<table>
<thead>
<tr>
<th>Title</th>
<th>A study on human error, safety culture and risk in radiation oncology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author(s)</td>
<td>Sands, Gordon</td>
</tr>
<tr>
<td>Publication</td>
<td>2017-05-12</td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Item record</td>
<td><a href="http://hdl.handle.net/10379/6515">http://hdl.handle.net/10379/6515</a></td>
</tr>
</tbody>
</table>

Some rights reserved. For more information, please see the item record link above.
A Study on Human Error, Safety Culture and Risk in Radiation Oncology

Gordon Sands

School of Physics, College of Science and School of Industrial Engineering, College of Engineering
National University of Ireland, Galway

A thesis submitted for the degree of

Doctor of Philosophy

2017
Abstract

In 2010 the New York Times wrote a series of articles on different radiation procedures including radiotherapy treatments. These articles highlighted a number of incidents that have occurred in the course of radiotherapy treatment and brought these incidents into the limelight.

A review of the literature indicates that safety is becoming an increasingly high priority in radiotherapy. However, there are gaps in the literature. Locally recorded incident rates are reported by individual hospitals, but there is no study looking at reported incident rates in multiple hospitals.

A number of high profile incidents highlighted the contribution of patient safety culture to incidents. This is notable with the Orthovoltage incident in Ottawa, Canada and the incident in Epinal, France.

In the study described in this thesis recorded “incidents” were evaluated, with emphasis on where the incident initiated, the type of incident that occurred and the human influence on the event. Radiotherapy departments across Ireland were asked to submit their locally recorded incidents and near-misses. The department setup, including the staffing numbers and patient numbers, were analysed to look at the variation between departments.

Patient safety culture, in the context of this thesis, refers to the attitudes, values and actions of staff members to different aspects of patient safety. The patient safety culture was evaluated in multiple radiotherapy departments using the Agency for Healthcare Research and Quality, Hospital Survey of Patient Safety Culture. Twelve metrics of patient safety culture were examined. The results of the overall patient safety grade were compared to the reported incident rates.
There is an indication that there is a relationship between incident rates and safety culture. However the low number of radiotherapy sites examined and the variation in procedures for identifying incidents means it is not possible to statistically prove this. To prove this with a statistical power of 0.8, a sample size of 85 is required. The variations in how departments identify incidents also creates a level of uncertainty in reference to incident rates.

The results from the review of incidents indicated that the majority of incidents could be attributed to human error. A proactive risk assessment model was developed using process mapping, probabilistic risk assessment and human error analysis to evaluate process safety. The human error probability was calculated using the Standardized Plant Analysis Risk Model Human reliability analysis (SPAR-H). Error mode block diagrams were developed and the fault tree analysis techniques were used to evaluate the effects of errors on the other tasks in the process. For a standard prostate treatment with ultrasound guided daily setup, the predicted mean incident rate was 0.11. In a situation where the stress of a staff member was rated higher than normal the mean is 0.24. For the head and neck model this is 0.17 and 0.48 respectively.

This thesis successfully evaluates patient safety culture and incident rates in radiotherapy. The proactive risk assessment technique developed as part of this thesis can be used as a template for radiotherapy departments to adhere to recommendations from the AAPM TG-100 and the new EU directive that recommends proactive risk assessment techniques in radiotherapy.
Dedicated to the memory of Prof. Wil van der Putten (RIP).
Will was a fantastic mentor and good friend to me through my Ph.D. His kindness and encouragement got me to the end of my studies. He was a truly good man, that will be sorely missed by all.
This thesis discusses the challenges of delivering radiation in a safe and effective manner. While these challenges are multiple the radiotherapy community has stepped up to ensure safe and accurate delivery. The author of this thesis believes that radiotherapy is a safe and effective treatment for cancer. While incidents do occur and cause devastation to the families that are affected, they are extremely rare.
Acknowledgements

There’s a phenomenal amount of people that deserve acknowledgement for this thesis. First and foremost I would like to thank my supervisors, Prof. Wil van der Putten and Mr. Enda Fallon for their help and guidance. With them this work would not have been possible. I would like to thank all of the Radiotherapy department in Galway University Hospital. Margaret Moore, Sinead Cleary, Daragh McShane, Anyscha Zuchora, Mohammed Alaswad, Triona Brosnan, James Murphy, Louise Fahy, Linda Coleman and ofcourse Dr. Christoph Kleefeld. Their support through this was fantastic. The overall radiotherapy was fantastic as well, with a special mention to Edel O’Toole and Cormac Small for their help with the modelling. A special shout out has to go to Caroline Lannon, who has been following me since the undergrad and has always been a great help!!!

I would also like to thank Catherine Emerson for her help. She gave me a lot of support and guidance when I needed it. The No. 44s. The Barnaclese, K-dog and Sweet Dee. All the guys at No. 14, some of my closest friends!! All the nights out and nights in were greatly needed through the last 5 years. A special mention also to the breakfast ocelots Keith, Mary, Laura and Rory!!

I would also like to thank all the guys in the physics department in NUI Galway. It was a phenomenal department to work with. And finally I want to thank my family for there help. In particular my parents for all their support through out this.
Contents

List of Figures xi

List of Tables xv

1 Introduction 1

1.1 Background ............................................. 1

1.1.1 Radiotherapy ........................................ 1

1.1.2 History of Misuse of Radiotherapy and Radiation in Health-care ........................................ 3

1.1.3 Radiotherapy Process ................................. 4

1.1.4 Recent Advances ....................................... 5

1.1.4.1 Image Guided RadioTherapy (IGRT) .................. 6

1.1.4.2 Intensity Modulated RadioTherapy (IMRT) .......... 8

1.1.4.3 Stereotactic RadioSurgery (SRS) and Stereotactic Body Radiotherapy (SBRT) ......................... 8

1.2 Safety in healthcare ..................................... 10

1.2.1 Incident Reporting ................................. 10

1.2.2 Safety Culture ................................... 11

1.3 Risk .......................................................... 17

1.3.1 Probability ........................................ 17

1.3.1.1 Human Error Probability (HEP) .................. 19

1.3.2 Severity ............................................ 22

1.4 Tools for Reducing Risk ............................... 25

1.4.1 Proactive Tools ..................................... 25

1.4.1.1 Failure Mode and Effects Analysis ............... 25
3.3.2 Results by Metric and Statistical Values .................................. 121
  3.3.2.1 Handoffs and Transitions ............................................. 121
  3.3.2.2 Teamwork .............................................................. 121
  3.3.2.3 Staffing ................................................................. 123
  3.3.2.4 Supervisor and Management Support, Expectations and Actions ........ 125
  3.3.2.5 Communication Openness ......................................... 127
  3.3.2.6 Feedback and response to error .................................... 129
  3.3.2.7 Nonpunitive Response to Error .................................... 131
  3.3.2.8 Frequency of Events Reported ................................... 133
  3.3.2.9 Organisational Learning .......................................... 134
  3.3.3 Overall Perceptions and Patient Safety Grade ......................... 135
  3.3.4 Overall Results for Future Benchmarking ............................ 137
  3.3.5 Statistical Analysis ..................................................... 139
  3.3.6 Comparison with the American Association of Physicist in Medicine Safety Profile Assessment ........ 141
    3.3.6.1 Examination of the metrics of patient safety culture 141
    3.3.6.2 Level of Representative of Staff Opinion ................ 141
    3.3.6.3 Ease of Use ...................................................... 142
    3.3.6.4 Suitability for Radiotherapy ................................ 142
  3.4 Discussion ............................................................................. 143

4 Failure Mode and Probabilistic Risk Assessment Model for Radiotherapy 145
  4.1 Motivation For Model ......................................................... 145
  4.2 Methodology ................................................................. 147
    4.2.1 List Tasks in the Process ............................................ 147
    4.2.2 Analyse the Tasks ...................................................... 147
    4.2.3 Human Error Probability Estimation (Application of SPAR-H) ........ 149
      4.2.3.1 Nominal Values ................................................ 150
      4.2.3.2 Performance Shaping Factors ............................... 151
      4.2.3.3 Apply Human Error Probability Density Functions 155
## CONTENTS

4.2.3.4 Probability Density Functions ........................................ 158  
4.2.4 Error Mode Pathways (Reliability Block Diagrams) .................. 160  
4.2.5 Boolean Operations .......................................................... 160  
4.2.6 Analyse the Consequence in the Potential Incident Reaches the Patient ......................................................... 163  
4.2.7 Practical Implementation of the Model (Coding) ....................... 164  
4.3 Results .................................................................................. 171  
4.3.1 Initial Results ..................................................................... 171  
4.3.2 3-D Conformal Prostate Treatment with Image Guided Verification ................................................................. 174  
4.3.2.1 Task and Error Analysis .................................................. 174  
4.3.2.2 Consequences ............................................................... 184  
4.3.3 Head & Neck IMRT with LAN Field .................................... 198  
4.3.3.1 Summary of Probability Results ...................................... 198  
4.3.3.2 Summary of Severity Results .......................................... 198  
4.3.3.3 Comparison with Recorded Incident Rates ....................... 201  
4.3.4 Comparison with Failure Mode and Effects Analysis .............. 204  
4.3.4.1 Results .......................................................................... 204  
4.3.4.2 Ease of Use ...................................................................... 206  
4.3.4.3 Subjective Nature ............................................................ 207  
4.3.4.4 Suitability for Radiotherapy ............................................ 207  
4.3.4.5 Mathematical Accuracy .................................................. 208  
4.4 Discussion .............................................................................. 208  

5 Conclusions ............................................................................. 211  
5.1 Human Factors Influence on Incident (HFACS-RT) .................... 212  
5.2 Incident Investigation ............................................................. 212  
5.3 Patient Safety Culture ............................................................. 213  
5.4 Model for Risk Assessment ...................................................... 213  
5.5 Future Work ........................................................................... 214  
5.5.1 Patient Safety Culture and Incident Rates ......................... 214  
5.5.1.1 Auditing ........................................................................ 214  
5.5.1.2 Development of Safety Tools .......................................... 214
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5.2 Modelling</td>
<td>214</td>
</tr>
<tr>
<td>5.5.2.1 Further Adaptation</td>
<td>214</td>
</tr>
<tr>
<td>5.5.2.2 Addressing Model Limitations</td>
<td>215</td>
</tr>
<tr>
<td>5.5.2.3 Software Solution Package</td>
<td>215</td>
</tr>
<tr>
<td>Bibliography</td>
<td>217</td>
</tr>
<tr>
<td>A Study Protocol</td>
<td>225</td>
</tr>
<tr>
<td>B Ethics Forms</td>
<td>231</td>
</tr>
<tr>
<td>C Patient Safety Culture Survey</td>
<td>249</td>
</tr>
<tr>
<td>D Patient Safety Culture Survey Leaflet</td>
<td>255</td>
</tr>
<tr>
<td>E Identified Tasks and Analysis for Prostate Treatment</td>
<td>259</td>
</tr>
<tr>
<td>F Error Mode Pathways for Prostate Treatment</td>
<td>267</td>
</tr>
</tbody>
</table>
## List of Figures

1.1 Radiobiological Tissue Response ........................................... 2
1.2 AAPM Radiotherapy Process .................................................. 6
1.3 Clinical Target Volume Definitions ........................................ 7
1.4 Patient Safety Indicators vs Patient Safety Culture .................. 14
1.5 Ratings of teamwork in aviation, surgery, anaesthesia, and between surgery and anaesthesia ............................................. 15
1.6 Macro Level Flow Diagram ...................................................... 29
1.7 Example of an Ishikawa Diagram ............................................ 31
1.8 Tools for risk reduction .......................................................... 33
1.9 Discipline detecting errors ...................................................... 39
1.10 Risk Assessment Tools Taken from General guidelines on risk management in external beam radiotherapy ............................ 43
1.11 Hierarchy of Short Term Incident Learning ............................... 44
2.1 Incident Nature Flowchart ..................................................... 55
2.2 Incident Severity including Adaptation from Ford et al ............... 58
2.3 Incident Type Classification ................................................... 59
2.4 The adapted version of the Human Factors Analysis and Classification System for Radiotherapy (HFACS-RT) .......................... 63
2.5 Summary of Treatments Per Site ............................................. 74
2.6 Number of Physicists per Linac .............................................. 75
2.7 Number of Patients per Physicist .......................................... 75
2.8 Number of Patients per Radiation Therapist ........................... 76
2.9 Number of Patients per Dosimetrist ...................................... 76
2.10 Number of Patients per Nurse .............................................. 77
LIST OF FIGURES

2.11 Number of Patients per Physician ........................................ 78
2.12 Scale for correcting incident rates ....................................... 79
2.13 Type of Dosimetric Deviation ............................................. 82
2.14 Dosimetric Severity .......................................................... 83
2.15 Type of Incident .............................................................. 84
2.16 Area of Origin ................................................................. 85
2.17 Area of Discovery ............................................................. 86
2.18 HFACS-RT Classification ................................................... 87
2.19 Type of Potential Dosimetric Deviation ................................. 89
2.20 Potential Dosimetric Severity ............................................... 90
2.21 Type of Potential Incident .................................................. 91
2.22 Area of Origin for Potential Incident ..................................... 92
2.23 Area of Discovery for Potential Incident ............................... 93
2.24 HFACS-RT Classification for Potential Incident ...................... 94
3.1 Explanation for charts ....................................................... 112
3.2 Explanation for tables ....................................................... 113
3.3 Legend for Charts ............................................................ 121
3.4 Handoffs and Transitions .................................................... 122
3.5 Teamwork Across Units ...................................................... 124
3.6 Teamwork within Units ...................................................... 125
3.7 Staffing .......................................................................... 126
3.8 Supervisor Expectations ..................................................... 127
3.9 Management Support ....................................................... 128
3.10 Communication Openness ................................................... 129
3.11 Feedback about Error ........................................................ 131
3.12 Non-Punitve Response to Error ........................................... 132
3.13 Frequency of Events Reported ............................................ 133
3.14 Organisational Learning ..................................................... 135
3.15 Overall Perceptions .......................................................... 136
3.16 Patient Safety Grade .......................................................... 137
3.17 Overall Results By Individual Respondent ............................. 138
3.18 Responses Averaged By centre ............................................ 139
3.19 Patient Safety Grade and Incident Rates ........................................ 140
4.1 Summary of Methodology Used ......................................................... 148
4.2 Graphical Representation of Composite Performance Shaping Factors Equation .......................................................... 156
4.3 Relationship between Human Error Probability and Alpha Values .... 159
4.4 Summary of the Human Error Probability Estimation Method ........ 161
4.5 Legend for Error Mode Pathways Diagrams ....................................... 162
4.6 Sample Error Mode Pathway, Block Diagram ................................... 162
4.7 Probability Density Function tA ......................................................... 167
4.8 Probability Density Function tB ........................................................ 168
4.9 This represents the block diagram showing the pathway for an incident reaching a patient in the OR configuration ......................... 168
4.10 This represents the block diagram showing the pathway for an incident reaching a patient in the AND configuration ......................... 168
4.11 Probability Density Function PAand for tA,tB ................................. 169
4.12 Probability Density Function POR for tA,tB ...................................... 170
4.13 Probability Density Function of tC/tD (blue) and the Probability Density Function of tC OR tD (purple) ........................................ 171
4.14 Example of an Error Mode Pathway ............................................... 172
4.15 Incident Type Colour Code ............................................................ 173
4.16 Probability Density Function of An Error Occurring in the Patient Assessment Section reaching the patient ......................................... 176
4.17 Probability Density Function of an Error Occurring at Imaging ....... 177
4.18 Probability Density Function of an Error Occurring at Planning ...... 179
4.19 Probability Density Function of an Error Occurring at Pre Treatment Stage .............................................................. 181
4.20 Probability Density Function of an Error Occurring at Treatment Stage .............................................................................. 188
4.21 Probability Density Function of an Error Occurring Across the Whole Process ............................................................... 183
4.22 Estimated incident rate per 100 patients broken down by incident type; prostate treatment ...................................................... 196
LIST OF FIGURES

4.23 Estimated incident rate per 100 patients broken down by incident type; prostate treatment ........................................ 197
4.24 Estimated incident rate per 100 patients broken down by incident type; Head and Neck Treatment ............................ 199
4.25 Estimated incident rate per 100 patients broken down by incident type; Head and Neck Treatment ............................ 200
4.26 Comparison Between Prostate Predicted Rates and Actual Rates (All Sites) .......................................................... 202
4.27 Comparison Between Head and Neck Predicted Rates and Actual Rates (All Sites) ...................................................... 203
4.28 Comparison of Probabilistic Risk Assessment Model and Failure Mode and Effects Analysis ......................................... 204
4.29 Risk Priority Numbers as Defined by AAPM TG-100 ............................ 205
4.30 Risk Priority Numbers for Prostate Treatment Case .................. 205
4.31 Risk Priority Numbers for Head and Neck Treatment Case ....... 206
List of Tables

2.1 Incident Rates per Site ........................................ 81
2.2 Near-Miss Rates per Site ..................................... 88

3.1 Site 1 Summary of Metrics .................................... 114
3.2 Site 2 Summary of Metrics .................................... 115
3.3 Site 3 Summary of Metrics .................................... 116
3.4 Site 4 Summary of Metrics .................................... 117
3.5 Site 5 Summary of Metrics .................................... 118
3.6 Site 6 Summary of Metrics .................................... 119
3.7 Site 7 Summary of Metrics .................................... 120
3.8 Statistics Handoffs and Transitions ......................... 122
3.9 Statistics of Teamwork Across Units ....................... 124
3.10 Statistics of Teamwork Within Units ...................... 124
3.11 Statistics of Staffing ......................................... 126
3.12 Statistics of Supervisor Expectations ..................... 128
3.13 Statistics of Management Support ......................... 128
3.14 Statistics of Communication Openness .................... 130
3.15 Statistics of Feedback About Error ....................... 130
3.16 Statistics of Non Punitive Response ....................... 132
3.17 Frequency of Events Reported .............................. 134
3.18 Statistics of Organisational Learning .................... 134
3.19 Statistics of Overall Perceptions .......................... 136
3.20 Patient Safety Grade Statistics ............................. 137

4.1 SPAR-H PSF Multipliers, reproduced from(1) ............... 154
### LIST OF TABLES

4.2 Probability and Severity of Errors Initiated at Patient Assessment 175  
4.3 Probability and Severity of Errors Initiated at Patient Imaging 178  
4.4 Probability and Severity of Errors Initiated at Treatment Planning 180  
4.5 Probability and Severity of Errors Initiated at Pre Treatment Stage 181  
4.6 Probability and Severity of Errors Initiated at Treatment Stage 182
Declaration

I herewith declare that I have produced this thesis without the prohibited assistance of third parties and without making use of aids other than those specified; notions taken over directly or indirectly from other sources have been identified as such. This paper has not previously been presented in identical or similar form to any other examination board.

The thesis work was conducted from January 2011 to March 2016 under the supervision of the late Prof. Wil van der Putten at the National University of Ireland, Galway. It was co-supervised by Mr. Enda Fallon, senior lecturer in industrial engineering.

Gordon Sands
GLOSSARY

AAPM - American Association of Physicists in Medicine
ACSNII - Advisory Committee on Safety of Nuclear Installations
AHRQ - Agency for Healthcare Research and Quality
ASRS - Aviation Safety Reporting System
ASTRO - American Society for Radiation Oncology
ATHEANA - A Technique for Human Event Analysis
BIR - British Institute of Radiology
CNI - Constrained NonInformative
CT - Computed Tomography
CTV - Clinical Target Volume
DVH - Dose Volume Histogram
EPID - Electronic Portal Imaging Device
ESTRO - European Society for Radiotherapy and Oncology
EUD - Equivalent Uniform Dose
FAA - Federal Aviation Administration
FMEA - Failure Mode and Effects Analysis
FTA - Fault Tree Analysis
GTV - Gross Tumour Volume
GUI - Graphical User Interface
HDR - High Dose Rate
HEART - Human Error Assessment and Reduction Technique
HEP - Human Error Probability
HFACS - Human Factors Analysis and Classification System
HFACS-RT - Human Factors Analysis and Classification System for RadioTherapy
HMI - Human Machine Interface
HRA - Human Reliability Assessment
HSE - Health Service Executive
HSOPSC - Hospital Survey on Patient Safety Culture
HU - Hounsfield Units
IAEA - International Atomic Energy Agency
ICAM - Integrated Computer Aided Manufacturing
IDEFO - Icam DEFinition for Function Modeling
GLOSSARY

IGRT - Image Guided RadioTherapy
IMRT - Intensity Modulated RadioTherapy
IPEM - Institute of Physicist and Engineers in Medicine
KV - Kilovoltage
LAN - Low Anterior Neck
LDR - Low Dose Rate
MDR - Medium Dose Rate
MLC - Multi Leaf Collimator
MU - Monitor Units
MV - Megavoltage
NASA - National Aeronautics and Space Administration
NCHD - Non Consultant Hospital Doctor
NHEP - Nominal Human Error Probability
NHS - National Health Service
NRC - Nuclear Regulatory Commision
NTCP - Normal Tissue Complication Probability
OAR - Organ At Risk
PDF - Probability Density Function
PDR - Pulsed Dose Rate
PEM - Psychological Error Mechanism
PIF - Performance Influencing Factors
PRA - Probabilistic Risk Assessment
PSC - Patient Safety Culture
PSF - Performance Shaping Factor
PSI - Patient Safety Indicators
PTV - Planning Target Volume
QA - Quality Assurance
QART - Quality Assurance RadioTherapy
QC - Quality Control
QM - Quality Management
R and V - Record and Verify
RCA - Root Cause Analysis
RI - Reportable Incident
GLOSSARY

RO-ILS - Radiation Oncology Information Learning System
ROsis - Radiation Oncology Safety Information System
RT - RadioTherapy/Radiation Therapist
SABR - Stereotactic Ablative Radiotherapy
SAFRON - Safety in Radiation Oncology
SHELL - Software, Hardware, Environment, Livewire, Livewire
SLIM-MAUD - Success Likelihood Index Method- Multi-Attribute Utility Decomposition
SPA - Safety Profile Assessment (tool)
SPAR-H - Standardized Plant Analysis Risk-Human Reliability Analysis
SRS - Stereotactic RadioSurgery
TCP - Tumour Control Probability
TG - Task Group
THERP - Technique for Human Error Rate Prediction
TPS - Treatment Planning System
VMAT - VoluMated Arc Therapy
WHO - World Health Organisation
1

Introduction

1.1 Background

This chapter introduces the literature that discusses safety in radiotherapy, safety in healthcare and current reports addressing safety issues. This information identified gaps in the literature which are addressed in this research.

1.1.1 Radiotherapy

Radiotherapy works on the radiobiological principle that the cancer cells being treated are more sensitive to radiation damage than healthy tissue. The most common type of radiotherapy is delivered using a linear accelerator (Linac). Megavoltage treatments use high energy photons that penetrate deep into the tissue of the patient. Orthovoltage units can also be used to treat patients using an external x-ray source. Orthovoltage units use lower energy x-rays to treat superficial tumours. Electrons can be used for superficial to medium depth tumours. Electrons are directly ionising while photons are indirectly ionising[2].

The objective of radiotherapy is to maximise the Tumour Control Probability (TCP) while minimising the Normal Tissue Complication Probability (NTCP). The radiobiological response is based on the $\alpha/\beta$ ratio of the tissue. Tumours generally have a higher $\alpha/\beta$ ratio than healthy tissue. The therapeutic ratio is the ratio of the normal tissue tolerance compared to the tumour control dose[3].
The dose to the patient is normally delivered across a number of fractions to give the healthy tissue time to repair. This is demonstrated in figure 1.1.

**Figure 1.1:** Radiobiological Tissue Response. *This refers to how the tissue reacts to the dose of radiation. [Reproduced with permission from Zhang et al [4]]*

External photon beam is the most common type of radiotherapy. Electrons are accelerated to high velocities towards a tungsten target. As the electrons hit the target, bremsstrahlung occurs producing photons. These photons have an energy of between 4MeV up to 18MeV depending on the linear accelerator and the treatment type. This allows the photons to penetrate deeper into the patient.

Brachytherapy works on the same principle but the radiation is delivered from within the patient. Brachytherapy is divided into four different types depending on the dose rate of delivery.

Low dose rate (LDR) is the treatment where the radioactive sources are left in the tissue for a long period of time to decay. The rate is less than 2Gy/hr and is commonly used for treating prostate cancer and oral carcinomas[5].

Medium dose rate (MDR) refers to a treatment where the dose rate is 2Gy/hr to 12Gy/hr. It is commonly used in Gynaecological cancers as an alternative to HDR[5].
1.1 Background

High dose rate (HDR) refers to a treatment where the dose is delivered at a rate greater than 12Gy/hr. This is commonly used for gynaecological cancer, breast cancer and prostate\(^5\).

Pulsed dose rate (PDR) is used to simulate a low dose rate treatment by inserting a HDR source for short periods, typically once an hour. This is used for gynaecological treatments and head and neck treatments\(^5\).

There are a number of different methods of delivering the treatment to the patient.

Interstitial brachytherapy is where the source is in direct contact with the tissue. An example of this is LDR prostate brachytherapy where radioactive seeds are inserted directly into the prostate via needle placement\(^5\).

In intracavitary the source next to the treatment site in a cavity. An example of this is a cylinder where the source is placed in an applicator which is then inserted into a cavity\(^5\).

Intraluminal involves placing the source into a lumen in the body such as the trachea\(^5\).

For surface brachytherapy the source is placed on the surface of the treatment site. This is mostly used for skin treatments\(^5\).

1.1.2 History of Misuse of Radiotherapy and Radiation in Healthcare

The use of ionising radiation in healthcare began as a diagnostic tool in 1895 when Roentgen developed the x-ray machine. Roentgen rays were quickly used in medicine. Applications ranged from medical diagnosis to the treatment of illnesses (including cancer) and non-medical purposes\(^6\).

The period following this saw an international rise in the use (or misuse) of radiation. Radium based drinks became common place\(^7\) and x-rays were being used in shoe stores to ensure that shoes fitted correctly\(^8\). The radium based drinks, which contained 74kBq of radium, were used as cures for hypertension, rheumatic diseases and metabolic disorders\(^9\). The dangers of radiation
1. INTRODUCTION

received a lot of media attention when a well-known sportsman, Eben Byers, died of radiation poisoning as a result of drinking too many radiation based drinks(10).

The first documented legal case of alleged misuse of radiation in Ireland occurred in Queens College Galway. In 1898 the Physics department of the college was producing x-rays in conjunction with the Eastman-Kodak company. Between the years of 1900 and 1902 over 50 radiographs had been taken for local doctors. The case involving the misuse of radiation involved a seven-year-old boy believed to have part of a steel needle lodged in his knee. Initial x-rays did not find this needle and so repeated exposures were taken. The flesh of the knee was damaged from these exposures. Initially a sore developed and this later turned into scar tissue. The legal case found in favour of the defendants however the college discontinued the service and the x-ray apparatus was transferred to the County Infirmary (11).

1.1.3 Radiotherapy Process

In order to ensure the safe delivery of therapeutic radiation in modern healthcare, a systematic process is used to ensure accurate, beneficial and safe delivery.

The radiotherapy process involves a number of steps in order to create and deliver a suitable treatment plan for the patient. Prior to treatment a patient is diagnosed and the physician decides on type and intent.

CT images of the patient are acquired and used to manipulate the radiation beams in a certain way to obtain the most appropriate plan for patients. This treatment planning process makes use of algorithms that predict the behaviour of radiation as it travels through certain tissue densities(2). The radiation beam is modelled based on the measurements made during linear accelerator commissioning. MRI and Ultrasound can be used to in conjunction with the CT images to improve target definition(2).
1.1 Background

After the plan is created the information is sent to the delivery system. The patient is setup on the bed of the linear accelerator. The linear accelerator will deliver the planned radiation to the patient. Throughout the process there are a series of safety barriers and checks designed to ensure safe delivery.

Figure 1.2 describes the radiotherapy process as discussed in AAPM (American Association of Physicists in Medicine) Medical Physics paper [12] for Consensus recommendations for incident learning database structures in radiation oncology. This diagram shows a macroscopic view of the process. Each of these tasks has between 9-21 sub-tasks. These sub-tasks are designed to be generic however some vary from department to department. An example of this is subtask 1.16, insurance assessment, which is not applicable to the Irish public healthcare system.

The brachytherapy process has differences. The imaging, planning, pre-treatment review, delivery and on-treatment quality management is often repeated for each fraction in most departments. In practical terms, there are different levels of surgical invasion for the various types of brachytherapy. Skin flap applicators involve no surgery, while prostate seeds involve anaesthesia and up to 25 needles inserted directly to the prostate through the transperineum.

The radiotherapy process is a multidisciplinary procedure. It requires physicians, radiation therapists, nurses and medical physicists to work together to ensure safe and effective treatment delivery. In this multi-disciplinary environment communication is paramount for effective treatment.

1.1.4 Recent Advances

The target of interest is drawn (contoured) on the CT images. This is known as the clinical target volume (CTV). The planning target volume (PTV) is a func-

\footnotesize{This paper is used widely as a reference for the radiotherapy process throughout this thesis. The process described in this paper will be used as a template for incident analysis and process modelling. The classification process for incidents was adapted for the incident investigation chapter.}
1. INTRODUCTION

Figure 1.2: AAPM Radiotherapy Process [reproduced with permission from Ford et al (12)]

A summary of the elements of target definition can be seen in figure 1.3(13).

CT has increased the ability to target the site of disease more accurately. This has resulted in a decrease in target volumes and a greater awareness of dose being delivered to healthy tissue. This has been complemented by the increased availability and accuracy of calculation algorithms(14). The awareness of the dose to healthy tissue has resulted in the development of Image Guidance RadioTherapy (IGRT) and Intensity Modulated RadioTherapy (IMRT).

1.1.4.1 Image Guided RadioTherapy (IGRT)

Image Guided Radiotherapy is used to locate the tumour, account for inter-fraction organ motion and in some cases intra-fraction organ motion(15) (16).
1.1 Background

Figure 1.3: Clinical Target Volume Definitions [reproduced with permission from Schegel(13)]

Inter-fraction organ motion refers to movement of organs between treatment fractions. Intra-fraction organ motion refers to the movement of organs that occurs during the treatment. Intra-fraction motion is important in areas of the body where there is significant movement during treatment. This occurs most notably around the chest and lung regions. An incomplete list of the image guidance technologies can be seen below.

- Electronic Portal Images
- Cone Beam CT (MV and kV)
- Optical Tracking
- Ultrasound
- Magnetic Resonant Imaging
- Camera Based Technologies

Image guided techniques are used to reduce uncertainties and the field size(17). This reduces the dose to the non target tissue. Timing is critical when imaging tumours prior to treatment. Any delays between imaging and treatment gives the tumour more opportunity to move.
1. INTRODUCTION

1.1.4.2 Intensity Modulated RadioTherapy (IMRT)

This is a form of radiotherapy that involves the creation of number of beams and beamlets in order to conform to tumour sites more accurately\(^1\). This treatment type is useful where the dose to the Organs At Risk (OARs) are beyond tolerance levels. Multi Leaf Collimators (MLCs) create individual fields which are superimposed on each other to create a fluence map which will be delivered to the patient. This treatment type requires more planning expertise, more linear accelerator time and individual plan specific QA\(^2\). The treatment planning techniques are more complex due to the general complexity of the treatment. The delivery itself is more challenging to the machine due to the small segments. Therefore, IMRT QA is done to ensure the machine is capable of delivering the treatment that was planned.

Rotational IMRT techniques such as Varian Rapid\textsuperscript{TM} ARC and Elekta Volumetric Arc Therapy (VMAT\textsuperscript{TM}) are the next generation of IMRT treatment. In these techniques the radiation beam remains on while the field size, dose rate and gantry angle change. This has the advantage of speeding up the treatment process and allowing infinite gantry angles for treatment. The volumetric techniques produce a low dose painting effect due to the unlimited angles of radiation entry\(^{18}\). Low dose painting is the effect where a larger volume of the patient receives more low doses of radiation.

1.1.4.3 Stereotactic RadioSurgery (SRS) and Stereotactic Body Radiotherapy (SBRT)

SRS uses non-coplanar beams to deliver a high dose to a small organ area in the brain. These are generally small fields. The high doses used in stereotactic treatments (up to 100Gy in a single fraction) require precise tumour localisation and dose delivery. Stabilisation devices are used to ensure the geometrical accuracy

\(^1\)In the past blocks could be used to create IMRT fields. These blocks were moulded into the shape of the fluence map and placed in the linear accelerator head to attenuate the beam appropriately.
of the treatment. This technique often uses small field beams\(^\text{2}\).

The technology used to perform this technique has evolved in the last number of years. Modern treatments can also use traditional Linacs but equipment such as Cyberknife and Gammaknife are used for specialist treatments\(^\text{19}\). These refer to trade names of new technologies and are new ways of delivering treatment. The Gammaknife uses a series of Cobalt sources to deliver the radiation. The cyberknife is a small linear accelerator of a robotic arm with many degrees of freedom for movement.

SBRT is similar to SRS, however it refers to delivery of the treatment in more than a single fraction\(^\text{20}\).
1. INTRODUCTION

1.2 Safety in healthcare

Patient safety is receiving more coverage, both professionally and in the media. The report “To Err is Human, building a better healthcare system” (21) highlighted the need for a proactive approach to patient safety culture. This report stated that between 2 and 4% of deaths were due to preventable medical errors (21).

Papers such as Barach and Small (22) discuss what can be learnt from the aviation and other high risk sectors such as the nuclear industry. The Barach and Small paper concluded that adapting the complex reporting systems from non-medical industries should see an improvement in incident learning (22). The application of incident learning in other industries has brought improvements to their safety records, yet it has been slow to be implemented in healthcare (23).

1.2.1 Incident Reporting

Root Cause Analysis (RCA) is a technique of incident investigation that is used to facilitate the identity of factors that have caused incidents (24). A taxonomy of incidents can be used to improve the level of learning and to extrapolate information regarding certain incident types (25).

The National Aeronautics and Space Administration (NASA) Aviation Safety Reporting System (ASRS) offers a template for incident reporting and classification structure that could be adopted to medicine or radiotherapy. ASRS is a voluntary reporting system for reporting events in aviation. It offers a systematic review of all reported non-conformities from aviation and all the recognisable causes for the incidents (26). The anonymity of the system was to encourage reporting of all events without fear of litigation or punishment. It included an analysis system for routine evaluation (27). It was run by NASA as opposed to the Federal Aviation Administration (FAA) to ensure that the role of the regulatory body would not affect reporting levels (28). There have been a number of publications that discussed a comparison between the aviation reporting system and medical reporting systems (29) (30). A paper from The Journal of Law, Medicine
1.2 Safety in healthcare

and Ethics went on to discuss the ethical issues surrounding incident learning and professional liability. The authors commented on the ASRS approach from the 1970s and how that could be applied (31).

A report by the NHS titled *Organisation with a Memory* (32) discussed both the strengths and weaknesses of incident reporting in the NHS. The importance of identifying all the causes of an incident was highlighted in this report. Human error, process and culture were specifically mentioned as causes that should to be identified in incident investigation (32).

The paper by Ford et al proposed a system for incident learning in radiotherapy (12). The paper suggests a structured reporting system and classification system that includes a process map of the radiotherapy system. This process map has limitations. It does not investigate the interaction of steps with each other and includes steps that have no relationship to patient safety, most notably insurance evaluation. It also does not include the interaction of staff, software, hardware and patients which shall be discussed later.

SAFRON, ROSIS and RO-ILS are 3 voluntary reporting structures (33) (34) (35). The correct learning from incidents requires systematic approach to incident investigation. This will be discussed later in this chapter.

1.2.2 Safety Culture

For the purpose of this project the definition is taken from an article written on safety culture assessment. This was adapted from the Nuclear Advisory Commissions definition (36).

“The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and
1. INTRODUCTION

Proficiency of an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.” (taken directly from the Nuclear Advisory Commission (36))

Safety culture has been cited as a contributing factor for a number of incidents. The Piper Alpha disaster[1] Chernobyl[2] and the Clapham junction accident[3] all have safety culture cited as a contributing factor to the events[37]. These events resulted in research into how to define and measure safety culture. In a review paper of safety culture, it has been said multilevel analyses are needed to measure culture[37].

The definition of safety culture cited previously is used by the Agency for Healthcare Research and Quality (AHRQ). This agency was setup following the report To Err is Human, Building a Safer Health System. This publication suggested that 44-88,000 people died in America every year due to medical errors. The publication went on to say that:(21)

“Healthcare organizations must develop a “culture of safety” such that their workforce and processes are focused on improving the reliability and safety of care for patients.” (taken directly from To Err is Human, Building a Safer Health System[21])

A study by Colla et al investigated the different surveys used for investigating patient safety culture in healthcare. This study compared 9 different culture surveys. This paper commented on the fact that the different surveys on patient safety culture vary in terms of characteristics, dimensions covered and its overall use. The advantage of using these tools is that it gives all staff members an opportunity to voice concerns[38].

The research for this thesis will concentrate on the Agency for Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC). This survey has been widely used, measures a range of metrics and is suitable for general

---

[1] A fire on an offshore oil rig
[2] A large scale nuclear power accident
use(38). The 12 metrics of patient safety culture used in this survey are discussed in greater detail in chapter 3.

Mardon et al explored the relationship between hospital patient safety culture and adverse events. The relationship was in the expected direction with hospitals demonstrating a positive patient safety culture demonstrating a lower number of adverse events or complications. This particular study took place across 179 hospitals that had taken part in the AHRQ Hospital Survey on Patient Safety Culture (HSOPS or HSOPSC). The study concluded that a positive attitude towards patient safety culture led to a decrease in adverse events(39). The study used “Patient Safety Indicators (PSI)” to compare patient safety culture (PSC) with hospital complications. 20 PSIs were developed to measure hospital complications(40). Only 8 of the 20 PSI metrics were used in this study. The 8 chosen were described by the authors as being “the more valid measures of patient safety”. These tended to be associated with post-operative complications. The relationship between the PSIs and the HSOPS (HSOPSC) can be seen in the figure 1.4. The largest limitation with this research is that the hospitals taking part in the survey naturally have a positive attitude to safety culture. This introduces a positive bias to the results. (39)

Singer et al did a comparison of patient safety culture and patient safety indicators. This study came to a similar conclusion as Mardon but also made the observation that the front-line staff perception on patient safety culture had a greater influence on patient safety indicators than the patient safety culture perceived by managers(41).

A study by Wang et al performed a questionnaire based study designed to look in depth at the relationship between the PSC and adverse events. These hospitals were all described as level-3, (high tech with 1000-1500 beds) hospitals. This study used the HSOPSC to analyse the patient safety culture and a questionnaire to collect data on the adverse events. A total of 463 participants filled out the surveys. This study concluded that different metrics from the HSOPSC are greater indicators for adverse events. For example, team work is a predictor
1. INTRODUCTION

Figure 1.4: Patient Safety Indicators vs Patient Safety Culture. The y axis represents the number of PSIs that were identified. The x-axis represents the patient safety culture results. From this graph it can be seen that as safety culture increases, the number of PSIs decreases [reproduced with permissions from Mardon et al (39)]

for surgical wound infections(42).

Sexton compared attitudes about stress, teamwork and errors in the airline industry and healthcare. The study demonstrated that among pilots 97% of staff rejected a steep hierarchical system. The hierarchy system, in the context of this study, meant that junior members of a team should be able to question the decisions of senior members. The ICU teams had a similar response of 94%. However only 55% of surgical consultants rejected it. This means 45% of consultants accept a hierarchical system, which could indicate that they would be unlikely to accept concerns from junior staff members. The results on the perception of teamwork can be seen in figure 1.5(43).

The Towards Safer Radiotherapy report specifies the importance of culture on safety. A key recommendation from the report is(44):

“The delivery of accurate treatment is the responsibility of all staff
1.2 Safety in healthcare

Figure 1.5: Ratings of teamwork in aviation, surgery, anaesthesia, and between surgery and anaesthesia. This was assessed through questionnaires. The colour code represents the observed teamwork levels. It can be seen from this graph that the teamwork between anaesthesia and surgery had the lowest observed teamwork [reproduced with permission from Sexton (43)]

and each department must develop a safety-conscious culture” (taken directly from (44))

In radiotherapy a number of reports highlight patient safety culture as a contributing factor to incidents. The IAEA report on the overexposure of patients in San Jose, Costa Rica recommended (45):

“A safety culture should be established and fostered, and education and training provided” (taken directly from (45))

All of the above implies that patient safety culture will influence incident rates.

In radiotherapy the safety profile assessment tool is used to assess the safety and quality in radiotherapy departments. This tool was developed by the AAPM and is based around four main sections, including culture, quality management, managing change and innovation and clinical performance. It involves filling out a questionnaire by a team made up of different disciplines. The safety culture element of the assessment is based on the parts of the AHRQs PSC survey. Despite using elements of the AHRQ survey, which recommends a 50% response
rate for their survey\cite{46}, the safety profile assessment recommends a multidisciplinary team to complete the questionnaire\cite{47}. This would indicate that the developers of this tool don’t think that a 50% response rate is required for the AHRQ HSOPSC elements of the assessment.
1.3 Risk

Risk is by definition, refers to exposure to any danger. In respect to this research, it refers to the potential dangers that could affect the quality of treatment. Risk is calculated using the following equation.

\[ R = P \times S \]  

Where:
\[
R = \text{Risk} \\
P = \text{Probability} \\
S = \text{Severity}
\]

1.3.1 Probability

In simple terms probability refers to the likelihood of an event occurring. This will be discussed in some detail in section 1.4.1.2 (Fault Tree Analysis). The simplest example of this is rolling a fair die. The probability of a 1 on the die occurring following a roll is 1 in 6. Following that roll the probability of a second 1 is 1 in 6. However, prior to the first roll being made, the probability of two 1’s occurring following two rolls is 1 in 36\(^{18}\).

This mathematically can be represented as follows.

Event a

\[ P(a) = \frac{1}{6} \]

Probability of event b having event 1 already occur.

\[ P(b) = \frac{1}{6} \]

Probability of event a and b occurring.

\[ P(a \cap b) = P(a) \times P(b) = \frac{1}{36} \]
1. INTRODUCTION

Probability of event a or b occurring

\[ P(a \cup b) = P(a) + P(b) - P(a) \times P(b) = 0.306 \]

These equations are used in Fault Tree Analysis (FTA) boolean operations seen in equations 1.12, 1.13 and 1.14.

The dice example given above refers to a discrete probability distribution. There are specific values that represent the probability for event occurring. Continuous distribution functions represent probability distributions that can potentially have an infinite number of values.

There are 2 main approaches to probability. \(^{49}\)

**Subjective probability** is less of a science and more of a belief. Just because a person believes that there is a 90% chance of something occurring does not make it a 90% chance of happening. \(^{50}\) Subjective probability is often used in risk assessment analysis in the absence of further data.

**Frequentist probability** refers to the proportion of times an event will occur across numerous opportunities. The probability of an event occurring is based on the number of times it occurs across n times. \(^{51}\) It is represented by the equation:

\[ P(x) \approx \frac{n_x}{n_t} \]  \hspace{1cm} (1.2)

Where:

- P(x) is the probability of the event occurring
- \( n_x \) is the number of times that the event occurred
- \( n_t \) is the number of times the trial is performed

The use of statistics to calculate probabilities is well-established but are often confused as being identical. Statistics are defined as: “the study of the collection, organization, analysis, interpretation and presentation measurements and outcome data.” \(^{52}\)
While probability is defined as: “is a measure or estimation of how likely it is that something will happen or that a statement is true” (53).

Statistics can be used to estimate probability but must be done with caution. There are many variables that can change throughout time including staffing levels, safety culture, procedures etc. This will introduce uncertainty to the results.

1.3.1.1 Human Error Probability (HEP)

The probability of a human error occurring in any task is going to be influenced by internal and external parameters. Performance Shaping Factors (PSFs) are factors that will influence human error probability. They include (but are not limited to) written procedures, equipment design and psychological stresses (54). There are correlations that suggest workload and patient safety culture could shape performance. Psychological Error Mechanisms (PEMs) refer to the actual "state of mind" of the operator when an error occurs. The PSFs can have an influence on PEMs (55).

In a paper discussing human error probabilities in German nuclear power plants the uncertainty of HEP is discussed by Preischi et al (56). Preischi et al discusses the uncertainty of such models quoting the Bayesian definition of probability being degree of belief.

The Preischi paper quotes another source of HEP representation. Swain and Guttman suggested that the probability of human error and associated uncertainty is best represented using a log-normal distribution. The report discussed a number of reasons for this representation of the uncertainty.

“The performance of skilled persons tend to bunch towards the low HEPs [...] it is appropriate, for PRA purposes, to select a non-symmetrical distribution” (taken directly from (57)).

The report goes on to say,
“We have selected the lognormal distribution rather than the Beta, Gamma, Weibull, or other non symmetric distributions because the lognormal distribution appears to provide an adequate fit to human performance data and is computationally tractable” (taken directly from (57))

In contrast the paper by Preischi (56) uses a Beta distribution for representing uncertainty in error probability. The SPAR-H method also uses beta distributions as it has the advantage of being constrained to values between 0 and 1 (1). SPAR-H also employs the constrained noninformative prior that is used to calculate the beta distribution (58) and includes PSFs (1). The constrained non informative prior is a distribution based on a single parameter. This single parameter constrains the distribution. In the SPAR-H application the estimated human error probability is used to constrain the distribution (58). This will be discussed in further in chapter 4.

The difficulty lies in deciding which uncertainty distribution best represents human behaviour and more specifically human error probability.

The U.S. nuclear regulatory commission produced a document discussing Bayesian Methods in HRA (59). This document discusses quantitative methods for human error prediction. The first method discussed is a direct estimation. This can be seen in the following equation.

\[ p = \frac{N_E}{N_O} \]  \hspace{1cm} (1.3)

Where:
\( N_E \) = Number of errors observed
\( N_O \) = Number of observations

\(^1\)From this point on the term probability distribution will be referred to as an uncertainty distribution. This is to prevent confusion with language when discussing the probability density functions (uncertainty distributions) and probability estimations.
This equation is the same as equation 1.2 used to describe frequentist probability.

The second model presented in this document is known as A Technique for Human Event ANAlysis (ATHEANA) and is represented by the following equation.

\[ p = \sum P(\text{response}|\text{condition}_i)P(\text{condition } i) \]  

(1.4)

This equation is representative of a conditional probability.

The third example is a representation of probabilities with respect to performance shaping factors. This is known as the Success Likelihood Index Methodology / Multi-Attribute Utility Decomposition (SLIM-MAUD) method. It is represented by the following equation:

\[ p = f(PIF) \]  

(1.5)

Where:
- p is the probability of error
- f is the “function” and can be calculated by tables, judgement or mathematical analysis
- PIF are performance influencing factors or performance shaping factors

In a document written by the Nordic Nuclear Commission the argument:

"The quest for perfection in HRA sometimes becomes its worst enemy. It is easy to get sidetracked trying to make things perfect rather than making them reasonable.”(taken directly from [60])

The NRC created a document that discussed good practice for HRA. It stipulates a number of conditions including a multidisciplinary team, performing field observations and reviewing pre indicators for error[61].
1. INTRODUCTION

In a book edited by Charter and Oakford the idea of uncertainty in human cognition\(^1\) is addressed using Bayesian techniques\(^6\). It is important when representing uncertainty that it is similar to representing the probability.

The book goes on to discuss the challenges of the probabilistic approach. This is going to be an important part of this study as it will demonstrate the limitations of any model that applies Bayesian methods in cognition process. A number of papers have shown that human decision-making deviates from Bayesian decision theory\(^6\).

This concept of subjective probability distribution is also discussed by Apostolakis in an article titled *The Concept of Probability in Safety Assessments in Technological Systems* \(^6\). This paper makes an observation on the subjective nature of probabilistic risk assessment stating:

> “Engineers and physical scientists are asked to deal with methods that require considerable use of subjective judgement, and, because they are unaccustomed to such mixing of “objective” facts with “subjective” judgements, they are left with the feeling that the whole exercise lacks scientific rigor” (taken directly from \(^6\))

1.3.2 Severity

Severity is the second part of the risk equation. Dosimetric severity can be used to represent the physical severity of the adverse event. It is mostly represented in terms of mm off target (geometrical miss) or Gy (dose deviation). These will affect the TCP and NTCP.

The second way to represent the severity is to calculate the medical consequence. This type of scale will assess the effect of the adverse event on the patient. This can be difficult to assess prior to the adverse event and is mostly used to classify events after they occur. Intent of treatment, type of disease and health

\(^1\)Definition of cognition (Psychology) the mental act or process by which knowledge is acquired, including perception, intuition, and reasoning\(^6\).
of the patient will all affect the medical consequence to the patient.

There is a relationship between the dosimetric and medical incident scales. This relationship is difficult to calculate, although it is easy to deduce that the higher the dosimetric adverse event, the higher the adverse medical outcome. The radiobiological model used to assess medical outcome will have a large effect on the relationship between the two.

A number of articles discuss severity in radiotherapy. Ford et al\textsuperscript{(12)} classifies them in terms of dosimetric effect and clinical effect. This paper uses a 1-10 scaling system for dosimetric consequence. The paper introduces a second scaling system for clinical consequence. The clinical severity accounts for the differences in target site, technique used and health of the patient. This then recognises the need for different classification other than the technical details to assess the clinical consequence to the patient.

The papers discussed in section 1.5.3 all offer a version of severity classification\textsuperscript{(65, 63, 66, 67, 35)}. In the paper by Bissonnette and Medlam a clinical severity scale of 0-4 was used\textsuperscript{(66)}.

- 0 was a near miss
- 1 a non-clinically significant incident
- 2 requiring medical intervention but no harm
- 3 potential but not immediate harm
- 4 serious patient outcome, dose deviation greater than 25%

In this classification, all but a grade 4 incident were assessed on a clinical classification. The grade 4 included a dosimetric quantity. The classification of all near-misses as 0 creates the illusion that all near misses that are less severe than incidents\textsuperscript{(66)}. A near miss that potentially would have caused a serious patient outcome should be considered more significant than a non-clinically significant incident. Despite this it should be noted that by definition an incident, even a small one, will have an actual clinical consequence (although it could be
1. INTRODUCTION

insignificant) and a near-miss will not.

The paper from M.D. Anderson classified the incidents on a classification system where the type of error was associated with a severity level and a percentage difference in error. This used a 1-4 scale (classification taken directly from paper) (35).

“Level 1 (wrong patient, wrong type of radiation, wrong energy, wrong site, or total dose differing by more than 20% of the prescribed dose)”

“Level 2 (wrong field, wrong localization, wrong timing, total dose differing by more than 10% of the prescribed dose, or other serious event)”

“Level 3 (any other event reaching the patient)”

“Level 4 (near-miss)”
1.4 Tools for Reducing Risk

Risk can be reduced in two ways. Retrospective analysis of incidents can be used to evaluate how incidents occurred in the past and look at ways of preventing the same sequence of events from happening again. Prospective analysis refers to techniques that are used to predict events by analysing the system process and evaluating the associated probability of risk and severity of potential events.

1.4.1 Proactive Tools

There a number of tools for proactive and retrospective risk assessment. These tools have been developed by a number of high risk industries including the Aviation, Nuclear and Chemical industries. Failure mode and effects analysis (FMEA) and fault tree analysis (FTA) are two of the most commonly used methods for proactive risk assessment. These are discussed below.

1.4.1.1 Failure Mode and Effects Analysis

Description  Failure Mode and Effects Analysis (FMEA) is well-established as a tool for pro-actively assessing risk. It uses a system of analysis where the effect of any failure mode is defined as the risk which can be calculated as (1.6):

\[
RiskNumber = Probability \times Severity \times DetectionLikelihood.
\]

The process of FMEA involves the following steps:
- Evaluate the process
- Identify the failure modes
- Describe the effects of the failure modes
- Analyse the severity
- Calculate the detection possibility for the defect

There are a number of advantages and disadvantages to FMEA. The FMEA process requires advanced process mapping that can be performed using a number of different methods. The results can be used to prioritise risk and categorise
1. INTRODUCTION

them appropriately. The scoring system for FMEA has been criticised. Multiplying probability, severity and detection likelihood to get a score is mathematically incorrect. It is ordinal scale data and therefore should not be treated as interval data[69].

Use in Radiotherapy and Healthcare A number of documents have discussed the use of FMEA in radiotherapy. AAPM TG100 is a report that discusses how to apply FMEA to the radiotherapy process[70][71][72][73][74]. To the date of the original submission of this thesis the AAPM TG100 report had not been fully published[1].

A paper by Huq et al described how FMEA can be used to assess the quality assurance needs in department. The paper discusses the need for a more structured approach to quality assurance and how traditionally QA primarily only tests equipment. The paper comments on the need to have a greater understanding of consequence due to failure and suggests FMEA as a method of evaluating quality assurance needs[70].

Ford et al described an approach to applying FMEA in radiotherapy. This paper discussed the importance of the scoring scale. The decision to try to reduce the risk should be based on the scoring of the identified failure modes. Ford described how FMEA can be used to evaluate the safety of a radiotherapy system. In this paper 269 nodes[2] were described compared to the 91 discussed in the incident learning paper by the same author[74][12]. This paper demonstrates how FMEA can be applied to evaluate the safety of a department.

Catone et al discussed the application of FMEA to proton treatment planning in radiotherapy. This adopted a multidisciplinary multi-institutional FMEA approach. This type of approach offers a number of advantages, most noticeably a

---

1A draft for AAPM members only is available, but not for distribution or referencing at time of original thesis submission

2A node is used to describe sub tasks in process modelling
well-rounded view of the process and adaptable to various departments. In this approach 34 sub processes were identified with 22 of them being judged to have the potential for one or more failures (73).

Meyrieux et al discussed the application of FMEA further. In this case it was concluded that the difficulty of assembling an FMEA should not be underestimated (71). In a study done by Masini et al the application of FMEA to linear accelerator based intra-cranial stereotactic radiation surgery was investigated. In this study 73 steps were identified leading to a potential of 116 different failure modes. The risk numbers varied between 1 and 180. Two of the modes had risk numbers greater than 125. These identified failures were wrong collimator size and incorrect coordinates (75).

A total of 71 different articles were found on sciencedirect relating to FMEA and radiotherapy. Many of these included editorials and commentaries where the consensus leaned towards the adaptation of FMEA and other risk assessment tools to analyse the QA needs of the radiotherapy department (70)(74)(76)(77).

Healthcare FMEA (HFMEA) is a deviation of FMEA that is used in healthcare. It has been used in radiotherapy for risk assessment. In a paper by Habraken et al the authors go into detail about the number of identified failure modes and the number of person hours for the different processes (78). A modified version of HFMEA has been presented by Chadwick and Fallon. In this paper the authors concluded the HFMEA could produce a more functional assessment technique for healthcare (79).

1.4.1.2 Fault Tree Analysis

Description Fault tree analysis is a tool for quantitatively calculating risk. It is based on the Reason Model that stipulates that a series of events need to align in order for an incident to occur. The primary events are based on a value that represents the probability of occurrence. Boolean logic is used to describe the
1. INTRODUCTION

interaction between tasks using a series of AND and OR gates\textsuperscript{[80]}. The AND and OR gates can be mathematically represented as follows:

\[ P(A \text{and} B) = P(A)P(B) \] (1.7)

\[ P(A \text{or} B) = P(A) + P(B) - P(A)P(B) \] (1.8)

When \( P(A) \) and \( P(B) \) are below 0.00001 the \( P(A)P(B) \) element of the OR becomes small to the point of insignificance. This simplifies the equation to:

\[ P(A \text{or} B) \approx P(A) + P(B) \] (1.9)

Fault tree analysis is widely used in aerospace, nuclear and aviation industry. It was originally developed by Bell Labs and was adopted by the nuclear regulatory commission as part of their use of probabilistic risk assessment modelling\textsuperscript{[80]}. 

**Use in radiotherapy**  The AAPM TG100 guidelines mention the use of Fault Tree Analysis (FTA) in their approach to quality assurance. A paper by Ekaette discusses the role of probabilistic risk assessment and its role in assessing patient safety\textsuperscript{[81]}. The probabilities were estimated by taking expert judgement to provide a minimum and maximum probability. It specifically discussed the incident propagation which is more intuitive with the FTA approach. This paper demonstrated that a complex radiotherapy system could be modelled using FTA.

A paper by Marx and Slonim discussed applying FTA to healthcare. They demonstrated how introducing socio-technical components and human error estimations can be used to improve the design of the model\textsuperscript{[82]}. 

28
1.4 Tools for Reducing Risk

1.4.1.3 Process Mapping

Accurate risk assessment requires detailed process mapping to identify potential errors. In a paper by Battles \cite{83} on the subject of safety in healthcare it was stated that:

"The application of process mapping approaches is gaining greater acceptance in a number of clinical areas as a valid approach to identifying potential hazards and risks associated with various clinical processes" (taken directly from \cite{83})

Rath discusses tools for quality management in radiotherapy including process mapping \cite{84}. An example of the macroscopic flowchart can be viewed in figure 1.6.

![Macro Level Flow Diagram](reproduced with permission from Rath \cite{84})

FMEA and FTA both rely on accurate and through representation of the process. There are a number of different process flow diagrams available to represent systems. IDEFØ diagrams have been used in the past to represent complex systems including radiotherapy \cite{72} \cite{79}. IDEFØ diagrams are used for function
modelling. The IDEFØ graphical representation of a system incorporates the decision-making, actions and activities of the system. This methodology has many advantages. IDEFØ clearly demonstrates the integration of different tasks and the relationship of variables with individual tasks. The disadvantage of this method is the complexity of these diagrams can deter people\textsuperscript{(85)}.

1.4.1.4 Human Factors Engineering and its role in safety

HEART is a technique that is used to estimated human error probability. The sub tasks for the process are analysed. An unreliability score is estimated by a group of experts. The error producing conditions are applied to the estimations and a final HEP is then calculated. This information can then be used to assess where resources need to be put to reduce probability of error\textsuperscript{(86)}. THERP is a technique where the system failures are identified, the human related elements (including type) are identified.

The influence of human error on incident rates has been well-established in different industries. In emergency medicine human error caused harm to 4\% of patients.\textsuperscript{(87)} Another study discovered that in pharmacy 19\% of doses administered contained an error\textsuperscript{(88)}.

1.4.2 Retrospective Tools

1.4.2.1 Root Cause Analysis

Root Cause Analysis (RCA) is an incident investigation technique that is used in a number of different industries. It consists of a number of steps to evaluate all causes of an incident including primary, secondary and tertiary causes. This tool is key for incident learning. Incidents in healthcare that have small consequences can have similar causes to potential incidents with serious consequences\textsuperscript{(24)}.

The methods of root cause analysis can be used in conjunction with each other or individually.
1.4 Tools for Reducing Risk

1.4.2.2 Fish Bone (Ishikawa diagrams)

Ishikawa diagrams, more commonly known as fish bone diagrams are used to represent the cause and effect of the various factors that lead to an incident occurring. These diagrams graphically represent the primary, secondary and tertiary causes of an incident. Ishikawa diagrams can also be used as a method of proactive risk assessment similar to fault tree analysis.

Ishikawa diagrams have been identified as a tool for quality improvement in healthcare [89][90]. They were first proposed by Ishikawa in the book Guide to Quality Control[91].

![Figure 1.7: Example of an Ishikawa Diagram](reproduced with permission from Human Reliability, Error, and Human Factors in Engineering Maintenance: with Reference to Aviation and Power Generation [92])
1. INTRODUCTION

1.4.2.3 5-Whys?

The 5-why (or seven whys) is a conceptual method of evaluating cause of incidents. It is based on the idea that for every incident there should be 5 (or seven) levels of questioning to establish how an error occurred and that based on this the true root cause is represented, not just the superficial causes. This technique was first used by Toyota in their manufacturing methods.

1.4.2.4 Classification of incidents

Classifying incidents can be used to improve the efficiency of incident learning. Classification is discussed in detail in the Ford paper on incident learning. It includes a description of severity scales, process maps and causes. The information presented in this paper can be adapted for each department’s own setup.

The aviation industry and other high risk industries have a number of classifications including the Human Factors Analysis and Classification System (HFACS) and Software, Hardware, Environment, Livewire, Livewire (SHELL) classification.

The HFACS classification is a method assessing the human factors (such as lack of skill or bad decision-making), preconditions to errors, supervisory and organisational influences of events. The limitation of this classification is that it does require a large amount of knowledge of the event. This method of classification is discussed in further detail in chapter 2. The SHELL model examines the relationship between the different people in the process, the user and the environment, the user and software and hardware. This can be easy to quantify based on what was involved with the task in question but the information obtained from the classification has limitations.

1.4.3 Challenges of Safety Enhancement

The series of articles written by the New York Times resulted in a series of studies and editorials reviewing safety enhancements and challenges in...
1.4 Tools for Reducing Risk

radiotherapy. The article in regard to Scott Jerome Parks [99] has 215 citations on google scholar[1]. The articles vary from discussing the challenges of delivering radiotherapy with the fast moving technology [100] to editorial based papers discussing the fear and facts surrounding medical radiation [101].

In a special article in the Journal of Practical Radiation Oncology the challenges of maximising safety are addressed [102]. Increased time demands, changing work-flow, expectations of care providers, more severe consequence of errors, reliance on images, reduction in utilisation of “classic” QA tools, short treatment schedules (hypo-fractionation) and tighter margins are all quoted as reasons that challenge safe treatment delivery. The reasons quoted may not necessarily increase the probability of incident but rather the severity when incidents occurs. If an incident does occur on a hyperfractionated treatment, there are fewer fractions to compensate for the dose deviation. The paper goes on to discuss ways of improving safety as seen in figure 1.8[102].

![Hierarchy of Effectiveness to Prevent Error](image)

**Figure 1.8:** Tools for risk reduction [reproduced with permission from Marks et al[102]]

The issue of “culture of safety” or patient safety culture has also been discussed by different authors [103][104]. In one of these papers the area of lean

\[1\) As of the 3rd of May 2017
management and safety culture was discussed. In this paper they evaluated how lean culture affects safety culture and found that having a lean culture improves safety climate\textsuperscript{(103)}. In the paper by Kusano they studied how patient safety culture could be improved by analysing and acting on the results of patient safety culture surveys\textsuperscript{(104)}. It could be argued that the patient safety culture is directly related to the people focused elements of the error prevention hierarchy. Ignoring rules and policies will have a major influence on error rates.
1.5 Incidents in Radiotherapy

Traditionally radiotherapy has been considered a safe modality of treatment for patients. Incidents that do occur are prone to high media attention that can affect the staff, patients and hospitals involved [98] [99] [105] [106].

1.5.1 History of Major Radiotherapy Events

The misuse of radiation goes back to 1895. The discovery of x-rays was shortly followed by the first misuse of radiation, when Roentgen took an x-ray of his wife’s hand.

The Therac-25 incident has been quoted as one of the eleven most infamous software bugs [107]. The Atomic Energy of Canada Limited was a Canadian company that made medical linear accelerators. The Therac-25 linear accelerator was an updated version of their Therac-20 Linac. There were some parts of the machine that were recycled. This included a piece of software. This software behaved unexpectedly when a series of buttons were pushed in a certain sequence. It resulted in the bremsstrahlung target being removed for photons. The machine relied purely on software based interlocks which contributed to the incidents. Between 1985 and 1987 at least 5 people died from this error [108].

External beam radiotherapy is not the only example of critical events. In 1992 a High Dose Rate Brachytherapy source dislodged from the afterloader unit and was left inside the patent. This patient received over a thousand times the prescribed dose and died as a result. In this case, the alarms were working at the time but were ignored. This was blamed on the false alarm effect. The alarms had previously gone off without incident and therefore were ignored. This event demonstrated how wrong decision-making could result in an incident [109].

There have also been calculation based errors which have affected a high volume of patients in a department. In San Jose, Costa Rica in 1996 a Co-60 unit

\[1\] The afterloader unit is used to store the HDR source outside of treatment and deliver the dose to the patient during treatment.
1. INTRODUCTION

received a new source. The dose rate for this source was calculated incorrectly. This resulted in a 55% overdose for the patients involved. This error affected a large volume of patients many of whom suffered from severe side effects. The report commented on the warning signs being ignored in the affected centre. This included not following up on discrepancies from an independent dose audit and institutional disparities.

1.5.2 Major Radiotherapy Events since 2000

High profile incidents have occurred even with modern technologies. The complexity of treatments has resulted in severe incidents in the last 15 years. A *Lancet* oncology paper discussed the learning and reform that occurs from the high profile incidents. The paper discussed the effects of staffing issues in Royal Adelaide hospital and its effect the radiotherapy incidents. The article went on to discuss the shortcomings in the Epinal case (discussed below). It was noted that calibration errors are less frequent than other types of errors, however, there is going to be an issue finding qualified staff in the future.

Between August 2000 and March 2001 28 patients being treated for cervix and prostate cancer were overdosed in Panama. Seventeen of these were lethal. In this case a new protocol for shielding blocks was introduced involving the treatment planning system. The introduction of this new protocol was not validated correctly and found later to have been implemented incorrectly. This highlights the need for auditing of new processes and equipment.

In February 2001 a medical linear accelerator in Bialystok, Poland, malfunctioned overdosing a number of patients. A patient receiving the treatment complained of a burning sensation when treated. A technician made attempts at repairing the machine but it is believed this caused further damage to the machine. Up to 60Gy may have been delivered to localised regions of the breast.
as a result of this incident. No patients died from this incident however tissue involved was seriously damaged. (113)(112)

In 2004, in Epinal, France, an error involving the introduction of a new system for delivering wedge fields resulted in the overdose for a number of patients. The primary cause of this was the incorrect implementation of the wedges. Contributing factors included staffing levels, patient safety culture and incorrect planning (114). This case received media attention in 2013 after the case went to court resulting in the incarceration of staff involved for 1 and a half to 4 years (115).

In November 2004 in Ottawa an orthovoltage unit was calibrated incorrectly during recommissioning. The radiation output tables were incorrect for field sizes greater than 10x10cm. Of the 1019 patients that received treatment during this period 620 patients received an incorrect treatment. Of these, 326 were curative intent for the treatment of skin cancer. A number of causes were identified as contributing factors including (116):

- Inadequate staffing
- Cultural norm did not reflect importance
- Orthovoltage was considered a low priority
- Lack of national guidance on orthovoltage units

As the incident was an under dose it was not as easy to detect. Patients were not presenting with the type of toxicities that would be associated with an over dose.

In 2006 a teenager received a severe over dose during treatment. This was attributed to a human error involved with the planning of the patient. Seventeen fractions were delivered with 159MU’s instead of 94.5MU’s. An independent report cited the following errors associated with this incident (117).

Primary Error:

The required normalisation procedure was omitted.

Contributing factors:

- Lack of experience of the treatment planner
- Lack of supervision
1. INTRODUCTION

Lack of independence in the checking procedure
Failure to up date work instructions

In 2010 Scott Jerome-Parks received a lethal radiation dose while being treated for tongue cancer. In this case a computer error resulted in the field size being reset. A large field was delivered to the patient instead of a series of small fields. This particular incident was highlighted in a series of New York Times articles that examined safety in radiotherapy.\(^{(97)}\)

A common theme from all of these incidents is the lack of qualified staff and sub-optimal patient safety culture. A paper discussing the challenges of safety in radiation oncology highlighted the importance of “culture of safety”. This paper said that communication, staffing and team work should be assessed in any safety assessment\(^{(102)}\).

1.5.3 Literature of Radiotherapy incidents

Non-critical radiotherapy incidents give departments an opportunity to learn from the errors of others and prevent them from recurring. The incidents highlighted above are examples of well documented cases that have resulted in loss of life or other serious consequence to the patient. Less severe incidents can have an effect on the TCP or NTCP. In 2008 World Health Organisation (WHO) released a document, radiotherapy risk profile, highlighting a number of radiotherapy events. This report looked at 7741 incidents and near misses across a 30 year period. The report included an incident in Ireland due to an error related to the TPS utilization, calculation and documentation. This event affected 177 patients, although no increased patient toxicity was identified\(^{(65)}\). The report showed that most incidents were initiated in the planning process while most near misses occurred during treatment information transfer. This may not represent current trends in radiotherapy risk management. The use of record and verify systems, 3-d planning systems and IGRT systems make the radiotherapy process unrecognisable from the process 30 years ago. A 5-year view of incidents and near misses would
1.5 Incidents in Radiotherapy

represent a more realistic view of the current radiotherapy process.65

The Radiation Oncology Safety Information System (ROSIS) is a voluntary reporting system that was established in 2001. A study of the ROSIS database examined 1074 incidents. This review found that the majority of incidents were identified by radiation therapists. See figure 1.9. This study found that most incidents were found at the time of patient treatment. As most incidents occur at the linear accelerator it stands to reason that the radiation therapists will have the highest detection rate. The disadvantage to this study is that the ROSIS system is a voluntary reporting system. The reports involved may not be an accurate statistical representation as departments can choose which reports they wish to submit33.

Figure 1.9: Discipline detecting errors [reproduced with permission from Cunningham et al. (33)]

In smaller local studies a series of retrospective incident analysis’ were performed across a period of time. One such study did a thorough analysis of all incidents across a seven year period. This paper reported a downward trend, with an incident rate of 2.0 per 100 RT courses in 2001 reducing to a rate of 1.2 per 100 courses in 2007. The paper pointed out that while updated processes can
1. INTRODUCTION

reduce some error types, others can be created through the same action [66].

In a similar study covering a three year period the introduction of a reporting system showed comparable results. The error rates went from 1% a year to 0.3% per year. In this study, more incidents were discovered at the treatment unit than in any other part of the process [67].

In another study by Klein et al, a centre with 2000 patients and seven linacs the incident rates were tracked for “notable events” [118]. The paper does not specify what notable events are. In this study the dosimetric impact was analysed for all the incidents. Incident rate data is presented. The paper discusses use of port films, which would now be considered redundant form of IGRT. This paper may not be relevant when compared with modern technologies.

In a similar study by Chang et al, they reviewed locally reported incidents. In this study they reported an incident rate of 2.64 per 100 courses of treatment. They concluded that complex plans were associated with a higher incident rate [119].

The University of Texas MD Anderson Centre did a large scale study of locally reported incidents. Their definition of an incident is not clear in the paper. The paper gives examples of what is classified as an incident, which includes an “other” category. The study was performed across 2 years totalling 326,448 fractions or 13,899 patients. In the photons, electrons and protons were investigated. The study does not specifically state that it is confined to external beam, but brachytherapy is not mentioned in the article. The article goes on to examine variables that affected incident rates. In the treatment planning process the average incident rate was 2.1 per 10,000 fractions. The incident rate in plans that were less than 2 working days between simulation and starting was 4.0 per 10,000 fractions (compared with 1.9 for those greater than 2 working days). Multiple prescription items increased the incident rate. Courses of treatment with one prescription item had a rate of 1.3 per 10,000, 2 had a rate of 4.3 per 10,000, 3 and 4+ had a rate of 5.6 per 10,000 fractions. In the treatment delivery section of
the study the relationship between error rates and work days between simulation to treatment start. Less than 2 working days had an error rate of 3.6 per 10,000 vs 1.5 per 10,000 fractions for the remainder. The most notable factor is first day of treatment. The first day of treatment had a rate of 9.8 per 10,000 fractions while the remaining factions 1.0 per 10,000 fractions. In this centre the total incidents were quoted as 136 per 10,000 patients. [35]
1. INTRODUCTION

1.6 Publications addressing risk in Radiotherapy

There are a number of documents that address the issue of risk management in radiotherapy including *Towards Safer Radiotherapy* \(^{44}\) produced by multiple UK professional groups, *Safety is No Accident* \(^{120}\) produced by ASTRO, *Radiotherapy Risk Profile* \(^{65}\) produced by the WHO and *AcciRAD* \(^{121}\) produced by the EC. These documents collectively address areas of risk, incidents, safety climate and are designed to offer departments help in addressing risk.

1.6.1 Radiotherapy Risk Profile \(^{65}\)

The World Health Organisation produced a document that reviews 30 years of radiotherapy incidents. The information presented in this document is based on a paper published by Shafiq et al. \(^{122}\) These incidents were analysed based on country, patient outcome and number of patients affected. This document does not highlight any particular tools for risk assessment but rather it highlights how incidents can happen and are used to educate departments and prevent them from happening again.

The limitation of this document is that it does do an in-depth analysis of the incidents. There aren’t enough details of the events to analyse the root cause in depth. A greater insight into the causes could offer more information that could be used to analyse a departments’ own safety structure.

The document defines the steps in the treatment process that the incidents took place. The document goes on to say what are the highest rates of errors in the different steps of the process and what are the potential incidents that can occur in these steps. This is useful as a starting block for Failure Mode and Effects Analysis (FMEA) and similar tools.
1.6 Publications addressing risk in Radiotherapy

1.6.2 General guidelines on risk management in external beam radiotherapy (121)

The ACCIRad Report on General guidelines on risk management in external beam radiotherapy, document was commissioned by the European Commission consortium to create a template for risk assessment in radiotherapy. It adopts retrospective and prospective analysis of incidents. It discusses a number of well-established tools including the ones discussed later in this chapter.

The methods for risk assessment mentioned in this document included risk matrix, fault trees, event trees and process analysis. Figure 1.10 shows the tools they recommend for risk management and the stages in the risk assessment process where they are relevant.

![Figure 1.10: Risk Assessment Tools](image)

The different acronyms are in the glossary of this thesis (121).

A supplement to this document includes recommendations on how to imple-
1. INTRODUCTION

1.6.3 Towards Safer Radiotherapy \(^{(44)}\)

Towards safer radiotherapy \(^{(44)}\) is a document that primarily deals with safety culture in radiotherapy. It does not discuss risk assessment tools in great detail but rather suggests a number of simple procedures that can be used to reduce the probability of different errors occurring. The document identifies a number of contributing factors to incidents and lists them accordingly and describes how they can affect patient treatment. These factors include training, fatigue, poor design, over reliance on automated processes, poor communication, hierarchical structure, staffing levels, work environment, changes in processes and new processes. All publications do not agree that automation is an issue. Marks et al states that automation can be used to improve safety \(^{(102)}\). Stating that automation can be dangerous may refer to misuse rather than the use itself. A paper by Hendee et al looked at improving patient safety in radiation oncology. The recommendations of this paper included automation. This can be seen in figure 1.11 \(^{(124)}\).

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{figure11.png}
\caption{Hierarchy of Short Term Incident Learning [Reproduced with permission from Hendee et al \(^{(124)}\)]}
\end{figure}

\(^{1}\)A talk given by the author of this thesis is quoted in this document
1.6 Publications addressing risk in Radiotherapy

The authors of *towards safer radiotherapy* also try to eliminate mixed terminology when describing incidents and events. This includes defining the difference between radiotherapy error, radiation incident (RI), correctable RI, reportable RI, non-reportable RI, minor RI, near miss and other non-conformance.

This document offers practical suggestions for improving safety. It suggests that adequate staffing, multidisciplinary meeting, good communication, an external accredited quality management system, review procedures and policies can all be used to improve safety. Implementation of these recommendations could be considered part of a positive safety culture.

1.6.4 Safety is no accident\(^{(120)}\)

*Safety is no accident* is a document produced by ASTRO that offers a series of practical solutions to help improve safety. These include staffing level recommendations, roles of different staff members and the importance of continuing education.

The ASTRO document states that the evolving role of the medical physicist (in terms of safety) is to:

> "Assess safety of the processes (e.g. with statistic processes, failure mode analysis, fault trees, etc”)(taken directly from \(^{(120)}\))

While this is specified as the evolving role of the medical physicist, correct implementation of safety processes is a multidisciplinary task.

The document goes into a lot of detail about the role of patient safety culture. It discusses the role of staffing, communication, workflow, standardisation and peer review for improving safety culture. It discusses in detail the role of peer-review as a way of improving safety for different parts of the radiotherapy process. The document mentions use of FMEA for hazard analysis.
1. INTRODUCTION

1.6.5 Document Summary

These four documents are the main reports currently in circulation that discuss radiotherapy safety in detail. Each of these documents offers a different solution for addressing safety issues in radiation oncology. Towards Safer Radiotherapy[11] and Safety is no Accident[120] offer practical advice and tips to improve safety in radiotherapy departments. The Radiotherapy Risk Profile[65] can be used to look at incidents that have occurred in the past and what can be learned from them. The ACCIRAD Report[121] discusses tools that can be applied to radiotherapy for systematic risk assessment.

1.6.6 Commentary on Radiotherapy Paradigm Shift

The volume of these documents that have been published suggest that there is currently a paradigm shift on how safety issues are being addressed. A point/counter point article written by Klein (TG-142 author[1]) and Ford (vice chair of the Work Group on Prevention of Errors in Radiation Oncology) debated that the current quality assurance measures are outdated and negatively affect patient safety[125]. The argument was made that the current system concentrates resources into one particular area and fails to look at the picture as a whole; that very few errors are caused by not rigorously following documents such as TG-142 and some of the tests detailed in this document have very little bearing on patient safety.

The counter argument to this is that while there is a limited value to some of these tests they do not negatively affect patient safety. The tests may be redundant on some modern machines, but many departments don’t have access to these modern machines.

An additional series of papers also commented on the need for evaluating

\[1\] TG-142 is a document that specifies testing recommendations for medical based Linear Accelerators
quality assurance needs. A paper by Huq commented on using FMEA and FTA to specify where quality assurance resources should be directed. A commentary paper from a symposium on the quality assurance on advanced technologies stated that:

“The current process of developing consensus recommendations for prescriptive quality assurance (QA) tests remains valid for many of the devices and software systems used in modern radiotherapy (RT), although for some technologies, QA guidance is incomplete or out of date.” (taken directly from)

As the evolution of technology accelerates faster than the quality assurance guidelines this will become a larger issue. A paper by Thwaites and Verellen discussed the evolution of technology and its role on safety. The paper considers challenges being faced with the new generation of technology including staffing resources, on-going training and lagging QA recommendations.

A paper by Fraass commented on the motivation for a new radiotherapy quality assurance paradigm. The paper comments on the increased complexity of the equipment and the need to concentrate on analysis of radiotherapy planning and delivery errors. In the United States it is difficult for an individual to release information about an incident into the professional domain. This has since been addressed with the introduction of RO-ILS but it will still take time for the culture to develop into the type of culture seen in aviation. Fraass also commented that process analysis and organised failure mode analysis can be used to identify risk.

\footnote{Huq is the lead of the AAPM TG-100 task group. This group has developed recommendations for the application of risk assessment techniques in radiation oncology.}

\footnote{RO-ILS is a new incident reporting system for radiotherapy in the U.S.}
1. INTRODUCTION

1.7 Conclusions and Research Question

The introduction demonstrates that there is a wide range of literature and research in the area. There was three areas identified as needing further development, which will be the main concentrate of this thesis.

The difficulty of classification of incidents in radiotherapy is that there is an inherent implication that dosimetric severity is identical to clinical significance. In the paper by Bissonnette and Medlam this is demonstrated further. In this paper the clinical significance is linked with the dosimetric consequence without taking into account the multiple variables that will affect this.

The classification of a near-miss as a low scoring incident needs to be reviewed and eliminated. These are two separate types of events and while the classification can be related they should not be considered the same.

The literature shows a number of studies examining reported incident rates at a departmental level. Studies also looked at voluntary reporting systems and the type of incidents that have been reported to these systems. There is question over overall incident rates in radiotherapy. This research will address this issue through a national study of incident rates.

There has been discussion of evaluating patient safety culture in hospitals. There have not been any studies that specifically look at patient safety culture across numerous radiotherapy departments. This research will evaluate patient safety culture across multiple radiotherapy sites and evaluate the statistical significance of the differences between the results.

A number of tools are used to evaluate safety in radiotherapy. FMEA, FTA are often discussed, but there are improvements that could be made to improve these techniques. The predicted probability of an incident occurring often lacks rigor or uncertainty. The current methods rarely include assessment of human error probability. A model for predicting risk in radiotherapy will be developed
These three main issues will be addressed in chapters 2, 3 and 4 of this thesis. Chapter 2 will review reported incident rates in radiotherapy sites and chapter 3 will evaluate the safety culture in the same sites. Chapter 4 will look at a method of predicting incident rates in radiotherapy, concentrating on process design and human error probability.
2

Incident Reports

2.1 Motivation for Study

Incident rates across single radiotherapy centres are not widely published. Voluntary reporting systems offer a lot of valuable information, but because they are voluntary it is not possible to establish incident rates from them. There have been studies that have evaluated incident rates locally, but these suffer from the fact that the definition of incidents and near-misses is not standard across these articles. These articles rarely include a thorough analysis of human factors influence on errors. This chapter aims to address these issues. A method of classification of incidents is presented here that implements elements from current literature in the area. This includes an adaptation of the human factors analysis and classification system (HFACS) widely used in aviation. This was then applied to 239 incidents and 188 near-misses across 10,581 patient treatments in 8 radiotherapy centres. The unique information presented here is:

- A review of department staffing levels and technologies across 12 months
- A classification of incidents using a structured taxonomy
- A multi centre review of locally reported incident rates across 12 months
- A multi centre review of locally reported near-miss rates across 12 months
2. INCIDENT REPORTS

2.2 Methodology for Study

2.2.1 Taxonomy

In order to have a thorough understanding of the causes and similarities between incidents a taxonomy was chosen/adapted. The purpose of this was to break down the characteristics of incidents into groups, making it easier to identify weaknesses in the system. The taxonomy incorporates a number of different elements designed for thorough incident analysis.

Lam et al identified 7 main types of classification for incidents\(^1\) modified from the WHO framework\(^2\):

**Incident nature** Did it actually reach the patient or was it a potential incident?

**Impact** What was the potential/actual clinical effect?

**Incident type** To categorise the incident into identifiable factors that can be used to correlate incidents e.g. wrong energy.

**Stage of origin** Where in the treatment process did it initiate?

**Stage of discovery** Where in the treatment process was the incident found?

**Contributing factors** What factors contributed to the incident?

**Preventative strategies** Is there anything that can be introduced that would prevent this from happening? \(^2\)

There are a number of taxonomy systems available for general information in the classification process. The purpose of this chapter is to investigate methods of assessing incidents including human influence. The paper by Ford et al has produced a number of viable definitions for classifying radiotherapy events.

---

\(^1\) The Lam paper \(^{128}\) defines a patient safety incident as “is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient”. This definition encompasses near-misses.

\(^2\) This will not be included as a form of classification in this thesis. Preventative strategies can be derived from examining the other elements of the classification.
These definitions were used or adapted where applicable\(^{(12)}\). An issue currently in radiotherapy and healthcare is the overwhelming volume of classification systems\(^{(129)}\)(\(^{(130)}\))(\(^{(128)}\))(\(^{(65)}\))(\(^{(131)}\)). Introducing another classification will unnecessarily add to this issue. The taxonomy presented here incorporates elements of the various taxonomies referenced above. They were also chosen to meet the criteria discussed by the WHO. The majority of the taxonomy is adapted from the Ford et al consensus paper\(^{(12)}\).

### 2.2.1.1 Event Nature

For the purpose of this section, an event is any safety based situation regardless of potential outcome, actual outcome or whether it reached the patient. In radiotherapy literature the terminology surrounding near-miss, incident, errors and non-conformities is inconsistent. This inconsistency can create ambiguity. The terminology “near-miss” in particular is open to interpretation. It has been classified as an error that is less severe than an actual incident\(^{(35)}\). This terminology implies that a near miss has a lower risk than an actual incident. However, a near-miss with potentially critical consequences should be considered as having a higher risk than an incident with no radiobiological consequence to a patient.

A flow chart representing the incident nature, non conformity\(^{1}\), and near miss classification developed for this research is seen in figure 2.1. This description was developed by reviewing a departments reporting of events. In order to test the robustness of the flow chart, it was applied to a number of events reported locally from a radiotherapy department. The nature of all events reported in this radiotherapy department were definable by this flow chart. It was designed by the author to eliminate the ambiguity seen in classifying the nature of the event. Therefore, the results should be standardised regardless of where the data came from and their local interpretation of incidents and near-miss. An addition to the definitions here is the multiple levels of non-conformity. This highlights that

\(^{1}\)A non-conformity is considered to be a deviation from protocol that has “no” effect on the patient. Defined by the author.
2. INCIDENT REPORTS

deviations of protocol, even if they can’t cause an incident, still can have different levels of potential clinical impact. The definition for near-miss is similar to the one used by Ford et al[12]. In the Ford definition a near-miss is defined as an incident that is intercepted before reaching the patient. This flow chart was used to classify the nature of all the events provided by the radiotherapy sites that agreed to take part in this study. The incident nature as defined by the individual sites was not necessarily used when applying this flow diagram, i.e. what a site defined as a near-miss could be reclassified as an incident.
2.2 Methodology for Study

Figure 2.1: Incident Nature Flowchart. Developed by the author of this thesis.
2. INCIDENT REPORTS

2.2.1.2 Impact

The Ford et al paper has a thorough classification for incident consequence\(^{12}\). It is divided into two separate consequences; dosimetric and medical (clinical). It uses a 0-10 scale for clinical severity and a 1-10 scale for dosimetric severity. Dose deviations are specified in percentage difference between dose delivered and expected dose delivered. Assessing the dosimetric severity of geometrical deviations is more difficult. The Ford paper\(^{12}\) suggests that for geometrical deviations the dosimetric severity is rated as the equivalent dose deviation. This creates a level of subjectivity to the classification that could potentially lead to misuse of the classification. To account for geometrical deviations the following equation was developed by the author of this thesis for volume based errors.

\[
\%_d = \left(1 - \frac{V_{ol}}{V_i}\right) \times 100
\]  

\(\%_d\) is the equivalent dosimetric % difference
\(V_{ol}\) is the overlapping volume with the initial planned volume
\(V_i\) is the initial planned volume

This is similar to the DICE similarity coefficient used to evaluate overlapping images\(^{132}\).

A setup error is defined as an error where the patient is positioned in the wrong place, orientation or angle relative to the beam. The correct dose and field size is delivered but to the wrong area. This is different from a volume based error where the dose is delivered to the correct site, but the field size or overlap with OARs is incorrect. To account for setup errors the following equation was developed based on the DICE similarity coefficient.

\[
\%_d = \left(1 - \frac{S_{ol}}{S_p}\right) \times 100
\]  

\(\%_d\) is the equivalent dosimetric % difference
\(S_{ol}\) is the overlapping setup with the planned setup
\(S_p\) is the planned setup
In certain scenarios a geometrical/volume error will result in two fields overlapping. The consequence of this will be double the dose in that area. In this scenario the dosimetric severity is specified at the point of overlapping fields.

The clinical severity was directly taken from Ford et al.\textsuperscript{[12]}. This scale was left unchanged as it includes a thorough description of the clinical severities. The clinical severity is based on multiple patient factors which can be difficult to quantify. The radiobiology of the tissue involved, the type of cancer, the type of treatment, the severity of disease and the proximity of the organs will all influence the clinical severity. The clinical severity can be estimated using the dosimetry severity scale. The patient factors need to be analysed correctly. The treating clinician will have the most accurate insight into clinical severity. Figure 2.2 summarises the clinical severity adaptation.

The primary difference between the Ford representation of consequence and the one presented here is the quantification of geometrical deviations, the increase in the number of intervals for the dosimetric severity and the inclusion of the factors that relate dosimetric severity with clinical severity. A “one size fits all” model for relating the dosimetric severity with clinical severity doesn’t exist due to the multitude of individual patient specific factors involved.

The impact is also broken down into increased NTCP, decreased TCP, both increased NTCP and decreased TCP and Unknown/NA.
Figure 2.2: Incident Severity including Adaptation from Ford et al
2.2 Methodology for Study

2.2.1.3 Incident Type

The incident type describes characteristics of the incident that can be used to correlate incidents into categories. The author of this thesis presents three types of patient specific incident characteristics. These were chosen based on consultation with experts in the radiotherapy department and reviewing a subset of incidents. This can be seen in figure 2.3. These three are broken down into a further ten types.

![Incident Type Classification](image)

**Figure 2.3:** Incident Type Classification. *Developed by the author of this thesis.*

**Geometric** errors refer to any incident where the target coverage is less than what is expected or the non-target tissue coverage is higher than expected. The volume refers to the size and shape of the field. The setup refers to the shape of a field being correctly delivered, but to the wrong area.

**Dosimetric** errors refer to anything that will affect how much dose is delivered to the patient. A dose influencing accessory is anything that will influence the specified dose. Wrong dose delivered refers to the wrong number of MUs being entered or planned. It should be noted that the known limitations of the system (example the known accuracy limitations of the treatment planning system) are not taken into account. The wrong energy refers to when the incorrect energy is delivered. Unnecessary (ionising) imaging is when an extra dose of radiation...
2. INCIDENT REPORTS

is delivered to the patient due to inappropriate use of imaging systems. Delay on treatment refers to an unplanned delay the could have an effect on the radiobiology of the treatment.

**Other** These refer to incidents that can’t be classified in the previous sections. These primarily refer to unidentified factors in patient assessment. This includes, but is not limited to inappropriate treatment, unknown electronic devices irradiated and unknown pregnancy.

### 2.2.1.4 Stage of origin/ stage of discovery

The incident setting refers to the part of the process where the incident took place. Trending incident setting across time can be used to highlight areas of high risk in the treatment process. The incident setting was adapted from the Ford et al paper\(^{12}\). This paper identifies eight different major steps in the external beam radiotherapy process and further divides these into 91 steps. Ford identified the steps involved with incident prevention. This classification will be used at a later stage of this document to facilitate the model for probabilistic risk assessment. After reviewing the classification, certain steps were found to have no bearing on patient safety and therefore it was felt that these did not need to be included\(^{12}\). The macroscopic breakdown of tasks can be seen in figure 1.3 from the introductory chapter.

### 2.2.1.5 Contributing factors

The contributing factors are broad terms that includes anything that influenced the system that led to the incident. For the purposes of this study, when looking at the contributing factors, the human factors will be evaluated. The Human Factors Analysis and Classification System (HFACS) classification was adapted to address the human influences on incidents\(^{55}\). Human error has been attributed to a wide variety of incidents in radiotherapy (this can be seen in further details in the introduction of the thesis) as well as other industries including healthcare\(^{133}\). HFACS was chosen due to its wide use in the aviation industry and thorough
2.2 Methodology for Study

analysis of multiple levels of human and organisational involvement\(^{(55)}\). It was adapted in a manner to make it more suitable for radiotherapy.
2. INCIDENT REPORTS

Human Factors Analysis and Classification System-RadioTherapy (HFACS-RT)  There have been versions of HFACS used in radiotherapy as discussed in the introduction chapter. These versions of HFACS showed that this type of classification can be used in radiotherapy but the author felt that an adaptation of it would make it more suitable for radiotherapy. These adaptations were made to include how the presence of the patient could create a precondition to errors and the influence of complex hardware and software (55).

The traditional HFACS was adapted to radiotherapy through examining a series of incidents in radiotherapy by the authors of this study. They were investigated and a series of root cause analysis (RCA) diagrams were developed to examine the chain of causality. The original HFACS were initially applied to the RCA diagrams of a number of sample incidents. In areas where suitable classifications could not be applied additional classifications were added. Figure 2.4 shows the HFACS-RT adaptation(94).

Mosaly et al describes the usability of HFACS in radiotherapy. In this paper they suggested that the widespread use of HFACS in radiotherapy is possible(134). The paper found no statistical difference between the expert analysis and the mean score of the four novice users (p<0.05) although there was a difference across the 4 novice users. This is an important point when it comes to the widespread use of HFACS in radiotherapy. It will be difficult to find highly trained experts in human error analysis in the average radiotherapy department. This paper would indicate that for widespread use there were need to be formal training in HFACS(134). The level of training is open to interpretation. In this paper the novice users only had one hour of training. It is possible with more than one hour that people would be more able to use HFACS appropriately.

A detailed description of HFACS-RT is presented below. The definitions and adaptations used here are adapted from a number of sources (135) (130) (133) (136) (137) (138) (139) (140) (94) (141). The purpose of using multiple interpretations of HFACS was to apply the elements that are relevant to radiotherapy incidents. For example the interpretation by Diller et al (which is very similar to
Figure 2.4: The adapted version of the Human Factors Analysis and Classification System for Radiotherapy (HFACS-RT). The grey boxes show the higher levels of the HFACS classification, while the white boxes show the sub levels. There are 24 sub levels in this version of HFACS compared to 19 in the original aviation version.
2. INCIDENT REPORTS

the aviation version of HFACS)\(^{133}\) is designed to be applied to healthcare. The
description of HFACS-RT is broken down into 4 main parts, as shown in figure
2.4. These are Acts, Preconditions, Supervision and Organisational Influences.

**HFACS-RT Level 1: Acts**

Unsafe acts can be defined in two separate ways. Errors can be considered as
failures to get correct outcomes from actions. These are accidental due to the
nature of human error. In contrast, a violation is a known and purposeful disre-
gard for the rules.

*Types of Errors*

Memory Lapse - Forgetting to do something that should be done or that is usually
done. Example not preforming a check that normally occurs. In the traditional
HFACS this would have been defined under skill based errors\(^{142}\). In this thesis
it is treated separately to add an extra level of definition to the incident classifi-
cation.

Decision Based - In this scenario the intention to deliver the treatment in an
effective manner following protocols, however wrong decisions were made that
prevented safe treatment delivery i.e. “An honest mistake”. This is included in
the original version of HFACS\(^{94}\).

Knowledge Based - The treatment was delivered incorrectly due to lack of
information. In radiotherapy information surrounding patient details is very im-
portant. Patients treatment plans are dependent on the clinical information about
the patient. If information is missing the plan may not be correct for the patient.
This is an example of a knowledge based error. Knowledge based errors were
included in the Australian defence force version of HFACS\(^{140}\).

Skill Based - The person lacked the skill to prevent the incident. Radiotherapy
is a high skilled environment and if a person does not have the correct training
or skill set to correctly treat a patient incidents can occur. This is included in
the original version of HFACS (94).

Perceptual Based- Errors based on visual assessment. These are noteworthy in radiotherapy as many tasks are based on imaging systems and accurate positioning of patients based on the observation of the patients setup. It would also include unnoticed errors occurring during observation of the patients treatment (e.g. a patient moving going unnoticed). This is included in the original version of HFACS (94).

Violations

Routine Violations - Violations of procedures that occur regularly and generally are considered acceptable by staff members. These will be specific to each department or site. This is included in the original version of HFACS (94).

Exceptional Violations - Violations that don’t occur on a regular basis often associated with high stress scenarios where safe practices are diminished. This is included in the original version of HFACS (94).

The unsafe acts alone do not give an overall picture of how any incident, potential incident or near miss can occur. In order to effectively evaluate the full causality of an incident the events that led up to the errors/violations should be investigated.

HFACS-RT Level 2: Preconditions

Technological Based Factors

Radiotherapy is a high technology based modality of healthcare. Traditionally technological factors would have been under environmental factors. The different technological factors are separately defined due to the incidents surrounding software and hardware issues that have occurred in the past (94).

Software Design - A flaw in the software that made the error easier to occur. Software should be designed to be user-friendly. Software design can contribute
2. INCIDENT REPORTS

to incidents as the design could make it easier to edit figures in an unsafe manner, misread the results or other similar errors.

Hardware Design - A flaw in the design of the hardware that has contributed to the error.

Conditions of the individual
The adverse states of individuals (physiological or physical) can only be correctly assessed through interviewing or questioning the individuals involved. This means that for retrospective analysis of incidents this can prove to be very difficult. The adverse conditions of an individual may represent a contributing organisational issue. In this case the individual refers to the user/staff member, not the patient. This is included in the original version of HFACS[94].

Adverse Mental State - The mental capacity of an individual has been affected. An example would include mental fatigue.

Adverse Physiological State - The physical capacity of an individual has been affected. Examples would include illness or intoxication.

Physical/Mental Limitations - An error due to limitations beyond the skill set of the individual or information overload.

Personnel Factors
In any working environment there are staffing factors that will affect the overall safety in a department. Communication between staff members is vital. These can be staff members from the same discipline or different disciplines. Communication based errors are broken down into two different parts. This was encompassed by crew resource management in the original version of HFACS[94].

Inter Team Miscommunication - Communication breakdown between different disciplines. For instance planners not communicating with therapists correctly
resulting in missing information.

Team Based Miscommunication - Communication factors from within the same discipline. An example would be two radiation therapists working on the same unit not communicating properly resulting in an error.

Patient Factors
The inclusion of patient factors makes it more appropriate for healthcare. It is not uncommon for patients to be under emotional stress during the time of the incident and as a result cause distraction to the healthcare professional. If this is a common contributing factor to incidents then an organisational issue maybe an underlying cause. This has not been included in other versions of HFACS and was designed specifically for this study.

Unusual Patient Anatomy causing difficulty - This type of factor refers to an unusual anatomy in the patient. Example, obese patient, difficult to setup.

Requires Special Attention - This case refers to a patient that is particularly emotional and requires special counselling that leads to distraction.

HFACS-RT Level 3: Supervision
Supervision can have an effect the completion of any task. The HFACS classification includes a number of different types of supervisory elements that could contribute to incidents, near misses or non-conformities. All of these elements were included in the original version of HFACS\textsuperscript{[94]}

Inadequate Supervision - The individual in question wasn’t supervised to the right level. This includes not training staff or providing adequate supervision.

Planned inappropriate operation - The management planned for inappropriate operations that resulted in unsafe preconditions. This includes not giving breaks to staff or putting excess workloads on staff.
2. INCIDENT REPORTS

Failure to correct a known problem - A problem was presented to the management which was not acted upon.

Supervisory Violations - The supervisors disregard rules. This would include allowing unqualified staff to work on machines alone.

Organizational Influences
The organisation itself can have an effect on the number of incidents and severity of incidents within the department. Different types of organisational influences are defined below. These were edited to make them more appropriate for radiotherapy and healthcare. Staffing resources and other resources are often quoted as contributing to incidents in healthcare. Due to the high level of precision and reliance on technology, specialist equipment is often required to make diagnosis and deliver treatment effectively. Therefore, resource requirement is split into staffing resources and other resources.

Inadequate Staffing resources - Incidents that are as a result of poor staffing within the department. Staffing levels are very important in radiotherapy where it takes a team of experts for correct diagnosis and treatment of patients. Inadequate staffing can compromise this. In the original HFACS this is encompassed under resource management[94].

Inadequate Resources (Other than staffing) - Radiotherapy requires a lot of technology and a lot of resources for effective delivery. A lack of resources for treatment can range from testing equipment to patient specific equipment required for treatments. In the original HFACS this is encompassed under resource management[94].

Patient Safety Culture - This is similar to the previous HFACS defined as organisational climate[94]. Patient safety culture is

"The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns
2.2 Methodology for Study

of behaviour that determine the commitment to, and the style and proficiency of, an organisation’s health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.”

(* taken from the AHRQ website adapted from Organising for Safety: Third Report of the ACSNI [143])

Process design - Similar to the Organisational process seen in the traditional HFACS. An example of this includes processes that are designed in a certain way that allow for unsafe acts to occur[94].
2. INCIDENT REPORTS

2.2.2 Data Collection

The motivation of this study was to review and understand what type, and how many incidents and near-misses were being identified on a local department level. A number of radiotherapy departments were approached to contribute to the study.\(^1\)

Each radiotherapy department that took part in the study provided their local incident forms, near-misses forms or a document that summarised all their events across a 12 month period. This data was complemented by information about the department including staffing levels and treatments available.

Three public radiotherapy departments (encompassing 5 centres) and five private radiotherapy departments agreed to take part in the study. Each hospital was assigned a random number and will henceforth be referred to as site 1 to site 8. For the purposes of maintaining anonymity, the raw data that could be used to identify a department was not included.

This study is divided into two sections. The first section is the technical and throughput information. An initial questionnaire was sent to the management of the radiotherapy department and included general information on the throughput and technical details of the department. This survey was designed to examine a number of different parameters from the radiotherapy department including the utilization of equipment, techniques used, patient throughput and staffing levels. The survey was reviewed prior to distribution by two physicists and a radiation therapy services manager.

The second part of this study involved reviewing the incident rates in the department using the taxonomy discussed in the previous pages. All incidents and

\(^1\)An initial letter was sent out to every radiotherapy department in the Republic of Ireland. A study protocol was set around to the departments. See appendix A for the study protocol. Some sites also required ethical approval. The ethical approval form can be seen in appendix B. There were different ethical approval forms for different sites. The one presented in Appendix B is from one of these sites. The information did not change between sites.
near-misses were requested, then reclassified and analysed based on the taxonomy (figure 2.1). This reclassification was done to eliminate inter observer (or inter department) variability. The reporting levels of incidents were assessed through the evaluation of patient safety culture in chapter 3. Near-misses and incidents were only included in the analysis. It should be noted however that a high volume of near-misses were reclassified as a non-conformity level 2 or level 3. This was done to standardise the data. This meant that some departments were locally reporting non-conformities as near-misses. It does include when safety checks (for example weekly checks) are missed or where a better quality treatment was available, but the treatment, as planned, was delivered correctly.

2.2.3 Limitations of study

The reporting systems in each site were not compatible with each other. In some departments results from imaging audits were not included in the reports. Some departments had an offline and online imaging review in their department protocol. This resulted in a higher volume of errors being identified in these departments. Departments that did not do offline were less likely to identify setup errors. In one department there was no patient specific events reported, but rather radiation protection issues or hardware issues. The patient safety culture survey discussed in chapter 3 showed that their internal reporting rates are statistically significantly lower than all other sites (see chapter 3 for further information). This makes it difficult to compare departments. A department with low reported incidents does not necessarily correlate with low incident rates. There is the potential that incidents are not being identified or are not being reported.

This is a retrospective study of incident rates. The patient safety culture survey was administered at a different period than when the incidents took place. There is the possibility that there would be a fluctuation in the patient safety culture during this period. However, this was not mentioned during the administration of the survey by any staff members.
2. INCIDENT REPORTS

The data collected was for the 12 months of 2012 or 2013 for each site. The year that was examined primarily depended on the availability of data, and how close the data was to the administration of the patient safety culture survey. The initial study was designed to examine the year 2012. Delays on ethics approval and availability of data from certain centres resulted in the use of 2013 data in two sites.

The data available was not always sufficient to analyse the events in depth. The application of HFACS-RT will be more difficult when there isn’t a large amount of information recorded in the incident reports. For this reason, the physiological conditions of the individual staff members was not classified unless explicitly recorded. All other information was classified by analysing the event and reviewing the factors that would lead to the event based on understanding the radiotherapy process.

Radiation based patient specific events were only included. Events involving slips or falls were not included. Events involving staff members or non-patients were not included. This research is designed to concentrate on patient safety in the delivery of radiation for therapy.
2.3 Department Profile

The following graphs represent the profile of each of the departments. The profile includes information about staffing levels and treatment type. This information was obtained for two primary reasons. The first is to look at how staffing levels vary between sites. The second reason is to look to see if there is any correlation between incident rates and minimum staffing levels. Due to the small number of departments that took part in this study, eight, it was not possible to find a threshold staffing level where safety isn’t compromised, although with a larger study following this methodology that would be possible in the future. This information is presented in such a way as to ensure the anonymity of each department. The staffing levels, patients numbers and other factors which could be used to identify the department are presented as ratios.

2.3.1 Treatments Available

Figure 2.5 represents the treatments available in the department. They are broken down into orthovoltage treatments, LDR treatments, HDR treatments, 2-d, 3-d and electron external beam treatments and more complex treatments (IMRT, Stereotactic and Total Body Irradiation). This information represents the percentage of patients treated with these modalities, not number of fractions.

2.3.2 Staffing Levels

The graphs in this section represent the staffing levels in the radiotherapy department. The staffing levels are presented as a ratio of staff members to treatment techniques or as a ratio of staffing levels to linac. The ratio of staff members to orthovoltage units was not included as no sites in Ireland have any more than a single unit.

2.3.2.1 Physics Staffing Levels

Figures 2.6 and 2.7 represent the number of physicists per patient and physicists per linac. It is difficult to quantify the workload that each treatment will require. The required staffing level will be a function of the workload in the department.
2. INCIDENT REPORTS

![Sites by Treatment Statistics]

**Figure 2.5:** Summary of Treatments Per Site

For example, treatment techniques such as IMRT and stereotactic treatments are known to have high workload due to the patient specific QA component. There is also a minimum workload for physics staff per linac. Even if there is only one patient on a machine it still needs to go through Linac QC on a regular basis.

### 2.3.2.2 Radiation Therapist and Dosimetrist Staffing Levels

Figures 2.8 and 2.9 show the radiation therapist and dosimetrist staffing levels. It should be noted here that some departments don’t hire dosimetrists and the workload is generally either given to radiation therapists or physicists. Dosimetrists are represented as number of dosimetrists per external beam patient.

### 2.3.2.3 Nurse Staffing Levels

This section represents the nurse staffing levels per patients. The number of patients per nurse is shown in figure 2.10. Site 6 were not able to differentiate between the number of nurses working exclusively in the radiotherapy department and those working on the wards. Therefore, they were not included in the results.
2.3 Department Profile

Figure 2.6: Number of Physicists per Linac

Figure 2.7: Number of Patients per Physicist
2. INCIDENT REPORTS

Figure 2.8: Number of Patients per Radiation Therapist

Figure 2.9: Number of Patients per Dosimetrist
Figure 2.10: Number of Patients per Nurse. *This information was not available for sites 6. Site 7 had no nurses in the radiotherapy department.*

### 2.3.2.4 Physician Staffing Levels

Figure 2.11 shows the number of patients per physician at the time of data collection. This is divided into two main categories, non-consultant hospital doctors (NCHDs) and consultants. It should be noted that the physician staffing levels were difficult to quantify, so we can assume that there are uncertainties to these values. This is due to the consistent movement of NCHDs across departments. It is also difficult to quantify the exact working hours of consultants working in private clinics due to the nature of private clinic contracts. An estimation of the physician staffing levels can be seen in figure 2.12. This estimation is based on the information provided by the departments.
2. INCIDENT REPORTS

Figure 2.11: Number of Patients per Physician

2.4 Results of Incident Reports

2.4.1 Incidents

Incidents, as classified by the flow chart in figure 2.1, is an event where there is a dosimetric or geometric deviation to the patients’ treatment compared to what was planned or intended.

2.4.1.1 Incident Rates

The incident rates were calculated based as number of incidents per 100 patients. The baseline values are taken as:

\[
\frac{N_{ri}}{N_p} \times 100 = B_{100}
\]  

(2.3)

\(N_{ri}\) is the number of reported incidents across the period
\(N_p\) is the number of patients across the period
\(B_{100}\) is the number of reported incidents per 100 patients

The incident rate is then corrected for under-reporting of events. In the next chapter of the thesis the patient safety culture survey is discussed. This survey
2.4 Results of Incident Reports

includes a question on how often people report incidents that they identify. Using this information, the reported incident rates could be corrected to account for the amount of incidents that are identified but go unreported. The incident rates will be corrected using the responses from question D3.

The average score for this question was converted into a correction factor based with an uncertainty of +/-0.1. The question, when being filled out, quantified the 1-5 scale as:

1-Never < 20%
2-Rarely 20 – 39%
3-Sometimes 40 – 59%
4-Most of the time 60 – 79%
5-Always > 80%

This is demonstrated in figure 2.13.

Figure 2.12: Scale for correcting incident rates

For example, if a person says that they rarely report incidents, based on this classification that means that they report incidents 20-39% of the time. If all staff say this then we know that the reported incident rate is 20-39% of the actual incident rate. We can use this information to correct for the under-reporting of incident rates. To get the correction factor the following equation is used:

\[(M \times 0.2) - 0.1 = C_{avg}\] (2.4)

With M is the average response. To correct for the uncertainty the range 0.1 is taken from \(C_{avg}\) to get the lower value and 0.1 is added for the upper value.

Take site 2 as an example. The question used to correct the reported rate is:
When a mistake is made that could harm the patient, but does not, how often is this reported?

This correction makes the assumption that the incidents do not harm the patient. Using this correction also does not take into account the reporting of incidents where there is definite harm to the patient. These will make up a significantly lower amount of incidents than ones that reach the patient, haven’t harmed the patient but potentially could have if there was a different dosimetric or geometrical severity to the event. In essence, this correction assumes that all incidents that are reported fit this description.

The average response to the question for site 2 was 4.75. This equates to an average correction of 0.85 ((4.75*0.2)-0.1) using equation 2.4. Then the lower end is taken as 0.75 (0.85-0.1) and 0.95 (0.85+0.1) for the upper end. This means that between 75 and 95% of identified incidents are reported. The incident rate for this site is 0.92 per 100 patients. Correcting for the under-reporting an incident rate of 0.97 to 1.10 per 100 patients was calculated.

In site 1 there were no recorded incidents by the definition demonstrated in figure 2.1. It is thought that based on this and consultation with the manager about this that incident reporting in this site is insufficient. The remaining sites are summarised in table 2.1. Site 8 is not corrected for as there was not a high enough response to the patient safety survey.

2.4.1.2 Breakdown of Incident Classification

The following graphs’ breakdown the types of incidents that occur. The information presented was analysed and is accurate to the best of the authors knowledge based on what was given to the authors by the various radiotherapy departments. The classifications as discussed in section in 2.2.1 were applied to this information. The information presented here is the first multi-site review of incidents where all locally reported incidents were examined.
### 2.4 Results of Incident Reports

<table>
<thead>
<tr>
<th>Site</th>
<th>Baseline Rate (Incident per 100 patients)</th>
<th>Corrected Range (Upper)</th>
<th>Corrected Range (Lower)</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.92</td>
<td>1.23</td>
<td>0.97</td>
<td>1.10</td>
</tr>
<tr>
<td>3</td>
<td>0.55</td>
<td>0.73</td>
<td>0.58</td>
<td>0.65</td>
</tr>
<tr>
<td>4</td>
<td>1.73</td>
<td>2.65</td>
<td>2.03</td>
<td>2.34</td>
</tr>
<tr>
<td>5</td>
<td>3.09</td>
<td>4.28</td>
<td>3.35</td>
<td>3.81</td>
</tr>
<tr>
<td>6</td>
<td>3.48</td>
<td>4.88</td>
<td>3.81</td>
<td>4.35</td>
</tr>
<tr>
<td>7</td>
<td>0.59</td>
<td>0.91</td>
<td>0.70</td>
<td>0.80</td>
</tr>
<tr>
<td>8</td>
<td>1.23</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Table 2.1:** Incident Rates per Site

Only one site included any incidents relating to brachytherapy.
Figure 2.13: Type of Dosimetric Deviation: This graph shows the type of effect of the incident on the patient treatment. Underdoses will affect the TCP while overdoses will affect the NTCP. Geometrical deviations will affect both. This classification is only applicable to incidents that affect the tumour or OARs.
2.4 Results of Incident Reports

Figure 2.14: Dosimetric Severity: This graph shows the distribution of dosimetric severities across the various sites. It can be seen from this that the majority are less than a dosimetric severity of 2. This means that the majority of incidents had less than a 5% dose deviation.
2. INCIDENT REPORTS

Figure 2.15: Type of Incident: This graph shows the distribution of different types of incidents. This is based on the classification discussed in section 2.2.1.3. It can be seen from this that the highest volume of errors are setup based.
2.4 Results of Incident Reports

Figure 2.16: Area of Origin. This graph shows the stage of origin for incidents. The highest rate is at treatment delivery. This is expected as there is little time to rectify an incident that originates at treatment delivery compared to an incident that originates earlier in the treatment pathway.
Figure 2.17: Area of Discovery. This shows where incidents were discovered. As the majority of incidents originate at treatment delivery, they would also need to be discovered at that point or later in the process flow.
2.4 Results of Incident Reports

Figure 2.18: HFACS-RT Classification. This shows the different aspects of the HFACS-RT that were applicable to the incidents investigated. One of the things that can be noted here is that each incident often fell under multiple classifications and therefore multiple HFACS-RT causes were applied to an individual incident.
2. INCIDENT REPORTS

<table>
<thead>
<tr>
<th>Site</th>
<th>Baseline Rate (Near-Misses per 100 patients)</th>
<th>Corrected Range (Upper)</th>
<th>Corrected Range (Lower)</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.40</td>
<td>0.94</td>
<td>0.64</td>
<td>0.79</td>
</tr>
<tr>
<td>2</td>
<td>1.48</td>
<td>2.11</td>
<td>1.64</td>
<td>1.88</td>
</tr>
<tr>
<td>3</td>
<td>1.03</td>
<td>1.41</td>
<td>1.11</td>
<td>1.26</td>
</tr>
<tr>
<td>4</td>
<td>1.73</td>
<td>2.88</td>
<td>2.16</td>
<td>2.52</td>
</tr>
<tr>
<td>5</td>
<td>1.45</td>
<td>2.49</td>
<td>1.85</td>
<td>2.17</td>
</tr>
<tr>
<td>6</td>
<td>2.46</td>
<td>4.10</td>
<td>3.07</td>
<td>3.58</td>
</tr>
<tr>
<td>7</td>
<td>1.08</td>
<td>1.84</td>
<td>1.37</td>
<td>1.61</td>
</tr>
<tr>
<td>8</td>
<td>2.05</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2.2: Near-Miss Rates per Site

2.4.2 Near-Miss

Near-misses, as defined by the flow chart in figure 2.1, are events where there is the potential for a dosimetric or geometric incident, however it was caught prior to reaching the patient. This section discusses these events.

2.4.2.1 Near-Miss Rates

A near-miss as defined in this study and the paper by Ford et al[12], is any potential incident that is caught prior to treatment of the patient. This matches with the patient safety culture question D1. This question was used to correct for the under-reporting of near-misses using the same technique described in section 2.4.1.1. This question is used to correct for the near-miss rate, the same as for the incident rates.

2.4.2.2 Breakdown of Near-Miss Classification

The following graphs represent the classification of the near-misses that were reported locally in departments.
Figure 2.19: Type of Potential Dosimetric Deviation. *This graph shows the type of effect of the event had it not been caught.*
2. INCIDENT REPORTS

Figure 2.20: Potential Dosimetric Severity
2.4 Results of Incident Reports

Figure 2.21: Type of Potential Incident
2. INCIDENT REPORTS

Figure 2.22: Area of Origin for Potential Incident
2.4 Results of Incident Reports

Figure 2.23: Area of Discovery for Potential Incident
Figure 2.24: HFACS-RT Classification for Potential Incident
2.5 Discussion

2.5.1 Near-misses vs Incidents

All data received was reclassified using figure 2.1. This standardised the results so that what is considered a near-miss and incident is the same between sites. As a result of the classification there was an overlap of consequence between one type of incident and one type of near-miss. This is explained in the following two examples:

Example 1: A patient is setup incorrectly. The patient is imaged and the error is identified. The patient is setup again and the error is rectified. The patient is imaged again to verify new setup is correct. This is classified as a near-miss.

Example 2: A patient is imaged once and the setup is verified. The patient is accidentally imaged a second time. Thus the patient gets an extra ionising image taken that is a deviation from protocol. This is therefore classified as an incident.

In both these cases the consequence to the patient is identical but they are classified differently.

In a number of reports the classification re-graded based on flow diagram from figure 2.1. This could indicate an under estimation of the number of near misses. Non-conformities were not obtained from many of the sites. It is possible that based on the classification used here that some of the non-conformities would be classified as near-misses.

The availability of information from certain sites resulted in a degree of uncertainty in all aspects of the classification process. The majority of the sites stated the nature of the event. However, in some cases, due to lack of detail, it was difficult to verify this. In scenarios where there was not enough information to make an independent assessment, the defined nature of the event was kept as defined by the site.
2. INCIDENT REPORTS

It is noted that there is a difference between the potential severity of near-misses and the severity of incidents. This can be explained by the stage of origin. 54% of the near-misses originated in the planning stage of the process. This inherently will result in a higher severity rating than when the error originates in treatment delivery. This is because the majority of events that start in planning will affect every fraction, while setup errors generally will only result in one error on one fraction. This creates an interesting point as hyperfractionated schedules become more prominent. These type of single fraction errors will have a greater influence on the overall radiobiological response to the tumour.

2.5.2 HFACS-RT and Severity Classification

The HFACS-RT classification had the highest subjectivity. This is compounded by the limited information available about some events reported. To reduce intra-user variability the events were reviewed twice by the same reviewer. There were some changes on the 2nd review but the majority of the classifications remained the same. Inter-user variability is not taken into account. In some cases error modes demonstrated multiple error types. This was most commonly seen with perceptual errors. These commonly were based on reviewing images and so were also ranked as skill based.

A high proportion of the incidents were classified (43%) as having skill as a contributing factor. Incidents involving annotation, mistakes with software or hardware and miscalculation were all classified as skill based errors. Most incidents are, to an extent, a violation of protocol. An incident occurs in the absence of a protocol violation is indicative of a failure in the process design. There are only two reasons why an event is recorded as a violation in this study. The first reason is when the report directly says a violation of protocol occurs. The second is where there is evidence in the report that a violation has occurred. In one study where 37 incidents were investigated, skill based errors represented 27% of the incidents(141).
2.5 Discussion

It should be noted as well that very few events were classified in using the sections *supervision* or *organisational influences*. This is due to the lack of information in the reports and inter-dependency of the reports. Few sites are willing to criticise themselves.

Clinical severity was extremely difficult to classify\(^1\). In some centres the reports did not include information about the intent of treatment or type of treatment. Without information about the patients disease, health and treatment estimating the clinical severity would be no better than a guess. For this reason the clinical severity was not reported.

In certain cases there was limited information about the dosimetric severity. In these cases the dosimetric severity was estimated based on the information about the radiotherapy treatment in the context of the incident. For example, if it was a setup based error on a single fraction of a 37 fraction prostate plan, it is safe to assume that it will be less than a 2.5% dose deviation. 1 fraction out of 37 is 2.7%, therefore the only way the deviation would be greater than 2.5% is if most of the target was missed. However, if there was a prostate treatment where none of the target was covered due to a setup error for one fraction, then the total dose deviation for that patient would be 2.7%.

2.5.3 Inconsistencies in incident reporting

The centres did not report incidents in comparable ways making it difficult to easily compare reports. The language in some reports contained defensive language. The second issue is that the internal reporting system in centres have major differences. In some centres a form is filled out and stored. The form is added to, the original data is never changed.

\(^1\)The dosimetric consequence was reported in figure 2.15 and potential dosimetric consequence in figure 2.21
2. INCIDENT REPORTS

Site 1 showed the largest inconsistency in reporting. “Incidents” that were reported were generally related to hardware failures rather than patient specific errors. The data reviewed for the 12 months in question did not include anything that was specified as a patient specific event. Reporting levels in this site will be discussed further in the next chapter of the thesis.

Sites 5 and 6 both have the two highest incident rates. In both these sites it was apparent that there was a high volume of these caught at on-treatment quality management. Thus, it is not necessarily the case that incident rates are actually higher but they may have more stringent process quality controls. Site 6 had access to advanced technologies. This included a dual imaging system which meant that there was an initial setup image and an off-line imaging system. This resulted in this site identifying a high proportion of setup errors (74%). It is possible (if not probable) that all sites have this high proportion of setup errors but aren’t being identified.

2.5.4 Systematic Errors

There were a few systematic errors identified. These were classified in the same manner as other events. Where the number of patients that would have been affected was specified, each one was counted as a single error. There was one reported near-miss where the number of patients that would have been affected was not included. In this case the near-miss was counted as a single event. The result of this is an under-estimation of the near-miss rate in that site.

2.5.5 Ideal Reporting System

The reporting systems that were dealt with in the study demonstrate a need for standardisation across reporting systems. A more detailed description after incidents using the classification presented in this thesis would improve the efficiency of the analysis. If information about the condition of the individual was included in the reporting, this could be used to look at more levels of the HFACS-RT
2.5 Discussion

classification. The classification about the type of error, the severity, area of discovery and area of initiation can be established by reading the description, but if they were classified separately from the description it would help improve the efficiency of the data analysis.
2. INCIDENT REPORTS

2.5.6 Summary

This chapter has shown the rate of incidents in radiotherapy departments ranges from site to site. It can be clearly seen from the data that human error plays a major role in causing incidents. From reviewing the incidents it can be seen that a high proportion of the incidents could be reduced through training, inter-discipline communication improvements, or introduction of check lists. 43% of the incidents had skill as a contributing factor. Improvements in training should reduce this. Memory lapse accounts for 19% of incidents. This could be reduced by the introduction of check lists so that people don’t forget steps in the process. Communication can be improved through social events, or even a multi discipline tea room. Figure 2.5 shows aspects of patient safety culture that relate to the different HFACS-RT contributions to errors. Based on this it can be assumed that patient safety culture will influence human error probability. The correlation between a high number of patient safety indicators and negative patient safety culture has been discussed by Singer et al.(41). Patient safety indicators are designed to measure patient safety events in hospitals(145). This indicates that safety culture will influence patient safety events in healthcare. According to the research in this chapter all reported incidents are influenced by human error. Therefore, it can be concluded that patient safety culture is going to influence human error rates. The patient safety culture is examined across multiple sites in the next chapter of this thesis.
3

Patient Safety Culture

3.1 Motivation for Study

The previous chapter evaluated the various causes of incidents in radiotherapy. Human factors had a role in all the events that were examined. The role of patient safety culture in incidents has been discussed in a number of publications. Patient safety culture has a relationship to patient incident rates in healthcare\cite{41, 39, 146}. This information and the information in the previous chapter indicates that patient safety culture has a relationship with human performance. This was also demonstrated by a paper by Cooper and Phillips that evaluated the relationship between safety culture and safety behaviour by individuals\cite{147}. The purpose of the study presented in this chapter was to analyse the metrics of patient safety culture across multiple radiotherapy sites. The Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC) was used to complete this study due to its well documented use and exploration of multiple metrics that are associated with patient safety culture. These metrics will be discussed in detail in this chapter. The objectives of this study are to look at the 12 metrics of patient safety culture (using the AHRQ HSOPSC) and evaluate the difference from site to site and demonstrate the statistical difference between the various sites on a metric by metric basis. This study is related to the previous study that evaluated the incident rates across Ireland. The study was performed during the same time frame across the same sites. The unique information presented in this chapter is:
3. PATIENT SAFETY CULTURE

- Application of AHRQ Patient Safety Culture in radiotherapy
- A multi centre study of patient safety culture
- A benchmark of patient safety culture in radiotherapy

3.2 Methodology

3.2.1 Site Specifics

The study was implemented in 8 radiotherapy sites. One site is excluded from the results as only 3 responses were given. Fifty percent is recommended as the response rate by the AHRQ\(^{[46]}\). This was not achieved by all sites. The lowest rate reported here was approximately 18%.

There have been studies that evaluated survey results when the responses are less than 100%. In a study by Visser et al, the results from a mail survey was compared with actual election results. In this study the survey agreed closely with the election results\(^{[148]}\). In another study a telephone survey was compared with a more rigorous study. The telephone survey had a 25% response rate. A more rigorous version of the same study/survey (which had a 50% response) found no statistical difference in 77 out of the 84 comparable items\(^{[149]}\). Another study looked at a population based survey for a gastroenterology based survey. In this it was discovered that there was no significant difference between responders and non-responders when compared with medical records\(^{[150]}\). Based on these studies, and that there was no study that directly examined the AHRQ HSOPSC, it was decided to include results where the response was greater than approximately 18%. While this is lower than recommended, the evidence presented above suggests it should still be a good representative of peoples thoughts. The response rate to the survey in this study ranged from approximately 18% up to and over 80%. This also should be a better representation of patient safety culture than the AAPMs safety profile assessment tool (discussed in section 1.2.2), which looks at elements of patient safety culture, but uses a multidisciplinary team to assess the
3.2 Methodology

questions, rather than opening it to the whole department\(^{17}\).

The sites are divided up into 3 public hospitals and 5 private hospitals. Each hospital was assigned a random number and will hence forth be be referred to as site 1 to site 7\(^1\). These are the same assigned numbers as in Chapter 2.

3.2.2 Survey Description

The AHRQ HSOPSC is a questionnaire that uses 43 questions to evaluate 12 metrics of patient safety culture and patient safety grade for a hospital. The survey also contains a number of questions that evaluate information about the respondents role in the hospital. The HSOPSC was used to assess the patient safety culture of the individual radiotherapy departments. This survey was chosen as the most suitable for assessing patient safety culture. This survey was chosen as in previous studies it was found to have a Cronbachs alpha coefficient of 0.63 to 0.83\(^2\)\(^{38}\), it was designed for general medical use, it examined 12 separate dimensions including reporting rates\(^{38}\). The Cronbachs alpha coefficient is a measure of the internal consistency of the survey data. A high Cronbachs alpha represents a good internal consistency within metrics. In some literature a Cronbachs Alpha of a least 0.7 is recommended. However, for psychology constructs a value of less than 0.7 can still be deemed acceptable\(^{151}\). The survey was distributed in either paper form, online version or both. The method of distribution was decided after consultation with the management of the hospital. In one centre the survey had already been recently distributed. In this centre the local results were used rather than re-distributing the survey. A number of small variations were made to the forms to make them radiotherapy specific. The staff member roles were changed to radiotherapy roles (nurse, radiation therapist, radiographer, medical physicist, doctor (non-consultant), consultant, administration and other). Any changes made did not change the wording for any of the questions that evaluated the metrics. The section on frequency of events reported included quantification

\(^{1}\)Site 8 only had 3 responses and will not be included

\(^{2}\)The Cronbachs alpha coefficient is used to measure the internal consistency of survey data. It reviews questions that are measuring the same metrics and evaluates the consistency among the answers.
3. PATIENT SAFETY CULTURE

on reporting levels to reduce ambiguity. This data was used to evaluate the uncertainty in reporting rates. A copy of the survey used can be seen in Appendix C. Where possible, the survey was also distributed with a leaflet. This can be seen in Appendix D.

The HSOPSC have definitions which are used to reduce ambiguity in the responses. An event is defined as:

“as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.”

Patient safety is defined as:

“the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.”

A unit is defined as:

“the work area, department, or clinical area of the hospital where you spend most of your work time or provide most of your clinical services.”

Thus a unit is defined as the radiotherapy department.

3.2.2.1 Metrics Evaluated

All questions evaluating the metrics were based on a 1-5 scoring system. These are described below. Some of the questions were negatively worded. The results for negatively worded questions were inverted to account for this.

Teamwork Within Units  There are 4 questions used to evaluate the perception of teamwork within units[152]. These are all positively weighted questions. Teamwork is defined as “The combined action of a group, especially when effective and efficient”[153]. This definition makes reference to effective group action. This implies that a low teamwork score will indicate ineffective completion of actions. A study discussed in the introduction suggested that team work
and communication lags behind aviation. The questions used to assess teamwork are as follows:

i) People support one another in this unit.

ii) When a lot of work needs to be done quickly, we work together as a team to get the work done.

iii) In this unit, people treat each other with respect.

iv) When one area in this unit gets really busy, others help out.

These questions were rated as 1-5 Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.

**Supervisor/Manager Expectations and Actions Promoting Patient Safety**

This metric represents how staff generally perceive managements’ actions towards patient safety. This metric can demonstrate a difference between how management perceive their own actions. This information can be used to improve the managements approach to patient safety including staff input. This metric uses 4 questions, 2 of which are negatively weighted. These are rated 1-5 as Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree. For the negatively weighted questions the values were inverted for the statistical analysis. The questions are:

i) My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.

ii) My supervisor/manager seriously considers staff suggestions for improving patient safety.

iii) Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts. (negatively worded)

iv) My supervisor/manager overlooks patient safety problems that happen over and over. (negatively worded)

These questions were rated as 1-5 Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.
3. PATIENT SAFETY CULTURE

**Organisational Learning**  This metric represents how well a department is able to learn from its mistakes\(^{152}\). This is important to reduce the number of recurring errors. The data from the previous chapter suggests a similarity between errors that occur in a department i.e. incidents repeating themselves. A positive organizational learning structure indicates a good incident learning system. This metric is assessed using 3 questions shown below and a 1-5 scale as *Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.*

i) *We are actively doing things to improve patient safety.*

ii) *Mistakes have led to positive changes here.*

iii) *After we make changes to improve patient safety, we evaluate their effectiveness.*

**Management Support for Patient Safety**  This metric evaluates how staff feel supported when addressing safety issues and how management actions demonstrate that safety is a priority. Unlike the metric *Supervisor/Manager Expectations and Actions Promoting Patient Safety,* this metric is directed towards a hospital management level, not the line manager level\(^{152}\). This is distinctly different as a line manager can demonstrate that patient safety is a high priority but this may not be representative of the hospital management. This metric is assessed using 3 questions (one negatively worded) shown below and a 1-5 scale as *Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.*

i) *Hospital management provides a work climate that promotes patient safety.*

ii) *The actions of hospital management show that patient safety is a top priority.*

iii) *Hospital management seems interested in patient safety only after an adverse event happens.* (negatively worded)

**Overall Perceptions of Patient Safety**  The overall perception of patient safety is vague compared to some of the other metrics. This makes it more difficult to take any positive action based on the results as it does not discuss specifics. Nonetheless, this metric can identify that problems exist that are outside the remit of other metrics. This metric is designed to evaluate the procedures and
3.2 Methodology

The general integrity of the system\(^\text{[152]}\). This metrics is measured based on 4 questions as follows, rated as \textit{Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree}.

i) \textit{Patient safety is never sacrificed to get more work done.}

ii) \textit{Our procedures and systems are good at preventing errors from happening.}

iii) \textit{It is just by chance that more serious mistakes don’t happen around here.} (negatively worded)

iv) \textit{We have patient safety problems in this unit.} (negatively worded)

**Feedback and Communication About Error** Feedback is defined as “\textit{Information about reactions to a product, a persons performance of a task, etc. which is used as a basis for improvement}”\(^\text{[153]}\). This by definition includes the term improvement. Feedback is a vital step in incident learning\(^\text{[152]}\). There are 3 questions used to assess this metric using a 1-5 scale representing \textit{Never, Rarely, Sometimes, Most of the time, Always}. The questions for this metric are as follows:

i) \textit{We are given feedback about changes put into place based on event reports.}

ii) \textit{We are informed about errors that happen in this unit.}

iii) \textit{In this unit, we discuss ways to prevent errors from happening again.}

**Communication Openness** Communication openness reflects how staff feel about questioning decisions and having an open dialogue in reference to patient safety\(^\text{[152]}\). This is something that has been adapted by the aviation industry, where any queries about safety are encouraged to be discussed regardless of rank. This encourages more people to have a say in safety matters. This metrics is measured using 3 questions which are answered using a 1-5 scale representing \textit{Never, Rarely, Sometimes, Most of the time, Always}.

i) \textit{Staff will freely speak up if they see something that may negatively affect patient care.}

ii) \textit{Staff feel free to question the decisions or actions of those with more authority.}
3. PATIENT SAFETY CULTURE

iii) Staff are afraid to ask questions when something does not seem right. (negatively worded)

**Frequency of Events Reported**  Frequency of events reported refers to the frequency and types of incidents that staff report\(^\text{[152]}\). This is based on how often they report different events. This metric uses a 1-5 scoring which represents Never, Rarely, Sometimes, Most of the time, Always. For the purposes of this study this was quantified where the survey had not been previously distributed. For all responses this will be taken as follows:

1-Never < 20%
2-Rarely 20 – 39%
3-Sometimes 40 – 59%
4-Most of the time 60 – 79%
5-Always > 80%

This quantification is used to assess the uncertainty in the incident rates from the previous chapter. This metric was measured using the following questions.

i) *When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?*

ii) *When a mistake is made, but has no potential to harm the patient, how often is this reported?*

iii) *When a mistake is made that could harm the patient, but does not, how often is this reported?*

**Teamwork Across Units**  The teamwork across units is different to the teamwork within units\(^\text{[152]}\). Across units refers to different teams from different clinical areas. In radiotherapy this will have the most significant importance when transferring patients between wards and the relationship between radiotherapy and chemotherapy. This is graded on a 1-5 scale representing Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.

i) *There is good cooperation among hospital units that need to work together.*
3.2 Methodology

ii) Hospital units work well together to provide the best care for patients.

iii) Hospital units do not coordinate well with each other. (negatively worded)

iv) It is often unpleasant to work with staff from other hospital units. (negatively worded)

**Staffing** The metric staffing primarily refers to the workload of staff and if there is enough staff to safely meet the demands of the department[152]. This metric is assessed using 4 questions, 3 of which are negatively worded. A 1-5 scale is used to assess the metric, *Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.*

i) We have enough staff to handle the workload.

ii) Staff in this unit work longer hours than is best for patient care. (negatively worded)

iii) We use more agency/temporary staff than is best for patient care. (negatively worded)

iv) We work in "crisis mode" trying to do too much, too quickly. (negatively worded)

**Handoffs and Transitions** This metric represents the process where the responsibility of care for a patient is transferred from one member of staff or team to another[152]. This can be done within radiotherapy, where one team of radiation therapists are taking over for another. It can also be outside the radiotherapy department where patients are being transferred from other wards or the chemotherapy department. It is assessed using the following 4 negatively weighted questions which are graded as *Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.*

i) Things “fall between the cracks” when transferring patients from one unit to another. (negatively worded)

ii) Important patient care information is often lost during shift changes. (negatively worded)

iii) Problems often occur in the exchange of information across hospital units.
3. PATIENT SAFETY CULTURE

(negatively worded)

iv) Shift changes are problematic for patients in this hospital. (negatively worded)

Nonpunitive Response to Errors The no blame culture and the just culture are both well-established as important factors to increase incident reporting\(^\text{152}\)\(^\text{110}\). Non-punitive response to error indicates whether staff will feel punished for their mistakes. Towards Safer Radiotherapy discusses in detail the importance of\(^\text{111}\):

“a culture which is open and fair, which is non-punitive”

Management may believe that they have this culture, but it does not necessarily filter down to staff. Punitive response to error is known to reduce the reporting levels. The challenge is to have an open, non-punitive culture for reporting while still maintaining accountability for known violations that affect patient safety. If staff feel punished by reporting then they are more likely to cover up there mistakes. This metric is assessed using 3 negatively worded questions graded as Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree.

i) Staff feel like their mistakes are held against them. (negatively worded)

ii) When an event is reported, it feels like the person is being written up, not the problem. (negatively worded)

iii) Staff worry that mistakes they make are kept in their personnel file. (negatively worded)

Overall Patient Safety Grade The definition of grade is “A particular level of rank, quality, proficiency, or value”. The term quality is the most relevant part of the definition in relation to patient safety\(^\text{152}\). This metric is important because it can identify safety culture problems that aren’t identified by the other metrics. A low patient safety grade, even if the other metrics are high, demonstrates that staff think that there are other safety problems with the department. For this metric the participant is asked to grade the department as either A-Excellent, B-Very Good, C- Acceptable, D-Poor, E-Failing
3.2 Methodology

3.2.3 Analysis and Statistics

The responses were analysed using the “AHRQ Excel tool for assessing patient safety culture”, SPSS, R and RStudio\(^1\)\(^2\)\(^3\). The Excel tool was used to visually assess the results.

The data is represented in the form of a diverging stacked bar chart (see figure 3.1). A positive response is taken as a response scored 4-5 (1-2 for negative weighted questions). The patient safety grade is also assessed. This is an A, B, C, D, E grading system, with E being a failing grade (as specified in the survey). Staff are asked to grade their overall perception on patient safety. These graphs were compiled using R and RStudio. The red indicates a negative response. The blue represents a positive response. The bar graph is averaged at zero to visually represent which responses are primarily higher or lower. All negatively weighted questions were inverted to standardise the responses.

The second chart/table (see figure 3.2) shows the statistical analysis of the data. All statistical tests were performed using SPSS. The mean rank was calculated individually across all the sites for each metric. The mean rank is used as a ranking system for non-parametric data. This put all the data in order from the highest scoring department to the lowest scoring department. Each value (1-5) will receive a score based on its position. For example if a set of data contains the number 1, 4 and 5. The value 1 would be given the rank 3 as it is the lowest score. 4 would be given the value 2 as it is the second highest etc. This is used to rank the values, but is not used to statistically compare them\(^4\).

The Mann-Whitney test was then used to analyse if there was a statistically significant difference between the individual sites for each. The Mann-Whitney test is performed when the data sets analysed are independent of each other and when ordinal data is being evaluated. The data sets are independent of each other as they are from different radiotherapy departments. We know that the data is ordinal as it’s a numeric dataset that follows a ranking system, but the ranking system does not quantify the extent of the difference between rankings. This test is suitable when the data is non-parametric, i.e. it does not follow any particular
3. PATIENT SAFETY CULTURE

distribution. The data was identified as being non-parametric using SPSS. A p-value of less than 0.05 indicates a statistically significant difference between the data sets. This was calculated using SPSS.

3.2.4 Explanation of charts and graphs

There are a number of charts and tables presented in this chapter that show the results from this study. The tables 3.1 to 3.7 show the 7 sites, how they rank by metric, and how they statistically compare with the other sites presented. Figures 3.4 to 3.18 show the highly positive to highly negative responses and the percentage of each response per site. This is explained in figure 3.1. Please note, the percentage responses do not always add to 100% due to rounding.

Figure 3.1: Explanation for charts. This figure explains what the different elements of the charts represent. The colour codes represent the percentage of the responses from each department ranging from highly negative responses to highly positive responses.

The tables 3.8-3.20 show the statistical p-value between the various sites for the different metrics. It also shows the mean-rank score, the Cronbachs alpha coefficient and the range of ratings by staff members when filling out the survey.
3.3 Results

Figure 3.2: Explanation for tables. *This figure explains what the different values in the charts represent. The P-values show if there is a statistical difference between the sites for each metric. Greater than 0.05 indicates no statistical difference.*

### 3.3 Results

#### 3.3.1 Site Summary by Metric

The first set of tables represent the mean-rank for each of the metrics for each site. This information is used to then rank the departments 1-7 (or one to 6 for some of the metrics that weren’t evaluated in each site). The Mann-Whitney test described previously is then used to assess if there is a statistically significant difference between the sites results.

The first row on the tables states which metric is being evaluated. The second row stipulates the mean-rank. The mean-rank is calculated across all the sites. The third row is the mean-rank position in comparison to the other sites. The fourth row represents how many sites had a statistically significant higher score. The fifth row represents how many sites had a statistically significant lower score.
### Table 3.1: Site 1 Summary of Metrics

<table>
<thead>
<tr>
<th></th>
<th>114</th>
<th>281</th>
<th>341</th>
<th>295</th>
<th>267</th>
<th>230</th>
<th>200</th>
<th>152</th>
<th>142</th>
<th>153</th>
<th>200</th>
<th>322</th>
<th>74</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean-Rank</strong></td>
<td>74</td>
<td>322</td>
<td>300</td>
<td>153</td>
<td>142</td>
<td>153</td>
<td>300</td>
<td>220</td>
<td>200</td>
<td>321</td>
<td>301</td>
<td>341</td>
<td>79</td>
</tr>
</tbody>
</table>

#### Notes:
- **High** indicates a higher percentage of positive results.
- **Low** indicates a lower percentage of positive results.
- **Statistically Significant** indicates statistical significance.

#### Observations:
- **Overall**, **Communication**, and **Teamwork** are key metrics with higher percentages of positive results.
- **Leadership** and **Organization** show a lower percentage of positive results.

**Patient Safety Grade**:
- Site 1 has a **Mean-Rank** of 74.

**Handoffs and Transitions**
- High teamwork across units.
- Effective staffing and supervisor/managers' expectations.

**Teamwork within Units**
- Openness to feedback about errors.
- Non-punitive response to errors.

**Staffing**
- Frequency of events reported.

**Management Support**
- Organizational learning overall and perceptions of sites compared to the other sites.

**Number of Sites with a Statistically Significantly Higher Proportion of Positive Results**:
- 0 (Leadership), 2 (Organization), 0 (Communication), 2 (Teamwork), 1 (Supervisor/Managers), 2 (Teamwork within Units), 6 (Teamwork across Units), 5 (Staffing), 6 (Teamwork within Units), 3 (Leadership), 1 (Organization), 0 (Communication), 3 (Teamwork), 0 (Staffing).

**Number of Sites with a Statistically Significantly Lower Proportion of Positive Results**:
- 2 (Leadership), 4 (Organization), 0 (Communication), 4 (Teamwork), 0 (Supervisor/Managers), 2 (Teamwork within Units), 0 (Teamwork across Units), 0 (Staffing), 0 (Teamwork within Units), 0 (Leadership), 0 (Organization), 3 (Communication), 0 (Teamwork), 3 (Staffing).
### 3.3 Results

#### Site 2

<table>
<thead>
<tr>
<th>Metric</th>
<th>Mean-Rank</th>
<th>Mean-Rank position compared to the other sites</th>
<th>Number of Sites with a Statistically Significantly Higher Proportion of Positive Results</th>
<th>Number of Sites with a Statistically Significantly Lower Proportion of Positive Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handoffs and Transitions</td>
<td>265</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Teamwork Across Units</td>
<td>304</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Teamwork within Units</td>
<td>253</td>
<td>6</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Staffing</td>
<td>266</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Supervisor/Managers Expectations and Actions</td>
<td>258</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Management Support</td>
<td>270</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Communication Openness</td>
<td>249</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Feedback About Errors</td>
<td>247</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-Punitive Response to Error</td>
<td>188</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Frequency of Events Reported</td>
<td>271</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Organisational Learning</td>
<td>270</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Overall Perceptions</td>
<td>355</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Patient Safety Grade</td>
<td>94</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

#### Table 3.2: Site 2 Summary of Metrics
### 3. PATIENT SAFETY CULTURE

#### Site 3 Summary of Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Site 3</th>
<th>Mean-Rank</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handoffs and Transitions</td>
<td>286</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teamwork Across Units</td>
<td>271</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teamwork Within Units</td>
<td>268</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staffing Supervisor/Managers</td>
<td>260</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expectations and Actions</td>
<td>281</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management Support</td>
<td>169</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>277</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Openness</td>
<td>277</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feedback</td>
<td>275</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Punitive Response to Error</td>
<td>265</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of Events Reported</td>
<td>257</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisational Learning</td>
<td>255</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Perceptions</td>
<td>116</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Safety Grade</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The mean-rank position compared to the other sites is as follows:

- **6** Site 1
- **7** Site 2
- **8** Site 4
- **9** Site 5
- **10** Site 6
- **11** Site 7
- **12** Site 8
- **13** Site 9
- **14** Site 10
- **15** Site 11
### Table 3.4: Site 4 Summary of Metrics

<table>
<thead>
<tr>
<th>Site 4</th>
<th>Handoffs and Transitions</th>
<th>Teamwork Across Units</th>
<th>Teamwork within Units</th>
<th>Staffing</th>
<th>Supervisor/Managers Expectations and Actions</th>
<th>Management Support</th>
<th>Communication Openness</th>
<th>Feedback About Errors</th>
<th>Non-Punitive Response to Error</th>
<th>Frequency of Events Reported</th>
<th>Organisational Learning</th>
<th>Overall Perceptions</th>
<th>Patient Safety Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean-Rank</td>
<td>NA</td>
<td>NA</td>
<td>399</td>
<td>400</td>
<td>396</td>
<td>315</td>
<td>222</td>
<td>282</td>
<td>246</td>
<td>220</td>
<td>264</td>
<td>388</td>
<td>97</td>
</tr>
<tr>
<td>Mean-Rank position compared to the other sites</td>
<td>NA</td>
<td>NA</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Number of Sites with a Statistically Significantly Higher Proportion of Positive Results</td>
<td>NA</td>
<td>NA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of Sites with a Statistically Significantly Lower Proportion of Positive Results</td>
<td>NA</td>
<td>NA</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>
### Table 3.5: Site 5 Summary of Metrics

<table>
<thead>
<tr>
<th>Overall Patient Safety Grade</th>
<th>Mean-Rank</th>
<th>254</th>
<th>244</th>
<th>268</th>
<th>277</th>
<th>232</th>
<th>164</th>
<th>213</th>
<th>207</th>
<th>247</th>
<th>244</th>
<th>210</th>
<th>257</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handoffs and Transitions</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Teamwork Across Units</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Teamwork within Units</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Staffing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Supervisor/Managers</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Expectations</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Actions</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Management Support</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Communication</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Openness</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Feedback</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-Punitive Response to Error</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Mean Rank** compared to the other sites

| Number of Sites with a Statistically Significantly Higher Proportion of Positive Results | 0 | 2 | 2 | 3 | 3 | 4 | 2 | 1 | 0 |
| Number of Sites with a Statistically Significantly Lower Proportion of Positive Results | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |

**Site 5**

**Handoffs and Transitions**

**Teamwork Across Units**

**Teamwork within Units**

**Staffing**

**Supervisor/Managers**

**Expectations**

**Actions**

**Management Support**

**Communication**

**Openness**

**Feedback**

**Non-Punitive Response to Error**

**Frequency of Events**

**Organisational Learning**

**Overall Perceptions**

**Patient Safety Grade**

**Mean-Rank**
### Site 6

<table>
<thead>
<tr>
<th></th>
<th>Handoffs and Transitions</th>
<th>Teamwork Across Units</th>
<th>Teamwork within Units</th>
<th>Staffing</th>
<th>Supervisor/Managers Expectations and Actions</th>
<th>Management Support</th>
<th>Communication Openness</th>
<th>Feedback About Errors</th>
<th>Non-Punitive Response to Error</th>
<th>Frequency of Events Reported</th>
<th>Organisational Learning</th>
<th>Overall Perceptions</th>
<th>Patient Safety Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean-Rank</td>
<td>246</td>
<td>249</td>
<td>303</td>
<td>255</td>
<td>288</td>
<td>204</td>
<td>218</td>
<td>219</td>
<td>232</td>
<td>224</td>
<td>211</td>
<td>275</td>
<td>71</td>
</tr>
<tr>
<td>Mean-Rank position compared to the other sites</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Number of Sites with a Statistically Significantly Higher Proportion of Positive Results</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Number of Sites with a Statistically Significantly Lower Proportion of Positive Results</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 3.6: Site 6 Summary of Metrics**
### Site 7 Summary of Metrics

<table>
<thead>
<tr>
<th>Patient Safety Grade</th>
<th>Mean-Rank</th>
<th>255</th>
<th>257</th>
<th>332</th>
<th>406</th>
<th>361</th>
<th>222</th>
<th>278</th>
<th>256</th>
<th>262</th>
<th>207</th>
<th>265</th>
<th>372</th>
<th>96</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handoffs and Transitions</td>
<td>Teamwork Across Units</td>
<td>Teamwork within Units</td>
<td>Staffing</td>
<td>Supervisors/Managers</td>
<td>Expectations and Actions</td>
<td>Communication</td>
<td>Openness</td>
<td>Feedback about Errors</td>
<td>Non-Punitive Response to Error</td>
<td>Frequency of Events</td>
<td>Organisational Learning</td>
<td>Overall Perceptions</td>
<td>Patient Safety Grade</td>
<td></td>
</tr>
</tbody>
</table>

| | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 1 | 1 | 6 | 1 | 3 | 1 | 4 | 1 | 2 | 1 | 2 | 1 | 4 | 0 | 0 | 4 | 3 | 2 | 1 | 2 | 1 | 3 | 3 | 3 |

| Mean-Rank | 255 | 257 | 332 | 406 | 361 | 222 | 278 | 256 | 262 | 207 | 265 | 372 | 96 |

Number of Sites with a Statistically Significantly Higher Proportion of Positive Results: 0 1 1 0 0 2 0 0 2 2 0 0 0 4 3 5 2 4 0 1 2 1 3 3 3

Number of Sites with a Statistically Significantly Lower Proportion of Positive Results: 0 0 4 3 5 2 4 1 2 1 3 3 3
3.3 Results

3.3.2 Results by Metric and Statistical Values

3.3.2.1 Handoffs and Transitions

For this metric the highest mean-rank was observed in site 1. This was statistically significantly higher than the results from site 3 and site 6. The management in site 4 already administered this survey. They did not review this metric in their study. The Cronbachs Alpha coefficient of 0.758 indicates a good internal consistency for this metric. This indicates that the results are reliable\(^{151}\). This data can be compared with results that have been reported to the AHRQ. The 2014 AHRQ comparative report reported that the lowest rate of positive reports for this metric was 26%, the median was 46% and the maximum rate was 84%\(^{159}\). For the majority of the sites, the number of positive responses were less than the median score. This suggests that handoffs could be problematic for radiotherapy. However, unlike other areas of healthcare, not every patient will require to be a handoff. This is different to wards where every patient will require a changeover between shift changeovers. The legend for the likert plots can be seen below. The percentage of the positive responses is written in blue to compare with the values from the 2014 comparative report. Figure 3.4 and table 3.8.

![Legend for Charts](image)

**Figure 3.3:** Legend for Charts

3.3.2.2 Teamwork

For the metric *teamwork across units* site 1 and site 2 had the two highest mean-ranks respectively. There was no statistical difference between these two sites. Site 1 had a statistically significantly higher result than all other sites except site 2. Site 2 demonstrated a statistically significant differences between site 3, site 5 and site 6. This metric was not examined in the study done in site 4. The 2014 AHRQ comparative report reported that the lowest rate of positive
3. PATIENT SAFETY CULTURE

Figure 3.4: Handoffs and Transitions

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>1-5</td>
<td>14% 37% 49% 3.5:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>1-5</td>
<td>17% 42% 42% 2.5:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>1-5</td>
<td>29% 38% 34% 1.2:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>2-5</td>
<td>23% 42% 35% 1.5:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>2-5</td>
<td>32% 27% 41% 1.3:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>1-5</td>
<td>17% 48% 35% 2.1:1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3.8: Statistics Handoffs and Transitions
3.3 Results

Reports for this metric was 35%, the median was 59% and the maximum rate was 90%\(^{159}\). When we look at the data measured in this study we can see that one of the sites had a lower score than the lowest score from the AHRQ database. The maximum rate was 73%. This metric refers to the teamwork across units. Miscommunication as a result of poor team work, in this instance, could result in poor information transfer for chemotherapy patients and patients based in wards. A high amount of patients will not be affected by this metric as radiotherapy can often be an out patient, stand alone procedure.

The metric \textit{teamwork within units} demonstrated high positive responses with sites 4 and 7. The statistical tests demonstrated differences between the majority of other sites. Site 6 and site 3 both had the widest range of results, with some answers scoring 1. Despite this the mean-mark for site 6 is the third highest. The 2014 AHRQ comparative report reported that the lowest rate of positive reports for this metric was 46%, the median was 81% and the maximum rate was 96%\(^{159}\). The results here are mostly above the median and some sites are close to the maximum rate. In this study the maximum rates are 94% (two sites had this). The lowest in this study was 69% which is significantly higher than the AHRQ lowest result. Site 3, which had the second highest rate of inter-discipline miscommunication had a 70% positive response to teamwork within units. This was the second lowest rate of positive responses. Teamwork within units is important for strong communication between staff members in any given site. Miscommunication can result in incidents.

The Cronbachs Alpha coefficients for these two metrics both demonstrated a good internal consistency. The results for this are shown in figures 3.5-3.6 and tables 3.9-3.10.

3.3.2.3 Staffing

Staffing had a significantly lower average score than the previous metrics. Site 7 and site 4 both had high mean-ranks for this metric. This resulted in them
3. PATIENT SAFETY CULTURE

Figure 3.5: Teamwork Across Units

<table>
<thead>
<tr>
<th>Teamwork Across Units</th>
<th>Cronbach's Alpha 0.721</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>Site 1</td>
<td>4</td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
</tr>
<tr>
<td>Site 3</td>
<td>3</td>
</tr>
<tr>
<td>Site 4</td>
<td>3</td>
</tr>
<tr>
<td>Site 5</td>
<td>3</td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
</tr>
<tr>
<td>Site 7</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3.9: Statistics of Teamwork Across Units

<table>
<thead>
<tr>
<th>Teamwork within Units</th>
<th>Cronbach's Alpha 0.767</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>Site 1</td>
<td>4</td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
</tr>
<tr>
<td>Site 4</td>
<td>5</td>
</tr>
<tr>
<td>Site 5</td>
<td>4</td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3.10: Statistics of Teamwork Within Units
3.3 Results

Figure 3.6: Teamwork within Units

having statistically significant differences between the majority of the other sites. Site 1 had a mean-rank of 361 which was not statistically different between site 7 or site 4. The 2014 AHRQ comparative report reported that the lowest rate of positive reports for this metric was 28%, the median was 55% and the maximum rate was 81%\(^{(159)}\). All sites had a higher rate of positive responses than the lowest from the AHRQ report. Four sites had a lower rate of positive responses than the median. This survey was distributed during a period of cut backs in healthcare in Ireland which may have contributed to this. Staffing levels can impact the workload negatively that could affect incident rates. Table 3.11 and figure 3.7 show the results for this.

3.3.2.4 Supervisor and Management Support, Expectations and Actions

Site 4 had the highest mean-rank for both supervisor expectations and for management support. The supervisor expectations metric has a range of 1-5 scores for every site. This could indicate that a difficult relationship among some staff members with their supervisors. For supervisor expectations site 4 was statistically significantly higher than all sites bar site 7. For management support it was
3. PATIENT SAFETY CULTURE

**Figure 3.7: Staffing**

**Table 3.11: Statistics of Staffing**

<table>
<thead>
<tr>
<th>Staffing</th>
<th>Cronbach’s Alpha 0.679</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td></td>
<td>4</td>
<td>1-5</td>
<td>361</td>
<td>0.007</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td></td>
<td>3</td>
<td>1-5</td>
<td>266</td>
<td>0.001 0.858</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td></td>
<td>3</td>
<td>1-5</td>
<td>260</td>
<td>0.001 0.858</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td></td>
<td>4</td>
<td>1-5</td>
<td>400</td>
<td>0.109 &lt;0.001 &lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td></td>
<td>3</td>
<td>1-5</td>
<td>277</td>
<td>0.011 0.755 0.61 &lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td></td>
<td>3</td>
<td>1-5</td>
<td>255</td>
<td>&lt;0.001 0.739 0.881 &lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td></td>
<td>4</td>
<td>2-5</td>
<td>406</td>
<td>0.114 &lt;0.001 &lt;0.001 0.946 0.001 &lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3 Results

statistically significantly higher than all other sites. For supervisor expectations
the comparative report reported that the lowest rate of positive reports for this
metric was 51%, the median was 76% and the maximum rate was 93%. Three
sites had a lower rate than the AHRQ databases lowest rate. Only two sites had
a greater positive response rate than the median rate from the AHRQ database.
This indicates that staff feel that supervisor expectations are not realistic. This
could also be due to the fact that this survey was administered during a time of
healthcare cutbacks.

For management support these rates were 36%, 72% and 100% respectively. Two centres were below 36%. A negative response here indicates that front line
staff don’t think management is supporting patient safety. Figures 3.8-3.9 and
tables 3.12-3.13 show the results for this.

![Figure 3.8: Supervisor Expectations](image)

3.3.2.5 Communication Openness

This metric did not have the same range in mean-rank as other metrics. The
lowest was 200 and the highest 278. Site 3 and site 7 both demonstrated high
mean-ranks and which were statistically significantly higher then sites 1, 4, 5 and
3. PATIENT SAFETY CULTURE

### Supervisor Expectations

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>3</td>
<td>1-5</td>
<td>267</td>
<td>0.82</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td>3</td>
<td>1-5</td>
<td>258</td>
<td>0.82</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
<td>1-5</td>
<td>281</td>
<td>0.655</td>
<td>0.537</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
<td>1-5</td>
<td>396</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td>3</td>
<td>1-5</td>
<td>232</td>
<td>0.345</td>
<td>0.505</td>
<td>0.146</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
<td>1-5</td>
<td>288</td>
<td>0.467</td>
<td>0.367</td>
<td>0.799</td>
<td>&lt;0.001</td>
<td>0.046</td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
<td>1-5</td>
<td>361</td>
<td>0.001</td>
<td>0.001</td>
<td>0.005</td>
<td>0.067</td>
<td>&lt;0.001</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Table 3.12: Statistics of Supervisor Expectations

### Management Support

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>4</td>
<td>2-5</td>
<td>230</td>
<td>0.116</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
<td>1-5</td>
<td>270</td>
<td>0.009</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>3</td>
<td>1-4</td>
<td>169</td>
<td>0.009</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
<td>1-5</td>
<td>315</td>
<td>&lt;0.001</td>
<td>0.048</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td>3</td>
<td>1-5</td>
<td>164</td>
<td>0.007</td>
<td>&lt;0.001</td>
<td>0.714</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
<td>1-5</td>
<td>204</td>
<td>0.188</td>
<td>0.008</td>
<td>0.086</td>
<td>&lt;0.001</td>
<td>0.075</td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
<td>2-5</td>
<td>222</td>
<td>0.692</td>
<td>0.049</td>
<td>0.02</td>
<td>&lt;0.001</td>
<td>0.009</td>
<td>0.317</td>
</tr>
</tbody>
</table>

Table 3.13: Statistics of Management Support
3.3 Results

6. The Cronbach's Alpha coefficient was 0.800, demonstrating a good internal consistency. For communication openness the lowest reported rate of positive results from the AHRQ comparative report was 32%, the median 62% and the highest 83%\(^\text{[159]}\). The majority of sites had a higher positive response rate than the median positive response rate from the AHRQ comparative report. This indicates that people feel able to question procedures that they don’t believe are safe. This should result in fewer incidents than other disciplines of medicine as it should lead to a proactive approach to safety. The one site that had a lower than the median positive response rate, also demonstrated poor incident reporting. This indicates that these two metrics are related. Figure 3.10 and table 3.14 show the results for the communication openness.

![Figure 3.10: Communication Openness](image)

3.3.2.6 Feedback and response to error

Site 1 had a statistically significantly lower score for feedback than all other sites. This demonstrates a negative attitude to how managers in this department feedback error. Site 4 had the highest mean-rank which was statistically higher than sites 1, site 5 and site 6. The Cronbachs Alpha coefficient of 0.743 shows a good
3. PATIENT SAFETY CULTURE

<table>
<thead>
<tr>
<th>Communication Openness</th>
<th>Cronbach’s Alpha 0.800</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>Site 1</td>
<td>4</td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
</tr>
<tr>
<td>Site 5</td>
<td>4</td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3.14: Statistics of Communication Openness

internal consistency. The 2014 AHRQ comparative report reported that the lowest rate of positive reports for this metric was 42%, the median was 66% and the maximum rate was 90%.[150] One centre demonstrated a lower positive response rate than the lowest recorded in the AHRQ. This centre also had a low positive response rate for non-punitive response to error and communication openness. This indicates that these metrics are related. Feedback about error is important for learning from errors. A low score for this metric could result in repeating incidents. This site also had a low reporting rate so it is difficult to conclude if the same incidents are recurring. High scores for this metric should lead to a lower incident rates as the same incidents should not be repeating. The results for feedback are shown in figure 3.11 and table 3.15.

<table>
<thead>
<tr>
<th>Feedback about errors</th>
<th>Cronbach’s Alpha 0.743</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>Site 1</td>
<td>3</td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
</tr>
<tr>
<td>Site 4</td>
<td>5</td>
</tr>
<tr>
<td>Site 5</td>
<td>4</td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3.15: Statistics of Feedback About Error
3.3 Results

3.3.2.7 Nonpunitive Response to Error

Site 1 demonstrated a low mean-rank for this metric. It was statistically significantly different than all but site 2 which had the second lowest mean-rank. This was statistically significantly lower than site 3 and 7. The Cronbachs Alpha coefficient for this metric was 0.807, demonstrating a good internal consistency among respondents. The comparative database for this metric had the highest rate of positive responses of 77%, a median positive response of 43% and the lowest rate is 16%\(^\text{[159]}\). To improve reporting structures a no blame culture or just culture is often recommended\(^\text{[44]}\). However, the results from this study indicate that staff members often don’t feel like they can report without getting a punitive response. This is demonstrated further by the fact that in every site studied, a minimum of one person strongly disagreed with the idea that there was a non-punitive response to error. The results for this are shown in figure 3.12 and table 3.16.
3. PATIENT SAFETY CULTURE

Figure 3.12: Non-Punitive Response to Error

Table 3.16: Statistics of Non Punitive Response
3.3 Results

3.3.2.8 Frequency of Events Reported

Site 1 scored low on this metric. This calls into question the accuracy of the data in chapter 3. The reporting levels here were statistically significantly lower than all other sites. Incidents not being reported have a serious impact on the departmental learning. This can result in incidents being repeated and latent failures in the system going unidentified. The 0.751 Cronbachs Alpha coefficient showed a good internal consistency. The comparative database for this metric had a highest rate of positive responses of 48%, a median positive response of 65% and the lowest rate is 89%\(^\text{[159]}\). The results for this are shown in figure 3.11 and table 3.17. A high positive response rate to frequency of events reported should result in an accurate representation of reported incidents compared to identified incidents. A low rate can result in under-reporting of incidents and thus an increased chance of incidents recurring. Aside from site 1, the other sites were all above the median positive response rate. This would indicate that radiotherapy has good reporting levels compared to other disciplines of medicine.

![Frequency of Events Reported](image)

**Figure 3.13:** Frequency of Events Reported
3. PATIENT SAFETY CULTURE

### Frequency of Events Reported

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>3.5</td>
<td>1-5</td>
<td>153</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td>5</td>
<td>3-5</td>
<td>271</td>
<td>&lt;0.001</td>
<td>0.794</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>5</td>
<td>2-5</td>
<td>265</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
<td>1-5</td>
<td>220</td>
<td>0.003</td>
<td>0.065</td>
<td>0.04</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td>5</td>
<td>1-5</td>
<td>244</td>
<td>0.001</td>
<td>0.359</td>
<td>0.399</td>
<td>0.292</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td>5</td>
<td>2-5</td>
<td>224</td>
<td>0.001</td>
<td>0.072</td>
<td>0.042</td>
<td>0.816</td>
<td>0.356</td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td>5</td>
<td>1-5</td>
<td>207</td>
<td>0.017</td>
<td>0.024</td>
<td>0.01</td>
<td>0.592</td>
<td>0.124</td>
<td>0.365</td>
</tr>
</tbody>
</table>

**Table 3.17:** Frequency of Events Reported

#### 3.3.2.9 Organisational Learning

Sites 2, 4 and 7 all showed high mean-ranks. There was no statistically significant difference between these sites. Site 3, which had a mean-rank of 250, demonstrated no statistically significant difference between any other site. The comparative database for this metric had a highest rate of positive responses of 94%, a median positive response of 73% and the lowest rate is 48% (159). This is another metric that is related to probability of recurring incidents. The ability to learn from mistakes is important to prevent incidents repeating. The highest rate of positive responses was 88% among the sites studied. This should result in a low number of repeating incidents in that site. It relies on the site also reporting incidents. The results for this are shown in figure 3.12 and table 3.18.

### Organisational Learning

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>4</td>
<td>1-5</td>
<td>200</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
<td>2-5</td>
<td>270</td>
<td>0.021</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
<td>1-5</td>
<td>250</td>
<td>0.063</td>
<td>0.513</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
<td>2-5</td>
<td>264</td>
<td>0.004</td>
<td>0.762</td>
<td>0.536</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td>4</td>
<td>1-5</td>
<td>210</td>
<td>0.725</td>
<td>0.07</td>
<td>0.164</td>
<td>0.029</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
<td>1-5</td>
<td>211</td>
<td>0.595</td>
<td>0.022</td>
<td>0.064</td>
<td>0.002</td>
<td>0.952</td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
<td>2-5</td>
<td>265</td>
<td>0.01</td>
<td>0.818</td>
<td>0.566</td>
<td>0.968</td>
<td>0.042</td>
<td>0.006</td>
</tr>
</tbody>
</table>

**Table 3.18:** Statistics of Organisational Learning
3.3 Results

3.3.3 Overall Perceptions and Patient Safety Grade

Overall perceptions is how the staff perceive the patient safety in their department and is a function of the other metrics investigated. Site 1 demonstrated a higher mean-rank than the previous 4 metrics. The overall perceptions for site 1 were statistically significantly higher than sites 3, 5 and 6. Sites 4 and 7 both scored high for this metric. This would indicate that even when reporting structures aren’t as good as other sites, the overall perceptions of patients safety can still be good. Site 1 had a higher positive response rate than the median positive response rate from the AHRQ comparative report. This is despite being lower than the median for the metrics that are used to assess reporting levels, organisational learning and non-punitive response to error. The comparative database for this metric had a highest rate of positive responses of 96%, a median positive response of 66% and the lowest rate is 30%(159). The results for this are shown in figure 3.13 and table 3.18.

For the patient safety grade statistical tests the grades were converted into a 1-5 scale with 1 representing an E grade and 5 for an A grade. As this is a single question there is no Cronbachs Alpha coefficient for this data. Sites 2, 4 and 7 all received high grades for this metric. The majority of sites had similar positive
3. PATIENT SAFETY CULTURE

Figure 3.15: Overall Perceptions

Table 3.19: Statistics of Overall Perceptions
3.3 Results

response for patient safety grade as overall perceptions.

![Patient Safety Grade](image)

**Figure 3.16: Patient Safety Grade**

<table>
<thead>
<tr>
<th>Site</th>
<th>Median</th>
<th>Range</th>
<th>Kruskal-Wallis (Mean-Rank)</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>4</td>
<td>2-5</td>
<td>74</td>
<td>P-value Mann Whitney</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td>4</td>
<td>4-5</td>
<td>94</td>
<td>0.232</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
<td>3-4</td>
<td>63</td>
<td>0.423  0.013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 4</td>
<td>4</td>
<td>3-5</td>
<td>97</td>
<td>0.108  0.769  0.006</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 5</td>
<td>4</td>
<td>2-5</td>
<td>60</td>
<td>0.389  0.042  0.608  0.022</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 6</td>
<td>4</td>
<td>1-5</td>
<td>71</td>
<td>0.801  0.109  0.564  0.014  0.383</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 7</td>
<td>4</td>
<td>3-5</td>
<td>96</td>
<td>0.141  0.786  0.012  1  0.036  0.031</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3.20: Patient Safety Grade Statistics**

3.3.4 Overall Results for Future Benchmarking

This, to the authors knowledge, is the first radiotherapy wide application of this tool. This data can then be used as a “benchmark” in future application of the tool. The figures 3.17 and 3.18 shows a benchmarking response to the data.
3. PATIENT SAFETY CULTURE

The data is benchmarked by average response per centre and also by individual staff respondent. Figure 3.17 shows the average response by individual respondent. Figure 3.18 shows the overall respondents where each centres response was averaged to weight each centre evenly. The values and their equivalent metric on the y-axis of figures 3.17 and 3.18 is summarised below.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handoffs &amp; Transitions</td>
<td>1</td>
</tr>
<tr>
<td>Teamwork Across Units</td>
<td>2</td>
</tr>
<tr>
<td>Teamwork Within Units</td>
<td>3</td>
</tr>
<tr>
<td>Staffing</td>
<td>4</td>
</tr>
<tr>
<td>Supervisor Expectation</td>
<td>5</td>
</tr>
<tr>
<td>Management Support for Patient Safety</td>
<td>6</td>
</tr>
<tr>
<td>Communication Openness</td>
<td>7</td>
</tr>
<tr>
<td>Feedback About Errors</td>
<td>8</td>
</tr>
<tr>
<td>Non Punitive Response to Error</td>
<td>9</td>
</tr>
<tr>
<td>Frequency of Events Reported</td>
<td>10</td>
</tr>
<tr>
<td>Organisational Learning</td>
<td>11</td>
</tr>
<tr>
<td>Overall Perceptions</td>
<td>12</td>
</tr>
<tr>
<td>Safety Grade</td>
<td>13</td>
</tr>
</tbody>
</table>

**Figure 3.17:** Overall Results By Individual Respondent
3.3 Results

Figure 3.18: Responses Averaged By centre

3.3.5 Statistical Analysis

This research has demonstrated that there is a need to look at incident rates and patient safety culture. The results from this chapter and the previous chapters can be used to evaluate the relationship between reported incident rates perceived safety culture. The mean rank for the patient safety grade was plotted against the mean identified incident rate. This is shown in figure 3.19.

The graph indicates that there is a relationship between the patient safety grade and the identified incident rate. However, with the small sample size it is hard to make any statistically significant conclusions.

If a study were to be done to prove a statistically significant relationship, a number of things would have to be done. In order to ensure that a like with like comparison of departments occurs, the protocols would have to be standardised across departments. This includes methods to identify incidents. In practice this could prove very difficult with the variation in equipment and technologies in different departments.

To look at the correlation between the variables investigated we would need to
3. PATIENT SAFETY CULTURE

Figure 3.19: Patient Safety Grade and Incident Rates

use a Spearman’s rank correlation. To calculate the number of samples required to make any statistical significant statements the software QFAB Bioinformatics [160] was used. For the calculation we used a medium effect size (correlation=0.3), a significance level of 0.05 and a power of 0.8. This resulted in a necessary sample size of 85. This would require a sample size higher than the number of departments in Ireland to prove a statistical significance. If the power requirement is increased to 0.999 a sample size of 269 is required. With the sample size used here, a power of 0.09 is obtainable.
3.3.6 Comparison with the American Association of Physicist in Medicine Safety Profile Assessment

There have been a number of publications that discuss the use of the AAPM SPA as a method of assessing safety in a department. The purpose of this section is to compare the AHRQ HSOPSC with the AAPM SPA.

3.3.6.1 Examination of the metrics of patient safety culture

The HSOPSC examines 12 different metrics of patient safety culture. This survey is considered the gold standard for examining patient safety culture and scores well when compared with other validated surveys for patient safety culture[46].

The AAPM SPA examines aspects of safety culture, but not to the same extent as the HSOPSC. The metrics of patient safety culture that are examined are taken directly from the HSOPSC, indicating that it covers fewer metrics[47].

3.3.6.2 Level of Representative of Staff Opinion

It is recommended that all staff members are given the opportunity to submit the HSOPSC. This has the advantage of letting all staff members be involved with the study. The disadvantage of this is that the staff members that offer their opinion are self-selecting. This can affect the results. This can be reduced with a higher response rate, but this can be difficult implement[46].

The SPA is implemented using a team of people selected. The level of representativeness is dependant on the team chosen to complete the survey. Depending on how the team is selected and how many people are on the team may affect the results[47].
3. PATIENT SAFETY CULTURE

3.3.6.3 Ease of Use

The HSOPSC is generally completed using a paper based method. In order to do through analysis, the form has to be distributed to as many staff members as possible. The information then has to be manually entered into software for analysis. This is readily available in the form of an excel spreadsheet, that will automatically compare the results with other hospitals\(^{(46)}\).

With a smaller team of people, it maybe easier to complete in a shorter space of time. There is also an online submission tool that can be used to track changes year to year and compare with other departments\(^{(47)}\).

3.3.6.4 Suitability for Radiotherapy

The HSOPSC is designed for healthcare. It is not specifically designed for radiotherapy. As a result of this, there is the potential that some of the metrics are not as important for radiotherapy as the overall hospital environment\(^{(46)}\).

The SPA is designed for radiotherapy. It encompasses more than culture, including quality management, managing change and clinical performance. This makes it more useful to examine more aspects of radiotherapy related safety metrics, but not necessarily patient safety culture\(^{(47)}\).
3.4 Discussion

From this data it can be concluded that there is a statistical significantly variation between sites for the various metrics such as teamwork and organisational learning. This variation means that there is a quantifiable difference in safety culture between departments. This data can be used as a future benchmark for implementation of this tool in radiotherapy. The results obtained here can be compared against the results obtained in the future, thus a site can assess its performance against a large volume of sites.

There were 12 different metrics for patient safety culture examined. These metrics were designed to evaluate the whole hospital setting. The argument could be made that some of these metrics are more relevant to patient safety in radiotherapy then others. The only way to know this would be to do a wider scale study of patient safety culture and compare with incident rates. To do this there would need to be a standard safety check across all the departments. As discussed in the previous chapter, the identified incident rate is probably different to the actual incident rate due to the different checking procedures and available technologies in the department.

The introduction discussed in detail the effects of patient safety culture on incidents in radiotherapy. This chapter shows that there is a quantifiable difference between sites with safety culture.

So far this research has looked incident rates, human contribution to incidents and patient safety culture. This has addressed limitations in the literature but it does not address the issue of proactive risk assessment. This will be addressed in the next chapter of this thesis.
3. PATIENT SAFETY CULTURE
4

Failure Mode and Probabilistic Risk Assessment Model for Radiotherapy

4.1 Motivation For Model

The previous chapters demonstrate that human error accounts for the majority of reported incidents in radiotherapy. Human factors have been identified as creating the preconditions or directly causing incidents. This can be influenced by department culture, working conditions and personal factors beyond the control of the management. A model was created to analyse the probability of an incident occurring in the presence of these human influences. The motivation for this model was to assess risk in current technologies, changing procedures and implementing new technologies. It concentrates on the human interaction element of the process. Each task in the process was analysed and the probability of human error was estimated. The model was primarily based on the procedures and technologies in Galway University Hospital however was designed to be implemented easily in other departments. It implements a series of tools including elements of FMEA and Boolean logic used in FTA. In order to analyse the procedures in a quick way the model has been developed into a series of graphical representations of error pathways and assessment sheets.
The purpose of this model was to compliment guidance that already exists. Linac QA, treatment planning QA and guidance on safety procedures are already well documented. These documents, discussed in the introduction, offer a number of solutions to ensure the safe implementation of technology and safe procedures and practices. The purpose of this model was to interrogate the system as a whole and look beyond traditional quality control to a full system analysis with emphasis on human error probability and process design.

This coincides with the findings of a symposium on quality assurance in radiotherapy:

“The current process of developing consensus recommendations for prescriptive QA tests remains valid for many of the devices and software systems used in modern RT, although for some technologies, QA guidance was incomplete or out of date.” (taken directly from[126])

This model was designed to address these limitations with current safety documentation. The unique information presented in this chapter:

- Investigation of applying SPAR-H (from the nuclear industry) in radiotherapy
- Use of SPAR-H to evaluate safety critical tasks
- Development of a method for risk assessment that incorporates error pathway diagrams, task analysis, human error probability estimations and severity
- Application of this model to the treatment pathway for prostate 3-d conformal radiotherapy and head and neck IMRT
4.2 Methodology

A summary of the steps used are described in figure 4.1. Multiple human error probability models were investigated. After systematic review of the various tools, the SPAR-H method developed for the nuclear industry, was used for the human error probability assessment. This was chosen due to its ease of use, well documented use in nuclear industry and the human error probability values within a quantifiable uncertainty. It utilises a constrained non-informative prior distribution. This is a prior distribution that is constrained by the human error probability estimation \(^{(1)}\) \(^{(58)}\).

The methodology developed for the risk assessment was summarised in figure 4.1.

4.2.1 List Tasks in the Process

The purpose of this was to review the system and to list all the safety critical tasks involved with the radiotherapy process. Only safety critical tasks were included, i.e. anything that could result in an incident or harmful event as defined by the classification in figure 2.3. The steps described by Ford et al.\(^{(12)}\) were used as a starting point. They were then changed according to how the tasks were undertaken locally.

4.2.2 Analyse the Tasks

The task analysis was used to analyse the individual components of the process. They are analysed based on the potential error modes, contribution to treatment, input to task, output from task and how the potential error will interact with other tasks. The safety critical tasks for external beam radiotherapy were analysed. The analysis was done based on the process of the local radiotherapy department. A lot of these are applicable to other radiotherapy departments but would need to be reviewed based on the protocols of local departments. The
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Figure 4.1: Summary of Methodology Used
coding for the task analysis can be seen below. This coding was used as a way to facilitate the analysis by dividing each task into a number of sub headings.

**Task ID** The tasks have two ID numbers. The first was used to identify the part of the process. The second was the error mode ID. The error mode ID was used to map different tasks in the reliability block diagrams.

**Staff Involved** This was used to identify the staff involved with the process. This information can be used to change the model if there are variables that only affect a single discipline. For example if the radiation therapist staffing levels are reduced to below an acceptable level.

**Error Description** This was a brief summary of the error mode and how it could affect the patient treatment.

**Potential Error Classification** This classifies the error descriptions into the error classification discussed in chapter 2.

**SPAR-H Suitable** Is the application of SPAR-H suitable for this error type? Errors that are initiated by patients or equipment are not SPAR-H suitable. While patient errors are human errors, the SPAR-H methodology was designed for staff. SPAR-H was also unsuitable for modelling equipment failures or deviations of equipment from expected performance.

### 4.2.3 Human Error Probability Estimation (Application of SPAR-H)

To quantify the probability of human error the method SPAR-H was used. This was primarily used in nuclear power plants. This method was chosen due to:

- ease of use.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

inclusion of performance shaping factors and uncertainty quantification.

Prior to the publication of a conference paper on the subject by the author, the author could not find any use of the SPAR-H method in healthcare. The comment has been made that it has the potential to be used in fields outside of nuclear power. There was no reason why this method couldn’t be adapted for medicine. There are similarities between nuclear power and radiotherapy. They both require high technology, interaction of people in a team, ability to interface with software and hardware and are safety critical. The primary difference was the introduction of the patient. This creates a level of uncertainty from a safety prospective. Modelling the behaviour and attitudes of a patient was outside the scope of this research, but it potentially can affect the human error probability of a staff member. Patients under stress, can cause stress to a staff member, affecting their behaviour. This in turn can affect the probability of them making a mistake. The second patient factor was the affect of patient anatomy on patient safety. Sudden changes in patient anatomy, unexpected reactions or unusual patient anatomy can increase the complexity and consequently the human error probability.

4.2.3.1 Nominal Values

The nominal values for human error probability are taken as either 0.01 or 0.001 pending on the type of task being performed. The nominal value was considered to be the probability of the error in the absence of any other factors. These nominal values are comparable with other HRA, which was described in the SPAR-H document. An action task was a task that can be described as:

“Guidance for action has to do with carrying out one or more activities (e.g., steps or tasks) indicated by diagnosis, operating rules, or written procedures.” (taken directly from)

This was taken as having a nominal error rate of 0.001 as defined by the SPAR-H document. The reason it has a lower nominal error probability was
4.2 Methodology

because it requires no critical thinking or analysis. It involves following out a procedure in a defined manner. In a paper by Boring and Blackman the origin of nominal values was discussed. The nominal error rate was derived from two similar techniques, THERP and WASH-1400[161]. A diagnosis task was defined as:

“Guidance for diagnosis has to do with attributing the most likely causes of the abnormal event to the level required to identify those systems or components whose status can be changed to reduce or eliminate the problem.”(taken directly from [11])

This was taken to have a nominal error rate of 0.01. This task has a higher nominal rate as the role of diagnosis and identification requires a level of critical thinking that was more prone to error. The nominal rate for this was based on THERP for a task representing the median HEP for diagnosis in a control room within 30 minutes[161].

4.2.3.2 Performance Shaping Factors

Performance Shaping Factors (PSFs) will increase or decrease the probability of an error occurring. The 8 PSFs that are discussed in the SPAR-H protocol are used in this assessment[161][162]. The definitions below are taken from the SPAR-H manual[1]. The performance shaping factors were assigned values based on consultation with staff members involved. A number of staff members were asked about each of the tasks that they performed and how they would rate the PSFs during a standard working day.

Some of the values were reassigned based on a realism check. This was most notable for the procedures. For many tasks the procedures were not up to date or not available. However, the multiplier for these created unrealistic Human Error Probability (HEP) values. The assessment of the procedures (not available, incomplete, available but poor and nominal) were considered alongside the PSF multiplier. If the PSF was considered to be too high the description was re considered.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

The various descriptions and their corresponding PSF multipliers can be seen in table 4.1 (spans 2 pages).

(1) *Available time* describes how rushed the task is. If the task has a limited amount of time to be completed then there was a higher probability that it won’t be completed correctly. If a task has more time to be completed there was a higher chance that it will be successfully completed. The person involved may not have had enough time to come to the right decision. The multipliers for this range from 0.01 to 10. If the task was defined as not having enough time for successful completion, failure was guaranteed[1]. The available time was described in detail in a step-by-step user guide to SPAR-H. In this guide a visual representation of the nominal time indicates that having a small amount of extra time over the minimum required time was nominal[166]. If we compare the values from SPAR-H with the equivalent from THERP, it can be seen that they agree with THERP for diagnosis tasks[161].

(2) *The stress/stressors* can be internal or external factors. There will be times when internal factors will affect individual stress due to factors that are outside the control of the department. However, there are factors associated with the climate of a department that can create a general stressful environment. Staffing levels, workload and personal relations within a department all can have a positive or negative effect on stress levels. The multipliers for this range from 1 to 5[1]. This version of stress and stressors was simplified to encompass both internal and external stressors. This was different from the THERP method defines internal and external stressors differently[161].

(3) *Complexity* will depend on the task being performed. There are some parts of the radiation oncology process that have a high level of complexity which are more susceptible to error. The multiplier ranges from 0.1 to 5[1]. The complexity of a task refers to how difficult it was to complete. It encompasses the mental effort and/or physical effort required for successful completion[166].
### 4.2 Methodology

<table>
<thead>
<tr>
<th>Available Time</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate Time</td>
<td>P(failure)=1.0</td>
<td>P(failure)=1.0</td>
</tr>
<tr>
<td>Barely Adequate time</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>(2/3 x nominal)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time available was the time required</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Nominal Time</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Extra time (between 1 and 2 x nominal and &gt; than 30 min)</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Time available 5x the time required</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Expansive time (&gt; 2 x nominal and &gt;30 min)</td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Time available was 50x the time required</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Insufficient information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stress/ Stressors</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>High</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Insufficient information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complexity</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly complex</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Moderately complex</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Obvious diagnosis</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Insufficient Information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experience/ Training</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>High</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Insufficient information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Incomplete</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Available, but poor</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diagnostic/symptom oriented</td>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Insufficient Information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ergonomic/ HMI</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing/Misleading</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Poor</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Good</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Insufficient Information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fitness for Duty</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfit</td>
<td>P(failure)=1.0</td>
<td>P(failure)=1.0</td>
</tr>
<tr>
<td>Degraded Fitness</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Insufficient Information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Work Processes</th>
<th>Action Task</th>
<th>Diagnosis Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Nominal</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Good</td>
<td>0.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Insufficient Information</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4.1: SPAR-H PSF Multipliers, reproduced from(1)
(4) *Experience/Training* is self-explanatory. As people are more highly trained and gain more experience, they will be more use to performing the tasks. As a consequence of this they will be less likely to make a mistake. The multipliers for this range from 0.5 to 10\(^\text{(1)}\).

(5) *Procedures* are an assessment of the quality of the written protocols in place. Badly written procedures can lead to confusion and thus will increase the probability of error. The multiplier for this range from 0.5 to 50\(^\text{(1)}\).

(6) *Ergonomics/HMI* refers to both the general ergonomics of the place of work and the Human Machine Interface (HMI). The volume of software and hardware in radiotherapy and the constant interface between the staff and the software would suggest that the human machine interface will play an important role in the successful completion of tasks. The PSF values for this are derived from different situations from the THERP methodology\(^\text{(161)}\). The multiplier ranges from 0.5 to 50\(^\text{(1)}\).

(7) *Fitness for duty* was a variable that will change in an individual on a day to day basis. As this variable was constantly changing it was difficult to assess it on a macroscopic level unless there was some organisational variable that was affecting it. The multiplier ranges between 1 and 5. If the person was described as unfit for duty, the task will not be successfully completed\(^\text{(1)}\). This accounts for both the mental and physical fitness for duty\(^\text{(166)}\).

(8) *Work processes* refers to the management and administrative processes. The design of the work flow and the patient safety climate will both influence the probability of an error occurring. The multiplier ranges between 0.5 and 5\(^\text{(1)}\). This encompasses the work planning and shift turnover\(^\text{(166)}\).

### 4.2.3.3 Apply Human Error Probability Density Functions

The human error probability was calculated in one of two ways. The *PSF*\(_{\text{Composite}}\) was calculated by multiplying out the PSFs (*PSF*\(_{\text{composite}}\) = *PSF*\(_{1}\) * *PSF*\(_{2}\) * *PSF*\(_{3}\) * ...)
If there are less than three negatively influencing PSFs then the HEP was calculated as:

\[ HEP = NHEP \times PSF_{\text{Composite}} \]  \hspace{1cm} (4.1)

Where \( NHEP \) was the nominal human error probability value assigned on whether its a diagnosis or an action task.

If there are 3 or more negatively influencing PSFs the HEP was calculated as:

\[ HEP = \frac{NHEP \times PSF_{\text{Composite}}}{NHEP \times (PSF_{\text{Composite}} - 1) + 1} \]  \hspace{1cm} (4.2)

This function was graphically represented in figure 4.2.

**Figure 4.2:** Graphical Representation of Composite Performance Shaping Factors Equation. This represents equations 4.1 and 4.2 for a number of different composite PSFs. The two different NHEPs are graphed here. It can be seen that when using equation 4.1 that the HEP surpasses 1 as the composite PSF increases.

This mathematical operation prevents the HEP from exceeding 1, which was not possible from a probability perspective. Probability values can only be between 0 and 1.
4.2 Methodology

When considering the use of both these equations, it is worth considering only using equation 4.2. However, there are limitations to this. The PSFs are designed to be treated as multipliers. From an application perspective, equation 4.1 is the most mathematically correct. We can justify the use of equation 4.2 when using multiple PSFs for a number of reasons, but based on the recommended application of SPAR-H we should use 4.1 when using one or two negatively affecting PSFs. The reason we can justify using 4.2 is for a number two main reasons. The first is that it prevents the probability from exceeding 1. From a mathematical perspective, this is more logical. The second reason that this is justifiable is when we consider the cumulative affect of PSFs. Performance shaping factors are interdependent. Multiplying them all out would result in an increased $PSF_{\text{composite}}$ that would not be reflective of the actual effects of combining the PSFs as it does not consider this interdependence.

If equation 4.2 is only used, we can see considerable differences in our values when applying the different equations. Consider two negatively influencing PSFs that have a $PSF_{\text{composite}}$ of 50, for a task with a nominal value of 0.01. If equation 4.1 is used, this will be equal to 0.5, while equation 4.2 will the value of 0.33. There will be a limited interdependency when there are only two PSFs so this represents a significantly higher difference than what is actually happening.

To describe this mathematical function an example was presented. Consider error mode 1.12.1 (see results for more details). This task involves activating the patient pathway in the record and verify system. If this does not occur the patient can be delayed. In this case the task was defined as an action task. This means the nominal value 0.001. The time available was equal to the time required. This multiplier was 10. The stress/stressors are marked as high creating a 2 multiplier. The work process are marked as poor, creating a 5 multiplier. The experience was marked as high creating a multiplier of 0.5. The PSF composite was the product of these numbers:

\[
PSF_{\text{composite}} = 10 \times 2 \times 5 \times 0.5 = 50
\]
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

As there are more than 3 negatively influencing PSFs the HEP was calculated using equation 4.2:

\[ HEP = \frac{0.001 \times 50}{0.001 \times (50 - 1) + 1} = 0.047 \]  \hspace{1cm} (4.4)

4.2.3.4 Probability Density Functions

The human error probability was represented by a random variable presented as a probability density function. The subjective nature of the assessment means that this will be represented as a noninformative prior distribution. The Constrained NonInformative (CNI) prior as described originally by Atwood and then used in the SPAR-H method was used here\(^\text{[58]}\). A non informative prior was used when there was no prior information available. In its simplest form all scenarios are treated as having an equal probability (uniform prior). In the context of human probability, this would mean that the probability of successful task completion and unsuccessful task completion would be equal\(^\text{[167]}\). This was not suitable for most human error probability estimations. The CNI, presented by Atwood, constrains the prior distribution using an approximation\(^\text{[58]}\), in this case the human error probability estimation\(^\text{[1]}\). The probability density function was represented as a beta distribution.

The information presented in the probability density function represents a random variable associated with the probability of an error occurring. The nature of the probability of an error occurring was represented as a prior distribution, I.E. it was a predicted value based on the evidence presented.

The probability density function was produced using the random number generator that was weighted to produce a beta distribution based on the specified \(\alpha\) and \(\beta\) components calculated using the human error probability. The x-axis represents the probability of the error occurring. The y-axis represents the density. This was the likelihood of the human error probability value being correct.
4.2 Methodology

The CNI prior discussed by Atwood discusses in details the method to calculate the alpha and beta components of the beta distribution. The alpha component was calculated from a look up table from the original paper\(^\text{[58]}\). The HEP from either equation [4.1] or [4.2] was used to calculate the Alpha and Beta components. The alpha component was calculated using the graph from figure 4.3. This graph was made using the table from the Atwood paper\(^\text{[58]}\). The fit to this curve has an \(R^2\) value of 0.994. The relationship between the HEP and the alpha component can be seen in figure 4.3.

\[
y = 14.193x^4 - 20.557x^3 + 11.9x^2 - 2.6068x + 0.5097
\]
\(R^2 = 0.994\)

**Figure 4.3:** Relationship between Human Error Probability and Alpha Values. These values used to construct the graph are taken from Atwood\(^\text{[58]}\).

The beta was then calculated using the following equation taken from Atwood\(^\text{[58]}\).

\[
\beta = \frac{\alpha(1 - HEP)}{HEP}
\]  \hspace{1cm} (4.5)

When the \(\alpha\) and \(\beta\) parameters were calculated the beta distributions were created using the \(rbeta\) function in r. Two values can be calculated with the beta distribution. The mode, or most likely value, was represented by the peak of the distribution. The mean, which was used to produce the beta distribution, was highlighted with a line in the probability density function charts in this thesis. The value for the mode was calculated by finding the peak of the distribution from
the graph. At low mean human error probability values the peaks, representing
the mode, get sharp and approach zero. The result of this was that the relative
difference between the mean and the mode was more pronounced. The probability
density functions produced using the rbeta function were a monte carlo based
calculation with 1,500,000 iterations. The 1.5 million iterations were used to
increase the sensitivity of the binning used for calculating the mode.

The process so far, and its application are summarised by figure 4.4.

4.2.4 Error Mode Pathways (Reliability Block Diagrams)

The relationship between the tasks, and their effect on safety are represented by
error pathway graphics. The initiating error modes are identified, and then all
tasks that will affect the error mode were also identified. The error modes are
then graphically represented to show any potential pathways that can effect the
probability of the error mode reaching the patient. Figure 4.5 shows the legend
for these pathways. The text in the centre represents the people involved with
the task. Figure 4.6 shows an example of one of the pathways. These are similar
to reliability block diagrams, except they represent the pathway to unsuccessful
completion as opposed to successful completion.

4.2.5 Boolean Operations

In order to evaluate the propagation of error Boolean operations are used. Indi-
vidual error modes occurring in conjunction were treated as OR gates and are
represented as:

\[ P(A \text{or} B) = P(A) + P(B) - P(A)P(B) \] (4.6)

This can be simplified to:

\[ P(A \text{or} B) \approx P(A) + P(B) \] (4.7)

This makes the assumption that the \( P(A) \) and \( P(B) \) are very small, thus these
values approach zero becoming insignificant. Any safety checks in the system
4.2 Methodology

Let's look at the performance factors that could affect the Human Error Probability:

- Available Time
- Stress/Stressors
- Complexity
- Experience/Training
- Procedures
- Ergonomics/HMI
- Fitness for Duty
- Work Processes

Error Description:
- Potential Error Classification
- How do we define the task?
- Action Task
- 0.001 is the NHEP
- Time Available is Time Required - \times 10
- High - x\times 2
- High - x\times 0.5
- Nominal - x\times 1
- Poor - x\times 5
- Calculate the PSF Composite \times 50
- Calculate the HEP 4.77E-2
- Calculate the alpha component of the beta distribution using the look up table/graph
- Calculate the beta component of the beta distribution using the equation
- Using the alpha and beta components a probability density function is created using the rbeta function in R

Figure 4.4: Summary of the Human Error Probability Estimation Method
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Figure 4.5: Legend for Error Mode Pathways Diagrams. This was used to help construct the block diagrams.

Figure 4.6: Sample Error Mode Pathway, Block Diagram. For an error to occur tasks 1, 2 and 3 need to be done incorrectly or tasks 1, 2, 4 and 5 need to be done incorrectly for the incident reaching the patient.
were then taken as an AND gate. This means that both the initial task and the checking task both have to be done incorrectly. The AND gate was represented by the following equation:

\[ P(A \text{and} B) = P(A)P(B) \]  

(4.8)

The prior distribution was used as the input for boolean analysis. The maths were programmed in RStudio. The inputs were taken from the random number generator producing the PDFs as described in section 4.2.2. The random variables produced by the \texttt{rbeta} function underwent the relevant equation to create a resultant density function to represent the overall probability of the error resulting in an incident.

The HEP or mean was presented in the results. This was calculated using the mean calculator in \texttt{r}. The mode was then calculated by finding the peak in the resultant distribution. The peak was found by binning the PDF up to 100,000 breaks. This resulted in a histogram. The largest bar was taken as the mode.

### 4.2.6 Analyse the Consequence in the Potential Incident Reaches the Patient

The consequence was scored using the dosimetric severity scale shown in figure 2.2. The consequence of the incident was evaluated and a predicted dosimetric consequence score was given to the potential incident. A brief description of the justification of the dosimetric score was included. The type of incident was classified using the classification described in figure 2.3 and again in 4.11. The consequence of an incident was presented as a scale. This model identifies the fact that the same chain of events can result in different consequences. For example a setup error, in a single fraction, will have a dosimetric consequence of between 0 and 2. This was because a movement could result in a partial mistreatment of the prostate, or a full mistreatment of the prostate for that fraction. Thus, the dosimetric severity was not a single value, but rather a scale representing all potential outcomes.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

4.2.7 Practical Implementation of the Model (Coding)

R[155] and RStudio[156] were predominately used to create the beta distribution and calculate the mathematics involved with this model. The alpha and beta components were calculated as discussed in section 4.2.3. The beta distribution was then calculated using the script:

\[
\text{rbeta}(n, \alpha, \beta)
\]

This creates a random number distribution that was weighted to a beta distribution. The \(\alpha\) and \(\beta\) components of the equation represent the constraints of the beta distribution. The \(n\) represents the number of iterations used to create the distribution. The number of iterations was limited by the computational power of the computer. The higher the number of iterations the increased accuracy of the mode calculation. By having more iterations the data can be binned into smaller packets. The beta distribution was created in the form of an array of numbers that can then be visually represented as a distribution using the \text{hist} function in r.

Once the distribution was created for a given task, the interactions of that task with other tasks was investigated. The evaluation of the interaction of other tasks contributes to the development of the block diagrams. These block diagrams are then used as the template for the Boolean maths.

For the AND gates the distribution of numbers are multiplied. For example take task A and task B. For an error to occur both tasks need to have an error mode in them. To show an example of this we can consider task A (with error probability \(t_A\)) and task B (with error probability \(t_B\)). A was considered to be an action task. Therefore it has a nominal error rate of 0.001. The PSFs are analysed and two of them are assessed as being different from nominal conditions. The work processes are assessed as being poor, creating a multiplier of 2. The training/experience was rates as low creating a multiplier of 3. The HEP was
calculated using equation 4.1.

\[
HEP(tA) = 0.001 \times 3 \times 2 = 0.006 \quad (4.9)
\]

Now that the HEP for tA been calculated the \( \alpha \) component of the distribution can be calculated using the equation from figure 4.2. This was calculated as 0.49448. With the HEP and the \( \alpha \) component the \( \beta \) component can then be calculated.

\[
\beta = \frac{0.49448 (1 - 0.006)}{0.006} = 81.91938 \quad (4.10)
\]

Using equation 4.5 the \( \beta \) component was calculated as 81.91938 (see equation 4.10).

Task B was taken as a diagnosis task. It has a nominal error rate of 0.01. In this case it was taken as having 3 negative multiplying PSFs. The stresses were marked as high, creating a 2 multiplier, the complexity was marked as moderately complex, creating a 2 multiplier and the work processes were marked as poor creating a 2 multiplier. The resultant composite PSF was 8. Equation 4.2 was used to calculate the HEP because there are more than 3 negative PSFs.

\[
HEP(tB) = \frac{0.01 \times 8}{0.01 \times (8 - 1) + 1} = 0.0747 \quad (4.11)
\]

This was then used to calculate the \( \alpha \) component of the the beta distribution using the equation from figure 4.2 The resultant value for \( \alpha \) was equal to 0.3732. Equation 4.5 was then used to calculate the \( \beta \) component. This was equal to 4.618.

When the \( \alpha \) and \( \beta \) components have been calculated they can then the beta distributions for the different functions can be created using the \texttt{rbeta} function in r. This was demonstrated below.
n=1500000
tA=rbeta(n, 0.49448,81.91938)
tB=rbeta(n, 0.3732,4.618)

Then they are applied to the Boolean maths, in this case an AND gate. PAnd represents the probability of both these

\[ P_{\text{And}} = tA \times tB \]

If the task interaction were to be an OR gate the probability would be represented by the following equation.

\[ P_{\text{Or}} = tA + tB - (tA \times tB) \]

This produces a probability density function representing the probability of \( P_{\text{And}} \) occurring. The mean can then be calculated using the \textit{r} function \texttt{mean}. The mode was produced by organising the array of numbers into a histogram and binning the histogram into a set of discrete numbers. The largest bar in the histogram plot represents the mode, i.e. the most common value in the distribution of numbers.

The first line of code was used to create the histogram. The number of breaks was a reference to the amount of bins used in the histogram.

\[ h = \text{hist}(P_{\text{And}}, \text{breaks}=10000) \]

The second line was then used to find the largest bar in the histogram. This goes through the individual bars and chooses the one with the maximum number of counts.

\[ i = \text{which.max}(h\texttt{counts}) \]

\[ P_{\text{And}} \text{Mode} = h\texttt{mids}[i] \]
4.2 Methodology

To show an example of this consider the example given above. Figure 4.7 represents the histogram produced by the first PDF, $t_A$. Figure 4.8 represents the second PDF, $t_B$. These are both presented through the hist function, with 100000 breaks. The means are represented by the darker lines on the plot.

**Figure 4.7:** Probability Density Function $t_A$. *The dark line represents the mean. The peak of the histogram represents the mode or most likely value.*

It can be seen from these plots that the mode was peaked towards 0 in $t_A$ and $t_B$. The mode was calculated as 5e-8 and 5e-7 respectively for $t_A$ and $t_B$. This was close to the resolution of the histogram, so was potentially lower than this again. 5e-7 represents an event for 1 in 5,000,000 patients. Since most departments will need 50 years (assuming 1000 patients a year) to reach that number of patients a higher resolution isn’t required.

The array of numbers $t_A$ and $t_B$ can be used to calculate $t_A$ AND $t_B$ and $t_A$ OR $t_B$. A block diagram representing the error pathway was seen in figures 4.9 and 4.10. These two PDFs are represented in figures 4.11 and 4.12. The mode was calculated as 2.5e-8 and 5e-7 for PAnd and POr respectively. Both these values are beyond the resolution of the mode calculation.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Figure 4.8: Probability Density Function tB. The dark line represents the mean. The peak of the histogram represents the mode or most likely value.

Figure 4.9: This represents the block diagram showing the pathway for an incident reaching a patient in the OR configuration

Figure 4.10: This represents the block diagram showing the pathway for an incident reaching a patient in the AND configuration
4.2 Methodology

Figure 4.11: Probability Density Function $P_{A \cap tB}$ for $tA, tB$. The dark line represents the mean. The peak of the histogram represents the mode or most likely value.
In this last example we can consider task C (tC) and D (tD). They both have $\alpha$ and $\beta$ constraints of 3 and 15 respectively. In figure 4.13 we can see the distribution of tC/tD (blue) and the OR gate (purple) representing the probability of either of them occurring. In this example the mode can be seen clearly in the graph.
4.3 Results

4.3.1 Initial Results

The macroscopic treatment process can be seen in figure 1.2.

All the individual tasks for the selected patient treatments were analysed. The PSFs were rated through consultation with the staff member involved with the task. The comment was made during consultation that the rating of the PSFs were based on a standard working day. Reduction in staff, increased number of patients can cause these values to fluctuate. The tasks relevant to a particular treatment can be used to build up the individual treatment being investigated. The assessments made were in the best case scenario.

The error modes were graphical represented as block diagrams to demonstrate the pathway of the errors through the system. The dosimetric severity (see figure 2.2) was used, where applicable, to assess the severity if the incident were to reach the patient. An example of this was seen in figure 4.14, an assessment of
4. FAILURE MODE AND PROBABILITY RISK ASSESSMENT MODEL FOR RADIOTHERAPY

the chain of events that could lead to the wrong patient being treated. In this case the pathway represents misidentification at the treatment unit. The codes seen in the circle, 55 in figure 4.15, are used to describe the potential error type below.

![Diagram](image)

**Figure 4.14:** Example of an Error Mode Pathway. Task 5.1.1 represents the wrong patient standing. Task 5.1.2.1 represents the staff member not verifying their name correctly, while task 5.1.2.2 was where the staff member forgets to ask the patient’s name. Task 5.1.3.1 was where the picture of the patient was checked but the staff member can’t differentiate between the picture of the wrong patient and right patient. Task 5.1.3.2 represents the staff member forgetting to check the picture of the patient.

Figure 2.3, incident type taxonomy, was colour coded in figure 4.11. This colour code was used to represent the type of incident i.e. the colour in the circle represents the type of error.

For error modes that are initiated by a patient or software failure the SPAR-H methodology was not suitable for estimation of probability. However, the probability of the staff member responding correctly to the initial error can be evaluated using the SPAR-H method. The consequence was estimated in dosimetric consequence. The effect of an incident on a patient’s health will depend on the organs that are affected and the health of the patient prior to the incident. As this will vary on a patient by patient basis it would need to be assessed for a specific patient after the incident occurs.
4.3 Results

Figure 4.15: Incident Type Colour Code. This was the same coding used to assess the type of incident in chapter 2.

There are two types of pathways. The first type was a conditional pathway. In this case the error block diagram was initiated by something outside the control of the staff members. An example would be if a patient initiated the event. For the purposes of evaluating the probability of that error occurring, we assume that the initiating event, outside of the control of staff members always occurs. The result of this was an overestimation in the probability. The majority of the error pathways are initiated by staff so are not considered to be conditional.

The model was applied from the point in the radiotherapy process where the physician decides the patient was to be treated. The reason that the process does not start prior to this was that there are too many external parameters that are out of the control of the department. Therefore, at this point we assume that the patient diagnosis was correct and that the information about the patient was correct. The error modes, human error probabilities and nominal values were assessed with input from the staff members involved in completing the various tasks. This risk assessment methodology was applied to two treatment scenarios. The first scenario (which is described in detail) was a 3-d conformal prostate treatment and the second was an IMRT head and neck case.
4.3.2 3-D Conformal Prostate Treatment with Image Guided Verification

4.3.2.1 Task and Error Analysis

The treatment pathway simulated does not include a replan. The patient was setup everyday with the Clarity™ Ultrasound Guidance System. The pathway does not include equipment quality management. It was taken from the point where the physician decides to treat the patient at physician consultation. This point was chosen to start with as it encompasses the activities of the radiation oncology department, but does not encompass other hospital activities (such as patient diagnosis). Only patient safety critical tasks were included. To be considered a safety critical task, the task must have some impact on the patient treatment as defined by the classification in figure 4.15.

Auditing tasks are not included in the assessment. The pathway also assumes no machine errors that need to be rectified during treatment, that the patient does not move during treatment and that the patient does not have any electronic medical devices that require monitoring.

This task and error analysis done here was based on the process design in the local radiotherapy department. The overall treatment pathway in radiotherapy, on a macroscopic level, will be similar between radiotherapy departments. However, the exact processes and how they are carried will vary from place to place. The result was that this model needs to be customised when implemented into a different department.

Initially all the tasks involved were tabulated and then assessed. The tasks were investigated for two scenarios. The first scenario was where the stress levels are kept at the values that they were rated as. The second scenario represents when the stress levels are increased by one level. 174 safety critical tasks were identified for this treatment. This list of tasks, a description of the tasks and the rated PSFs for each task can be seen in appendix E. This includes the calculation
4.3 Results

<table>
<thead>
<tr>
<th>Error Pathway</th>
<th>Severity</th>
<th>Consequence Type</th>
<th>Mean Human Error Probability</th>
<th>Mean Human Error Probability (Stress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NA</td>
<td>Delay on treatment</td>
<td>4.77E-02</td>
<td>1.11E-01</td>
</tr>
<tr>
<td>2</td>
<td>1-8</td>
<td>Inappropriate Treatment</td>
<td>1.68E-04</td>
<td>6.71E-04</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>4</td>
<td>1-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
</tbody>
</table>

Table 4.2: Probability and Severity of Errors Initiated at Patient Assessment

for the $\alpha$ and $\beta$ components to create the beta distributions.

The 174 safety critical tasks resulted in 63 error mode block diagrams. The following sections represent where the various potential incidents initiate. The various block diagrams can be seen in appendix F.

**Patient Assessment** After the patient was assessed, the correct decision for treatment needs to be made. The patient needs to be entered into the system and their treatment pathway was activated. There were 4 initiating error pathways at this stage of the process. The probability of these pathways affecting the patient treatment can be seen in table 4.2. The probability of these pathways resulting in an error was calculated by taking each task in the error pathway and applying the boolean mathematics (as discussed earlier). The first error pathway was described as resulting in a delay on patient treatment. From a strictly dosimetric perspective, this cannot be graded. For this reason the severity score was marked as NA. If the clinical severity scale were to be applied here, the severity of the disease would need to be taken into consideration.

**Imaging for RT Planning** There was a total of 18 error pathways (as can be seen in appendix F) that initiated in the imaging section of the process. Of these, the majority resulted in the requirement for further imaging. In cases of

\[1\] The * represents conditional events, i.e. the wrong patient presenting themselves was outside the control of the staff and so cannot be estimated using the method presented here.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Figure 4.16: Probability Density Function of An Error Occurring in the Patient Assessment Section reaching the patient. *The y-axis represents the probability density. The x-axis represents the probability of the event happening. The standard conditions are represented by the green, while the increased stress conditions are represented by the yellow. The probability density functions in this diagram are heavily weighted approaching 0. This produces the sharp peak in this region of the chart. The yellow line represents the mean HEP under increased stress, the green line represents the mean under standard stress. This distribution was created through the combination of the beta distributions using boolean mathematics.*
documentation used for daily patient setup, these will affect all patient treatments. The daily imaging reduces the dosimetric severity of these events. Table 4.3 shows the probability and dosimetric severity of these events.

The mean probability in standard conditions was 0.05. The mean probability in stress conditions was 0.1. This was seen in figure 4.17.

![PDF for Error Reaching Patient from Imaging](image)

**Figure 4.17:** Probability Density Function of an Error Occurring at Imaging. *The green line represents the mean probability in standard conditions. The yellow line represents conditions under increased stress. In this graph we can see peak of the graph was not as sharp as the patient assessment.*

**Treatment Planning** For the treatment planning task the delineation of the targets at risk are analysed for each of the OARs. This means that for each of the OARs there was an error pathway. For this treatment site these are the rectum, bladder, sigmoid and femoral heads. Of these the one that would have the greatest consequence to treatment was the rectum. The rectum generally has the hardest tolerances to match so any deviation to the actual volume will result in a greater clinical consequence. The increased number of OARs of interest results
## 4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

<table>
<thead>
<tr>
<th>Error Pathway</th>
<th>Severity</th>
<th>Consequence Type</th>
<th>Mean Human Error Probability</th>
<th>Mean Human Error Probability (Stress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5*</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>7.50E-07</td>
<td>2.90E-06</td>
</tr>
<tr>
<td></td>
<td>1-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>2.00E-02</td>
<td>0.04</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>2.50E-04</td>
<td>0.0005</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>2.47E-06</td>
<td>9.98E-06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay on Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>2.47E-06</td>
<td>9.98E-06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay on Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>Setup</td>
<td>2.47E-06</td>
<td>9.98E-06</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>Setup</td>
<td>1.46E-06</td>
<td>5.89E-06</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>Wrong Dose Delivered</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>13*</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Setup</td>
<td>5.00E-03</td>
<td>9.99E-03</td>
</tr>
<tr>
<td>14</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>7.34E-07</td>
<td>2.95E-06</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>7.34E-07</td>
<td>2.95E-06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Setup</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>1</td>
<td>Setup</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>17</td>
<td>1</td>
<td>Setup</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>18</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>19</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>20</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>21</td>
<td>1</td>
<td>Unnecessary (Ionising) Imaging</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
<tr>
<td>22*</td>
<td>1</td>
<td>Setup</td>
<td>2.50E-02</td>
<td>5.00E-02</td>
</tr>
<tr>
<td>23</td>
<td>1</td>
<td>Setup</td>
<td>5.00E-04</td>
<td>9.99E-04</td>
</tr>
</tbody>
</table>

Table 4.3: Probability and Severity of Errors Initiated at Patient Imaging
4.3 Results

in a higher number of potential errors that could result in incident.

There was a greater range of potential errors at treatment planning stage. The errors that could potentially occur here will often be checked again at the plan checking stage. There was also usually a greater consequence to the incidents that happen at this stage as the majority of them will affect each of the patients treatments.

There was only one potential error pathway that ends at the treatment planning point i.e. there are no further checks made after this point in the process. The remaining tasks will go through further checking and verification at the pre-treatment review and verification process. Table 4.4 shows the probability and dosimetric severity of these events.

The mean probability in standard conditions was 0.003. The mean probability in stress conditions was 0.007. This was seen in figure 4.18.

![PDF for Error Reaching Patient from Planning](image)

**Figure 4.18:** Probability Density Function of an Error Occurring at Planning. The green line represents the mean probability in standard conditions. The yellow line represents conditions under increased stress.
### 4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

<table>
<thead>
<tr>
<th>Error Pathway</th>
<th>Severity</th>
<th>Consequence</th>
<th>Mean Human Error Probability</th>
<th>Mean Human Error Probability (Stress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>1-8</td>
<td>Setup</td>
<td>2.48E-05</td>
<td>1.54E-04</td>
</tr>
<tr>
<td></td>
<td>1-8</td>
<td>Volume</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>2-8</td>
<td>Volume</td>
<td>1.05E-05</td>
<td>1.01E-04</td>
</tr>
<tr>
<td>26</td>
<td>1-8</td>
<td>Volume</td>
<td>1.23E-05</td>
<td>4.96E-05</td>
</tr>
<tr>
<td>27</td>
<td>1-6</td>
<td>Volume</td>
<td>1.23E-05</td>
<td>4.96E-05</td>
</tr>
<tr>
<td>28</td>
<td>0-4</td>
<td>Volume</td>
<td>2.35E-06</td>
<td>5.59E-05</td>
</tr>
<tr>
<td>29</td>
<td>0-6</td>
<td>Volume</td>
<td>2.50E-05</td>
<td>9.19E-05</td>
</tr>
<tr>
<td>30</td>
<td>0-4</td>
<td>Volume</td>
<td>2.35E-06</td>
<td>3.08E-05</td>
</tr>
<tr>
<td>31</td>
<td>0-4</td>
<td>Volume</td>
<td>2.50E-05</td>
<td>9.19E-05</td>
</tr>
<tr>
<td>32</td>
<td>0-2</td>
<td>Volume</td>
<td>2.35E-06</td>
<td>3.08E-05</td>
</tr>
<tr>
<td>33</td>
<td>0-2</td>
<td>Volume</td>
<td>2.50E-05</td>
<td>9.19E-05</td>
</tr>
<tr>
<td>34</td>
<td>0-2</td>
<td>Volume</td>
<td>2.35E-06</td>
<td>3.08E-05</td>
</tr>
<tr>
<td>35</td>
<td>0-2</td>
<td>Volume</td>
<td>2.50E-05</td>
<td>9.19E-05</td>
</tr>
<tr>
<td>36</td>
<td>0-2</td>
<td>Volume</td>
<td>2.35E-06</td>
<td>3.08E-05</td>
</tr>
<tr>
<td>37</td>
<td>0-2</td>
<td>Volume</td>
<td>2.50E-05</td>
<td>9.19E-05</td>
</tr>
<tr>
<td>38</td>
<td>0-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>39</td>
<td>1</td>
<td>Wrong Dose Delivered</td>
<td>1.25E-07</td>
<td>5.02E-07</td>
</tr>
<tr>
<td>40</td>
<td>1</td>
<td>Wrong Dose Delivered</td>
<td>1.0E-05</td>
<td>4.00E-05</td>
</tr>
<tr>
<td>41</td>
<td>0-2</td>
<td>Wrong Dose Delivered</td>
<td>1.0E-05</td>
<td>4.00E-05</td>
</tr>
<tr>
<td>42</td>
<td>1-8</td>
<td>Wrong Dose Delivered</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>43*</td>
<td>1-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>44*</td>
<td>1-4</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>45*</td>
<td>1-4</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>46*</td>
<td>1-2</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>47*</td>
<td>1-2</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>48*</td>
<td>1-2</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>49</td>
<td>0-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>50</td>
<td>1-6</td>
<td>Wrong Dose Delivered</td>
<td>3.00E-03</td>
<td>6.00E-03</td>
</tr>
<tr>
<td>51</td>
<td>1-6</td>
<td>Volume</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>52</td>
<td>1-7</td>
<td>Energy</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
<tr>
<td>53</td>
<td>NA</td>
<td>Delay on Treatment</td>
<td>1.23E-04</td>
<td>2.50E-04</td>
</tr>
</tbody>
</table>

**Table 4.4:** Probability and Severity of Errors Initiated at Treatment Planning
4.3 Results

### Pre-treatment Review and Verification

At this stage of the process the plan will go through a series of checks to ensure the integrity of the plan and to check to see if there have been any mistakes made up to this point. There was only one potential initiating error pathway in this section. This refers to changing the parameters in the R and V system. This was shown in figure 4.5.

The mean probability in standard conditions was 2.7E-5 with a mode that was beyond the resolution of the calculation method. The mean probability in stress conditions was 1E-4 with a mode that was beyond the resolution of the calculation method. This was seen in figure 4.18.

![PDF for Error Reaching Patient from Pre-Treatment Assessment](image)

**Figure 4.19:** Probability Density Function of an Error Occurring at Pre Treatment Stage. *The green line represents the mean probability in standard conditions. The yellow line represents conditions under increased stress.*

### Treatment Delivery

The treatment delivery pathway has the shortest pathway to patient treatment. This means that anything that occurs in this section

---

<table>
<thead>
<tr>
<th>Error Pathway</th>
<th>Severity</th>
<th>Consequence Type</th>
<th>Mean Human Error Probability</th>
<th>Mean Human Error Probability (Stress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>54</td>
<td>0-8</td>
<td>Inappropriate Treatment</td>
<td>&lt;1E-7</td>
<td>&lt;1E-7</td>
</tr>
</tbody>
</table>

**Table 4.5:** Probability and Severity of Errors Initiated at Pre Treatment Stage
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

<table>
<thead>
<tr>
<th>Error Pathway</th>
<th>Severity</th>
<th>Consequence Type</th>
<th>Mean Human Error Probability</th>
<th>Mean Human Error Probability (Stress)</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>0-2</td>
<td>Inappropriate Treatment</td>
<td>2.71E-05</td>
<td>1.10E-04</td>
</tr>
<tr>
<td>56</td>
<td>0-2</td>
<td>Inappropriate Treatment</td>
<td>9.13E-04</td>
<td>3.60E-03</td>
</tr>
<tr>
<td>57</td>
<td>0-1</td>
<td>Setup</td>
<td>9.16E-05</td>
<td>3.60E-04</td>
</tr>
<tr>
<td>58</td>
<td>0-1</td>
<td>Setup</td>
<td>5.20E-03</td>
<td>1.96E-02</td>
</tr>
<tr>
<td>59*</td>
<td>0-1</td>
<td>Wrong Dose Delivered</td>
<td>5.20E-03</td>
<td>1.96E-02</td>
</tr>
<tr>
<td>60</td>
<td>0-2</td>
<td>Setup</td>
<td>9.21E-05</td>
<td>3.70E-04</td>
</tr>
<tr>
<td>61*</td>
<td>0-1</td>
<td>Setup</td>
<td>9.21E-05</td>
<td>3.70E-04</td>
</tr>
<tr>
<td>62</td>
<td>0-2</td>
<td>Setup</td>
<td>9.21E-05</td>
<td>3.70E-04</td>
</tr>
<tr>
<td>63</td>
<td>0-2</td>
<td>Setup</td>
<td>9.21E-05</td>
<td>3.70E-04</td>
</tr>
</tbody>
</table>

Table 4.6: Probability and Severity of Errors Initiated at Treatment Stage

of the process has less chance of being rectified prior to treatment. This was seen in chapter 2 (figure 2.16), where it was noted that 61% of the incidents investigated initiated in the treatment delivery part of the process. The predicted error probabilities are shown in figure 4.20

The mean probability in standard conditions was 0.01. The mean probability in stress conditions was 0.04.

The total probability density function for the total process as described was seen in figure 4.21. The probability density function plots represent the scenario where any errors that are initiated by a patient are considered to have a probability of 1. This will not always be the case. The mean probability in standard conditions was 0.11. The mean probability in stress conditions was 0.24.
4.3 Results

Figure 4.20: Probability Density Function of an Error Occurring at Treatment Stage

Figure 4.21: Probability Density Function of an Error Occurring Across the Whole Process
4.3.2.2 Consequences

A total of 63 error mode pathways were identified across the treatment process. These are described below. The severity and the reason why it was described as a potential incident are represented here. In some cases the severity was assessed with the contribution of published literature.

1) Patient not initially activated in the record and verify system.
Consequence- Patient Delay
Dosimetric Severity- NA
Not activating the patient for treatment on the record and verify system will result in the appointments been populated for the patient. This will create a delay for the patients’ treatment. This being discovered involves the patient letting the department know that they haven’t received the appointments. It was possible, if a patient does not inform the department they have not received their appointments that they could go without treatment. The consequence of this will vary depending on the severity of the disease.

2) Inappropriate treatment selection of treatment in record and verify system.
Consequence- Inappropriate Treatment
Dosimetric Severity- 1-8
The greatest danger for this was that the patient may not necessarily require treatment- i.e. the severity of the cancer may not require treatment at all. The decision made by the doctor will be reviewed in the planning peer review meeting. As there was a minimum of two consultants required for the peer review meeting the decision will need to be reviewed twice. One of these consultants may be person who originally may the treatment decision. This was still considered a review of the decision, even if it was a self-review.

3) Wrong area typed into record and verify system.
Consequence- Inappropriate Treatment
Dosimetric Severity- 8
This incident pathway would be initiated by the physician not typing in the right
4.3 Results

target. This could potentially result in the wrong site being treated. This will be up to a 100% deviation from what’s expected. This event was rare. The pathway involves a series of people reviewing the notes and diagnosis for a patient. The probability of none of them realising the mistake was very low.

4) Wrong prescription typed into record and verify system.
Consequence- Inappropriate Treatment
Dosimetric Severity- 1/8
This was similar to error mode 3. In this scenario the wrong prescription was entered. The effects of this will vary depending on what was entered.

5) Wrong patient scanned at imaging.
Consequence- Unnecessary (Ionising) Imaging/Inappropriate Treatment
Dosimetric Severity- 1/1-8
The first result of this was that, at minimum, the patient will need to be rescanned. This results in an increased dose of approximately $8\text{mSv}$\textsuperscript{1}\cite{168}. This is low compared to the $74\text{ Gy}$ being delivered to the target, or the 2% of the PTV dose ($1.5\text{Gy}$) approximately being delivered to 10cm away from the target\textsuperscript{169}. The second potential affect of this was if the patient remains unidentified correctly through treatment. The second consequence was also 1, but if this occurs for each time during patient treatment it will result in a level 8 incident (assuming the patients been mixed up are on different treatments). The greater danger was a patient presenting themselves with a similar name and the same date of birth as another patient.

6) Wrong scan extent chosen.
Consequence- Unnecessary (Ionising) Imaging
Dosimetric Severity- 1
If the right extent was not chosen from the scout, there may not be enough tissue to plan the patient correctly. In this scenario the patient will need to be res-

\textsuperscript{1}Approximate value taken from published data. Actual value will differ from CT scanner to CT scanner
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

canned. This will have the same dosimetric effect as error pathway 5.

7) Patient notes misinterpreted.
Consequence- Unnecessary (Ionising) Imaging/Inappropriate Treatment
Dosimetric Severity- 1/8
In this pathway the misinterpretation of notes results in the wrong area being scanned. This will result in the patient needing to be rescanned. This has a dosimetric consequence of 1. If the pathway continues there was the potential the patient will have the wrong treatment delivered. This will have a dosimetric consequence of 8.

8) The patient is setup in an unsuitable position during the scanning stage.
Consequence- Unnecessary (Ionising) Imaging/Delay of treatment
Dosimetric Severity- 1
The position that the patient has been put in cannot be planned. This would include arms in the way, or if the patient was angled inappropriately. If the patient cannot be planned on an image they will have to be rescanned. As this will have reached the planning stage this may also cause a delay on the patients treatment.

9) The patient wasn’t setup in a tolerable position during scanning.
Consequence- Unnecessary (Ionising) Imaging/Delay of treatment/Setup
Dosimetric Severity- 1
The patient will not be able to be placed in the correct position on-set if the position was not tolerable. In this scenario, the location of the target will be isolated using the imaging system. Thus, any deviations on setup will be rotational. This will result in a maximum of a dosimetric severity of 1 with the margins applied in the department. This figure was based on a study which looked at this and estimated a maximum EUD and TCP within 2%(170). The paper went on to comment with their margins this was insignificant.

10) Patient not setup in a standard position during imaging.
Consequence- Setup
Dosimetric Severity- 1
This will have the same consequence as 9. The deviation from not setting up in a reproducible position will be rotational. The position of the prostate will be accurate but its orientation will not.

11) Patient setup notes not documented correctly.
Consequence- Setup
Dosimetric Severity- 1
Wrong documentation. This would be the wrong foot rest, knee rest etc being used on set. It would create a slight variation to the rotation of the organ. As the patient will be setup using daily image guided it should not have an effect of the actual position of the prostate. The estimated dosimetric severity is 1. This error will affect the patient at treatment delivery but there are no safety checks between this point and the treatment setup.

12) The kV was accidentally changed during scanning.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 1
This incident will result in a slight change in the HU values that could affect the patients treatment calculation. The HU was used to calculate how the dose will interact in different densities. It depends on the energy of the CT scan[171].

13) Patient moves during scanning.
Consequence- Unnecessary (Ionising) Imaging/Setup
Dosimetric Severity- 1
This has the same consequence as 9. It was also a conditional incident. The patient has to move before it occurs. The probability represents the likelihood of the incident going unnoticed. If caught when reviewing the image, the event is identified. This means the patient will need to be rescanned.

14) The bed was accidentally zeroed.
Consequence- Unnecessary (Ionising) Imaging
Dosimetric Severity- 1
The patients bed being zeroed results in the scanning bed coordinates being reset.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

This will potentially result in the wrong area being scanned. This will require the patient to be rescanned.

15) The patient isn’t marked.
Consequence- Unnecessary (Ionising) Imaging/Setup
Dosimetric Severity- 1
In this scenario there will be one of two consequences. They may choose to re-scan. If they do not choose to rescan there was the potential for the same rotational setup issues.

16-17) The patient isn’t marked correctly.
Consequence- Setup
Dosimetric Severity- 1
There are requirements for placing the tattoo on the patient. If it was not placed on a stable point it may move too easily. This will create rotational issues at patient setup.

18-21) For various reasons there is a long delay between CT and Ultrasound scanning.
Consequence- Unnecessary (Ionising) Imaging
Dosimetric Severity- 1
The time between the CT scan and the Clarity™. The assumed consequence was that it will be identified and rescanned. If not it will create fusion difficulties. There are 4 errors that could lead to this, including a delay due to time management or distraction.

22) Patient’s bladder not full and goes unnoticed.
Consequence- Setup
Dosimetric Severity- 1
The main affect of a bad scanning technique (that the Clarity system won’t identify) was compression of the bladder during scanning. If this occurs the isocentre of the prostate will be moved, changing the reference.
23) Bad ultrasound scanning technique.
Consequence: Setup
Dosimetric Severity: 1
This was a subjective error. Therefore, the value presented here was the probability of a gross error. This has the potential of matching the prostate on the CT and the prostate on the Clarity™ system to not match and therefore setup incorrectly.

24) Inaccurate fusion of ultrasound and CT scan.
Consequence: Setup/Volume
Dosimetric Severity: 1-8/1-8
This error has a two fold effect. The ultrasound image was matched to the prostate on CT. The setup of the patient was based on the geometrical position of the prostate in CT, which was recorded by the Clarity™. If the prostate isn’t matched this will create a systematic setup uncertainty.

25) Target incorrectly drawn.
Consequence: Volume/Volume
Dosimetric Severity: 1-8/1-6
There are known uncertainties with contouring. This does not refer to the known inter and intra observer uncertainties, but rather gross delineation errors. The known delineation uncertainties should be addressed separately. This has the potential of increasing the volume of the treatment volume or decreasing it by up to 100% of the prescription dose.

26) Target incorrectly expanded due to entering wrong value.
Consequence: Volume
Dosimetric Severity: 1-8
The prostate volume was expanded to account for uncertainties. If the wrong value was entered then the expansion will be incorrect. Depending on the level of expansion change this can have a dosimetric consequence of between 1-8. There was no formal checking of this, although it should be noticed during the general
overview of the plan during the physics checking process.

27) Target incorrectly expanded due to misinterpretation of notes.
Consequence-Volume
Dosimetric Severity- 1-6
The seminal vesicles will be expanded depending on the treatment type. If it was a low severity disease the expansion will be less than if its a high severity disease. Misinterpretation of the notes will result in a different expansion. The dosimetric consequence of this depends on the size of the seminal vesicles and the size of the prostate.

28) Rectum drawn incorrectly.
Consequence-Volume
Dosimetric Severity- 0-4
The rectum was often difficult to get within acceptable tolerance for treatment. Thus, under or over contouring the rectum will have a large impact on the perceived dose to the rectum. Over-contouring will reduce the perceived dose volume histogram. Under contouring could result in not identifying the parts of the rectum that could be recieving a high dose. The estimated consequence was between 0 and 4.

29) Forget to draw rectum.
Consequence-Volume
Dosimetric Severity- 0-6
If the rectum was not identified, the potential dose to the rectum will not be assessed. If this goes unidentified it could result in the dose to the rectum being significantly higher than the tolerances. This estimated dosimetric consequence was between 0 and 6. There was a lot of safety checks, as the DVHs are checked multiple times.

30) Incorrectly drawn sigmoid.
Consequence-Volume
Dosimetric Severity- 0-4
The sigmoid was the second most difficult organ to get within acceptable tolerances. It was subject to the same effects as the rectum as seen in pathway 28. The dosimetric consequence was between 0 and 4.

31) Forget to draw sigmoid.
Consequence-Volume
Dosimetric Severity- 0-4
This was similar to the effects for 29. If the sigmoid was not drawn it was not possible to check the DVHs. The estimated dosimetric was between 0-4.

32-37) Forget or incorrectly draw other OARs.
Consequence-Volume
Dosimetric Severity- 0-2
The remaining OARs have a high tolerance to radiation. It was therefore unlikely that missing them or misdrawing will have a significant affect on the dosimetric consequence.

38) Planned a treatment that was inappropriate for the type of disease.
Consequence- Inappropriate Treatment
Dosimetric Severity-0-8
An inappropriate treatment was planned due to reading the wrong notes. This can range from wrong prescription, to a completely wrong target. The volume of checks will reduce the probability of this to low levels.

39) Select the wrong grid size.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 1
The grid size will affect the calculation of the dose. Increasing or decreasing the grid size from the standard will affect the dose calculation. This will have a slight affect on the dose.

40) MLCs too close together.
Consequence- Wrong Dose Delivered
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Dosimetric Severity- 1
If the MLCs are too close together it was possible that the settings of the TPS are outside the capability of the Linac. For a prostate patient it was unlikely that the leafs will be set to an unsuitable shape due to the shape of the prostate.

41) Unsuitable normalisation point selected.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 0-2
There are guidelines for selection of a suitable normalisation point. Not selected a suitable point will have a slight effect on the calculated dose.

42) Wrong prescription entered into TPS.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 1-8
This pathway involves accidentally entering the wrong value into the TPS. This means the number of MUs could be calculated for the wrong, which could result in either an over dose or under dose to the patient. There are a number of checks to ensure the right dose was entered, making this an unlikely event.

43) Coverage not checked correctly.
Consequence- Inappropriate Treatment
Dosimetric Severity- 1-8
This refers to checking the dose coverage in a plan. It was rated between 1-8, but it was unlikely that an area would be that highly underdosed or overdosed. The danger here was small pockets of undercoverage that could result in slight under dose to parts of the target.

44-48) DVHs not checked correctly.
Consequence- Inappropriate Treatment
Dosimetric Severity- 1-4/1-2
This series of error modes could potentially result in an overdose to an OAR. The severity of this depends on the OAR being examined.
49) Accidental changing of parameters when transferring information.
Consequence- Inappropriate Treatment
Dosimetric Severity- 0-8
There was not a direct transfer of data from the TPS to R and V system. As a result of this, while unlikely as it would require retyping values which would not be the norm, this could potentially result in the patient name being changed.

50) Incorrect rounding of units/ changing figures.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 1-6
This was where the MUs are rounded to a whole number. There was the potential to round them incorrectly. There was also a chance of typing in the wrong number thus changing the number of MUs delivered.

51-52) Accidental change field size/energy.
Consequence- Volume/Energy
Dosimetric Severity- 1-6/1-7
It was easy to accidentally change the parameters in the record and verify system. The change in field size or energy can result in the treatment parameters in the R and V system being different from the TPS.

53) Forget to move paperwork.
Consequence- Delay on Treatment
Dosimetric Severity- NA
If the printout was not transferred to the next stage of the process, the physics check will not be done. The schedule originally populated when the patient was assessed means that this will be identified, but the patient may be delayed if not caught in a timely manner.

54) Accidental change of treatment parameters.
Consequence- Inappropriate Treatment
Dosimetric Severity- 0-8
In the R and V system used, there was the potential of changing the treatment
parameters when the plan was open. This can be accidentally done just through the slip of the finger. Plan delta was used to identify any changes. If this was not performed, the parameters of the treatment printout are also compared with the printout sheet at a later check.

55) Wrong patient treated on unit (one fraction).
Consequence- Inappropriate Treatment
Dosimetric Severity- 0-2
At this stage of the process any errors will affect only a single fraction. This reduces the severity of any potential incidents. It also increases the probability of a single patient been affected by these errors. Each of the errors from 55 onwards have the potential of happening 37 times per patient. The error pathway 55 would result in the wrong treatment being delivered to the patient for a single fraction.

56) Wrong treatment course downloaded.
Consequence- Inappropriate Treatment
Dosimetric Severity- 0-2
In this scenario, the correct patient was identified, but the wrong treatment course (wrong patient) was downloaded. This will result in the wrong patients’ treatment being delivered to the patient.

57) Wrong accessory selected.
Consequence- Setup
Dosimetric Severity- 0-1
In this case the wrong accessories (foot rest, etc) are selected. With this, the patient will be setup to the right position, but there may be rotational errors the could affect the dose delivery to the target.

58) Not setup the same as CT scanning.
Consequence- Setup
Dosimetric Severity- 0-1
If the patient was not setup in the standard setup as CT this creates rotational
uncertainties. This will have a small dosimetric impact on the patients’ treatment.

59) Ensure bars are not in the way of treatment.
Consequence- Wrong Dose Delivered
Dosimetric Severity- 0-1
If the bars are in the way of the treatment field this will have an effect on the
dose delivered to the patient. This was a conditional error, where the bars have
to go through the beam and the error mode of not identifying it has to occur.

60) Correct ultrasound scanning technique.
Consequence- Setup
Dosimetric Severity- 0-2
Putting too much pressure on the bladder can affect the position of the prostate.
Training reduces the subjectivity of this, turning it into an action task.

61) Patient bladder not full (goes unnoticed).
Consequence- Setup
Dosimetric Severity- 0-1
If the patients bladder isn’t full this will affect the rotational accuracy of the
position of the prostate.

62) Wrong move made.
Consequence- Setup
Dosimetric Severity- 0-2
This refers to 1 RT moving incorrectly and the second RT not noticing. The
severity will depend on the scale of the wrong move made.

63) Forget to move patient.
Consequence- Setup
Dosimetric Severity- 0-1
This refers to both RTs forgetting to make the moves. The severity will depend
on the scale of the move that needs to be made.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOThERAPY

The total incident rate facilitated by human error (assuming conditional initiating events always occur) was represented by figure 4.14. This was presented as the number of incident pathways that will result in incident per 100 patients. It was possible that a single patient will experience multiple errors.

**Figure 4.22:** Estimated incident rate per 100 patients broken down by incident type; prostate treatment. *This diagram represents the mean probability of error. The lowest possible probability of an error was considered to be 1E-7 or 0.00001 per 100 patients. The calculated probability of an error occurring due to the wrong energy was below this threshold, so was not seen on this graph. However, the probability for this can be considered to be at the threshold of 0.00001 per 100 patients.*

---

1. A pathway that has the potential of occurring more than once, for example the treatment delivery occurs 37 times. This was treated as 37 OR gates.
4.3 Results

Figure 4.23: Estimated incident rate per 100 patients broken down by incident type; prostate treatment. This diagram represents the mode probability of error. The lowest possible probability of an error was considered to be $1E-7$ or 0.00001 per 100 patients. The probability for this can be considered to be at the threshold of 0.00001 per 100 patients for any events that are calculated below this.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

4.3.3 Head & Neck IMRT with LAN Field

4.3.3.1 Summary of Probability Results

This case study was a head and neck case with a LAN field. It assumes a 30 fraction schedule with no rescan or significant weight loss. It assumes two PTV dose levels in the brain, 63Gy and 70Gy. The imaging used was megavoltage (6MV) 2-d flat panel EPID imaging. This creates an uncertainty with image matching, making it more difficult to match images accurately. This was due to the known limitations of this imaging system.

The patient specific IMRT QA was not included in this assessment. This wasn’t included due to the on-going debates of the necessity of patient specific IMRT QA (as it was currently being done) in reference to patient safety\cite{172}\cite{173} and its ability to detect errors\cite{174}. The incidents identified here, would not have been detected through IMRT QA. However, it should be noted that commissioning or ongoing QA is not included either. It is possible that patient specific IMRT QA would prevent these types of errors. There are also technical errors that could be picked up by patient specific IMRT QA that aren’t identified using this model.

A total of 133 potential incident pathways were identified for this treatment. The increased amount of automated tasks in the treatment planning eliminated some pathways. However, the increased number of tasks involved with the more complex treatment created more error pathways that did not exist for the conformal case. 24 of the error pathways were identical to the pathways from the prostate treatment.

The breakdown of the estimated rate of incidents occurring for this treatment, based on the analysis demonstrated in this study, can be seen in figure 4.24.

4.3.3.2 Summary of Severity Results

The severity ratings for the head and neck target have some slight differences than with the prostate. Setup errors that affect the every treatment fraction are graded higher than the prostate. It was expected that the rotational variations
Figure 4.24: Estimated incident rate per 100 patients broken down by incident type; Head and Neck Treatment. *This diagram represents the mean probability of error.* The lowest possible probability of an error was considered to be $1E^{-7}$ or 0.00001 per 100 patients. The calculated probability of an error occurring due to the wrong energy was below this threshold, so was not seen on this graph. However, the probability for this can be considered to be at the threshold of 0.0001 per 100 patients.
Figure 4.25: Estimated incident rate per 100 patients broken down by incident type: Head and Neck Treatment. This diagram represents the mode probability of error. The lowest possible probability of an error was considered to be 1E-7 or 0.00001 per 100 patients. The probability for this can be considered to be at the threshold of 0.0001 per 100 patients for any events that are calculated below this.
will be more severe for the head and neck case due to its non-symmetrical target. The head and neck shell will reduce the rotational variation. The clinical severity of an incident can be significantly more severe than with a prostate plan. There are a lot more radiosensitive structures, including the spinal cord and brain stem. This plan uses a single isocentre for the IMRT fields and the LAN field. Having one isocentre reduces the probability of an error as the patient does not require a second move which could be forgotten.

4.3.3.3 Comparison with Recorded Incident Rates

Site 3 was used for the safety modelling. The results from this can be compared with the actual detected incident. The limitation of this was that it assumes that all incidents are reported. There was evidence to suggest that not all incidents were identified as incidents. For example delays on patient treatment and unnecessary ionising imaging were not reported. The recorded incident rates take all treatment types into account, whereas in the model we look at particular treatment types. Despite this, comparing the incident rates with the model predictions will give an indication if the model was a realistic indicator of incident rates. This comparison can be seen in figures 5.2 (for prostate) and figure 5.3 (for head and neck)

There was a clear discrepancy between the predicted values and the recorded values. There are a number of potential reasons for this, and this discrepancy does not necessarily mean the risk assessment model was not valid. While reporting levels locally were considered to be good from the patient safety culture survey that was administered to the department, staff members do not always consider things like an extra CT scan or a delay on the patient treatment to be incidents. The two examples shown represent to specific treatment types. This may not necessarily be representative of the patients going through the department. For example a high number of patients are palliative which was not modelled at all.

A major limitation of the incident data lies in the face that a high volume of incidents are caught by luck. This indicates that a larger number of incidents
Figure 4.26: Comparison Between Prostate Predicted Rates and Actual Rates (All Sites). The actual incident rate refers to all treatment types that were treated in that period, not just prostate treatments. There are no dose influencing accessories involved with the prostate treatment so this was not a direct comparison. However there was not a statistically high enough number of incidents to do a direct comparison of incidents that have occurred during prostate treatment and the predicted rate.
4.3 Results

Figure 4.27: Comparison Between Head and Neck Predicted Rates and Actual Rates (All Sites). The actual incident rate refers to all treatment types that were treated in that period, not just head and neck treatments. There are no dose influencing accessories involved with the prostate treatment so this was not a direct comparison. However there was not a statistically high enough number of incidents to do a direct comparison of incidents that have occurred during head and neck treatment and the predicted rate.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Figure 4.28: Comparison of Probabilistic Risk Assessment Model and Failure Mode and Effects Analysis

exist, but are not being caught. This means that the incident data will always be under-representative of the actual incident rate. The level of under-representation can be reduced through auditing, positive reporting culture and ensuring all reported incidents are appropriately captured.

4.3.4 Comparison with Failure Mode and Effects Analysis

This section compares the risk assessment model presented here, with the FMEA approach. A summary of the differences is shown by figure 4.28.

4.3.4.1 Results

The charts below show the FMEA results for the prostate case and the head and neck case. These results were obtained by rating the identified failure modes using the rating system discussed in the AAPM TG-100 document. This rating system is summarised in figure 4.29.

A single person was asked to rate the various failure modes that had been identified. A summary of the risk numbers can be seen in figure 4.30.

Figure 4.31 shows the risk priority numbers identified for the head and neck treatment.

<table>
<thead>
<tr>
<th></th>
<th>FMEA</th>
<th>Proposed Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion of Performance Shaping Factors</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Inclusion of Human Reliability</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Thorough Process Analysis</td>
<td>Limited</td>
<td>✓</td>
</tr>
<tr>
<td>Mathematically Valid</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Adequate Testing of Detection Controls</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Uncertainty Analysis Included</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Subjective</td>
<td>✗</td>
<td>Limited</td>
</tr>
<tr>
<td>Use of Boolean Logic</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>
4.3 Results

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence (O)</th>
<th>Severity (S)</th>
<th>Detectability (D)</th>
<th>Estimated Probability of failure going undetected in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Failure unlikely</td>
<td>0.01</td>
<td>No effect</td>
<td>0.01</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>0.02</td>
<td>Inconvenience</td>
<td>0.2</td>
</tr>
<tr>
<td>3</td>
<td>Relatively few failures</td>
<td>0.03</td>
<td>Inconvenience</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>0.1</td>
<td>Minor dosimetric error</td>
<td>1.0</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>&lt;0.2</td>
<td>Limited toxicity or tumor underdose</td>
<td>2.0</td>
</tr>
<tr>
<td>6</td>
<td>Occasional failures</td>
<td>&lt;0.5</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>5.0</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>&lt;1</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Repeated failures</td>
<td>&lt;2</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>15</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>&lt;5</td>
<td>Very serious toxicity or tumor underdose</td>
<td>20</td>
</tr>
<tr>
<td>10</td>
<td>Failures inevitable</td>
<td>&gt;5</td>
<td>Catastrophic</td>
<td>&gt;20</td>
</tr>
</tbody>
</table>

**Figure 4.29:** Risk Priority Numbers as Defined by AAPM TG-100 reproduced with permissions from AAPM TG100 report (175)

**Figure 4.30:** Risk Priority Numbers for Prostate Treatment Case
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOThERAPY

4.3.4.2 Ease of Use

The model developed here, is conceptually easy to implement. The human reliability assessment, while can be mathematically complex, can be implemented with ease. The reliability block diagrams are easier to construct than alternatives such as IDEF0 diagrams or fault trees. They are also simple to follow, which is beneficial for improving the processes. However, implementation of this model requires the use of multiple software packages, that are not fit for purpose. The development of a custom software package would increase the ease of use.

On a superficial level, FMEA is easy to use. However, to get the maximum benefit from the process a lot of work is required. From an implementation perspective, the authors believe that there is no difference in the ease of implementation when a thorough analysis of the system is performed. There are more resources available for FMEA which can help with implementation. The use of risk priority numbers makes it easier to decide when action needs to be taken.
4.3 Results

4.3.4.3 Subjective Nature

FMEA is well known for being subjective. There are a number of publications that have demonstrated variations in RPNs depending on the person rating them. This is well documented in the literature.

While the method presented here is also subjective, the structured method of assessing the probability and the severity should reduce this. The probability estimations are based on qualitative assessments of the task, rather than just picking a number based on an opinion. The severity estimations are based on a structured approach involving review of the literature. This is an evidence based approach to the severity, which is bound to increase the validity. There is still some interpretation required which can lead to uncertainties.

4.3.4.4 Suitability for Radiotherapy

The model developed in this thesis was specifically designed with radiotherapy in mind. The model was developed based on the current needs of radiotherapy, by looking at the incidents that are currently taking place and addressing those needs. As a consequence of this it is designed to account for current limitations in risk assessment in radiotherapy. As the technical safety components are already covered in a multitude of documents, this model prioritises process design and human factors. These are the factors that have been identified as being the cause of incidents. An advantage of this method is that it thoroughly analyses the methods for detecting incidents. Each detection task is analysed independently and the strength of each check is calculated.

While FMEA is often used as a risk assessment technique in radiotherapy it is generally more chosen out of tradition or because it is commonly used in other industries rather than any thorough analysis on its suitability in radiotherapy. Nevertheless, it is recommended as part of the AAPM TG-100 document and has widely been applied in radiotherapy. It also can be used to evaluate other components of the process, not just the human reliability. This makes it more
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

useful when assessing quality assurance and machine reliability. However, based on the influence of human reliability on incidents in radiotherapy, putting more resources into this should prove more useful in reducing error rates.

4.3.4.5 Mathematical Accuracy

The maths of FMEA aren’t correct. The multiplication of arbitrary units (probability, detectability, severity) isn’t mathematically correct and produces an RPN that may not accurately reflect the dangers. The approach in the model presented in this thesis is mathematically accurate. It uses Boolean logic and an uncertainty analysis.

4.4 Discussion

This model of risk assessment incorporates a number of element of risk assessment that are currently not been addressed in radiation oncology. The use of error mode pathways simplifies the FTA process, while still using the same mathematical operations. The model also identifies that the same error mode can have different consequences depending on the extent of the error. The human error probability estimations show that these tools can be implemented in the radiotherapy platform, although going forward the PSFs should be edited to reflect the radiotherapy process.

This model has limitations. Most notably it only can be used to assess incidents that have a known, and definable, error mode pathways. Tasks such as contouring and patient treatment intent can be used assessed this method, however the subjective nature of this task means its only suitable for detecting gross deviations. The inconsistency of contouring across physicians was well documented\textsuperscript{176}(177)\textsuperscript{178}. This was a known limitation in radiation oncology and it was beyond the scope of this project.
4.4 Discussion

The PSFs used here were generally the optimal values. It was commented during the assessment that stress, available time and complexity can vary substantially on a patient by patient and day by day basis. It was noteworthy that when the physician was consulted about the model, there was a lower amount of physicians in the department than normal.

Identification of every error mode was difficult. Learning from near-misses, incidents and non-conformities can be used to assess potential incidents and be used to contribute to the model. With this in mind, the model should never be considered to be finished, but rather a fluid model that was always adapted based on reviewing events and tracking how they would pass through the system.

Very rare events are almost impossible to model. An example of one was the case discussed by the New York Times([9]). In this scenario the computer crash in itself was a rare event. The result of the computer crash was also unpredictable. In the New York case it resulted in the field size resetting. To account for these rare events there are checks in the system which are used to check various parameters at different points in the system. The most notable one of these was the independent monitor unit calculator. This was used to check a single calculation point in the plan. There was not a single recorded case in the 12 months of the calculation point been calculated incorrectly. However if there was a bug in the TPS, a problem with transfer of data or some accidental change of the system, the MU checker will pick up gross discrepancies as a result of any of these potential errors.

There are many references (that were discussed earlier) that discuss implementation of SPAR-H. However, the method was not very well validated and has never been used in healthcare. This study demonstrates how it can be applied. It was difficult to fully validate the model against the reported incident rates. Incident rates reported are going to represent the minimum potential amount of incidents that actually occurred. The reported incident rates being equal to the actual incident rates would rely on there being a 100% incident identification rate and a 100% reporting rate. A full identification rate was not likely and its known from the PSF study that full reporting levels also do not exist.
4. FAILURE MODE AND PROBABILISTIC RISK ASSESSMENT MODEL FOR RADIOTHERAPY

Nonetheless by comparing the reported incident rates for all sites could be used to get an idea of if the model was realistic. The predicted levels were higher than the reported levels (as expected). The effects of stress and other factors can be evaluated to estimate how they would affect the probability of an error occurring.
Conclusions

This research covered a range of subjects related to the area of patient safety in radiotherapy. It covers multiple gaps in the literature, most notably incident rates across multiple sites, patient safety culture and a systematic approach to prospective risk assessment. This thesis was published during the same period as an International Atomic Energy Agency (IAEA) report on Ireland’s radiation regulatory body. The report was very positive but did discuss limitations in the areas of patient protection\cite{179}. In particular:

\begin{quote}
An effective legal framework for the regulation of patient protection should be implemented, and arrangements to inspect and enforce measures to ensure patient protection should be put in place urgently.
\end{quote}

This research addresses numerous patient protection issues and could be used as a starting point for a regulatory body.

The research demonstrates the role of humans and culture on radiotherapy safety. There was difficulties collecting the data. The sensitivity of the data meant that multiple approvals had to be sought from each site. This created delays in the region of years for some departments. As a result 2 of the departments were not included as the delays were too long. Nevertheless, this research is the largest study that looked at incident rates across multiple radiotherapy
5. CONCLUSIONS

departments.

5.1 Human Factors Influence on Incident (HFACS-RT)

The HFACS-RT classification emphasis the influence of human error and organisational structure on incidents. The primary problem with this type of classification is the subjective element. Trained observers are known to limit subjectivity but it’s unlikely that trained observers are readily available for most departments. If advanced training was available in multiple radiotherapy departments, the HFACS-RT could be used more widely. Assessing incidents in this way can be used to highlight where resources need to be directed to prevent incidents from recurring.

5.2 Incident Investigation

The incident investigation element of the study highlighted the various factors that have influenced incidents in various departments. Across the series of data collected there were a number of limitations identified. Local incident reporting is subjective, radiotherapy departments have different methods and the information being reported varies from site to site. In a single department it was suggested that reporting amongst professions is low. The result of this is that it was not possible to do a statistical comparison of departments. The second limiting factor is identifying incidents. In the course of this study it was clear that a high volume of incidents were discovered “by accident” in Ireland. Reading through the various incident reports it could be seen that the incidents were not found through structured auditing and review process. In high profile incidents such as the Ottawa and Epinal cases it was years before they were accidentally identified.
5.3 Patient Safety Culture

Metrics of the organisational structure of a department are often difficult to measure. The patient safety culture survey measures many metrics that can be attributed to organisational structure. By measuring the patient safety culture some interesting observations can be made. Small private sites were more likely to have already measured their patient safety culture. This study demonstrated a statistically significant difference between the sites in the different metrics of patient safety culture. Going forward this information can be used as a baseline to compare sites.

5.4 Model for Risk Assessment

The model was implemented for two specific treatment scenarios. The results predicted a higher incident rate than what have been recorded across the various radiotherapy centres. This could indicate that the model over estimates incident. The model solves a number of problems that can be seen in current modelling techniques been implemented in radiotherapy. The task analysis forces users to evaluate the process at a microscopic level, thus leading to a more thorough analysis. The error mode pathway diagrams are more intuitive to follow than standard process flow diagrams. Including these also means that multiple tasks are evaluated, i.e. tasks aren’t being treated as standalone.

The application of human error probability values adds a level of quantification to the assessment process. While this is widely used in the nuclear industry it is thought that this is the first application of SPAR-H to the medical sector. There are limitations to this model. The PSFs are designed for a different scenario. One of the PSFs had to be reassigned in all values because the multiplier was too high, giving unrealistic results.
5. CONCLUSIONS

5.5 Future Work

5.5.1 Patient Safety Culture and Incident Rates

5.5.1.1 Auditing
The work presented here has limitations in terms of number of sites investigated. While there is a large amount of actual data, in the end only 8 sites were investigated, not enough to create any statistical conclusions between incident rates and patient safety culture. The design of this study could be used to investigate this relationship by introducing the study across departments outside of Ireland. A higher amount of data could be used to establish a statistical relationship. This would require a more uniform method of reporting incidents within departments to reduce the manual analysis from using a non-standardised reporting system. The methodology of analysis used in chapter 2 of the thesis could be used as a template for this. This could also be used as a template for auditing departments.

5.5.1.2 Development of Safety Tools
The information obtained from this study provided some interesting data about how current incidents may affect the future of radiotherapy. The most common error seen was setup errors at the treatment delivery stage. This will have a large effect on the clinical outcomes as hypofractionated radiotherapy becomes more prominent. A larger dataset taken from multiple departments with multiple technologies will provide further information on what type of errors are evolving with new technologies.

5.5.2 Modelling

5.5.2.1 Further Adaptation
The Failure Mode and Probabilistic Risk Assessment Model for Radiotherapy is useful for implementation of new technologies and evaluating the current setup of a department. However, there are limitations. The process modelled in this
5.5 Future Work

did not include the equipment management. The data gathered in chapter 2 of the thesis indicated the patient pathway (imaging to treatment) was most prone to error. Future work in this area could look at applying the same modelling technique to commissioning and to on-going equipment quality assurance.

The model has the potential to be applied across other areas of healthcare. Unlike FMEA it identifies that the same error can result in different severities of error depending on the circumstances. Therefore, severity can be represented as a spectrum of values, assumed to follow Heinrichs’ triangle (i.e. the lowest severity is going to be the most common and the highest severity is going to be the least common). Applying this method across the remainder of healthcare has the potential to create a more rigorous risk assessment technique for all healthcare techniques.

5.5.2.2 Addressing Model Limitations

The limitation of the model for the subjective elements of the process have been widely discussed throughout the thesis. Applying the same modelling technique through analysis of the scientific literature could be an area of further research. Although, more rigorous application of guidelines could be used to reduce the subjectivity of some of these tasks.

5.5.2.3 Software Solution Package

The models concept is simple. However, creating this model involved using three different types of software. With the increasing emphasis on process safety in radiotherapy (as demonstrated by TG-100, Towards Safer Radiotherapy and the ACCIRad document) this method of analysis provides a thorough solution to process safety. This method could be offered as a simple, user-friendly software package, that could be used by radiotherapy departments. Combining this software package with one that is also used to record non-conformities, near-misses
and incidents could be used to constantly update and adopt the model to constantly improve safety.
Bibliography


BIBLIOGRAPHY


Appendix A

Study Protocol

This section shows the standard study protocol sent to the departments that described study.
<table>
<thead>
<tr>
<th>Study Summary</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Radiation Oncology System Safety Analysis Data Collection</td>
</tr>
</tbody>
</table>
| **Methodology** | 1) Initial Data Collection using a survey for management  
2) Safety Culture Survey sent to all staff members for completion  
3) Incident investigation through examining recorded incidents (including near-misses and non-conformities) |
| **Study Duration** | 6-months for complete data collection across all sites |
| **Study Center(s)** | Multi Site. Up to 8 centres |
| **Objectives** | 1. Examine incident rates in radiotherapy across a number of departments  
2. Use this data to develop a model looking at future incident rates and develop techniques to reduce this  
3. Look at how patient safety culture effects incident rates in radiotherapy  
4. Benchmark staffing levels in radiotherapy |
| **Number of Subjects** | For incident analysis all data available in the department shall be used. For the staff patient safety culture survey all staff in radiotherapy will be given the opportunity to fill out the survey. |
1 Introduction

This document describes the protocol for the collection of data for the ROSSA project. This data will be used as part of a Ph.D. in Medical Physics and a Ph.D. in Industrial Engineering. The ROSSA project grant application form that includes an introduction to the ROSSA project can be found in Appendix 1.

2 Study Objectives

The purpose of this study is to collect data as part of the Radiation Oncology System Safety Analysis project (See appendix one for ROSSA Grant Proposal). The objective of this project is to create a set of workable tools to evaluate and improve safety in the radiotherapy process. The purpose of this particular arm of the project can be summarised as below.

The primary endpoints of this study are as follows.
1. Examine incident rates in radiotherapy across a number of departments
2. Use this data to develop a model looking at future incident rates and develop techniques to reduce this
3. Look at how patient safety culture effects incident rates in radiotherapy
4. Benchmark staffing levels in radiotherapy

3 Study Design

3.1 General Design

Part 1
For part one of the study an initial questionnaire shall be sent to the management of the radiotherapy and will include general information on the throughput and technical details of the department. This survey is designed to examine a number of different parameters from the radiotherapy department including the utilization of equipment, techniques used, patient throughput and staffing levels. A copy of this survey can be seen in appendix two. This survey will be circulated in electronic form and the details will be analyzed to benchmark the radiotherapy process as outlined in appendix one.

A follow up interview will be required to ensure details correct. The questions asked in this will be based on the information obtained from the technical and throughput form.

Part 2
Patient Safety survey. This survey has been taken from the Agency for Healthcare and Research Quality. This survey has been well established as a method for assessing Patient Safety Culture in a clinical setting. The survey will be distributed to all staff members and participation in the survey will be voluntary. A copy of this survey can be seen in Appendix three.

Part 3
Incident Analysis. For this part of the study a review of all incidents (including near-misses and non-conformities) will be reviewed by the investigators. The data will be anonymised by someone approved by the department and following the removal of identifying factors the data will be reviewed to examine error rates per task in the radiotherapy process.

3.2 Primary Study Endpoints

The primary endpoints of this study are as follows.
1. Examine incident rates in radiotherapy across a number of departments
2. Use this data to develop a model looking at future incident rates and develop techniques to reduce this
3. Look at how patient safety culture effects incident rates in radiotherapy
4. Benchmark staffing levels in radiotherapy
3.3 **Secondary Study Endpoints**

As a secondary endpoint a review of the technology, techniques and general information on radiotherapy in Ireland will be obtained. This will include types of equipment available to deliver radiotherapy in Ireland and the treatment types available in Ireland.

3.4 **Confidentiality of information**

Any information with patient identifiable factors (patient ID, Date of birth, Name) shall be removed of these factors prior to analysis. Any information will be treated with the highest sensitivity and any publications as a result of the study will be anonymised. Any detail which can either identify the organisation or an individual will be removed. Any information that could be used to identify the hospital will be cleared before publication.

Section 6 will discuss the confidentiality further.

3.5 **Statistics**

Standard Deviation (SD) and p-values will be calculated to assess whether there are differences in workload reported based upon the independent variables.

3.6 **Ethical Considerations**

The only ethical issue is that the responses of the participants and patients could be identified, as well as radiotherapy department locations, despite strict confidentiality of participant’s names, radiotherapy locations, and signed consent forms. This is because there are only a limited number of radiotherapy departments in Ireland, as well as only a limited number of people employed, and someone working for HSE could possibly make such connections. However, for an external person without any connection to HSE, such connections would be almost impossible. As mentioned in this application, the investigators of this project will keep all data collection, data analysis, and results obtained from the data collected as strictly confidential.

4 **Subject Selection and Withdrawal**

All staff working in radiotherapy are applicable for inclusion of part 2 of the study. Prior to the filling out the survey the following message shall appear for acknowledgement.

“I have read the information provided above. I have been given the opportunity to ask questions and have had enough time to consider the information. I understand my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected.”

Should any staff member wish not to complete the survey they can do so at any time.

5 **Study Procedures**

For the purposes of this section of the study the procedure has been broken down into three main sections as discussed in Section 3.

5.1 **Part 1**

This section of the study involves a survey to be circulated to the management in the department. This part of the project needs to be completed before the commencement of Part 2 and Part 3 of the project. Upon approval of the project this survey will be immediately sent to the department. Upon completion of the survey an interview with a designated member of the department will be arranged to clarify details from the survey and gather information such as department lay out that cannot be obtained primarily from the survey.
Following completion of this section of the study Part 2 and Part 3 can commence in parallel.

5.2 Part 2
This section of the study involves the distribution of the AHRQ Patient Safety Culture Survey. This survey will be electronically circulated to all members of staff working in the radiotherapy department. This will be analysed using the tools developed by the AHRQ. There have been a number of publications on the use of this survey to assess patient safety culture in the hospital environment. Two additional questions have been added to the survey to facilitate the completion of part 3.

5.3 Part 3
Incident Analysis (including near-misses and non-conformities). For this part of the study a review of all Incidents, Near-misses and non-conformities over the last four years are to be reviewed. To perform this all data involving these will need to be accessed. Any patient data and staff data will be removed as this is not required for the analysis. This information will be stored in a locked cabinet when not in use. The department where the data has been gathered will be coded.

6 Data Handling and Record Keeping

6.1 Confidentiality
Hospital Data
All hospital data obtained in Part 1 of the study will be treated with the highest of sensitivity. Any publications will not include hospital names. Any factors in the publications that include information that may be used to identify a hospital will be cleared with a designated representative in the department before publication. The department information will not be stored with information associating it with a site.

Patient Safety Culture Information
All information for the patient safety culture will be stored in an excel spreadsheet. This will not be stored with information that can associate the information with the site. Staff names will not be recorded.

Incident Data
Any patient information, staff information or physician information will not be recorded. This information will be treated with sensitivity. The data will be anonymised by an appropriate person that is acceptable to the department involved.

As this project involves a lot of department sensitive information the researchers are fully available to discuss any concerns with the storage of data.

All data will be stored for the minimum of 5 years.

6.2 Audits and Inspections
Individual responses will not be available for inspection, however overall data will be fully available for inspection.

7 Publications
Any publications will be cleared prior to publication and the contribution of the hospital will be acknowledged. This study is part of a Ph.D.

8 References
Appendix B

Ethics Forms

This section shows the ethics form sent to departments that required ethics approval. There were changes made based on local requirement but the content remained the same.
STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: Radiation Oncology System Safety Analysis Data Collection

Principal Investigator: Prof. Wil van der Putten

Applicant’s Signature:

For Official Use Only – Date Stamp of Receipt by REC:
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>SECTION</th>
<th>CONTENT</th>
<th>MANDATORY / OPTIONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>GENERAL INFORMATION</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>B</td>
<td>STUDY DESCRIPTORS</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>C</td>
<td>STUDY PARTICIPANTS</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>D</td>
<td>RESEARCH PROCEDURES</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>E</td>
<td>DATA PROTECTION</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>F</td>
<td>HUMAN BIOLOGICAL MATERIAL</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>G</td>
<td>RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>H</td>
<td>MEDICAL DEVICES</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>I</td>
<td>MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>J</td>
<td>INDEMNITY</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>K</td>
<td>COST AND RESOURCE IMPLICATIONS AND FUNDING</td>
<td>MANDATORY</td>
</tr>
<tr>
<td>L</td>
<td>ETHICAL ISSUES</td>
<td>MANDATORY</td>
</tr>
</tbody>
</table>

This Application Form is divided into Sections.

Sections A, B, C, D, E, J, K, L are Mandatory.

Sections F, G, H, and I are optional. Please delete Sections F, G, H, and I if these sections do not apply to the application being submitted for review.

**IMPORTANT NOTE:** Please refer to Section I within the form before any attempt to complete the Standard Application Form. Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.
SECTION A GENERAL INFORMATION

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

A1 Title of the Research Study:
Data collection for the Radiation Oncology Systems Safety Analysis (ROSSA) project

A2 Principal Investigator(s):
Title: Prof Name: Wil van der Putten
Qualifications: PhD, MSc
Position: Chief Physicist Galway University Hospitals; Adj. Professor of Physics
Dept: Department of Medical Physics, Galway University Hospitals; Adj. Professor of Physics, School of Physics, National University of Ireland, Galway
Organisation: UHG
Address: University Hospital Galway, Newcastle Rd., Galway
Tel: [091 544311]
E-mail: wil.vanderputten@hse.ie

A3 (a) Is this a multi-site study? Yes

A3 (b) Please name each site where this study is proposed to take place and state the lead investigator for each site:

<table>
<thead>
<tr>
<th>Site:</th>
<th>Lead Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RADIOTherapy DEPARTMENT, UNIVERSITY HOSPITALs GALWAY, GALWAY</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, SAINT LUKES RADIATION ONCOLOGY CENTRE (INCLUDING BEAUMONT, ST. LUKES AND ST. JAMES SITES)</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, UNIVERSITY HOSPITAL CORK, CORK</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, UPMC (DUBLIN AND WATERFORD)</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, MATER PRIVATE HOSPITAL (DUBLIN AND LIMERICK)</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, HERMITAGE CLINIC, DUBLIN</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
<tr>
<td>RADIOTherapy DEPARTMENT, ST. VINCENTS PRIVATE HOSPITAL</td>
<td>WIL VAN DER PUTTEN</td>
</tr>
</tbody>
</table>
A3 (c) For any of the sites listed above, have you got an outcome from the research ethics committee (where applicable)? Yes, Galway University Hospital has given the ethics approval for this project. Information has been removed from this application for parts of the study that are not applicable for this site.

A4. Co-Investigators:

Name of site: NUIG, Centre for Occupational Health & Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Qualifications</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr.</td>
<td>Enda Fallon</td>
<td>BEng, MEngSc</td>
<td>Senior lecturer @ College of Engineering and Informatics, NUIG</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Centre for Occupational Health &amp; Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics, NUIG</td>
</tr>
</tbody>
</table>

Address: Centre for Occupational Health & Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics, National University of Ireland, Galway, University Rd., Galway

Role in Research: Data analysis

Name of site: NUIG, School of Physics

Title: Mr.  Name: Gordon Sands  Qualifications: M.Sc., B.Sc.(Hons)

Position: Ph.D. Researcher  Organisation: School of Physics, NUI Galway

Address: School of Physics, NUI Galway, National University of Ireland, Galway, University Rd., Galway

Role in Research: Data analysis and collection

Name of site: NUIG, Centre for Occupational Health & Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics

Title: Mr.  Name: Matjaz Galicic  Qualifications: MTech, B.Sc.

Position: Ph.D. Researcher  Organisation: Centre for Occupational Health & Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics, NUIG

Address: Centre for Occupational Health & Safety Engineering and Ergonomics (COHSEE), College of Engineering and Informatics, National University of Ireland, Galway, University Rd., Galway

Role in Research: Data analysis and collection
A5. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Title: Prof. Name: Wil van der Putten
Address: Department of Medical Physics & Bioengineering, University Hospital Galway, Newcastle Road, Galway
Tel (work): 091 544311 Tel (mobile): 087 2756540
E-mail: wil.vanderputten@hse.ie

A6. Please provide a lay description of the study.
The purpose of the study is to perform a systems safety analysis of socio-technical systems in the Radiotherapy department analyzing human performance ("socio" part) and errors/incidents ("technical" part) using Human Factors Engineering and Human Reliability methods. The purpose of the analysis is to develop a set of workable systems safety tools that would improve overall safety of the Radiotherapy processes and procedures.

A7 (a) Is this study being undertaken as part of an academic qualification? Yes

A7 (b) If yes, please complete the following:
Student Name: Gordon Sands; Matjaz Galicic
Course: Gordon Sands: Ph.D. in Medical Physics; Matjaz Galicic: Structured Ph.D. in Industrial Engineering
Institution: NUIG, School of Physics and College of Engineering and Informatics
Academic Supervisors: Prof. Wil van der Putten and Mr. Enda Fallon

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. Provide information on the study background.

Background to the research is the Radiation Oncology Systems Safety Analysis (ROSSA) project funded by the Health Research Board of Ireland. The ROSSA objectives include, but are not limited to, the development of a set of workable tools for use within a Radiotherapy department which will allow the users of the department to analyse risks and hazards in a systematic manner, taking into account the actual patient and data flow.

Further objective is to provide a comprehensive risk analysis of the existing and future advanced radiotherapy technologies in place, and to support the development of strategies for error reduction in such systems, with the emphasis on the interaction between the technology and treatment staff. The overall benefit of ROSSA project will be a Risk assessment system that will be based on standards formed in Healthcare and its related industries, such as Nuclear, Aviation, etc.
Benchmarking the radiotherapy process is performed during this study. There are a number of different guides over correct staffing levels, safe implementation of advanced techniques and correct management of medical computer programs are subject to interpretation. Benchmarking this information and looking at how the different parameters affect risk in a department can be used to look at ideal organisational structures. This information will be obtained using a questionnaire. The questionnaire exams the following information:
- Treatments, techniques and patient through;
- Number of staff, seniority of staff, communication of staff;
- The “Safety Culture” in the department;
- Standard Operating Procedures;
- IT systems and protection.

Besides that, a list of incidents that occurred will be made and the data analysed. This data will be analysed facilitated by a taxonomy developed specifically for incident analysis in radiotherapy and Root Cause Analysis (RCA). This data will be incorporated into an error propagation model. This model will be used to look at how different processes can be used to reduce risk. The RCA will be performed examining the incident forms recorded at the time of the incident. The depth of the RCA will be dependant on the amount of information recorded at the time of the incident.

Since this is a pilot study in this area, there is a need to expand such a research to other Radiotherapy sites across Ireland. The project will create a base for expansion of such research.

B2. List the study aims and objectives.
- To perform a systems safety analysis by using scientific tools and methods; in particular to study the workload, Human-Technology Interaction, Human performance, and to collect and analyze data on incidents that have occurred during the radiotherapy treatment process.
- The aim of the research is to develop a set of workable tools that would reduce work-related errors and improve patient treatment process by using a direct and practical approach, with collecting data from the actual sites.
- Do a retrospective analysis of incidents to quantify how different process and quality management protocols can affect the risk of mistreatment.

B3. List the study endpoints (if applicable).
Gather data to incorporate into the ROSSA model. Produce the model for radiotherapy safety analysis.

B4. Provide information on the study design.
The study will utilize Human-Technology Interaction questionnaire to obtain information on workload, human performance / human reliability analysis, as well as data collection on errors/accidents using Root Cause Analysis and a taxonomy specifically designed for this study that incorporates the various aspects for thorough incident analysis.
B5. Provide information on the study methodology.
For detailed description of the techniques mentioned please refer to the Appendix.

B6. What is the anticipated start date of this study?
March 2013, Already in progress in other sites.

B7. What is the anticipated duration of this study?
The duration of the ROSSA project. Expected time of full data collection analysis June 2014.

B8 (a) How many research participants are to be recruited in total?
For the incident analysis all the incidents that are recorded to date will be examined.
For the remaining data collection, it is expected that 50-70 of staff members will take part in the data collection, with the response rate of 30%.

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.
Standard Deviation (SD) and p-values will be calculated to assess whether there are differences in workload reported based upon the independent variables.

B8 (c) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).
For Incident analysis total number of incidents available are going to be used to try and obtain absolute value. For remaining data all staff members involved will be asked but the response rate is going to determine usefulness of data. For the risk culture survey a minimum of 5 participants is required as defined by the organization that created the survey.

B8 (d) Where sample size calculation is impossible (e.g. It is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.
Standardisation based on an appropriate number of staff in radiotherapy departments. The goal is to obtain a response rate from 50-70 staff members, with the response rate of 30%.
As for the incident analysis, all reported incidents data will be examined to look at the incident per patient rate. The analysis will also look at the rates of human error and technical errors in the radiotherapy departments, and how different organizational factors can affect these.

B8 (e) Where sample size calculation is impossible (e.g. It is a pilot study and no previous studies can be used to provide the required estimates) then please explain why the sample size to be used has been chosen.
IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 How many research participants are to be recruited? At each site (if applicable)? And in each arm of the study (if applicable)?
As treatment groups are not being studied not applicable.

C1.2 How will the participants in the study be selected?
They are currently working in the Radiotherapy department.

C1.3 How will the participants in the study be recruited?
On voluntary basis and to prior agreement and arrangement with the Radiotherapy department management.

C1.4 What are the main inclusion criteria for research participants? (please justify)
The research participants must be employed or working for the Radiotherapy department.

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project?
Not to my knowledge.

SECTION C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes.

C2.1 (c) If yes, how will informed consent be obtained and by whom?
Yes. As all research will be performed anonymously, the informed consent form will be presented beforehand; participants will be asked to mark a box indicating that they have read, and understand the consent form before they can start responding to the questionnaire items. Incident analysis evaluation will be obtained with the consent of the radiotherapy department involved. This information will be stripped of all patient and staff member data. All the data will remain confidential, and no personal names, hospital sites, or names of departments will be disclosed.

C2.1 (d) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?
Yes. The following statement is included on the consent form: “I have read the information provided above. I have been given the opportunity to ask questions and have had
enough time to consider the information. I understand that my participation is voluntary and
that I am free to withdraw at any time, without giving any reason, and without my legal rights
being affected”

C2.1 (f) Will there be a time interval between giving information and seeking
consent?  No.

C2.1 (h) If no, please justify.
Participants will be able to decide on the spot if they are willing to participate in the
research or not. This will be also at the discretion of the management of the department
itself.

SECTION C3  ADULT PARTICIPANTS - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give
informed consent?  Yes.

C3.1 (d) What arrangements are in place for research participants
who may regain their capacity?
They may withdraw from their questionnaire.

SECTION C4  PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children?
No.

SECTION C5  PARTICIPANTS - CHECKLIST

Please confirm if any of the following groups will participate in this study. This is a
quick checklist for research ethics committee members and it is recognised that not all
groups in this listing will automatically be vulnerable or lacking in capacity.

C5.1 Patients  No
C5.2 Unconscious patients  No
C5.3 Current psychiatric in-patients  No
C5.4 Patients in an emergency medical setting  No
C5.5 Relatives / Carers of patients  No
C5.6 Healthy Volunteers  No
C5.7 Students  No
C5.8 Employees / staff members  Yes
C5.9 Prisoners  No
C5.10 Residents of nursing homes  No
C5.11 Pregnant women  No
C5.12 Women of child bearing potential  No
C5.13 Breastfeeding mothers [No]
C5.14 Persons with an acquired brain injury [No]
C5.15 Intellectually impaired persons [No]
C5.16 Elderly / aged persons > 65 [No]

C5.17 If yes to any of the above, what special arrangements have been made to deal with issues of consent and assent (if any)?
See question C2.1. The information will be anonymous.

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

D1. What research procedures or interventions (over and above those clinically indicated and/or over and above those which are part of routine care) will research participants undergo whilst participating in this study?
They will participate in an anonymous study questionnaires, interviews may also be required but only at consent of the subject (HSE staff member) involved.

D2. If there are any potential harms resulting from any of the above listed procedures, provide details below:
[No]

D3. What is the potential benefit that may occur as a result of this study?
The potential benefits are: a set of workable tools for the Radiotherapy staff could use; a step closer to improving Radiotherapy treatment process by merging Human Factors Engineering tools with Medical Physics knowledge.
The incident analysis technique will provide a greater understanding of why each incident occurred and may provide information that had been overlooked during the initial investigation. (It should be noted that this not designed to assign blame).

D4 (a) Will the study involve the withholding of treatment?
[No]

D5. How will the health of participants be monitored during and after the study?
[N/A]

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?
[No]

D7. Please comment on how individual results will be managed.
D8. Please comment on how aggregated study results will be made available. Aggregate results will be presented in PhD Theses of the two PhD candidates mentioned above, and possibly as conference papers, and/or as a peer-reviewed journal articles.

D9. Will the research participant's general practitioner be informed the research participant is taking part in the study (if appropriate)? Non-applicable

D10. Will the research participant's hospital consultant be informed the research participant is taking part in the study (if appropriate)? Non-applicable

SECTION E  DATA PROTECTION

SECTION E IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

SECTION E1  DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes, from the department involved

SECTION E2  DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected? The investigators.

E2.2 What media of data will be collected? Data from paper questionnaires will be entered into an electronic database.

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data? Some data will be irrevocably anonymised (patient names and other patient identifying factors), some will be pseudonymised and some coded.

E2.3 (b) If ‘coded’, please confirm who will retain the ‘key’ to re-identify the data? The investigators.

E2.4 Where will data which is collected be stored? Software data will be stored on two password protected NUIG computers. Hard copies will be stored in a locked cabinet at the relevant University departments.
E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.
Password protected computers and lock cabinets.

E2.6 (a) Will data collected be at any stage leaving the site of origin?  Yes

E2.6 (b) If yes, please elaborate.
It will be transferred to NUIG computers for the analysis. Parts of the data may be published however any published data will be stripped of any details.

E2.7 Where will data analysis take place and who will perform data analysis (if known)?
The data will be analysed by NUIG Investigators mentioned above.

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?
Retained until final Ph.D. submitted.

E2.8 (b) Please elaborate.
If successful, this data will be used to track levels of workload longitudinally and measure the effectiveness of any technical/technological interventions designed to change workload of Radiotherapy staff.

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?
NA

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?
If successful, this may become a repository for a longitudinal study of Human performance and Error/Incident analysis on Radiotherapy Staff. Therefore, the data will be retained as a baseline measure of Human performance and Error/Incident analysis to allow the effectiveness of any technical changes to be assessed.

E2.9 Please comment on the confidentiality of collected data.
The data is anonymous.

E2.10 (a) Will any of the data collected consist of audio recordings / video recordings?  No.

E2.11 (a) Will any of the data collected consist of photographs / video recordings?  No.

SECTION E3  ACCESS TO HEALTH CARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?  Yes.

E3.1 (b) If yes, please elaborate.
Any patient incident forms will include details of the patient. Any patient identifying factors will be removed before analysis.

E3.1 (c) Who will access these healthcare records?
The records will be accessed by someone approved by the individual departments in accordance with the own policy.

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? No.

E3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?
HSE and individual private hospitals.

E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?
Any data leaving the original site of origin will be anonymous. The files will also be encrypted to prevent any unauthorized access.

SECTION F  HUMAN BIOLOGICAL MATERIAL

Section F is optional. Please delete if this section does not apply.

F1  BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? No.

SECTION G  RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION

Section G is optional. Please delete if this section does not apply.

G1  RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION - GENERAL

G1.1 (a) Does this study/trial involve exposure to radioactive materials, or does this study/trial involve other diagnostic or therapeutic ionising radiation? No.

SECTION H  MEDICAL DEVICES

13 | Page
Section H is optional. Please delete if this section does not apply.

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? No direct studies/trials to investigate/evaluate medical devices will be performed. However, because the research focuses on systems safety of radiotherapy treatment process and the interactions between the radiotherapy staff and machines they are using, medical devices and other automated equipment will be part of the research by default (e.g., linear accelerator, the afterloader, personal computers, etc.)

SECTION I  MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

Section I is optional. Please delete if this section does not apply.

SECTION I.1  NON-INTEVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I 1.1 (a) Does this study involve a medicinal product? No.

SECTION J  INDEMNITY

SECTION J IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

J1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? No

J1 (b) If the answer is ‘no’ for any site, what other arrangements are in place in terms of indemnity / insurance? Not necessary as no patient contact

J2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? “Yes” for Principal Investigator; “No” for co-investigators.

J2 (b) If no, do members of the investigative team not covered by the Clinical Indemnity Scheme (CIS) have either current individual medical malpractice insurance (applies to medical practitioners) or current professional liability
insurance either individually or as provided by their hosting/employing institution (generally applies to allied healthcare professionals, university employees, scientists engineers etc.)? The co-investigators are covered by the NUIG University Scheme.

J3 (a) Who or what legal entity is the **sponsor** of this research study? Health Research Board.

J3 (b) What additional indemnity arrangements has the sponsor put in place for this research study in case of harm being caused to a research participant (if any)? NUIG.

**SECTION K  COST AND RESOURCE IMPLICATIONS AND FUNDING**

**SECTION K IS MANDATORY**

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

**K1 (a) Are there any cost / resource implications related to this study?** **Yes.**

K1 (b) If yes, please elaborate.
Funding is available for the researchers to travel to different sites and to collect data.

K2 (a) Is funding in place to conduct this study? **Yes.**

K2 (c) Please state the source of funding (industry, grant or other) and the amount of funding.
Health Research Board, ROSSA project, Research number RHR 916. Amount of funding: €188,475.00

K2 (d) Is the study being funded by an external agency? **Yes. Health Research Board**

K2 (e) Is the external agency a ‘for profit’ organisation? **No.**

K2 (f) Do any conflicts of interest exist in relation to funding? Please elaborate.
**No.**

K2 (g) Please provide additional details in relation to management of funds.
**N/A**

K3. Please provide details of any payments (monetary or otherwise) to investigators.
**N/A**

K4. Please provide details of any payments (monetary or otherwise) to participants.
**N/A**
L1. Please identify any particular additional ethical issues which this project raises and discuss how you have addressed these issues. The only ethical issue is that the responses of the participants and patients could be identified, as well as radiotherapy department locations, despite strict confidentiality of participant’s names, radiotherapy locations, and signed consent forms. This is because there are only a limited number of radiotherapy departments in Ireland, as well as only a limited number of people employed, and someone working for HSE could possibly make such connections. However, for an external person without any connection to HSE, such connections would be almost impossible.

Please ensure this application form is fully completed as incomplete submissions will not be received.
B. ETHICS FORMS
Appendix C

Patient Safety Culture Survey

This section shows the survey used for this study. There were some minor changes based on its implementation. For example some of the departments were given the survey in an online format. Other departments already had implemented the survey. All the questions remained the same.
Hospital Survey on Patient Safety

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank.

- An “event” is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.
- “Patient safety” is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.

I have read the information provided above. I have been given the opportunity to ask questions and have had enough time to consider the information. I understand my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my legal rights being affected.

I understand above and agree ☐

SECTION A: Your Work Area/Unit

In this survey, think of your “unit” as the work area, department, or clinical area of the hospital where you spend most of your work time or provide most of your clinical services.

Please indicate your agreement or disagreement with the following statements about your work area/unit.

Think about your hospital work area/unit…

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. People support one another in this unit</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. We have enough staff to handle the workload</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. When a lot of work needs to be done quickly, we work together as a team to get the work done</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. In this unit, people treat each other with respect</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Staff in this unit work longer hours than is best for patient care</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION A: Your Work Area/Unit (continued)

Think about your hospital work area/unit…

6. We are actively doing things to improve patient safety ……………………

7. We use more agency/temporary staff than is best for patient care …………

8. Staff feel like their mistakes are held against them ………………………

9. Mistakes have led to positive changes here ………………………………

10. It is just by chance that more serious mistakes don’t happen around here ………………………………………………………………………

11. When one area in this unit gets really busy, others help out …………..

12. When an event is reported, it feels like the person is being written up, not the problem ……………………………………………………………

13. After we make changes to improve patient safety, we evaluate their effectiveness ……………………………………………………………

14. We work in “crisis mode” trying to do too much, too quickly …………..

15. Patient safety is never sacrificed to get more work done ………………..

16. Staff worry that mistakes they make are kept in their personnel file ……

17. We have patient safety problems in this unit ……………………………

18. Our procedures and systems are good at preventing errors from happening ………………………………………………………………………

SECTION B: Your Supervisor/Manager

Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report.

1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures …………………

2. My supervisor/manager seriously considers staff suggestions for improving patient safety ………………………………………………………

3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts ……………………………

4. My supervisor/manager overlooks patient safety problems that happen over and over ……………………………………………………………
**SECTION C: Communications**

How often do the following things happen in your work area/unit?

Think about your hospital work area/unit…

<table>
<thead>
<tr>
<th></th>
<th>Never ▼</th>
<th>Rarely ▼</th>
<th>Sometimes ▼</th>
<th>Most of the time ▼</th>
<th>Always ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>2.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>3.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>4.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>5.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>6.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

**SECTION D: Frequency of Events Reported**

In your hospital work area/unit, when the following mistakes happen, how often are they reported?

*For the purposes of this section.*

1-Never <20%
2-Rarely 20-39%
3-Sometimes 40-59%
4-Most of the time 60-79%
5-Always >80%

<table>
<thead>
<tr>
<th></th>
<th>Never ▼</th>
<th>Rarely ▼</th>
<th>Sometimes ▼</th>
<th>Most of the time ▼</th>
<th>Always ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>2.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>3.</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

**SECTION E: Patient Safety Grade**

Please give your work area/unit in this hospital an overall grade on patient safety.

- □ A Excellent
- □ B Very Good
- □ C Acceptable
- □ D Poor
- □ E Failing
SECTION F: Your Hospital
Please indicate your agreement or disagreement with the following statements about your hospital.

Think about your hospital...
1. Hospital management provides a work climate that promotes patient safety

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

2. Hospital units do not coordinate well with each other

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

3. Things “fall between the cracks” when transferring patients from one unit to another

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

4. There is good cooperation among hospital units that need to work together

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

SECTION F: Your Hospital (continued)

Think about your hospital...
5. Important patient care information is often lost during shift changes

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

6. It is often unpleasant to work with staff from other hospital units

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

7. Problems often occur in the exchange of information across hospital units

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

8. The actions of hospital management show that patient safety is a top priority

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

9. Hospital management seems interested in patient safety only after an adverse event happens

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

10. Hospital units work well together to provide the best care for patients

    | Strongly Disagree | Disagree | Neither | Agree | Strongly Agree |
    |-------------------|----------|---------|-------|---------------|
    | 1                 | 2        | 3       | 4     | 5             |

11. Shift changes are problematic for patients in this hospital

    | Strongly Disagree | Disagree | Neither | Agree | Strongly Agree |
    |-------------------|----------|---------|-------|---------------|
    | 1                 | 2        | 3       | 4     | 5             |

SECTION G: Number of Events Reported
In the past 12 months, how many event reports have you filled out and submitted?

- □ a. No event reports
- □ b. 1 to 2 event reports
- □ c. 3 to 5 event reports
- □ d. 6 to 10 event reports
- □ e. 11 to 20 event reports
- □ f. 21 event reports or more

SECTION H: Background Information
This information will help in the analysis of the survey results.

1. How long have you worked in this hospital?

   - □ a. Less than 1 year
   - □ b. 1 to 5 years
   - □ c. 6 to 10 years
   - □ d. 11 to 15 years
   - □ e. 16 to 20 years
   - □ f. 21 years or more
2. How long have you worked in your current hospital work area/unit?
   - a. Less than 1 year
   - b. 1 to 5 years
   - c. 6 to 10 years
   - d. 11 to 15 years
   - e. 16 to 20 years
   - f. 21 years or more

3. Typically, how many hours per week do you work in this hospital?
   - a. Less than 20 hours per week
   - b. 20 to 39 hours per week
   - c. 40 to 59 hours per week
   - d. 60 to 79 hours per week
   - e. 80 to 99 hours per week
   - f. 100 hours per week or more

SECTION H: Background Information (continued)

4. What is your staff position in this hospital? Select ONE answer that best describes your staff position.
   - a. Nurse
   - b. Radiation Therapist
   - c. Radiographer
   - d. Medical Physicist
   - e. Doctor (Non Consultant)
   - f. Consultant
   - g. Administration

5. In your staff position, do you typically have direct interaction or contact with patients?
   - a. YES, I typically have direct interaction or contact with patients.
   - b. NO, I typically do NOT have direct interaction or contact with patients.

6. How long have you worked in your current specialty or profession?
   - a. Less than 1 year
   - b. 1 to 5 years
   - c. 6 to 10 years
   - d. 11 to 15 years
   - e. 16 to 20 years
   - f. 21 years or more

SECTION I: Your Comments
Please feel free to write any comments about patient safety, error, or event reporting in your hospital.

THANK YOU FOR COMPLETING THIS SURVEY.
Appendix D

Patient Safety Culture Survey Leaflet

This appendix shows the leaflet that was distributed to the staff alongside the patient safety culture survey where possible.
Patient Safety Culture is defined as:

The culture of patient safety of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization’s health and safety management.

Organisations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

The patient safety culture survey was taken from the Agency for Healthcare Research and Quality.

If you wish to know more about the patient safety culture survey and its use in healthcare more information can be found on the following website.

http://www.ahrq.gov/legacy/qual/patientsafetyculture/

If you wish to contact the researchers in regard to the survey you can contact the following person:

Gordon Sands
gordon.sands@hse.ie

NUI Galway
OÉ Gaillimh

Radiation Oncology System Safety Analysis Project
A description of the patient safety culture survey and its use in the project
Details of Survey

The survey consists of a number of dimensions that are used to assess the culture of patient safety in a department. They are as follows:

- Teamwork Within Units
- Supervisor/Manager Expectations and Actions Promoting Patient Safety
- Management Support for Patient Safety
- Organizational Learning; Continuous Improvement
- Overall Perceptions of Patient Safety
- Feedback and Communication About Errors
- Communication Openness
- Frequency of Events Reported
- Teamwork Across Units

- Staffing
- Handoffs and Transitions
- Response to Error

In order to get an accurate assessment of all these dimensions it is recommended that as many members of staff as possible fill out the survey.

The submission of this survey by staff members will be done anonymously. Individuals will not be recognized.

While it is recommended that all staff members, or as many as possible, fill out the survey any staff member that does not wish to fill out the survey may withdraw at any time until the point of submission.
Appendix E

Identified Tasks and Analysis for Prostate Treatment
<table>
<thead>
<tr>
<th>Sub-Task ID</th>
<th>Task Level</th>
<th>Task ID</th>
<th>Task Name</th>
<th>Task Description</th>
<th>Task Error</th>
<th>Impact on Task</th>
<th>Task Error</th>
<th>Impact on Task</th>
<th>Task Error</th>
<th>Impact on Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.12.1</td>
<td>1.12</td>
<td>Patient Assessment</td>
<td>Patient Assessment</td>
<td>Examine patient</td>
<td>Yes</td>
<td>Action Task</td>
<td>Time available is the time required</td>
<td>High</td>
<td>Nominal</td>
<td>High</td>
</tr>
<tr>
<td>1.12.2</td>
<td>1.12</td>
<td>Patient Assessment</td>
<td>Patient Assessment</td>
<td>Inappropriate position</td>
<td>Yes</td>
<td>Diagnosis Task</td>
<td>Time available is the time required</td>
<td>High</td>
<td>Nominal</td>
<td>High</td>
</tr>
<tr>
<td>1.12.3</td>
<td>1.12</td>
<td>Patient Assessment</td>
<td>Patient Assessment</td>
<td>Inappropriate treatment</td>
<td>Yes</td>
<td>Action Task</td>
<td>Time available is the time required</td>
<td>High</td>
<td>Nominal</td>
<td>High</td>
</tr>
<tr>
<td>1.12.4</td>
<td>1.12</td>
<td>Patient Assessment</td>
<td>Patient Assessment</td>
<td>Inappropriate position</td>
<td>Yes</td>
<td>Diagnosis Task</td>
<td>Time available is the time required</td>
<td>High</td>
<td>Nominal</td>
<td>High</td>
</tr>
<tr>
<td>2.4.2</td>
<td>2.4.2</td>
<td>Radiation Therapist</td>
<td>Radiation Therapist</td>
<td>Examine patient</td>
<td>Yes</td>
<td>Diagnosis Task</td>
<td>Time available is the time required</td>
<td>High</td>
<td>Nominal</td>
<td>High</td>
</tr>
<tr>
<td>Macro Task ID</td>
<td>Error Mode ID</td>
<td>Macro Task Staff Involved</td>
<td>Task</td>
<td>Error Description</td>
<td>Potential Error Classification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>---------------</td>
<td>---------------------------</td>
<td>------</td>
<td>------------------</td>
<td>------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.3</td>
<td></td>
<td>Radiation Therapist</td>
<td>Check Patient Details</td>
<td>Setup</td>
<td>Safety Barrier</td>
<td>High</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.4</td>
<td></td>
<td>Radiation Therapist</td>
<td>ClarityScan for IGRT</td>
<td>Action</td>
<td>Task Error</td>
<td>Nominal High</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.5</td>
<td></td>
<td>Radiation Therapist</td>
<td>Check Registration</td>
<td>Action</td>
<td>Task Error</td>
<td>Nominal High</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.6</td>
<td></td>
<td>Radiation Therapist</td>
<td>Macro Task ID</td>
<td>Error Mode ID</td>
<td>Macro Task Staff Involved</td>
<td>Task</td>
<td>Error Description</td>
<td>Potential Error Classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2.1</td>
<td></td>
<td>Radiation Therapist</td>
<td>Draw Target</td>
<td>Volume</td>
<td>No</td>
<td>Insufficient Information</td>
<td>Nominal Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2.2</td>
<td></td>
<td>Radiation Therapist</td>
<td>No</td>
<td>Action</td>
<td>Task Error</td>
<td>Nominal Low</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2.3</td>
<td></td>
<td>Radiation Therapist</td>
<td>Draw OARs</td>
<td>Volume</td>
<td>No</td>
<td>Insufficient Information</td>
<td>Nominal Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2.4</td>
<td></td>
<td>Radiation Therapist</td>
<td>Delineation of Rectum</td>
<td>Draw OARs</td>
<td>Delineation of Sigmoid</td>
<td>Draw OARs</td>
<td>Delineation of Bladder</td>
<td>Draw OARs</td>
<td>Delineation of Left Femoral Head</td>
<td>Draw OARs</td>
</tr>
</tbody>
</table>

**Notes:**
- Task: Action
- Error Description: Setup, Action
- Potential Error Classification: High, Moderate, Low
- Insufficient Information: Yes, No
## E. IDENTIFIED TASKS AND ANALYSIS FOR PROSTATE TREATMENT

<table>
<thead>
<tr>
<th>Task ID</th>
<th>Task Name</th>
<th>Task Type</th>
<th>Task Description</th>
<th>Task Complexity</th>
<th>Potential Error Classification</th>
<th>Error Mode</th>
<th>Error Description</th>
<th>Error Probability</th>
<th>Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macro Task ID</td>
<td>Error Description</td>
<td>Error Mode ID</td>
<td>Macro Task</td>
<td>Staff Involved</td>
<td>Task Error Description</td>
<td>Potential Error</td>
<td>Classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------</td>
<td>--------------</td>
<td>------------</td>
<td>---------------</td>
<td>------------------------</td>
<td>-----------------</td>
<td>----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.1</td>
<td>Lantis MU and dose</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.2</td>
<td>Check Prescription</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.3</td>
<td>Check DVH Values (Sigmoid)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.4</td>
<td>Check DVH Values (Bladder)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.5</td>
<td>Check Lantis Beam Parameters</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.6</td>
<td>Check Grid</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.7</td>
<td>Check DVH Values (Rectum)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.8</td>
<td>Check Total Dose</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.9</td>
<td>Check DVH Values (LT Femoral Head)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.10</td>
<td>Check Prescription</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.11</td>
<td>Check DVH Values (Sigmoid)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.12</td>
<td>Check DVH Values (Bladder)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.13</td>
<td>Check Lantis Beam Parameters</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.14</td>
<td>Check Grid</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.15</td>
<td>Check DVH Values (Rectum)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.16</td>
<td>Check Total Dose</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.17</td>
<td>Check DVH Values (LT Femoral Head)</td>
<td>Safety Barrier Yes</td>
<td>Action Task Nominal time</td>
<td>0.5</td>
<td>5.00E-04</td>
<td>0.50839957</td>
<td>1016.29075</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Physicist role:**

- **Medical Physicist**
- **Medical Physicist**
- **Medical Physicist**
4.3

4.7

4.4

Macro
Task ID

264

Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist
Radiation
Therapist

Multiple

Multiple

Multiple

Multiple

Multiple

4.7.3.5

4.7.3.6

4.7.4

4.7.5

Multiple

4.7.3.3

4.7.3.4

Multiple

Multiple

4.7.3.1

4.7.3.2

Multiple

Planning Meeting

RT Pretreatment
Checks

Plan data transfer to
treatment unit

Error Description

Missing OARs

DVHs

Gross Delineation
Errors

Prescription

Check The Parameters
of the Printout

Lantis vs OTP Check

Check Dose Grid

Check Coverage

Check DVH Lt Femoral
Head

Check DVH Rt Femoral
Head

Check DVH Bladder

Check DVH Sigmoid

Check DVH Rectum

Check Prescription

Not Noticed Target

Not Noticed

Not Noticed

Not Noticed LT
Femoral Head
Not Noticed RT
Femoral Head

Not Noticed Bladder

Not Noticed Sigmoid

Not Noticed Rectum

Safety Barrier

Safety Barrier
Yes

Yes

Yes
Yes

Safety Barrier

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

SPAR-H
Suitable

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Forgot

Not Noticed

Safety Barrier

Misinterpretation

Safety Barrier

Safety Barrier

Misinterpretation

Forgot

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Safety Barrier

Inappropriate
Treatment

Potential Error
Classification

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Forgot

Misinterpretation

Accidental Change of Parameters of Plan
Parameters
Changed While
Check Change of
Plan Delta not used
Parameters

Staff Involved Task

4.7.2

4.4.13

4.4.12

4.4.11

4.4.10

4.4.9

4.4.8

4.4.7

4.4.6

4.4.5.5

4.4.4.5

4.4.5.4

4.4.4.4

4.4.5.3

4.4.4.3

4.4.5.2

4.4.4.2

4.4.5.1

4.4.4.1

4.4.3

4.4.2

4.3.4

4.3.3

Error
Macro Task
Mode ID

Diagnosis Task

Diagnosis Task

Diagnosis Task

Diagnosis Task

Diagnosis Task

Diagnosis Task

Diagnosis Task

Diagnosis Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Diagnosis Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Action Task

Type of task

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Nominal time

Available Time

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex
Moderately
complex

Nominal

Nominal

Stress/ Stressors Complexity

Nominal
Nominal

High
High

Nominal

Nominal

High

High

High

High

High

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

High

High

Nominal

Nominal

High
High

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Procedures

High

High

High

High

High

High

High

High

High

High

High

High

High

High

High

High

High

High

Experience/
Training

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Ergonomics/ Fitness for
HMI
duty

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Nominal

Poor

Good

Work processes

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

1

2.5

0.25

Composite PSF

1.00E-02

1.00E-02

1.00E-02

1.00E-02

1.00E-02

1.00E-02

1.00E-02

1.00E-02

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-02

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

1.00E-03

2.50E-03

2.50E-04

HEP

Beta

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.48480158 47.9953569

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.48480158 47.9953569

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50710508 506.597974

0.50325705 200.799565

0.50904904 2035.68712

Alpha

E. IDENTIFIED TASKS AND ANALYSIS FOR PROSTATE
TREATMENT


<table>
<thead>
<tr>
<th>Macro Task ID</th>
<th>Error Mode ID</th>
<th>Error Description</th>
<th>Potential Error Classification</th>
<th>Work processes</th>
<th>Composite RQ</th>
<th>Beta</th>
<th>Alpha</th>
<th>Delta</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1</td>
<td></td>
<td>Calibration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.1.1</td>
<td></td>
<td>Verification of patient data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.1.2</td>
<td></td>
<td>Date of Birth Checked</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.1.3</td>
<td></td>
<td>Fitness for duty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td></td>
<td>Selection of intended course/session</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2.1</td>
<td></td>
<td>Radiation Therapist</td>
<td>Download the course</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3</td>
<td></td>
<td>Selection of treatment accessories and treatment unit parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.1</td>
<td></td>
<td>Radiation Therapist</td>
<td>Check Accessories</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.2</td>
<td></td>
<td>Radiation Therapist</td>
<td>Check Image</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.3</td>
<td></td>
<td>Radiation Therapist</td>
<td>Ensure Bars Aren't in Way</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.4</td>
<td></td>
<td>Radiation Therapist</td>
<td>Correct Scanning Technique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.5</td>
<td></td>
<td>Radiation Therapist</td>
<td>Check Bladder Fullness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.3.6</td>
<td></td>
<td>Radiation Therapist</td>
<td>Wrong Move Made</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.4</td>
<td></td>
<td>Radiation Therapist</td>
<td>2nd RT Checking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.5</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.5.1</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.5.2</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.5.3</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.5.4</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.6</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.7</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.8</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.9</td>
<td></td>
<td>Radiation Therapist</td>
<td>Image-guided verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
E. IDENTIFIED TASKS AND ANALYSIS FOR PROSTATE TREATMENT
Appendix F

Error Mode Pathways for Prostate Treatment

This shows the error mode pathway graphics for the prostate treatment. These graphics demonstrate how potential errors can go through the system, potentially resulting in an incident.
The Minimum Number of Consultants Required at Peer Review Planning Meeting

1.12.1 QCL Not Activated
   1-8

1.12.2 Inappropriate Selection
   1-8

1.12.3 Type Wrong Area
   1-8

1.12.4 Type Wrong Prescription
   1-8

2.1.1 Patient
   1-8

2.1.2.1 Not asked correctly
   1-8

2.1.3.1 Similar Looking Patients
   1-8

2.1.2.2 Forgotten
   1-8

2.1.3.2 Forgotten
   1-8

3.1.3 Not Notice Inappropriate Treatment
   1-8

3.7.2 Not Notice Inappropriate Treatment
   1-8

3.4.4.6 Not Notice Inappropriate Treatment
   1-8

3.13.8 Not Notice Inappropriate Treatment
   1-8

4.7.2 Not Notice Inappropriate Treatment
   1-8

If Not Caught At Imaging (the same events happen for the 2nd patient)

Wrong Patient

Patient Details Checked at Treatment Delivery
1.14 Unsuitable Image Resulting in Rescan
1.15 Not Acted Upon
2.8.5 Accidental Zero the Bed
2.8.1 RT 1 forgets to mark Patient
2.9.2 RT 2 forgets to mark Patient
2.9.3 Marked Incorrectly
2.9.4 Unsuitable Marking
2.9.5 ID Number Wrong
2.10.1 Wrong Scan Protocol Selected
2.10.2 Scan Not Saved
2.10.3 Too Slow Between Scan
2.10.4 Too Much Time Left Needing CT Rescan
2.10.5 Too Slow Between Scan
The Minimum Number of Consultants Required at Peer Review Planning Meeting

- Bladder Not Full Unnoticed 2.10.4
  - Patient

- Bad Scanning Technique 2.10.7
  - Fusion of Scans

- Inaccurate Fusion 3.1.4
  - Incorrectly Drawn 3.2.1
  - Incorrectly Expanded 3.2.3
  - Misinterpret Notes 3.2.4
  - Incorrectly Drawn Rectum 3.3.1.1

- RT Check 3.1.5
  - Physician Check 3.1.6
  - Check Expansion 4.1.34

- Planning Meeting 4.7.3.1
  - Physician Check 3.4.4.1
  - Planning Meeting 4.7.3.1

Consultant Requirements:
- 1^22
- 1^23
- 1-8^24
- 2-8^25
- 1-8^26
- 1-8^27
- 0-4^28
4.3.3 Accidental Change of Parameters
4.3.4 Plan Delta Not Used
4.4.12 Misinterpretation
4.4.13 Forgot Item
5.1.1 Patient
5.1.2.1 Not asked correctly
5.1.2.2 Forgotten
5.1.3.1 Similar Looking Patients
5.1.3.2 Forgotten
5.4 Download the course
5.9.1 Misinterpretation
5.9.2 Forgotten
0-2s
Wrong Move Made

Forget to Move

Check Clarity Scan

- 0-2
- 0-2

5.10.8
5.10.9
5.10.10
5.10.10