any extraneous information is a distraction and a slow down
Memory	Users should not be required to memorise a lot of information to carry out tasks. Memory load reduces users' capacity to carry out the main tasks
Feedback	Users should be given prompt and informative feedback about their actions
Flexibility and efficiency	Users always learn and are always different. Give users the flexibility of creating customisation and shortcuts to accelerate performance
Message	Messages should be informative enough such that users can understand the nature of errors, learn from errors, and recover from errors
Error	It is always better to design interfaces which prevent errors from happening in the first place
Closure	Users should clearly be notified about the completion of a task
Undo	Users should be allowed to recover from errors.
Language	The language should always be presented in a form understandable by the intended users
Control	Do not give users the impression that they are controlled by the system
Document	Always provide help when needed

Using Zhang's (2003) categorisation of user heuristics, 75 violations were found in the software, mostly error, consistency and memory. Some eight of these violations were

classed as high severity, with the possibility to cause harm to a patient. The most vulnerable part of the process, demonstrated by more violations of user heuristics on the interface, was patient set-up (Chan *et al.* 2012). Yet it was found that all processes in radiotherapy violated some usability heuristics such as consistency, visibility and increased cognitive load *(Chan et al.* 2012). The interface involved in beam delivery (the process during which the final treatment check is conducted) had five low severity violations and six medium severity violations.

As patient set-up violated the most user heuristics, Chan (2010) conducted a usability test of re-designed components of the interface used during patient setup, recruiting student radiographers as participants. The re-designed interface was created using a user-centred approach and aimed to meet all user heuristics by; assisting the checking process with the inclusion of an automated checklist, combining all required information on one screen and reducing the number of steps required to check all information. A mock-up of the interface was created and simulated in the radiotherapy department. Three common errors were planted in the simulation and participants' rate of committing them using the re-designed interface was compared to previous real life error rates from the same department. The re-designed interface improved the error rate, shortened the time taken to complete patient set up and increased user satisfaction.

These two studies by Chan highlight the usability issues within radiotherapy systems, specifically the MOSAIQ system. However, the authors only looked at patient set-up in detail, which occurs before the final treatment check, and only compared three checking errors during this stage (overlooking an important note, overlooking changes in approval dates and shifting the treatment couch). Building upon this study, the research described here will focus specifically on the final treatment check. Similarly to Chan *et al*. (2012) a comparative simulated method will be used to investigate the impact of the interface, as will the use of planted errors.

This chapter will explore the role the design of the linear accelerator interface plays in the reliability of the final treatment check. This research aims to:

1. Re-design the interface used during the final treatment check to improve usability

2. Evaluate the resulting interface through subjective feedback and objective comparative testing with the existing display

10.2 Method

The aims will be met using the following methods, each of which will be detailed in turn:

Design:

- A review of user feedback given during the exploratory interviews in chapter 7
- A review of the current interface design against ISO design recommendations
- Formation of a design brief combining of user feedback and ISO recommendations
- Design of a new proposed interface design
- A review of the proposed interface design against ISO design recommendations

Evaluation:

- A comparative review of the current and proposed design against ISO design recommendations by lay users
- A comparative experimental evaluation of the current and proposed interface using the experimental paradigm presented in section 8.3.
- An evaluation of the proposed interface by qualified and student radiographer through group interviews

It was decided to use this mixed-methods approach to evaluating the proposed interface to ensure triangulation of research findings. It was not possible to evaluate a new interface design in situ, and therefore a laboratory based approach was more suitable. As with the previous experiments, detailed in chapter 8, this approach allowed for the interface variable to be isolated away from the influence of any confounding variables. Lay participants were used for the initial evaluations as the evaluation of the interface against ISO principles and experimental testing did not require any expert knowledge of radiotherapy. Expert opinions were then sought to validate the findings from the evaluation using lay participants. As discussed in section 5.5, this user-centred design approach is beneficial in the creation of new safety tools.

10.3 User feedback

The poor usability of the interface used to conduct the final treatment check emerged as a theme from the interviews with qualified and student radiographers, this detail can be found in section 7.3.5. The current MOSAIQ interface and the associated issues highlighted by users in these interviews are illustrated in figure 10.1. The final treatment check requires checking of the values associated with energy, monitor units, wedge monitor units and wedge position. These are highlighted in blue. Additionally, participants believed that if the interface required more active input on the part of the user, rather than mere passive checking, this would help maintain attention.

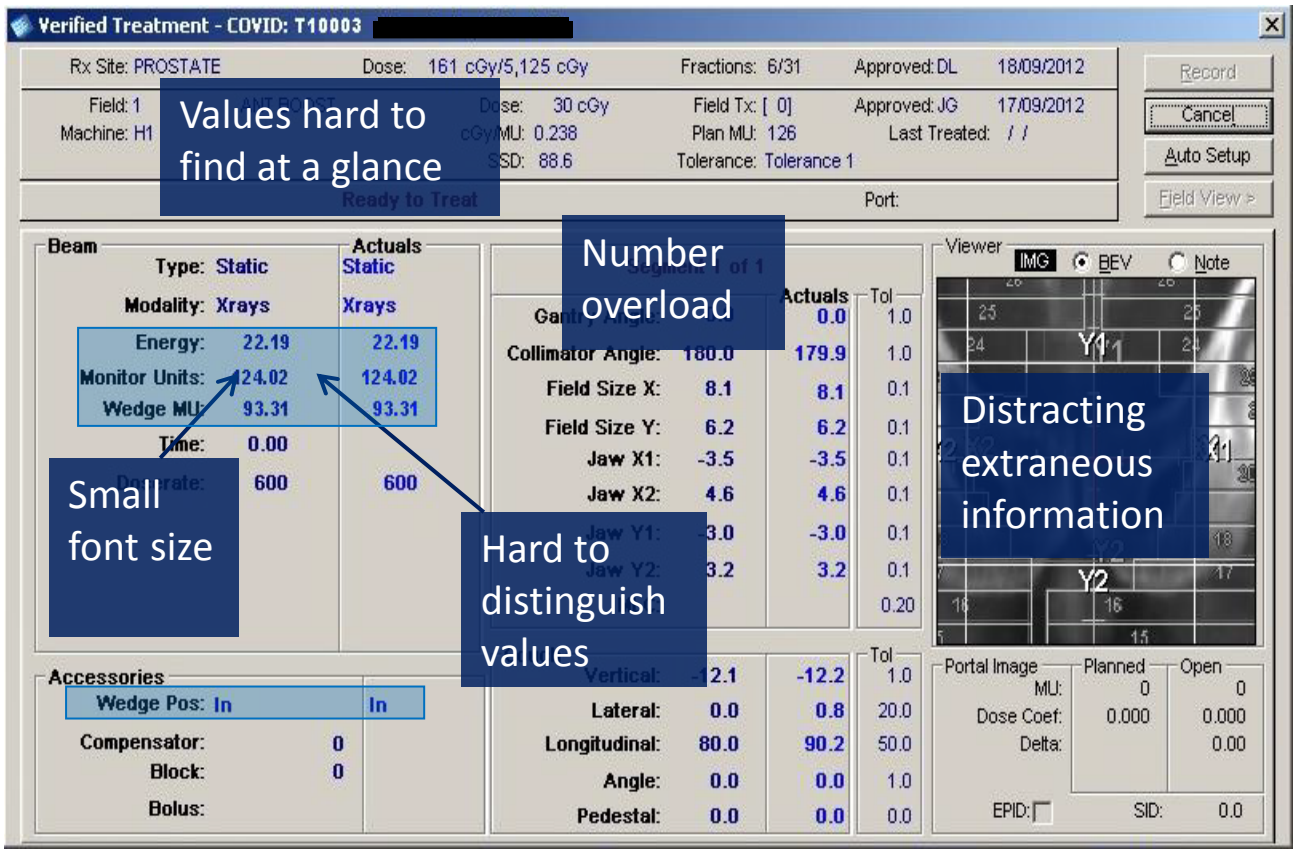


Figure 10.1: Current interface annotated with findings from interviews

10.4 Review of current interface against ISO 9241 recommendations

As participants reported issues with the design of the current software, the interface was reviewed against established recommendations for the display of visual information. The ISO 9241 "300" subseries was used for this purpose. This particular standard entitled "Ergonomics of human-system interaction" addresses software and hardware ergonomic aspects of human interaction with computers to ensure effective and comfortable viewing

conditions for those with normal and adjusted to normal eyesight, from workstation layout to display recommendations (British Standards Institute 1998). Part 12 of this standard is of interest here as it details recommendations for the display of static visual information and is intended to be used by interface designers and evaluators. These guidelines were chosen as they are international standards specifically for the display of static information. The final treatment check requires visual comparison of the paper-based prescription against the display of the information on a static display. It does not present dynamic information or require the user to input information into the system. However, it is recognised that the ISO may not represent current design research knowledge. As such compliance with the recommendations of the ISO is considered a bare minimum standard to adhere to. Yet, a safety critical environment, such as radiotherapy, would be expected to implement more advanced knowledge from other safety critical domains such as nuclear power and aviation where static displays for monitoring of information are in use. If MOSAIQ does not adhere to the ISO guidelines, this suggests a clear path for further development and the need for more specific research into the design of this safety critical interface.

ISO 9241 presents detailed and specific design recommendations for static interface design. The standard encourages designers and evaluators to adapt the recommendations to the context of the design. This is done by first ascertaining which recommendations are applicable to the design and then evaluating adherence to them. In this context, the applicable recommendations are those concerned with improving visual search and facilitating the discriminability of items within the interface, as these factors encompass what is involved during the final treatment check.

The standard states that adherence can be decided based on observation, which is defined as *"simply to examine or inspect the presentation of information to confirm that a particular observable condition has been met"*. From revisiting the interview data and examining the current interface, it is apparent that the current interface used for the final treatment check did not meet all recommendations given in ISO 9241. Figure 10.2 illustrates the ISO recommendations which the interface does not currently adhere to.

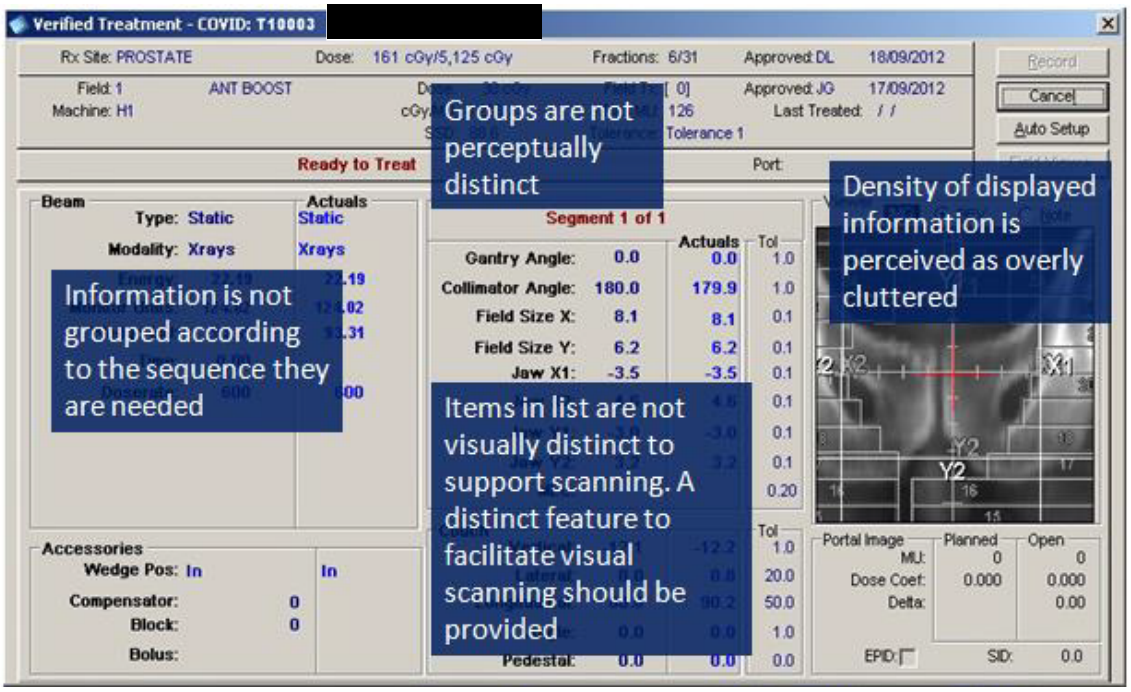


Figure 10.2: Current interface annotated with violations of ISO design recommendations

The standard also presents seven design principles which, when adhered to, ensure that the interface supports the user "*to perform perceptual tasks effectively, efficiently and with satisfaction*". These seven ISO principles of a good static interface are (British Standards Institute 1998):

1. Clarity: the information content is conveyed quickly and accurately.
2. Discriminability: the displayed information can be distinguished accurately.
3. Conciseness: users are not overloaded with extraneous information.
4. Consistency: a unique design, conformity with user's expectation.
5. Detectability: the user's attention is directed towards information required.
6. Legibility: information is easy to read.
7. Comprehensibility: the meaning is clearly understandable, unambiguous, interpretable, and recognisable.

The current interface is evaluated against these principles in table 10.2, and suggestions on how the interface can be improved to adhere to these principles are given.

Table 10.2: Evaluation of MOSAIQ interface against ISO design principles

ISO principle	MOSAIQ interface assessment by author	Design recommendation
Clarity	The screen is overloaded with numbers which means the value required cannot be found quickly.	Condense the information down into the vital values only.
Discriminability	It is difficult to distinguish which value corresponds to which label as they are densely presented	Make it easier to determine which value corresponds to which label
Conciseness	There is an overload of information on screen, some of which is not necessary for the final treatment check	Remove some extraneous information, or make it smaller so that the vital information dominates the screen
Consistency	Screen is consistent with other parts of the systems	-
Detectability	User's attention is not directed towards the vital values as all look the same	Highlight the key information
Legibility	Values are hard to read due to the font used and the size of the font	Increase the font size and change the font style
Comprehensibility	Due to the font style, size and layout, values are not always clearly understandable, unambiguous, interpretable, and recognisable	Increase the font size and change the font style. Improve the layout of text to ensure it is instantly interpretable

This review against ISO recommendations and principles suggests that the current interface does not adhere to the principles of a standard static interface. Therefore, there is scope for the interface to be significantly re-designed to improve usability and, as a minimum, sit in line with these ISO recommendations. It is argued that through improved usability the ease of checking during the final treatment check will be improved and the likelihood of errors passing undetected reduced.

10.5 Design Brief

The above ISO recommendations and principles were combined with user feedback (section 7.3.5) from the interviews to specify a design brief for the re-design of the interface used during the final treatment check. The following were specified: user accuracy was to be improved when reading out the four vital values, these values should be seen at a glance and be visually distinct from one another, and other information should be condensed down

to reduce visual clutter. This brief, displayed in figure 10.3, was then given to a designer to guide the redevelopment of the interface. The key design requirements from the earlier research and ISO are highlighted in bold. The designer was also given a copy of the MOSAIQ interface and briefed on radiotherapy and the final treatment check for context.

Design brief for a safer interface in radiotherapy

Interviews with users suggests that a re-design of the MOSAIQ interface **may improve user accuracy** and **maintain user attention**. The interface is used to conduct the final treatment check and as such the **important values are monitor units, beam energy and beam modification**. The other information currently on screen is required only occasionally. **Patient identification information must be retained.**

User feedback suggests that the current design is not user friendly. Users need to be able to **look briefly at the interface and retrieve the information that they need**. User accuracy needs to be improved when reading out the vital values, these **values should be seen at a glance** and be **visually distinct from one another**. The other information should be condensed down to **reduce visual clutter**. Users also suggested **that font size needs to be increased** on the vital values. **Increased utilisation of colour** was also suggested as the current design is monochrome. Yet **colour must be used sparingly** as it is used elsewhere in the system to indicate other errors (e.g. red to indicate errors and green to symbolise treatment can proceed). The use of **colour could be used distinguish and draw attention** to the location of important items, or to make items more distinguishable when in a list, whilst ensuring a **good contrast level to ensure readability**.

The interface must also **adhere to and achieve the seven ISO principles of a static interface**.

Figure 10.3: Design brief for proposed interface

Three design proposals were created by an independent designer. After each proposal was created it was discussed with a radiographer, to ensure the presentation of the information required during the final treatment check was adequate. The final design was considered to strike the right balance between highlighting only the values needed during the final treatment check, whilst still containing other parameters needed to identify patients or occasionally required during treatment.

10.6 The proposed interface design

The design brief led to a new proposed design for use during the final treatment check which aims to meet the ISO recommendations and address the design issues raised by participants in the interviews. The proposed interface design is shown below in figure 10.4.

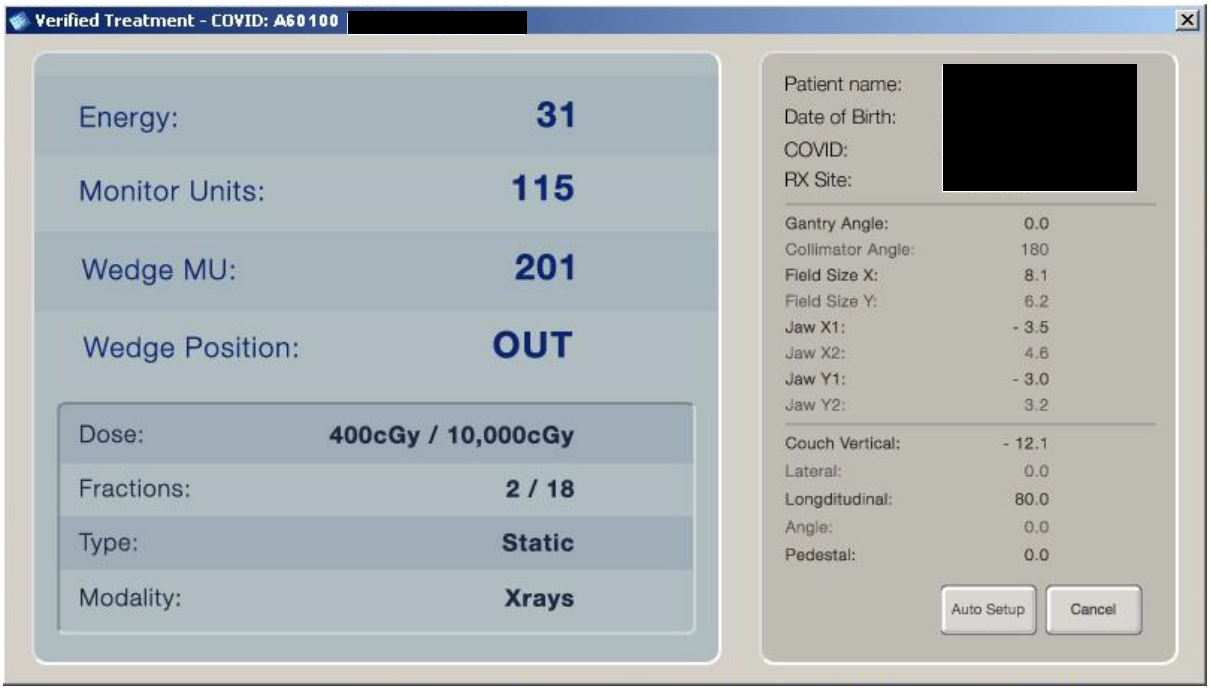


Figure 10.4: Proposed interface

10.7 Review of proposed interface against ISO 9241 recommendations

The proposed interface was then compared against the ISO design principles. Table 10.3 shows how the new interface design has addressed the seven ISO principles. The changes to the interface are annotated in figure 10.5.

Table 10.3: Evaluation of proposed interface against ISO attributes

ISO principle	MOSAIQ	New proposed interface
Clarity	The screen is overloaded with numbers which means the value required cannot be found quickly.	The vital values are much bigger and can be found quicker
Discriminability	It is difficult to distinguish which value corresponds to which label as they are densely presented	The use of colour and lines means it is easy to follow which label corresponds to which value
Conciseness	There is an overload of information on screen, some of which is not necessary for the final treatment check	All of the extraneous information has been removed, with the less important information condensed down. The vital values dominate the screen to ensure attention is drawn towards them.
Consistency	*not applicable as already met	
Detectability	User's attention is not directed towards the vital values as all look the same	The background and text colour, along with the position and size of the box containing the vital information means direction is directed towards the information required.
Legibility	Values are hard to read due to the font used and the size of the font	The values are easier to read due to a clearer and larger font
Comprehensibility	Due to the font style, size and layout, values are not always clearly understandable, unambiguous, interpretable, and recognisable	The values are instantly interpretable, due to the clearer and larger font, and text layout

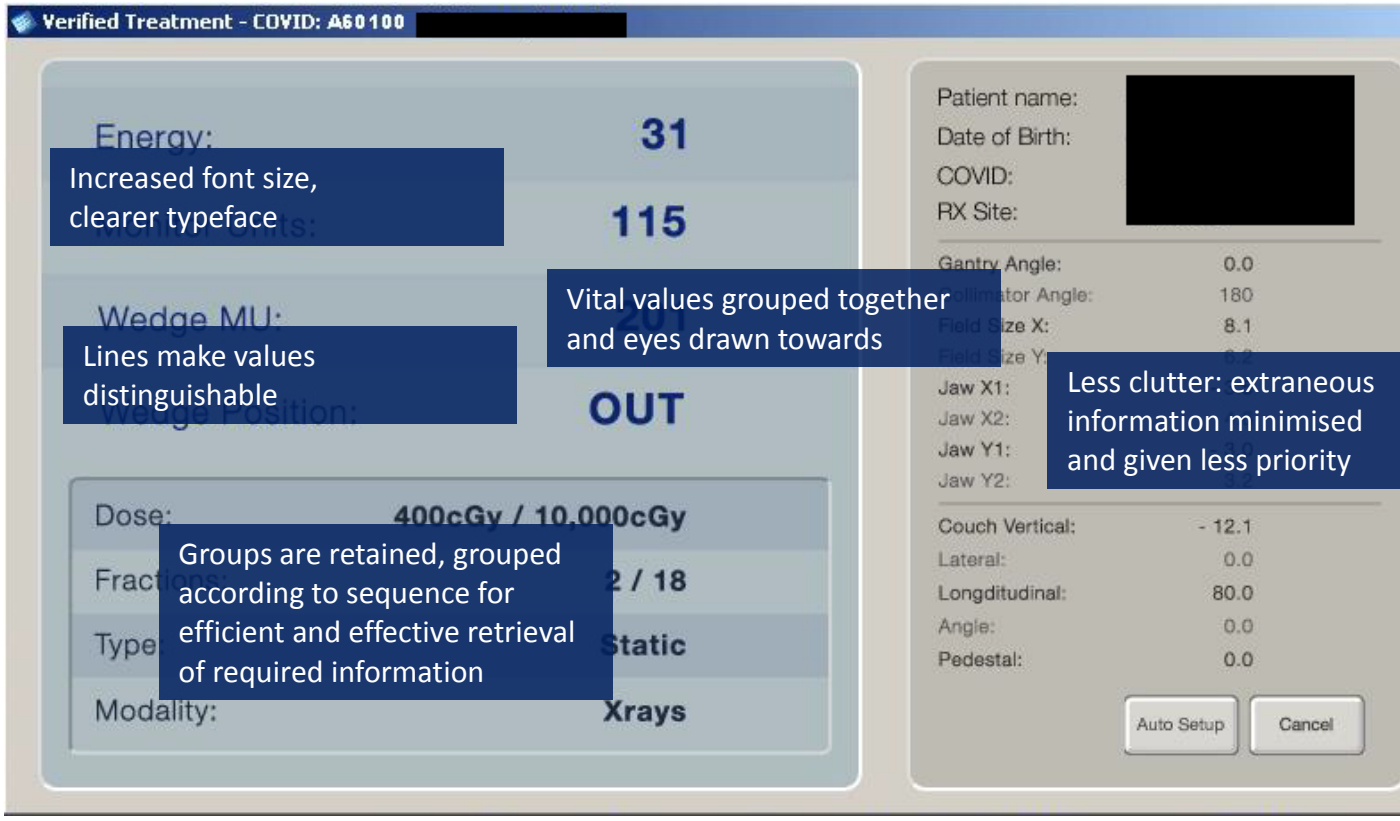


Figure 10.5: Proposed interface annotated with user feedback and ISO recommendations

The comparison in table 10.3 suggests improved compliance with ISO principles and therefore it is argued that this interface design may support a more reliable final treatment check.

10.8 Design evaluation from lay evaluators

The design was evaluated in order to determine whether it was considered to have improved in terms of how easy it is to use over the existing MOSAIQ interface.

10.8.1 Aim

To compare participants' assessments of compliance to the ISO principles of both the MOSAIQ interface and the proposed interface.

10.8.2 Method

A questionnaire based study was undertaken in order to gain comparative ratings of both interface designs.

10.8.2.1 Design

A within subjects, cross-over questionnaire design was used, so that there was no bias based on order of presentation of the two interface designs. Participants were asked to look at the interface and read out the energy, monitor units and wedge position to mimic how the interface would be used as part of the final treatment check. They then completed a short paper-based survey. Ten participants completed this task using the current interface first and ten participants used the proposed interface first.

10.8.2.2 Participants

20 participants were recruited from an undergraduate psychology course at Coventry University via opportunity sampling. The only inclusion criteria were that the participants must have normal or adjusted to normal eyesight. Participants were excluded if they had taken part in one of the other experiments run as part of this thesis, as this may have introduced practice effects. These participants were not trained in radiotherapy, and hence not familiar with the software, preventing any previous opinions or experience to influence their assessment.

10.8.2.3 Materials

A questionnaire was designed to assess how well users believed the principle had been met. Each of the seven ISO principles was converted into a statement, with a seven-point likert scale for the participant to indicate to what extent they agreed with that statement, with 7 being strongly agree and 1 strongly disagree. The statements are presented in table 10.4 and the full questionnaire can be found in appendix 18.

Table 10.4: ISO principle and questionnaire statements

ISO principle	Questionnaire statement
Clarity	I was able to find the information required quickly
Discriminability	It was easy to distinguish the value I required from other values
Conciseness	The interface contained only the information relevant to the task
Consistency	All the information I required was presented in the same way, according to my expectations
Detectability	My attention was directed towards the information I required
Legibility	The information was easy to read
Comprehensibility	The information I required was understandable and unambiguous

10.8.2.4 Procedure

Informed consent was collected from the participants. Each participant completed the study on their own. The participant was shown the first interface, and the purpose of the interface and the final treatment check was explained to them. Participants were then asked to complete the challenge-response checking task, with the researcher acting as the responder.

Participants completed three trials, using three iterations of the interface displayed on an iPad, using the screens created for the experiments detailed in section 10.10. After these three iterations participants were asked to fill in the questionnaire. The process was then repeated for the second interface.

10.8.2.5 Ethics

This study was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee, see appendix 17. The research was conducted according to BPS ethical code of conduct.

10.8.3 Results

Participants' responses were combined and SPPS was used to conduct descriptive and inferential statistics. The mean participant response for each design principles are shown in figure 10.6. As a higher score indicates that participants believe the principle has been met to a greater extent, it can be seen that the proposed interface scored higher on all ISO 9241 design principles.

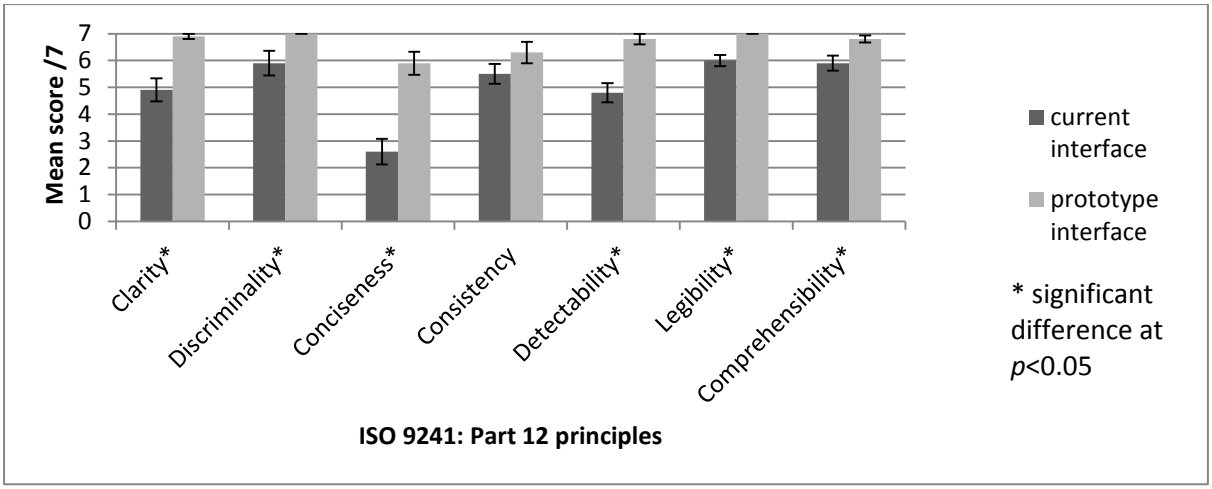


Figure 10.6: Graph showing results of evaluate feedback on both interface designs

The modes, means and standard deviations for each design principle are presented in table 10.5. Related t-tests were used to test for significance as an independent design was used and the data met parametric assumptions.

Table 10.5: Independent t-test results comparing current and proposed interface against ISO

Design Principle	N	Mode	Range	Mean (1dp)	SD (2dp)	T (2dp)	df	*p* (3dp)
Clarity old	10	6	4	4.9	1.37	-4.05	9	.003
Clarity new	10	7	1	6.9	0.32			
Discriminability old	10	7	4	5.9	1.45	-2.40	9	.040
Discriminability new	10	7	0	7	0.00			
Conciseness old	10	2	5	2.6	1.51	-5.91	9	<.001
Conciseness new	10	7	3	5.9	1.37			
Consistency old	10	6	3	5.5	1.18	-1.92	9	.087
Consistency new	10	7	3	6.4	0.25			
Detectability old	10	5	3	4.8	1.14	-6.71	9	<.001
Detectability new	10	7	2	6.8	0.63			
Legibility old	10	6	2	6.0	0.67	-4.74	9	.001
Legibility new	10	7	0	7	0.00			
Comprehensibilty old	10	6	2	5.9	0.88	-3.25	9	.010
Comprehensibilty new	10	7	1	6.8	0.42			

Related t-tests confirmed that this difference was significant for all design principles except consistency, see table 10.5. This suggests that the re-designed interface is an improved

version of the current MOSAIQ interface in terms of compliance to ISO 9241 principles, offering a more user-friendly and readable format. Of particular note are the improved ratings in terms of conciseness and detectability.

There was a non-significant result for consistency. This may be because participants only saw this one screen and hence were unfamiliar with other aspects of the system from which to judge consistency, or because both screens were consistent with their expectations based on other systems.

An improvement in usability is important to minimise the impact of poor design on user performance and likelihood of error. This is a small scale comparative study of user perception, but results point to improved usability. It is argued that the more useable a display is, the less likely it is to induce user error, for example through misidentification, or failure to identify key information. In order to test this premise, the next section describes an experimental study to compare participants' accuracy when using the MOSAIQ interface and the new proposed interface.

10.9 Experimental comparison of the MOSAIQ and proposed interface

To investigate if the new proposed interface is more effective at supporting users to maintain attention and correctly read aloud values, an empirical test of comparative efficacy was required.

10.9.1 Aim

The aim of this experiment was to investigate if accuracy when reading values was higher when using the proposed interface, compared to the current MOSAIQ interface. Based on the previous investigation into interface design, it was hypothesised that users of the new proposed interface will have a significantly higher percentage accuracy score when reading values aloud, than users of the current MOSAIQ interface.

10.9.2 Method

An experimental, laboratory based study was used, as it was not possible to investigate the impact of the proposed interface in situ.

10.9.2.1 Design

A between measures design was used, with two experimental conditions:

1. Using the current MOSAIQ interface
2. Using the proposed interface

The same experimental paradigm was used as in the previous experiments with participants completing a minimum of 60 final treatment checks within 45 minutes (see section 8.3). This paradigm and procedure is explained in detail in chapter 8, and therefore the methodological detail is not repeated here.

10.9.2.2 Participants

Participants were undergraduate psychology students recruited from the university psychology department's online experiment management system via opportunity sampling. The only inclusion criteria were that the participants must have normal or adjusted to normal eyesight. Participants were excluded if they had taken part in one of the other experiments run as part of this thesis, as this may have introduced practice effects. There were 40 participant pairs with 20 participant pairs in each condition, randomly assigned to either condition based on order of attendance. Participants did not receive payment for taking part in the study but received course credits.

It was decided to use participants who are not trained in radiotherapy for ease of recruitment and because the retrieval and reading of values is not considered a skill based task. Participants were briefed prior to the study commencing about the process involved in radiotherapy and an overview of the treatment, and given time to become accustomed to the interface, as in the prior experiment.

10.9.2.3 Materials

The same materials were used as in the last experiment (see section 8.4.3.3). In addition to the previous materials, the proposed interface design was adjusted using Photoshop to display different parameter values. Both the proposed and MOSAIQ interfaces displayed exactly the same values in the same order, so as not to introduce any confounding variables.

10.9.2.4 Procedure

This experiment followed the same procedure as detailed in section 8.4.3.5. All participants conducted challenge-response checking in pairs.

10.9.2.5 Data recording

As this experiment was only investigating the effect of the interface on challenger's accuracy during the final treatment check, only the challenger's accuracy was recorded for this experiment. The challenger's performance was measured by recording any mistakes the participants made when reading out the on-screen values, along with if they immediately corrected themselves. As previously discussed each mistake or correction is believed to indicate a lapse in attention. These mistakes were then converted into a percentage accuracy score. Hence, there were two scores for each participant: percentage accuracy (correctly reading the value) and percentage accuracy including corrections (reading the value incorrectly but correcting themselves immediately).

10.9.2.6 Ethics

This study was reviewed and approved by Coventry University Faculty of Health and Life Sciences Ethics Committee, see appendix 17. The research was conducted according to BPS ethical code of conduct.

10.9.3 Results

The scores for each participant were entered onto SPPS and aggregated to provide means for each experimental condition. SPSS was used to calculate the descriptive and inferential statistics.

Accuracy and accuracy including corrections were higher for those participants using the new proposed interface to complete the final treatment check. Table 10.6 and figure 10.7 display the average accuracy scores for participants using the current interface and the new proposed interface.

Table 10.6: Percentage accuracy means

Condition	% Accuracy mean (SD)	% Accuracy including corrections (SD)
MOSAIQ interface	97.29 (2.37)	92.32 (4.03)
New proposed interface	97.81 (2.2)	95.29 (3.24)

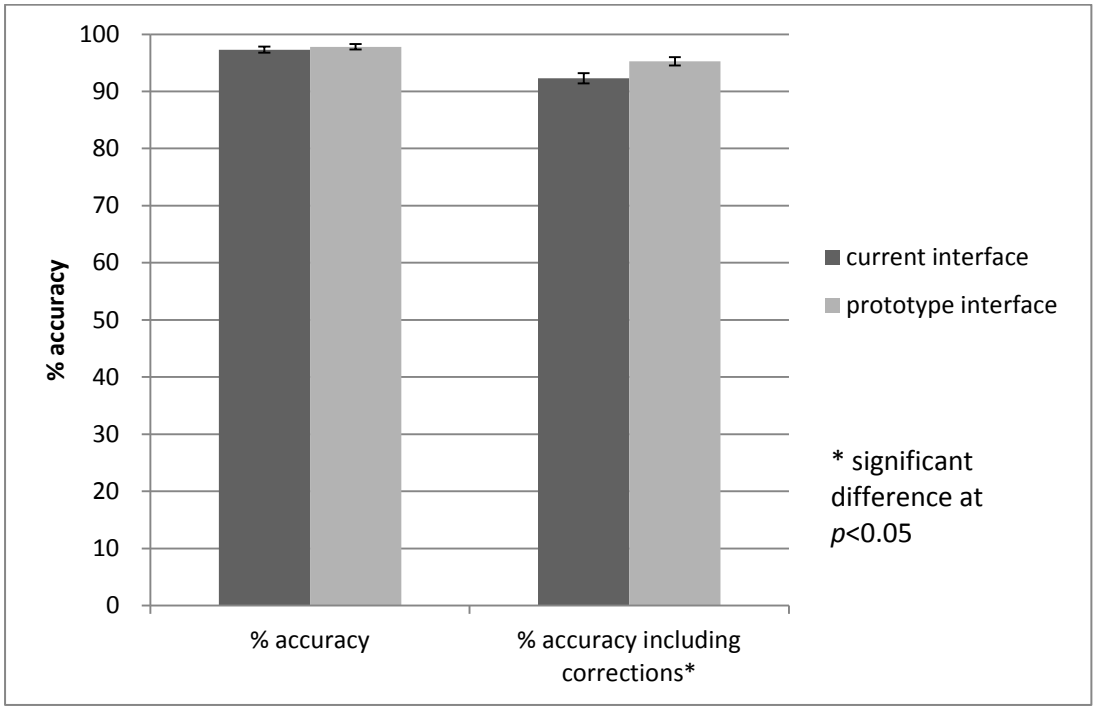


Figure 10.7: Mean accuracy scores for participants using the current interface and the new proposed interface

As can be seen in table 10.6 and figure 10.7 participants accuracy when reading values from screen was slightly higher in those using the proposed interface, however, an unrelated t-test suggested that this difference was not significant t(38)= -.73, *p*= .46. Participants accuracy when including instances when participants corrected themselves was also higher when using the proposed interface and an unrelated t-test showed this to be a significant difference, t(38), -2.57 *p*= .014.

These results suggest that participant's accuracy in reading the value aloud correctly in the first instance was slightly better when using the proposed interface as compared to the current MOSAIQ interface in use, although this was not significant. As a mistake in reading values was believed to indicate a lapse in attention, it is inferred that the new proposed interface design helped focus the users' attention during a repeated final treatment checks.

10.10 Evaluation of proposed interface with radiographers

Having established that the new proposed interface appears to focus the attention of the users, evaluation was extended to consider the views of radiographers on the new proposed interface design.

10.10.1 Aim

The aim of this study was to gather views on the new proposed interface design from those who were experienced in using radiotherapy systems to conduct final treatment checks.

10.10.2 Method

A qualitative approach to exploring the views of potential end-users was taken to build upon the experimental evidence collected by gaining a real world perspective. As discussed in section 5.5, a user-centred approach involves iterative design and testing with end-users to ensure the proposed design meets user requirements. The design work thus far had only involved lay participants, and as such the opinion of potential end users was considered beneficial.

10.10.2.1 Design

Group interviews were conducted with qualified and student radiographers using a semi-structured approach.

10.10.2.2 Participants

The participants were the same sample used in the study presented in section 9.3.1, recruited from BCU and Northampton General Hospital. Details of the participants' experience is provided again in table 10.7.

Table 10.7: Evaluative interviews participant experience

Grade	Number of participants
Band 5	4
Band 6	4
Band 7	4
Band 8	2
Second year student radiographer	5
Third year student radiographer	7

10.10.2.3 Procedure

The proposed interface was evaluated during the interviews described in section 9.2 that evaluated the checking protocol. Participants were asked questions relating to the interface design towards the end of the interviews. To avoid repetition, the detail on the method used to conduct these group interviews is not given here, but can be found in section 9.3.

Participants were shown the newly designed proposed interface and invited to comment on the differences between the proposed interface and the current interface in use. Participants were also asked if, and in what ways, the new proposed interface may improve checking accuracy. The full interview schedule can be found in appendix 14.

10.10.2.4 Analysis

The verbatim transcripts of the interviews were used to conduct a thematic analysis. Detail of this analysis process can be found in section 5.3.2.

10.10.3 Results

The participants were positive about the proposed interface, agreeing it was an improvement on the systems they currently use. Two themes were identified, how the interface had been improved and suggestions for further improvement. These are discussed below.

10.10.3.1 How the interface had been improved

The participants preferred the colours used in the new proposed interface as they were not as monochrome as their current systems and hence, more likely to capture their attention, and allow for easier identification of the values they need to check. Participants were also unanimous in their view that the new layout improves the clarity of the interface. All the required values are located in the same place, listed one after another, and easy to see:

> *"I like how it's all centred on the parameters you read out which are laid out one after each other. Whereas on my system you've got one there, and one there. You've got to search." Third year student radiographer*

Participants reported that they felt they had to search for the values in the current interface, and this new proposed interface would speed up the final treatment checking process as they would no longer have to spend time searching for the values to be checked. This was particularly beneficial for student radiographers who found the current systems rather daunting and difficult to use or get used to:

> *"You spend the entire year just sat there, trying to find where the wedges are!" Third year student radiographer*

The proposed interface was also seen to be an improvement as it contained only the required information, with all the extraneous information given much less presence on the

screen. Participants preferred only having the required information as they felt the other information was a distraction:

> *"I like a lot of things about it. The fact it is bigger is the stand out thing, the font is bigger and the specific parameters we are checking are the core ones we need to check. We don't have to sift through a multitude of useless information" Third year student radiographer*

10.10.3.2 Suggestions for further improvement

Participants also suggested a couple of further improvements to the proposed interface. The first suggestion from a couple of student radiographers was that the interface could mirror the prescription sheet. That is the interface orders the values to be checked in the same way on both the screen and prescription sheet. The second improvement suggestion was that it would be beneficial for the interface to be designed to work in tandem with the new checking protocol. Participants believed the interface could support them to follow the protocol by randomising the order of the values to be checked on screen:

> *"I think that would help the keeping it up and keeping it random, because I'm not very good at random! I settle into a pattern if I can. Yeah if it comes up in a different order, then you read it in a different order" Band 5 radiographer*

Participants also suggested that the interface could alert the radiographers to when they should switch roles of challenger and responder, either with an alarm or a change of background colour after a set amount of time. This would allow them to focus solely on the patient and checking task:

> *"A prompt would be good in a way, because it's the last thing on your mind, you're more concerned about the patient, that you're treating them correctly" Band 7 radiographer*

10.11 Chapter Discussion

Chapter 7 concluded that the design of the interface used during the final treatment check is likely to contribute to ineffective checking immediately prior to beam delivery. Having explored the design of the checking protocol, it was important to also consider the interface design as a source of risk. The findings summarised here support those of Chan *et al.* (2012) who found that the MOSAIQ software, which is commonly in use, violates software usability and design principles.

This chapter has identified some of the key usability issues presented by the MOSAIQ interface used during the final treatment check through a review employing the ISO design recommendations and principles. A new interface has been proposed. The initial evaluation has proved positive, suggesting better compliance to established design principles, better error rates when reading aloud from the screen, and positive feedback from potential end-users, when compared against the exisiting MOSAIQ interface.

The research also revealed further improvements which could be made to support users to conduct an effective final treatment check. The suggestions for further development are:

- The interface should mirror the layout of perscrption sheets
- The interface to randomly vary either the order or the presentation of parameters
- The interface to alert users to swap roles of challenger and responder, either with an audible alarm or change in background colour

A further result from the interviews with radiographers, is that although the new proposed interface was preferred, it could be improved further as participants would appreciate the interface randomising the order of the parameters for them. Further research is required to support this direction. Referring back to the underload theory of attention, taking away the effort of thinking about the order and autonomising it via the system, may prevent the beneficial effect of varying the order of parameters.

Initial contact was made at a conference, and discussions have been held over email with the user-centred design department at Elekta, the company who are responsible for the design of the MOSAIQ software. They are interested in the findings from this research and are themselves looking to increase the usability of their systems, as the safety benefit of this is recognised.

10.11.1 Study limitations and future work

This chapter has used a variety of research methods to address the aim of investigating the role of the interface during the final treatment check. This mix of methods is a strength of this research. The findings from each different method helps to strengthen the overall conclusions surrounding the role of the interface in the final treatment check. Furthermore,

whilst the experiment allowed the isolation of variables so that the effect of the interface could be measured, it could be argued that this may lack ecological validity, because the impact of the interface was not measured in-situ, along with the impact of surrounding variables such as noise and pressure. However, the evaluative feedback provided by participants experienced in radiotherapy departments, supported the experimental results. This triangulation of results from various methods demonstrates the reliability and validity of this research.

A possible limitation of this research is that the effect of the interface in situ was not possible to measure. However, as the proposed interface resulted in higher user accuracy, it is recommended that the design of the interface is explored further with software developers in order to implement these preliminary findings into practice for patient benefit. In particular it is recommended that future research explore how the interface can be programmed to make the final treatment check a more active process. If the software is developed to take account of these findings, this would present an ideal opportunity to conduct field research into the effect of the interface on checking accuracy.

The display for the final treatment check is an isolated component of the radiotherapy system. The research points to the need for a more thorough usability evaluation of the software that moves beyond compliance with the ISO and explores a more thorough exploration of the interface with users, for example through walkthroughs. It would also be useful to look beyond the static screen and consider the interaction with other elements of the task, in order to take a broader systems approach to error as this area of research develops.

It is noted that the design of the prescription sheets should also be subjected to a critical design review, as it is just as important that these allow users to maintain attention and complete the final treatment check without error. The design of the linear accelerator display was prioritised due to the experimental and interview data. The prescription sheets are locally designed and hence vary from department to department, unlike the software systems, so are harder to address. Yet, as a re-design of the interface has been shown to

potentially improve patient safety, it is recommended that prescription sheets are also subject to a critical review.

10.12 Chapter conclusion

This chapter has suggested that improved usability of the static interface, could result in a more effective final treatment check. The chapter concludes that the current interface in use across radiotherapy departments in the UK does not meet the ISO design recommendations and that an interface designed in accordance with these design recommendations may improve user accuracy when retrieving and checking the vital parameters prior to beam switch on. A simpler and more useable interface has been developed and tested. The laboratory based comparative experimental study suggested that this could help focus radiographers' attention during repeated final treatment checks, resulting in increased accuracy and potentially fewer errors passing undetected. The interview results suggested that a design change would be welcomed by radiographers, and if the interface was designed to work with the checking protocol, this could further assist them during repeated final treatment checks by making the process a less passive task.
The next chapter, will draw together the research findings across the preceding chapters, and discuss the implications for radiotherapy practice, along with suggestions for future research directions.

11 Chapter 11: Discussion

The final treatment check, conducted by two radiographers, is the final opportunity to prevent erroneous treatment being delivered to patients. This final treatment check has been demonstrated to be vulnerable to errors passing undetected (Toft and Mascie-Taylor 2005). Therefore, this body of research aimed to understand and investigate how this process could be improved. This chapter will start with a summary of the main findings and conclusions. The discussion will then continue with a summary of how this research has made a contribution to the existing literature. This is followed by a discussion of potential further research avenues, before the concluding remarks.

11.1 Summary of main findings

The aim of this research was to fully understand the process of the final treatment check prior to radiotherapy treatment delivery in order to determine how the reliability might be improved to help ensure errors are detected before treatment is delivered. The specific objectives were:

1. Examine and review the checking process immediately prior to beam delivery and identify factors affecting the reliability of this process to detect errors
2. Experimentally test the impact on performance of different approaches to checking in a laboratory setting, to develop an empirical evidence base
3. Specify and design an evidence-based revised checking process for use immediately prior to beam delivery
4. Evaluate the revised process to determine user acceptance

These objectives were achieved using a combination of qualitative and quantitative research methods. Throughout the research programme it was ensured that the research direction was informed by the results of the preceding study. This ensured the research path was relevant and applicable to current radiotherapy practice. This is illustrated in figure 5.1.

The literature pointed to a need to improve the final treatment check in order to increase the likelihood that any errors in a patient's treatment parameters are detected prior to treatment delivery. Checks are put in place at various points in a patient's treatment

journey in order to detect errors. During the final treatment check radiographers must ensure that the data displayed on a screen corresponds with the patient's paper prescription.

The final treatment check process and the potential reasons underlying error were investigated through a task analysis and exploratory interviews with radiographers in chapters 6 and 7. This revealed that the current methods of checking used could be unreliable. A number of reasons were identified as potential causes of errors within the checking process. In particular there was found to be variation in how the final treatment checks were conducted due to no current, national protocol. Human error was found to be the likely cause of errors passing undetected during this final check, specifically a slip due to interruptions in attention. It has been argued that during repeated final treatment checks, radiographers are susceptible to involuntary automaticity (Toft and Mascie-Taylor 2005). If this occurs, the final treatment check may be conducted on autopilot, without due attention, leading to errors between the paper prescription and on-screen values potentially passing undetected. The empirical research indicated that maintaining attention during repeated final treatment checks was challenging for radiographers. A significant reason for this is because the checks were repeated regularly and were almost identical for every patient. Radiographers themselves recognised that this can easily lead to involuntary automaticity occurring. Alongside the issue of attention, the interviews suggested there were many active and latent factors surrounding the final treatment check, which could contribute to human error. Many of the factors, such as noise and time pressure, also negatively impacted upon attention. Hence, attention failure was both a direct and indirect factor negatively impacting the efficacy of the final treatment check.

From the interviews, task analysis and literature review, it was found there were currently no defences against errors passing undetected, aside from it being normal practice for two people to conduct the final treatment check, as directed in *Towards Safer Radiotherapy* (Donaldson 2007). However, this was not believed to be a strong defence because the imprecise definition left this instruction open to interpretation by radiotherapy departments and individual radiographers. This openness to interpretation was observed in the variety of checking methods used by radiographers: one person checking, non-verbal two person

checking or chunking parameters. Consequently, it was apparent that a stronger defence against the many latent factors, and error producing conditions was needed.

It was concluded that there was a need to focus research on developing an evidence-base to support two main defences against error; firstly the checking protocol, and secondly the on-screen display of the treatment parameters. Figure 11.1 presents a representation of the final treatment check with the error influencing factors found and defences against error developed in this research, which is adapted from Reason's model of accident causation (Reason 1997).

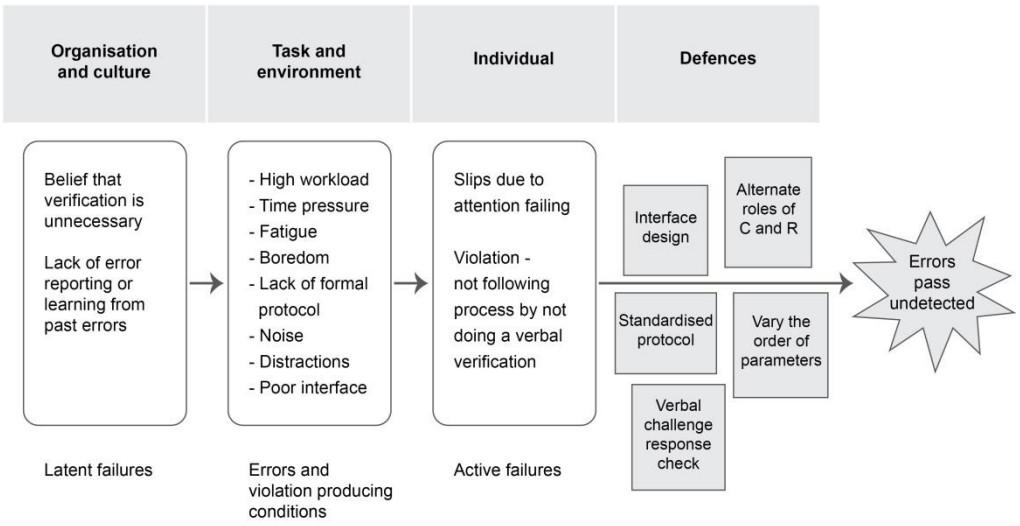


Figure11.1: Diagram detailing possible errors how the new protocol acts as a defence

A holistic approach to improving verification safety also considers eliminating, or minimising, the active and latent error factors which have been identified during the course of this research. This systems analysis approach seeks to understand all possible causes of error. It is argued that this approach is better than root cause analysis, which, as Vincent (2010) also argues, implies there is one cause of an error, when there is probably many. Table 7.4, following the exploratory interviews presented some preliminary practice based recommendations to lessen the risk of the latent failures and error producing conditions listed in figure 11.1. It is recognised that this may not be a comprehensive list, and that errors may still pass undetected despite the defences this thesis recommends.

Two avenues to improve the reliability of the final treatment check were taken in this body of research: design out some of the error producing conditions, and strengthen the defences against errors passing undetected. The protocol and interface design are defences against errors passing undetected, by standardising the process in a way which promotes variation in repeated final treatment checks, thereby minimising routine and the likelihood of involuntary automaticity.

11.1.1 Protocol

The main defence against errors passing undetected, developed in this body of research, was a clear, standardised method of conducting the final treatment check. A 'gold standard' method of checking, to be adopted by all radiographers, in all departments, to prevent variation in practice and ensure treatment details are checked in the most effective way. The literature provides evidence from healthcare and aviation to guide the design of an effective checking protocol. However, it was decided to design a domain specific protocol by reviewing the current processes in place, as well as gaining supporting evidence to inform the current debate in healthcare over single and double checking.

The domain of study is difficult to observe and measure error in. Therefore, the research took a simulated experimental approach. This involved devising a novel simulated radiotherapy checking task and exploring variables highlighted in the literature. The experimental context was employed to explore the optimal method of checking to increase the likelihood of error detection during repeated final treatment checks. The first of these experiments also engaged in the debate around single and double checking (Alsulami, Conroy and Choonara 2012). The results suggested that double (two person) checking is more effective at error detection than single checking (one person), but challenge-response checking is most effective at detecting errors. As such challenge-response checking formed the basis of the protocol. As it had been found that the final treatment checks were prone to involuntary automaticity, the second experiment investigated methods of maintaining attention, thereby increasing accuracy during repeated final treatment checks. The addition of switching the roles of challenger and responder and varying the order in which parameters were verified, were found to further increase the accuracy of challenge-response checking. It is thought this is because it reduced the routine of checking by

introducing variety, thus maintaining the attention of both people involved in the checks. This result aligns with the theory of attention underload discussed in section 6.3.3. A slight increase in cognitive load, helped maintain attention. These methods to keep checking an active process were built into a standardised protocol.

This protocol was evaluated using group interviews with qualified and student radiographers. Evaluation of the protocol was largely positive. Participants welcomed the introduction of a standardised protocol and believed this would improve patient safety. However, there was some debate as to the impact of the new method of checking on treatment time and if the benefit to safety was worth the additional time spent checking. Whilst the interview results suggested the protocol would be welcomed, it was suggested by participants that there may be resistance from some radiographers when implementing the new protocol. This finding was not unexpected. There is a large body of literature surrounding improvement science which documents the challenges often associated with change in healthcare. This evaluation has confirmed the need for further research into the best method of implementing a new checking protocol in radiotherapy.

11.1.2 Interface

Alongside the need for a standardised checking protocol, the role of the interface design on checking accuracy arose from the research findings. Therefore, a proposed interface for use during the final treatment check was created and evaluated. This preliminary investigation into the effectiveness and potential of a clearer and simpler interface, suggested that there is opportunity for the software to be developed, in a more user centred manner, to improve checking accuracy. It is also suggested, based on feedback on the protocol and proposed interface, that the interface design could be designed to link in with the protocol, in terms of varying the order of parameter presentation and providing prompts to radiographers to switch roles.

Table 11.1 summarises the research aims, method of investigation and a short summary of the findings.

Table 11.1: Summary of aims and findings

Aim	Findings
Examine and review the checking process immediately prior to beam delivery and identify factors affecting the reliability of this process to detect errors	• A hierarchical task analysis and semi-structured interviews suggested variation in how the final treatment check is currently done, which leaves the process vulnerable to error • This qualitative research identified number of likely causal factors to explain why the final treatment check may fail to detect errors; attention, noise, lack of training, time pressure, authority structures, environment, interface design • Interviews suggest a standardised checking protocol would be of value • The checking process needs to be less routine and more active to prevent involuntary automaticity
Experimentally test the impact on performance of different approaches to checking in a laboratory setting, to develop an empirical evidence base	• Simulated laboratory-based radiotherapy checking task developed to mimic the task and control variables • A number of methods checking defined, based on the literature and qualitative research, and comparatively tested • A challenge-response method of checking found to be more effective at error detection than single or double checking • Switching roles of challenger and responder regularly and varying the order of parameters helps to maintain attention during repeated challenge-response checking
Specify and design an evidence-based revised checking process for use immediately prior to beam delivery	• Findings from the experiments translated into a detailed challenge-response protocol in both written and diagram format • The current interface used during the final treatment check evaluated in terms of adherence to ISO principles • A new, simplified interface designed for use during the final treatment check • Qualitative and quantitative data to support the improved usability of the interface designed
Evaluate the revised process to determine user acceptance	• Semi-structured interviews suggested the protocol and proposed interface would be well received by radiographers and help to detect errors during the final treatment check • Potential barriers to implementation of the protocol identified as: time and resistance to change from qualified radiographers

11.2 Overall conclusions and contributions to existing literature

The literature review suggested a paucity of patient safety and human factors research within radiotherapy. This research has identified that a process designed to detect errors prior to treatment delivery is itself error prone. To improve this process a number of different research approaches were taken. Qualitative and quantitative research was combined with psychological theory and user-centred design to produce a new checking protocol and proposed interface design for use during the final treatment check immediately prior to beam delivery. This has the potential for positive impact on the field as, despite the weakness of checking being recognised in documents such as *Towards Safer Radiotherapy* (Donaldson 2007), there has been no effort to create a formal, standardised method of checking. The research also suggests that this would be well received by radiographers. Therefore, the research findings presented in this thesis have a number of implications. The main implication is on current radiotherapy practice, surrounding the final treatment check of a patient's treatment.

Alongside implications for radiotherapy practice, this research also has implications for training programmes in radiotherapy. This is because the research has suggested that current student radiographers would benefit from more training in patient safety and human factors. This increased training may also help minimise some of the factors negatively impacting upon the final treatment check by increasing radiographers' understanding of why they have a negative impact, such as distractions and deference to authority.

This research has also engaged in the debate surrounding single and double checking in healthcare. The literature is currently divided as to which is the safest method of checking, yet there is little empirical evidence to support either method (Alsulami, Conroy and Choonara 2012). This thesis has provided empirical evidence, from an experimental study which simulated the repetitiveness of radiotherapy checking, to support the claim that challenge-response checking is the safest method of checking. This is not in support of existing research which suggests single checking is more effective (e.g. Armitage 2007, Kruse 1992). However, this investigation of double checking was an experimental, comparative

study, rather than retrospective or small sample analysis, which forms the majority of existing research in this area.

This research also therefore has potential implications for healthcare in a wider context. Double checking is conducted in many areas of healthcare to prevent errors and ensure correct treatment is given to patients. This research provided evidence which supports challenge-response checking as the most effective method of checking. Therefore, this method of double checking can also potentially be applied to other areas of healthcare, with local modification, such as blood transfusions or drug administration, which use double checking as an error defence.

In summary the thesis has therefore resulted in the following original contributions:

1. A detailed understanding of the final treatment checking process in radiotherapy and identification and analysis of factors contributing to effectiveness
2. The design of a unique experimental paradigm designed and employed to mimic the repetitiveness of radiotherapy treatment checking
3. An empirical evidence base to support the validity of challenge-response checking in radiotherapy
4. The development and evaluation of a new evidence and theoretical based verbal safety protocol for use immediately prior to treatment delivery in radiotherapy
5. Recommendations surrounding the design of the radiotherapy interface to improve treatment checking accuracy
6. Practice recommendations to improve detection of errors in patient's treatment during the final treatment check prior to treatment delivery

11.3 Evaluation of research approach

This research employed a mixed methods approach to meet the research aims, namely qualitative interviews and experimental studies using a novel paradigm designed for this body of research. Specific limitations of each method were explored in each respective chapter. The pragmatism approach allowed the use of the most appropriate research method at each stage of the research. Each study was informed by the findings from the previous study, which resulted in fluidity of the research process, and ensured that the

research remained relevant and beneficial to the overarching aim of improving the safety of radiotherapy treatment delivery. The results of qualitative and quantitative research were collated to inform the design of standardised checking protocol and recommendations for interface design. This approach allowed for triangulation of the data which increases the validity of the results. Furthermore, at every stage the research was validated by discussion with radiographers.

The studies of the thesis both began and finished with qualitative methodology. This approach allows for exploration and understanding of the research topic. This is beneficial as an introduction to the topic, because as the literature review demonstrated, checking within radiotherapy is currently an understudied topic. The qualitative nature of the first study in this thesis provided descriptive data which informed the later avenues of research.

The exploratory qualitative research informed the aims of the experimental studies, as well as informing the design of the experimental paradigm, to ensure it was as close as possible to a reliable simulation of real life treatment checking. These laboratory-studies allowed methods of checking to be compared for effectiveness on error detection without any potential patient harm, and away from confounding environmental influences which would be present in a radiotherapy department.

A qualitative methods approach was also adopted to explore student and qualified radiographers' views, and feedback on the design of the checking protocol and proposed interface design. This informed the iterative development of these safety defences and ensured the end-user remained central to the design. It is believed this will help with the future implementation of the new protocol.

11.4 What this thesis did not explore

This thesis focussed just on the final treatment check, the few seconds which make up the final defence against errors in the amount of radiation delivered to the patient. As illustrated in figure 2.1, a patient's radiotherapy treatment consists of many stages, of which treatment delivery is the final stage. This body of research has not investigated the other stages of treatment in depth in order to explore if, or how, these earlier processes could be

improved to strengthen earlier defences against errors in treatment delivery. As transfer of patient's treatment prescription details, and entry onto RV systems, appears to be an area of safety risk, it is believed that there is scope to review the safety of these processes in the future.

This research has focussed on preventing errors in the amount of radiation delivered to the patient during treatment delivery; as such the area explored has not included geographical misses. These could occur when the patient is aligned on the bed, prior to the point of radiographers verifying treatment details at beam switch on, and could result in, for instance, radiotherapy treatment erroneously delivered to the incorrect part of the body. However, the process of checking patient position is thought to be conducted in a similar manner to checking of prescription parameters. Therefore, principles from this body of research could potentially be applied to this stage of treatment.

In addition to errors in treatment delivery, it is recognised that there may be errors within treatment planning. This body of research was focused on errors in treatment delivery, planning errors would have required an entirely different approach and knowledge of the physics involved in treatment planning and calculation. This area of investigation was beyond the scope of this research; although it is recognised there these are errors which need to be assessed in as much depth in order to ensure safety in all aspects of radiotherapy treatment.

In regards to the main output of this body of research, it is unknown to what extent this protocol could improve safety. This is in part to the paucity of available, current, and reliable data on error rates in radiotherapy, and the complexity of the domain. Furthermore, it has not been possible to implement this protocol in practice to observe and measure the effects and benefits. It is recognised that until the protocol is in use and embedded in practice, its efficacy cannot be fully evaluated.

11.5 Further research

Whilst this body of research has addressed the research aims, it has also posed a number of additional research questions, and lines of potential research.

11.5.1 Further evaluation

The main output from this body of research was the design of the checking protocol to be used immediately prior to treatment delivery, which was informed by an analysis of this process and factors affecting accuracy. According to Battle and Lilford's (2003) three step process of patient safety research, discussed in section 5.1.1, this research has addressed the first step, identification of risks and hazards, and begun to address the second, design, evaluation and implementation. Therefore, in order to provide a complete patient safety initiative more research would need to be conducted on the evaluation, implementation and sustained improvement to safety.

The protocol would also need to be evaluated in more depth prior to implementation. The protocol evaluation in this thesis was conducted with a small sample of radiographers. Therefore, it would be valuable for future research to evaluate how radiographers perceive changes to the method of checking and the introduction of a formal protocol on a wider scale. This could be achieved with the use of a questionnaire to collect views from a wide demographic, across many departments. It is also suggested that a usability test of the protocol is conducted, perhaps with observations of how radiographers use the protocol in practice and over time. This would be worthwhile to detect if radiographers develop work-arounds whilst using the protocol. It would also be valuable to ascertain the, if any, additional time this protocol would add to treatment time.

11.5.2 Implementation

This thesis focussed on the design of a final treatment check intervention. As such the process of implementing this intervention has been considered, but was not central to the thesis. Yet, the results of the research in this thesis suggest that further research on implementation would be valuable, following further evaluation of safety and acceptability, in order to maximise the benefit of the new protocol. When looking at literature in the field of implementation science, there are many factors which can impact upon successful implementation of new safety initiatives (Proctor, Powell and McMillen 2013). Research would therefore need to evaluate which factors will influence the implementation of the protocol, in order to decide upon the best method. Therefore, there is a need to evaluate the determinants of change specific to this specific area of healthcare, prior to

implementation. Some barriers and enablers to successful implementation have been uncovered in this research, yet, these must be analysed in more depth, to determine the best method of implementation.

The acceptability and feasibility of the checking protocol was positive in the interviews. There appears to be readiness to adopt change from the radiographers. Yet, due to the number of strategies described in the literature and the difficulty discerning and differentiating improvement or implementation strategies, the proposal of the best method of implementation is beyond the scope of this thesis but is a strong avenue of future research. It is likely that successful implementation and sustainability would involve some behavioural change techniques (Michie *et al.* 2013), alongside continued involvement from end users in the continuing development (Taylor *et al.* 2013). The literature has proposed the important role of middle managers (Birken, Lee and Weiner 2012 and Russ *et al.* 2015) and the protocol evaluation interviews in this research, suggested that they were willing to lead change. It may also be interesting and worthwhile to conduct a comparative study of methods of implementation. Comparison and evaluation of the different methods of implementation can lead to recommendations regarding the best method of implementation for other quality improvement initiatives in radiotherapy. There is also a need to understand if long term change surrounding the final treatment check is feasible and how to sustain the change in checking method that this protocol would involve. This could involve explicitly measuring the factors believed to contribute to QI sustainability, as summarised in table 3.3, prior to implementation, in order to target improvement on weaker areas of the system to optimise the sustainability. It is recognised, that despite the evidence-base for the success of this new checking protocol presented in this thesis, the key to the success of any SOP lies in the successful implementation process.

It is suggested that Normalisation Process Theory be applied to the implementation of this new final treatment check protocol. This is because there is a growing interest in applying this model to healthcare interventions, and as such, use of the NPT can not only add to the literature on radiotherapy practice, but also the literature on use of NPT (McEvoy *et al.* 2013). Furthermore, NPT provides a conceptual model and toolkit on which to base implementation process design and evaluation of the implementation and sustained

adherence over a long period of time from initial implementation, to when it becomes fully 'normalised' or integrated into everyday practice (May *et al.* 2009 and May *et al.* 2010). This longitudinal study would be beneficial for allowing identification of any required modifications to the protocol in the future and informing the design of future radiotherapy safety initiatives also.

11.5.3 Impact on error

The protocol is designed to prevent treatment errors, therefore valuable long term research into pre and post implementation error rates would assist in the evaluation of the checking protocol designed. The literature review into radiotherapy error rates presented in this thesis, suggested that more research into error rates is required, and with this more evaluation can be done into where and how errors occur, in order to help understand how to design out errors elsewhere in the system.

11.5.4 Software design and testing

Another major output from this body of research was the finding that the interface design is not optimal to support the final treatment check. This research has presented design recommendations surrounding the interface design. However, for experimental purposes this made use of simple static visual display without input from the user. This would need to be explored on a larger, and more in depth scale, with the manufactures of the software, in order for this line of research to be have real patient benefit. Therefore, there is need for further development and research to explore the potential for the interface to work in tandem with the protocol to improve the accuracy of the final treatment check.

11.5.5 Education and professional development

A few additional potential lines of research have emerged through the course of this research. The research has suggested that there is scope for an increase in patient safety and human factors training amongst radiographers. The results of the evaluative interviews suggested that the protocol itself does not require specific training; yet human factors training may help to ameliorate the negative impact of other factors which impede on the accuracy of the final treatment check, and other safety critical areas of radiotherapy. Therefore, it would be worthwhile for further research to explore, in depth, the specific training needs in radiographers at all career stages, with a view to creating radiotherapy

specific patient safety resources. There are online resources around training healthcare professionals in patient safety, from the WHO and Institute of Healthcare Improvement. However, something more formal, and specific to radiotherapy would be beneficial to illustrate and highlight the relevance to their practice.

An issue closely related to patient safety training, which this research touched upon, is the issue of vigilance and safety awareness decreasing with experience. It would be interesting to explore if there is a difference in awareness and attitude at difference time points in radiographers careers, for instance, between first year and final year of training or after qualification and five years post-qualification.

11.6 Concluding remarks

This research revealed many factors which can have a negative influence on the accuracy of the final treatment check in radiotherapy. Involuntary automaticity was a key issue, alongside many other factors which had either a direct or indirect negative impact on attention during repeated final treatment checks. Therefore, an evidence-based and theoretically driven protocol, and interface design recommendations, for use immediately prior to beam delivery were developed. To take a participant's words, the protocol and interface recommendations are "*a speedbump to automation*" during repeated final treatment checks. This protocol is currently an unfinished patient safety innovation requiring further development and exploration of the best method of implementation to achieve its full benefit and sustainability. This new SOP will require behaviour change from radiographers in order to ensure its success. It is known that behaviour change is the greatest challenge in successful implementation of QI initiatives. Yet, two of the factors with the greatest negative impact on implementation are negative attitudes and a lack of engagement with the new QI initiative. Preliminary evaluation of the protocol presented in this thesis suggests a positive engagement with, and attitude towards the protocol, in the majority of end users. Therefore, it is envisaged that with the correct process of implementation, the adherence rate to the new SOP will be high.

The ultimate risk of radiotherapy treatment errors is because the final defence against error is a human. Humans will always make mistakes, we are not infallible. Errors can pass

undetected during final treatment checks due to involuntary automaticity, or human error due to a disruption in attention. In accordance with a systems based approach to error, either the prior defences need to strengthen or the human supported to conduct the task effectively. Whilst it is recognised that this body of research is not a definitive answer to how to make the final treatment checks infallible, it has provided a protocol which details the best method of checking to increase the likelihood of error detection and recommendations intended to reduce some of the latent and error producing conditions in the wider system. Errors at the point of the final treatment check are rare, yet they can cause significant and potentially fatal harm to patients, therefore implementation of the recommendations presented in this thesis into radiotherapy practice, will go some way towards preventing patient harm. In the words of Reason, which are appropriate to end this discussion on:

> *"We can't change the human condition but we can change the condition under which we work"* (Reason 2000:769).

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13 Appendices

Appendix 1 – Ethical review for exploratory interviews

REGISTRY RESEARCH UNIT

ETHICS REVIEW FEEDBACK FORM

(Review feedback should be completed within 10 working days)

Name of applicant: Lucy Dwyer .....

Faculty/School/Department: [Health and Life Sciences] HLS Health & Lifestyle Interventions

Research project title: Understanding double checking in radiotherapy

Comments by the reviewer

1. Evaluation of the ethics of the proposal:

The project is well presented, the procedure and participants' involvement are described clearly and in details. All potential ethical considerations are discussed and resolved in the protocol. Appropriate data storage and management procedures to assure its security and participants' anonymity are clearly presented.

I have no concerns regarding ethical aspects of this study.

2. Evaluation of the participant information sheet and consent form:

All participant materials (PIS, consent form and debrief letter) are presented in clear, participant friendly manner. Participant information sheet comprises all necessary information including guidance regarding withdrawal from the study, data management and researcher contact details.

3. Recommendation:

(Please indicate as appropriate and advise on any conditions. If there any conditions, the applicant will be required to resubmit his/her application and this will be sent to the same reviewer).

X	Approved - no conditions attached
	Approved with minor conditions (no need to re-submit)
	Conditional upon the following – please use additional sheets if necessary (please re-submit application)
	Rejected for the following reason(s) – please use other side if necessary
	Not required

Name of reviewer: Anonymous.....

Date: 14/09/2012.....

Appendix 2: R&D approval for exploratory interviews

University Hospitals Coventry and Warwickshire NHS Trust

Research, Development and Innovation Department
Director of R,D&I: Professor Chris Imray - Tel: 02476 96 5222
Head of R,D&I: Ceri Jones - Tel: 024 7696 6196
Divisional Finance Manager: Chris Moore - Tel: 024 7696 6198
Deputy Divisional Finance Manager: Joanne Treadwell - Tel: 02476 966199
R,D&I Business Manager: Natasha Wileman - Tel: 02476 966197
Research Associate - Governance: Isabella Petrie - Tel: 02476 966202
R,D&I Administration Specialist: Joanna Geraghty - Tel: 02476 964995
Research Portfolio Development Manager: Deborah Griggs - Tel: 02476 96 6195

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5th November 2012

Lucy Dwyer
ARC-HLI
Whitefriars Building
Coventry University
Priory Street
CV1 5FB

Dear Miss Dwyer

Study Title: Understanding double checking errors in Radiotherapy

Thank you for submitting the above study for consideration by the Research & Development Office. I am pleased to inform you that your study has been approved.

Approved documents
The documents approved for use in this study are:

Document	Version	Date
Protocol	1	30.07.2012
Participant Information Sheet - Observations	1	27.07.2012
Participant Information Sheet – Interviews	1	27.07.2012
Participant Consent Form – Observations	1	27.07.2012
Participant Consent Form – Interviews	1	27.07.2012

- Should you wish to make any changes to the documents listed above, you must obtain R&D approval prior to use.
- An Annual Progress Report (APR) should be submitted to the main research ethics committee (REC) once a year throughout the trial or on request by R&D. The first report is due on **5th November 2013.** In addition, for CTIMP studies, a Development Safety Update Report (DSUR) should be submitted to the MHRA and the REC once a year. Guidance on the DSUR can be found in SOP 41 'Preparation and Submission of Annual Progress Reports and Development Safety Update Reports'.

R&D Reference: LD111412

- Notification of any serious breaches of GCP or the trial protocol must be reported to the R&D Department and a DATIX Clinical Adverse Event form completed within 24 hours of any suspected breach being identified and confirmed.

Sponsorship & Indemnity

Your research sponsorship & indemnity is provided by Coventry University.

Your project may be subject to ad hoc audit by our department to ensure these standards are being met.

May I take this opportunity to remind you that, as a researcher, you must ensure that your research is conducted in a way that protects the dignity, rights, safety and well-being of participants. Trust R&D Approval assumes that you have read and understand the Research Governance Framework and accept that your responsibilities as a researcher are to comply with it, the Data Protection and Health & Safety Acts.

The Trust wishes you every success with your project.

Yours sincerely

Natasha Wileman
R,D&I Business Manager

Cc: **Cori Jones, Head of Research, Development and Innovation**

Linda Farthing – Clinical Superintendent - UHCW NHS Trust
Louise Moody – Academic Supervisor – Coventry University

Appendix 3: BCU permission

BIRMINGHAM CITY University

MU/LH

31st August 2012

Lucy Dwyer
PHD Student
Applied Research Centre - Health and Lifestyle Interventions
Coventry University
Priory Street
Coventry
CV1 5FB

Dear Lucy

RE: Understanding Double Checking Errors in Radiotherapy

Following receipt of your application to conduct research within the Faculty of Health at Birmingham City University, I am pleased to inform you that you have satisfied all the necessary requirements in relation to ethical approval and indemnity cover.

I am therefore able to grant you my formal permission to begin your research project from 10th September 2012. Your access to the Faculty will expire on 8th March 2013. If an extension is required you must contact me to apply at least one month before the expiry date.

Julie Hall has been allocated as your lead contact from within the Faculty of Health.

Best wishes.

Yours sincerely

M. C. Lintern

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CC Julie Hall

Appendix 4: Exploratory interview schedule

Interview Schedule

Study Title: Understanding clinical double checking errors in Radiotherapy
Researcher: Lucy Dwyer

1. Please can you state your job title and grade?
2. How long have you worked in radiotherapy? / What year of training are you in?
3. What education do you receive around patient safety during training?
4. Have you received continuing training around patient safety in your workplace?
5. How often do you think radiotherapy incidents happen and what is the nature of these incidents?
6. Is there any type of error which you have made or which is made frequently?
7. If an error did occur, would you feel confident in knowing what to do? How to correct it? How to report it?
8. What do you understand by the term 'independent double check'/ 'independent verification'?
9. When should a double check/verification of treatment be conducted?
10. Have you received any training on how to conduct a verification/double check?
11. How do you do the double check/verification? /Is there a set protocol or descriptions of these?
12. How likely do you think it is for errors to be missed during a double check/verification
13. Thinking of the verification of treatment plans immediately prior to treatment delivery, what factors may influence how effective it is?
    a. Boredom?
    b. Conducting the check on auto-pilot?
    c. Noise?
    d. Stress?
    e. Who you are checking with?
    f. Method of check? i.e. screen compared against treatment plan or vice versa?
    g. Attention?
14. What is good about the way you verify?
15. How do you think verification can be improved?
16. What do you do to ensure that you check effectively?
17. What, if anything, prevents you from verifying effectively?
18. What, if any, processes or protocols could be put in place to reassure you that you are checking effectively?
19. Would you follow a new checking protocol if the process was clearly explained to you alongside the rational and evidence for it?
20. What impact has technology had on the nature of verification?

Students

21. Have you observed any difference across hospitals in their approach to checking or how checking is done?
22. Do you have any worries about errors?
23. How would you feel about reporting an error?
24. Do you feel that there is a risk of boredom due to the repetitive nature of the job?

Training staff

25. How do you teach students to reduce error?
26. How easy is it for students/newly qualified staff to speak up?
27. How much attention do you think students/ NQS pay to checks?
28. How routine does the job feel to students/NQS?

29. Any other comments?

Appendix 5: Exploratory interviews: Consent form

Applied Research Centre in Health and Lifestyle Interventions
Whitefriars Building
Faculty of Health and Life Sciences
Coventry University
Priory Street
Coventry
CV1 5FB

Tel: 024 7688 7450
Fax: 024 7679 5987

Consent form

Study Title: Understanding clinical double checking errors in Radiotherapy
Researcher: Lucy Dwyer

Please initial box

1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without consequences. ☐
3. I understand that my interview will be recorded and transcribed but that records will remain anonymous. ☐
4. If understand that my anonymous data will be used for research purposes and the findings may be published in an academic journal. Anonymous quotes may be used in publications. ☐
5. I understand that the data will be treated according to the British Psychological Society Code of Ethics. ☐
6. I understand that I can request any information I provide to be destroyed up to two weeks after participation. ☐
7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

Participant code _____

Applied Research Centre
Health and Lifestyle Interventions

Appendix 6: Exploratory interviews: Themes, subthemes and categories

Theme	Sub-theme	Category	Frequency of codes	Radiographer codes	Lecturer codes	Student codes
Lack of standardised protocol	Lack of standardised protocol	Students unaware of protocol	5	0	0	5
		Differences between departments	5	0	0	5
		Would like standardised protocol	8	2	0	6
	Single Vs Double	Challenge-response considered more effective	11	3	1	7
		Verbal considered more effective	5	2	0	3
		Unstructured checking considered unsafe	7	0	1	6
	Resistance to change	Balance needed between time taken to do check and safety	3	1	1	1
		Seniors more stubborn	6	0	2	4
		Protocol must be evidence based	4	1	0	3
Lack of training in patient safety and protocols for verification	No specific patient safety training	No specific patient safety training on course	7	2	3	2
		Suggest error training with case	6	0	1	5

		studies to educate				
	On-the-job training variance	Confusion over who is responsible for delivering which learning outcome	4	0	1	3
		Variation in the quality of on-the-job training	7	0	1	6
	Verification overlooked during training	No discussion between students on local protocols but considered beneficial	4	1	0	3
		The “fear factor” with doing verification correctly wanes with experience	7	0	4	3
Difficulty maintaining attention	Overreliance on technology	The computer does it all	9	1	4	4
		Might not notice if computer was wrong	2	0	0	2
	Automaticity	Switching roles helps prevent automation	5	3	1	1
		Number overload	3	2	0	1
		Conducting verification on auto-pilot	9	2	0	7
		Need to self- maintain attention	2	2	0	0
	Assumption treatment is correct	Less attention paid to verification mid- treatment	10	5	0	5
	Fatigue	Requires immense concentration	3	1	1	1
		Job is physically tiring	3	1	1	1
	Boredom due to repetitive nature of job	The job can be monotonous	11	4	1	6
		Same anatomical regions are treated on the same machine	3	0	1	2
		Would prefer machines to mix up anatomical regions	5	2	0	3
		Boredom has an impact on recruitment and retention	6	0	4	2

Interface design	Design	Different departments have different software which requires a period of getting used to it	4	1	2	1
		Monochrome	3	1	0	2
		Font size is too small	5	1	0	4
		Too much information displayed	6	0	0	6
	Active input	If values had to be manually input this was considered to improve attention	4	0	2	2
Working environment	Atmosphere	"gloomy" treatment rooms impact focus	2	0	0	2
		The impact of music	3	1	0	2
	Time pressure	Pressure to get patients treated quickly	12	1	1	10
		Pressure from other healthcare professionals	2	0	2	0
		Machine breakdowns	3	0	2	1
		Short staffed	3	2	0	1
	Distractions	Other staff distracting	11	2	4	4
		Patients distracting	3	1	1	1
Authority structures and team culture	Senior radiography sets the tone	Senior sets the tone	2	0	1	1
	Deference to authority	Some seniors are harder to speak up against	8	0	2	6
		Discourage juniors just agreeing but hard to avoid	4	1	1	2
	Culture surrounding verification	Commitment to following protocol	11	3	2	6
		Verification not considered important by some radiographers	6	1	1	4

Appendix 7: Exploratory interviews: Examples of codes, categories and themes

Example 1

Theme- Protocol

↓

Sub-theme- Lack of standardised protocol

↓

Category- Would appreciate standardised protocol

↓

Code – standardised protocol would be beneficial when moving to a new department

Student 8: Yeah because you might be able to then find a common ground which works well between different hospitals. If that get rolls out to everybody then everyone's doing the same thing, the same way.
Researcher: Absolutely so a gold standard for everyone to follow regardless of hospital?
Student 8: Yeah and regardless of where you go, that'll be something you already know and then staff might be more relaxed about you going in a doing the job.
Lines 301-306

Code- Protocol may increase awareness over importance of verification

Researcher: Ok. Do you have any other comments, either about verification or about patient safety or culture in general?
Student 4: I think that what the aims of what we're doing here today I think it would be good if a new set of protocols actually came in, because it would be like a whole shift pattern within all departments around all the UK, so it would make people realise that it's very important
Lines 306-310

Example 2

Theme- Protocol

Sub-theme- Lack of standardised protocol

Category- Students unaware of a verification protocol

Code – Not seen verification protocol

Researcher: So in the department that you're in, do you know if there are any set protocols or descriptions on how to do this verification check?
Student 5: Erm, I've never been shown one if there is.
Lines 83-85

Code- Unaware of protocol or reasoning behind process

Researcher: Do you think it's something that the department's aware of and are trying to...do you think it's bad habits or do you think it's more of a lack of departmental protocol?
Student 6: I think it's lack of department protocol because everyone does it the same way and nobody has ever said why we do it like this.
Lines 64- 67

Example 3

Theme- Protocol

Sub-theme- Resistance to change

Category- A change in protocol must be evidence based

Code – Change would be embraced if evidence based

Student 1: …I think people would probably take it on board. As long as it was something that was given, if it was a significant change, you know you had proper training in how to do it and explanation as to why….

Line 232-234

Code- Need evidence to support new implementation

Radiotherapist 3: We are constantly trying slightly different things or introducing something that might be, is this a better way? You can't say no until you've tried it and I think that you should be able to implement things if you have a good reason to do so.

Line 321-323

Appendix 8: Ethical approval for experiment 1

REGISTRY RESEARCH UNIT

ETHICS REVIEW FEEDBACK FORM

(Review feedback should be completed within 10 working days)

Name of applicant: Lucy Dwyer .....

Faculty/School/Department: [Health and Life Sciences] HLS Health & Lifestyle Interventions

Research project title: An investigation into the efficacy of different checking methods

Comments by the reviewer

1. Evaluation of the ethics of the proposal:

the study protocol is well written and describes the aim and procedure of the study in sufficient details. It also explains how participants data will be stored, analysed and used, and steps that will be taken to ensure participants' anonimity. I have no ethical concerns regarding this study.

2. Evaluation of the participant information sheet and consent form:

Participants materials are well presented and clearly explain the aim and procedure of the study, and how their data will be used. Participants will be informed about their right to withdraw from the study at any time. My only, very minor concern is referring to the British Psychological Society Code of Ethics in the consent form. Most participants will probably not be familiar with it so I would suggest that the author considers adding the link to the actual document in the PIS.

3. Recommendation:

(Please indicate as appropriate and advise on any conditions. If there any conditions, the applicant will be required to resubmit his/her application and this will be sent to the same reviewer).

X	Approved - no conditions attached
	Approved with minor conditions (no need to re-submit)
	Conditional upon the following – please use additional sheets if necessary (please re-submit application)
	Rejected for the following reason(s) – please use other side if necessary
	Not required

Name of reviewer: Anonymous.....

Date: 17/10/2012.....

Appendix 9: Participant instructions for experiments

Participant instructions for the experiment paradigm

The experiment you are about to take part in is designed the mimic the work of radiographers in real life hospitals. Immediately before they are about to deliver a dose of radiotherapy to a patient they must check that the dose details displayed on the radiotherapy machine's interface correspond exactly with what is on the patient's paper prescription. You will conduct the same checks using an exact copy of the interface and prescription used in real life hospital departments. These checks are vital to prevent administering the incorrect dosage to a patient which can be harmful and sometimes fatal. Hence these checks are very important and you must bear this in mind when conducting these checks.

This is an example of a prescription sheet and this is an example of the interface. The four values you must check and ensure they are the same on both the prescription and interface are; energy, monitor units, wedge monitor units and wedge position. To do this pick up the first prescription sheet, and swipe the interface to the right to reveal the first interface. Check the four values. If you believe them to be correct, sign the prescription sheet by writing your initials on the back. Place the prescription sheet to one side and swipe the iPad to clear the screen. If you believe there to be an error, do not sign the prescription sheet. Do not go back and alter your answer once you have decided if there is an error or not.

In between each check you must stand up and walk over to the desk with the Russian dolls. Un-stack and arrange the Russian dolls in the height order displayed on the picture plan. Once they are in the correct order, turn the picture plan over and restack the dolls. Return to the other desk and check the next prescription sheet and interface.
You must complete a minimum of 60 checks within 45 minutes. This gives you approximately 45 seconds per check. For every check you complete over the minimum you will receive a reward in the form of a wrapped sweet from a selection. There will be between zero and five errors placed randomly in the checks. If you fail to detect an error you will lose 2 sweets earnt. If you believe there to be an error when there is not you will also lose 2 sweets. Hence you must work quickly but accurately.

Single checking condition

You will be doing a single check so will check by yourself that the four values are correct. Sign the sheet if you think it is correct. Do not sign if you think there is an error.

Double checking condition

You will be doing a double check. That means that you must both check at the same time that the four values are correct. Do not talk whilst checking. You must both sign or both not sign depending on if you think there is an error or not. You must both complete the Russian doll task together.

Challenge-response condition

You will be conducting what is known as a challenge-response check. One of you is the challenger and the other the responder for the duration of the experiment. The challenger looks only at the iPad and the responder looks only at the prescription sheets. To check the challenger must read out the values one at a time, the responder then looks at the prescription sheet, signals agreement by saying yes and repeating the value from the

prescription sheet. For instance, “Energy:250”. The responder then looks at the paper prescription, checks it is correct and if it is, says yes and repeats the value, “Yes, energy 250”. This is repeated for all 4 values. If all are correct sign the sheet, if not do not sign. You must both complete the Russian doll task together.

Challenge-response with role rotation

You will be conducting what is known as a challenge-response check. One of you is the challenger and the other the responder for the duration of the experiment. The challenger looks only at the iPad and the responder looks only at the prescription sheets. To check the challenger must read out the values one at a time, the responder then looks at the prescription sheet, signals agreement by saying yes and repeating the value from the prescription sheet. For instance, “Energy:250”. The responder then looks at the paper prescription, checks it is correct and if it is, says yes and repeats the value, “Yes, energy 250”. This is repeated for all 4 values. If all are correct sign the sheet, if not do not sign. You must both complete the Russian doll task together. Every 15 minutes you will be told to switch roles by the researcher. When told to switch roles whoever was the challenger, becomes the responder. Whoever was the responder becomes the challenger.

Challenge-response with varying the order of values

You will be conducting what is known as a challenge-response check. One of you is the challenger and the other the responder for the duration of the experiment. The challenger looks only at the iPad and the responder looks only at the prescription sheets. To check the challenger must read out the values one at a time, the responder then looks at the prescription sheet, signals agreement by saying yes and repeating the value from the prescription sheet. For instance, “Energy:250”. The responder then looks at the paper prescription, checks it is correct and if it is, says yes and repeats the value, “Yes, energy 250”. This is repeated for all 4 values. If all are correct sign the sheet, if not do not sign. You must both complete the Russian doll task together. Each time you begin the check for a new patient you must vary the order in which you read out the four values.

Challenger-response with role rotation and varying the order of values

You will be conducting what is known as a challenge-response check. One of you is the challenger and the other the responder for the duration of the experiment. The challenger looks only at the iPad and the responder looks only at the prescription sheets. To check the challenger must read out the values one at a time, the responder then looks at the prescription sheet, signals agreement by saying yes and repeating the value from the prescription sheet. For instance, “Energy:250”. The responder then looks at the paper prescription, checks it is correct and if it is, says yes and repeats the value, “Yes, energy 250”. This is repeated for all 4 values. If all are correct sign the sheet, if not do not sign. You must both complete the Russian doll task together. Each time you begin the check for a new patient you must vary the order in which you read out the four values. Every 15 minutes you will be told to switch roles by the researcher. When told to switch roles whoever was the challenger, becomes the responder. Whoever was the responder becomes the challenger.

Appendix 10: Ethical approval for experiment 2

REGISTRY RESEARCH UNIT

ETHICS REVIEW FEEDBACK FORM

(Review feedback should be completed within 10 working days)

Name of applicant: Lucy Dwyer .....

Faculty/School/Department: [Faculty of Health and Life Sciences] Health & Lifestyle Interventions

Research project title: Investigating methods to combat automaticity during checking

Comments by the reviewer

1. Evaluation of the ethics of the proposal:

The ethics proposal is broadly sound. I am not an expert in this particular field but it did strike me as somewhat strange that no reference was made to the protocol and type of data collected. Is this protocol a standardised one? If so please cite a reference.

The only other concern i would have is in regard to inducing automaticity. This struck me as a protocol where 'mental fatigue' may be induced. Are there any plans in place to ensure that nothing untowards occurs post participation? There are a number of studies which show mental fatigue/vigilance type tasks, if undertaken for a prolonged period, can result in an array of cognitive,perceptual and physical deficits. What would happen if someone participates and then decides to drive home? would the protocol likely result in prolonged effects where errors might be made outside of the protocol and therefore influence wider aspects of the participants lives/well-being?

2. Evaluation of the participant information sheet and consent form:

The PIS is appropriate

3. Recommendation:

(Please indicate as appropriate and advise on any conditions. If there any conditions, the applicant will be required to resubmit his/her application and this will be sent to the same reviewer).

	Approved - no conditions attached
X	Approved with minor conditions (no need to re-submit)
	Conditional upon the following – please use additional sheets if necessary (please re-submit application)
	Rejected for the following reason(s) – please use other side if necessary
	Not required

Name of reviewer: Anonymous.....

Date: 16/09/2013.....

Appendix 11: Ethical review for protocol evaluation interviews

REGISTRY RESEARCH UNIT

ETHICS REVIEW FEEDBACK FORM

(Review feedback should be completed within 10 working days)

Name of applicant: Lucy Dwyer .....

Faculty/School/Department: [Faculty of Health and Life Sciences] Health & Lifestyle Interventions

Research project title: Evaluation of a verification protocol to be used in Radiotherapy

Comments by the reviewer

1. Evaluation of the ethics of the proposal:

Overall a very clear proposal for a high quality and important piece of research. There are no major ethical concerns.

2. Evaluation of the participant information sheet and consent form:

The information sheet indicates that participants can withdraw at any time up to two weeks after participation but the consent form indicates they can withdraw at any time (with no 2 week limit). Please could you amend these to ensure the message is consistent, and consider if it is possible for participants to withdraw their data once they have participated in a focus group (i.e. will it be possible to do this without also losing data from consented participants?)

On this information sheet you might also wish to give a little more information on the types of questions asked - i.e. perhaps reassure participants that they wont be asked directly to report any patient safety incidents they have been involved in (although there is the potential that other participants may disclose such information).

3. Recommendation:

(Please indicate as appropriate and advise on any conditions. If there any conditions, the applicant will be required to resubmit his/her application and this will be sent to the same reviewer).

	Approved - no conditions attached
X	Approved with minor conditions (no need to re-submit)
	Conditional upon the following – please use additional sheets if necessary (please re-submit application)
	Rejected for the following reason(s) – please use other side if necessary
	Not required

Name of reviewer: Anonymous.....

Date: 03/01/2014.....

Appendix 12: R&D approval for evaluation interviews

Northampton General Hospital NHS
NHS Trust

27 November 2013

Research & Development Centre
Cliftonville
Northampton
NN 5BD
Tel 01604 545941
Fax 01604 603143
R&D Manager: Mrs Julie Wilson

Ms Lucy Dwyer
Applied Research Centre Health & Lifestyle Interventions
Coventry University
Priory Street
Coventry
CV1 5FB

Dear Ms Dwyer

Evaluation of a double-check protocol to be used in Radiotherapy treatment delivery
Research Protocol Version 1.0 dated September 2013

Thank you for forwarding a copy of your proposal in relation to the above project.

As a service evaluation, I can confirm that this project is not one that is required to be ethically reviewed under the terms of the governance arrangements for NHS Research Ethics Committees. As such, Trust management approval from the R&D Office is not required.

Kind regards.

Yours sincerely

Julie Wilson

Julie Wilson
R&D Manager

c.c. Dr Chris Frank, Patient Safety Lead for Human Factors, NGH
Michael Graveling, Principal Superintendent, Radiotherapy, NGH

Appendix 13: BCU permission for evaluation interviews

BIRMINGHAM CITY University

Lucy Dwyer
PhD Student
Applied Research Centre – Health and Lifestyle Interventions
Coventry University
Priory Street
Coventry
CV1 5FB

Wednesday 28th January 2014

Dear Lucy

Re: Evaluation of a verification protocol to be used in Radiotherapy

Following receipt of your application to conduct research within the Faculty of Health at Birmingham City University, I am pleased to inform you that you have satisfied all the necessary requirements in relation to ethical approval and indemnity cover.

I am therefore able to grant you my formal permission to begin your research project from 10/02/14. Your access to the Faculty will expire on 28/03/14. If an extension is required you must contact me to apply at least one month before the expiry date.

Helen White (Head of Department) has been allocated as your lead contact from within the Faculty of Health.

Best wishes.

Yours sincerely

M C Lintern

Dr Maxine Lintern
Associate Dean and Director of Research
Centre for Health and Social Care Research
Faculty of Health
Birmingham City University
Seacole 263
Birmingham B15 3TW
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+44 [0] 121 331 6158
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Centre for Health and Social Care Research http://www.bcu.ac.uk/health/research

Appendix 14: Protocol evaluation interview schedule

Focus group discussion Schedule

Study Title: Evaluation of a double checking protocol to be used in Radiotherapy treatment delivery *Researcher:* Lucy Dwyer

1. Please can you state your job title and grade? How long have you worked in radiotherapy?
2. How clear is the written protocol? How clear is the protocol on the diagram?
3. Which is better at explaining how to verify?
4. How explicit are the roles of both checkers in the protocol?
5. What is the difference between this protocol and how you currently check?
6. What do you like about the protocol? What do you dislike about the protocol?
7. Do you have any suggestions on how to change or improve either the written protocol of the diagram?
8. Would this protocol be useful for students?
9. What do you think about the inclusion on the explanation about why you must vary the order and switch roles?
10. Currently the protocol is reliant on staff remembering to vary the order and rotate roles, do you think you would remember to do this or is some kind of a prompt required? Built into software? Paper checklist which varys parameter order for you?
11. How effective do you think the protocol would be at detecting any errors?
12. How effective do you think the protocol would be at maintaining radiotherapists' attention during repeated checking?
13. Do you think this protocol may increase awareness of the importance of verification?
14. Is there anything with how verification is currently done that this protocol cannot improve? Environment?
15. Thinking about how you currently check treatment parameters immediately prior to beam switch on, which method do you think is better and why?
16. Would you use this checking protocol if it was to be implemented in your department? Will it be used long term?
17. Do you think colleagues would be willing to follow this protocol?
18. How do you envisage this protocol being implemented? Would it require additional training?
19. How do you think this protocol may affect working relationships? Authority?
20. Do you think there could be any barriers to following this protocol?
21. Is there anything which could be done to increase likelihood of this protocol being followed?
22. Do you think that making this verification process standardised across all departments is a good or a bad thing?
23. Is this protocol applicable everywhere? Other hospitals? Other checks? With all software?

Training staff

25. How do you teach students to reduce error?
26. How easy is it for students/newly qualified staff to speak up?
27. How much attention do you think students/ NQS pay to checks?
28. How routine does the job feel to students/NQS?

29. Any other comments?

Appendix 15: Protocol evaluation interviews: Themes, sub-themes and categories

Theme	Sub theme	Category	Frequency of codes	Radiographer codes	Student codes
Challenge-response appreciated	Safer because more active	It's less passive more active	13	6	7
		Second checker forced to be involved/ remain focussed			
		Verbalised appreciated as they can be sure both have checked	9	3	6
		The clearly defined roles are appreciated	9	3	6
	Time implications	Slows the verification down in a good way	6	4	2
		May takes too long	11	6	5
		Worth spending extra time to prevent an error	4	2	2
Diagram preferred to written	Diagram more appealing	Diagram protocol is very different to other work instructions. Written can get forgotten.	5	2	3
		Diagram is clearer than written	6	5	1
		No time to read written protocol	5	2	3
		Written protocol not appealing	4	1	3
	Diagram as a permanent visual reminder	Diagram to go on wall near machine	6	3	3
		Diagram protocol as a reminder to glance at as it stands out	9	2	7
		Training benefits of it being visual	5	3	2
		Diagram easy to digest/visual reminder	8	4	4
	Both to be used together	Written needs breaking down into roles			
		Written protocol is clear	6	5	1
		More likely to adhere with the explanation of why	7	4	3
		Protecting radiographers from making mistakes	2	0	2
		Written used when radiographers join department	6	5	1
Implementation of	Standardisation	First formalised method of verification	5	3	2

new protocol	appreciated	Standardisation is a good thing and helps when moving to a new department	13	8	5
	Differences between now and this protocol	Similar to what is done now	8	5	3
		No 2nd verbal check currently	7	5	2
		Roles not rotated at the moment/informally rotated	5	4	1
		Values not varied at the moment	8	6	2
		Variation in how verification is done currently	8	2	6
	Implementing into practice	Enforce following through departmental audits and training	9	4	5
		Enforce national following from government	3	0	3
		Gentle/informal introduction/lunchtime seminars	10	6	4
		Explanation of why needed in introduction/evidence for it	7	2	5
		Needs support from seniors	6	1	5
		Trial period needed			
	Willingness	Would follow protocol	9	4	5
		Resistance from experienced radiographers	14	3	1
	Would get easier with time	Better the more they use it	7	4	3
		New generation will help its continuation	7	4	3
	Future use	Need to change habits to ensure longevity	3	0	3
		Would people to continue to check them individually?	3	3	0
		Need to increase accountability	3	0	3
		Extension to other areas of cancer treatment	4	2	2
Error prevention	Would help to maintain attention	Would prevent errors	9	5	4
		Speed bump to automation	4	2	2
		Healthy form of automaticity	2	1	1
		It makes you have to think more	6	4	2
		Switching roles maintains attention	9	4	5
		Varying order maintains attention	9	7	2

		Both especially beneficial during long treatments	4	2	2
	Issues the protocol does not address	Time pressure and staffing levels	10	5	5
		Distractions still present	13	9	4
		Design of department	4	3	1
		Authority gradients still present	5	2	3
		Human Factors Training still needed	7	5	2
Secondary benefits	Benefits for the individual	Secondary function increasing confidence to speak up	7	3	4
		Students find it useful as an introduction	10	7	3
	Team benefits	May increase the perception of verification importance/need to be silent during verification	7	3	4
		Improving relations between team members	3	0	3
		Improves team working	3	0	3
Design improvements	Assistance from software to vary the order of parameters	Varying order would be too hard/would forget	13	10	3
		Paper too easy to ignore	3	1	2
		Perhaps tick boxes needed built into software	8	3	5
		Good if interface varies the order	13	8	5
	Software prompt to swap roles	Colour changes to symbolise swap	3	1	2
		Sign in to signify roles have swapped	4	2	2
	Additions to protocol	Clearly display all values to be checked at the top on protocol	3	2	1
		Addition of a “patient introduction” check to place treatment in context	7	6	1
Interface	Proposed improvements	Colour of new interface better	3	1	2
		Interface layout aids clarity	9	4	5
		Don’t have to search for values on new interface	10	5	5
		New interface is quicker to use	5	3	2
		Only the required information is present	7	4	3
	Further improvements	Mirror the prescription sheet	2	0	2
		Mirror the protocol	5	1	4

Appendix 16: Protocol evaluation: Examples of codes into categories and themes

<u>Example 1</u>

Theme- Challenge-response appreciated

↓

Sub-theme- More active check

↓

Category- Second checker forced to remain focussed

↓

Code – Second checker cannot just say yes, they have to also concentrate in order to read the number aloud as well.

Student 3: So it's not just one person confirms it it's the other two, because I find that often the second checker just goes "yeah yeah, it's fine" and they don't really take notice. Whereas if they've actually got to focus and concentrate and read them aloud themselves, you are properly counter checking it, because you're doing it twice.
Lines 52-55

Code- Without the second verbal check and varying the order the second checker can just switch off

Radiographer 7: At the moment you don't actually have to listen. I mean, you need to listen, like the students, you don't have to listen, they just wait for someone to stop talking and they do their bit of talking. Whereas if you've got to mirror the order of the person that has told it to you, you've got to find them in the right order.
Lines 223-226

Example 2

Theme- Preference for the checking process illustrated on a diagram

Sub-theme- Diagram as a permanent visual reminder

Category- Diagram protocol as a reminder to glance at

Code – The design and colour of the diagram captures attention better than the written

Student 1: And there's something about it which just draws your attention to it, you know. If it's just right there in front of you, maybe it's the colours on the diagram but it does drag your attention more than this paper. You tend to push these written things to the side…
Lines 70-72

Code- Written protocol has the detail but diagram would be useful as a reminder near the machine

Radiographer 14: Once I've read this [written protocol] for the detail, this diagram is a nice handy reminder. You could almost have that laminated and put up nearby the machine.
Lines 50-51

Example 3

Theme- Process of implementation

Sub-theme- Would get easier with time

Category- New generation of Radiographers will help its continuation

Code – Students would not know any different so would always follow this protocol

Student 4: However as a student, let's say we would have started with this protocol in place. We would have just followed it and it would feel natural as a matter of fact.

Line 2221- 222

Code- The attitudes/usage of the protocol will increase as the new generations come through the department

Radiographer 8: I think probably in the long term, having something like this in place would be better, because I think you'd find that as the newer staff come into the department, they're much more aware of the new systems so they'll pick it up and then your students pick it up and then.....

Line 184- 187

Appendix 17: Interface experiment ethical reviev

REGISTRY RESEARCH UNIT

ETHICS REVIEW FEEDBACK FORM

(Review feedback should be completed within 10 working days)

Name of applicant: Lucy Dwyer .....

Faculty/School/Department: [Faculty of Health and Life Sciences] Health & Lifestyle Interventions

Research project title: Design of a safer radiotherapy interface

Comments by the reviewer

1. Evaluation of the ethics of the proposal:

Overall this is a considered ethics proposal with a sound informed consent and debrief process.

I only have once concern which is described below.

2. Evaluation of the participant information sheet and consent form:

Information sheet needs to be checked for an accurate 'minimum' number of checks required in the 45 minutes.

3. Recommendation:

(Please indicate as appropriate and advise on any conditions. If there any conditions, the applicant will be required to resubmit his/her application and this will be sent to the same reviewer).

	Approved - no conditions attached
X	Approved with minor conditions (no need to re-submit)
	Conditional upon the following – please use additional sheets if necessary (please re-submit application)
	Rejected for the following reason(s) – please use other side if necessary
	Not required

Name of reviewer: Anonymous.....

Date: 10/05/2013.....

Appendix 18: Interface questionnaire evaluation

Interface evaluation- Part 2

Participant _____

Please rate the interface you have just completed the task with on the following statements.

		Strongly disagree			Neither		Strongly agree	
	Question	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1	Overall I was satisfied with how the interface allowed me to complete the task							
2	I was able to find the information required quickly							
3	It was easy to distinguish the value I required from other values							
4	The interface contained only information relevant to the task							
5	All the information I required was presented in the same way, according to my expectations							
6	My attention was directed towards the information I required							
7	The information was easy to read							
8	The information I required was understandable and unambiguous							
9	The interface design enabled me to complete the task efficiently and effectively.							

Any comments?