

**Identifying Healthcare Errors in Adult Patients Undergoing Interventional Radiology
Procedures - A Systematic Approach**

A thesis submitted to Imperial College London

for the degree of Doctor of Philosophy

Faraidoon Rawf

Department of Surgery & Cancer

Imperial College London

SUPERVISORS

Professor Mohamad Hamady

Department of Surgery & Cancer

Imperial College London

Mr Colin Bicknell

Department of Surgery & Cancer

Imperial College London

Professor Lord Ara Darzi

Department of Surgery & Cancer

Imperial College London

London 2023

Acknowledgments

This PhD research journey has been monumental and life changing experience. I would like to express my deepest gratitude to all those who have supported and guided me throughout this long journey, and I am truly grateful for the invaluable contributions of numerous individuals.

First and foremost, I extend my sincere appreciation to my esteemed supervisors, Professor Mohamad Hamady, and Mr. Colin Bicknell. Their steady support, guidance, and dedication have been instrumental in shaping my research and academic growth. Their mentorship and intuitive advice, especially during difficult times, have provided me with invaluable lessons and the confidence to become an independent researcher in the future.

The IR staff of St Mary's Hospital have been great in showing their assistance and support during the data collection phase of my research. Their cooperation and willingness to lend a helping hand have been greatly appreciated. I am indebted to all of them.

I would like to extend a special thanks to my dear friends and colleagues, Dr Ali-Alsafi, Dr Ahmad Al-Rekabi, Dr Bhavna Pitrola, Dr Symoen Lechareas, Dr Vamisdhar Rachapalli, for their unwavering support and valuable contributions in conducting this research. Their dedication and assistance have been instrumental in enhancing the quality and comprehensiveness of my research.

I would like to deeply acknowledge my beloved mother, Mahbuba, back home in Kurdistan of Iraq. Her prayers, love, and upbringing as an orphan have been a source of inspiration and motivation throughout this journey. I am eternally grateful for her unwavering belief in me and her constant encouragement.

Personally, I want to express my deepest love and gratitude to my lovely and dear wife, Harmeh, for her infinite love, unwavering support, and understanding. She has been my pillar of strength, assuming the roles of both a father and a mother and has been my confidante and inspiration during the most challenging times. I am forever grateful for her presence in my life.

I cannot overlook the enormous contribution of my beloved sister, Shireen. She has been my backbone and my faithful advocate throughout these seven years. Her unwavering support, dedication, and selflessness have been pivotal in helping me overcome obstacles and achieve success. I cannot fathom how I would have completed this study without her unwavering support.

Finally, I want to express my heartfelt gratitude to my sons, Ahmed, Danar, Ara, Aryas, and Bahast. Their endurance, understanding, and unwavering belief in me during these years have been a constant source of motivation. Their presence in my life has given me the strength to persevere through the ups and downs of this journey.

To all those whose names may not be mentioned here but have contributed to my growth and success in one way or another, I extend my sincere appreciation. Each one of you has played a significant role in shaping my academic and personal development.

To conclude, the completion of this PhD thesis would not have been possible without the guidance, support, and encouragement of the aforementioned individuals. I am eternally

grateful for their contributions, and I carry their lessons and support with me as I embark on the next chapter of my academic and professional journey.

Thank you all from the bottommost of my heart.

Statement of Originality

I declare that the research presented in this thesis is my original work and contributions. Those contribution of other researchers and individuals have been appropriately acknowledged.

Copyright Declaration

‘The copyright of this thesis rests with the author. Unless otherwise indicated, its contents are licensed under a Creative Commons Attribution-Non-Commercial 4.0 International Licence (CC BY-NC). Under this licence, you may copy and redistribute the material in any medium or format. You may also create and distribute modified versions of the work. This is on the condition that: you credit the author and do not use it, or any derivative works, for a commercial purpose. When reusing or sharing this work, ensure you make the licence terms clear to others by naming the licence and linking to the licence text. Where a work has been adapted, you should indicate that the work has been changed and describe those changes. Please seek permission from the copyright holder for uses of this work that are not included in this licence or permitted under UK Copyright Law.’

Identifying Healthcare Errors in Adult Patients Undergoing Interventional Radiology Procedures - A Systematic Approach

Abstract

This PhD thesis systematically assesses and addresses the gap in the understanding of the healthcare errors within the Interventional Radiology (IR) pathway. The thesis encompasses several studies including a systematic review, observation studies by field-notes and by using error capture tool, questionnaire studies, and the development and validation of innovative tools such as the FERERI (Failure estimation Record in Radiology Intervention) error-capture tool and the FARADION (FAst RADiology InterventiON) mobile application (app).

A lack of studies on healthcare errors and patient safety in IR is highlighted requiring systematic assessment via validated tools.

Different approaches were taken to assess healthcare errors, such as field-note-based observation to map out and identify errors within the IR pathway. Further evaluation of these errors and pathways was needed via questionnaire studies and validated error-capturing tools.

Mixed models were used in a questionnaire to evaluate the perception of various healthcare professionals regarding the failure modes within the IR pathways.

This work resulted in the triangulation of the FERERI tool which then validated and used to assess the whole IR pathway in elective, urgent and ITU patients. This showed that healthcare errors, especially the non-technical errors are prevalent within the IR pathway. The most common errors are safety awareness, communication, and equipment-related errors.

Evaluating the WHO checklist, themes emerged related to the compliance and correct use. A simple pragmatic intervention through a structured task allocation to the IR consultant showed a significant improvement in the rate of the compliance which impacted positively on the overall rate of the errors.

The need to address the communication inefficiencies within the IR led to the FARADION app development which was recommended by the teams to enhance patient safety.

Overall, this thesis presents valuable awareness into healthcare errors in IR procedures. Multidisciplinary cooperation, effective communication, and the use of technology are necessary for supporting patient safety and reducing errors in the IR.

Contents

Abstract.....	6
1 Chapter One: A background about patient safety	36
1.1 Chapter overview	36
1.2 What is patient safety?	36
1.3 Is the Health System safe as it should be?	36
1.4 Why isn't there a consensus about understanding the adverse events and medical errors in general?.....	37
1.5 Adverse events or negligence.....	37
1.6 Definitions of medical errors based on Outcome.....	38
1.7 Approaches of dealing with errors: Person approach versus system approach.....	39
1.8 The healthcare defence _ Reason's model	40
1.9 Active versus latent failures	41
1.10 The global scale of Adverse Events in hospitalised patients.....	42
1.11 Adverse events in hospitalised patients in the UK	43
1.12 Comparison of the rate of reported adverse events among the studies across the globe. 43	
1.13 Frequency of medical errors in surgery	48
1.14 The World Health Organisation Checklist and its impact on the rate of AEs and Death 48	
1.15 Frequency of medical errors in Endovascular or IR procedures	49
1.16 How to measure safety parameters such as adverse events, medical errors and to analyse failures.....	50

1.1.1	Reporting adverse events and medical errors within institutions	50
1.1.2	Observational methodology to measure the healthcare errors in surgery and the IR.	50
1.1.3	Field-note- based observational methods.....	51
1.1.4	Field-note- based observational methods in surgery.	51
1.1.5	Fieldnote- based observational methods in IR.....	52
1.1.6	Questionnaire studies	52
1.17	Failure Mode and Effect Analysis (FMEA)	54
1.1.7	Health Failure Mode and Effect Analysis (HFMEA)	55
1.18	Conclusion	56
2	Chapter Two: The Healthcare Errors across the Interventional Radiology (IR) Pathway of Care: Where are we? _A Systematic Review	57
2.1	Introduction	57
2.1.1	What are the aims of this systematic review?	58
2.2	Materials and Methods	58
2.2.1	Inclusion criteria:	58
2.2.2	Exclusion criteria:	59
2.2.3	Assessing the risk of biases (Quality assessment) of the included studies:	59
2.2.4	Online Databases and utilising keywords:	62
2.2.5	Search Strategy:	62
2.2.6	The process of study selection:	63
2.2.1	Further search of the literature on 01/09/2021	64

2.3	Results:	66
2.3.1	Studies included in from the first search of the literature on 31/12/2013.....	66
2.3.2	Studies included from the second search of the literature on 01/09/2021.	66
2.3.3	Results from studies included in the systematic review.	67
2.3.4	Number of patients and case demographics.....	67
2.3.5	How were healthcare errors measured?	67
2.3.6	Frequency of healthcare errors in retrieved studies.	71
2.3.7	The landscape of healthcare errors within the retrieved literature.....	72
2.3.8	The severity of healthcare errors.....	73
2.3.9	Types of Intervention used in the selected studies:	73
2.4	Discussion:	74
2.4.1	The main aim of the reviewed articles	74
2.4.2	What is the main highlight of this systematic review?	74
2.4.3	Types of studies which are included in this review.	75
2.4.1	How healthcare were errors measured?	76
2.4.2	Frequency of Healthcare errors?	77
2.4.3	What is the nature of medical errors in IR?	78
2.4.4	IR Pathway of care:.....	78
2.4.5	Heterogeneity in the results of the retrieved studies	78
2.4.1	Was the WHO checklist being executed correctly?.....	79
2.4.2	Correlation between the healthcare errors and clinical outcome (i.e., patient safety)	79

2.4.3	Quantity of studies dealing with healthcare errors in IR versus Surgery	80
2.4.4	Recent retrieved studies looking into checklist process and associated safety issues. 80	
2.4.5	Limitations of the included studies:	82
2.5	The clinical implication of this systematic review:	83
2.6	Conclusion.....	83
3	Chapter Three outlining the current IR pathway of care: An observational study.	84
3.1	Brief Introduction.....	84
3.1.1	A brief historical background on field-note- based observational methods.	84
3.1.2	Field-note-based observational methods in surgery.	84
3.1.3	Fieldnote-based observational methods in IR.....	84
3.1.4	Interventional Radiology: a multi-station pathway.....	85
3.2	Aim of the study:.....	85
3.3	Methods.....	85
3.3.1	Ethical approval	85
3.3.2	The IR- pathway	86
3.3.3	Setting	86
3.3.4	Induction Period.....	86
3.3.5	Data collection and analysis.....	87
3.3.6	Inclusion criteria:	88
3.3.7	Exclusion criteria:	89
3.3.8	Outcome.....	89

3.4	Definition of minor and major healthcare errors.....	89
3.5	Results.....	94
3.5.1	Comparison of the novice and the expert observations	94
3.5.2	Demographics of the study population and the observed IR procedures.....	96
3.5.3	The frequency of the recorded healthcare errors in the IR pathway.....	101
3.5.4	The landscape of healthcare errors across the IR pathway	103
3.5.5	The degree of severity of the healthcare errors.....	103
3.5.6	The degree of interruption caused by the healthcare errors.	108
3.5.7	Correlation of the age of the patients with the mean total number of healthcare errors throughout the IR pathway	108
3.6	Discussion	109
3.7	Conclusions	113
4	Chapter Four : Evaluating the Safety Climate through Perception of Potential Failure Modes in image-guided-intervention pathways such as Interventional Radiology	114
4.1	Chapter outline	114
4.2	Background	114
	Failure Mode and Effect Analysis (FMEA).....	114
	Health Failure Mode and Effect Analysis (HFMEA)	115
4.3	The methodology used in an ordinary HFMEA.....	116
	Rationale of the current study	123
4.4	Aim of the study	124
4.5	Outcome measure.....	124

4.6	Methodology	125
	Setting	125
	Determining the sample size	125
	Mixed methodology used in the current study.....	125
	Methodology used to create the IR safety questionnaire	125
	Modification of the initial questionnaire.....	127
	The method of delivering the questionnaire	131
	The Statistical test used in validation of the questionnaire.	131
4.7	Results	133
	The results of the pilot study used in the power calculation of the study sample.....	133
	Rate of participation.....	133
	Measuring the internal reliability of the scale the individual items under different main domains	135
	The proportion of the participants by role	136
	Location of the participants' place of work.....	137
	The years of experience of the participants	138
	The categories of the Healthcare errors or Failure modes and their ratings	138
	How different team members perceive importance of the main domains of the failure modes throughout the IR pathway of care.	141
	Perception of the importance of the failure modes by the IR nurses and the vascular nurses	161
	Comparison of the severity ratings of the failure modes by the IR nurses and the vascular nurses	163

Comparison of the probability ratings of the failure modes between the IR and the vascular nurses	164
Comparison of the perception of the importance of the failure modes between the IR consultants and the vascular consultants.....	166
Comparison of the perception of the severity of the failure modes between the IR Doctors and the vascular surgery doctors	167
Comparison of the perception of the probability of the failure modes between the IR consultants and the vascular consultants.....	168
4.8 Discussion	169
Introduction.....	169
Internal reliability of the questionnaire.....	170
The perceived importance of the failure modes/healthcare errors by the participants ..	170
The perceived severity of the failure modes/ healthcare errors by the participants.....	170
Comparison of the ratings of various failure modes/ healthcare errors among different roles	173
Limitations	178
Generalisability	178
4.9 Conclusion.....	179
5 Chapter Five: Design and Development of a Computerised Error -Capture Tool in Interventional Radiology Entire Pathway of Care	181
5.1 Introduction:	181
5.2 Aim of the chapter.....	182
5.3 Methods.....	183
Study venue.....	183

Software used.....	183
The approach used to design of FERERI (Failure Estimation REcord in Radiology Intervention).....	183
The features of FERERI Error-capture Tool	183
Using Microsoft Excel 2013 to build FERERI Error-capture Tool.....	184
Content of the FERERI Tool	185
Definition of minor and major complications in the IR speciality	187
Parts of the FERERI Tool.....	190
How to calculate age in Microsoft Excel?	191
5.4 Discussion:	209
5.5 Limitation of the tool.....	212
5.6 Conclusion.....	213
6 Chapter Six: Validation of a Computerised Error -Capture Tool for Quality Assessment in Interventional Radiology Entire Pathway of Care”	214
6.1 Introduction:	214
6.2 Aim.....	214
6.3 Methods.....	215
Setting: 215	
Ethical approval	215
Training Induction period	215
Validation of FERERI tool	216
Patients 217	

Procedures:.....	218
Tools used for observation.....	218
During the observation time.....	218
Interobserver variability.....	218
Definitions.....	219
Data Collection	219
Data recording and statistical analysis	220
6.4 Results:	222
FERERI Validation:	230
6.5 Discussion:	232
6.6 Conclusion:.....	239
7 Chapter Seven: Landscape of Medical Errors across the entire IR pathway of care.	240
7.1 Introduction	240
7.2 The need for a study to systematically assess the healthcare errors across the whole IR pathway of care.	240
7.3 The aim of the chapter.....	240
7.4 Hypothesis.....	241
7.5 Methods.....	241
Ethical approval	241
Setting	241
Definition of healthcare errors in this study.	241
Inclusion criteria	242

Exclusion criteria:	242
7.6 Outcome measure	242
Data collection methods and privacy	242
Sample size	243
Statistical tests used.	243
Definition of different categories of healthcare errors used in this study:.....	244
Definition of degree of severity of healthcare errors used in this study.	248
7.7 Results	252
Demographics of studied patients and healthcare errors	252
The proportion of elective, urgent and ITU patients.....	253
The total number healthcare errors in elective, urgent and ITU patients and the difference in their means.....	254
The association between IR procedure category (elective, urgent and ITU) with the case complexity category (simple, moderate, and complex).	255
Complexity of the IR Procedures and the mean total number of healthcare errors across the IR pathway.	255
The difference in the mean total number healthcare errors in elective, urgent and ITU patients when controlling for the complexity of IR procedures.	256
Different time durations of the IR pathway	257
Healthcare errors according to the phases of the IR pathway.....	258
Preventability of Healthcare errors	259
Categories of Healthcare Errors Throughout the IR Pathway	261
Interruption Time caused by Healthcare Errors	262

Severity of patient harm caused by healthcare errors.	263
Proportion of categories of healthcare errors that caused cancellation of IR procedures. 264	
Types of Case Referrals to the IR Department	266
Types of the IR procedures	266
IR team number.....	267
The beginning of the IR pathway and the time of the day	268
Subcategories of safety awareness error	269
Subcategories of Communication error	270
Different forms of Distraction throughout the IR pathway	271
Subcategories of Equipment-related errors.....	272
Difference in the mean total number of healthcare errors across the entire IR pathway among male and female groups of the study population	273
Difference between type of referral and the total number of healthcare errors	274
Distribution of the total number of healthcare errors across different degrees of case complexity.....	274
The difference in the total number of healthcare errors across the entire IR pathway by different team member groups.	275
Difference between the mean total number of healthcare according to the time of admission to the IR department	275
Correlation between length of intraoperative IR procedures and the mean total number of healthcare errors across the entire IR pathway	275
Correlation between length of whole IR pathway and the Total number of healthcare errors across the entire IR pathway.....	276

Predictors factors for the healthcare errors	276
7.8 Discussion:	277
The need to study the healthcare errors across the whole IR pathway.	277
Healthcare errors in elective versus urgent versus intensive treatment unit (ITU) procedures	278
Healthcare errors and the phase of IR.....	279
Preventability of Healthcare errors	281
Rate of healthcare errors	281
Categories of Healthcare Errors Throughout the IR Pathway	282
Score of severity of patient's harm from the healthcare errors across the IR pathway..	283
Association of the total number of healthcare errors with different variables.....	283
What are the most predicting factors that impact the total number of healthcare errors in the entire IR pathway?	285
7.9 Limitations	285
7.10 Conclusion.....	286
8 Chapter Eight: Assessing the WHO Checklist for Radiological Intervention before and after new task allocation.	288
8.1 Introduction	288
8.2 Aim of the study.....	292
8.2.1 What is defined as good compliance to the WHO checklist for Radiology Intervention?	294
8.3 Material and Methods.....	295
8.3.1 Data collection	295

8.3.2	Intervention	296
8.3.3	Setting:	296
8.3.4	Patients	296
8.3.5	Procedures	296
8.3.6	Definition of healthcare errors in this study.	297
8.3.7	Definition of degree of severity of healthcare errors used in this study.	297
8.3.8	Outcome to measure	301
8.4	Results	303
8.4.1	Patients' demographics and other parameters.	303
8.4.2	WHO checklist characteristics	304
8.4.3	During which phase of the WHO checklist healthcare errors occurred?	305
8.4.4	Category of errors occurred during the WHO checklist.	306
8.4.5	Comparison of the mean total number of healthcare errors pre- and post- intervention	307
8.4.6	Comparison of the severity of the healthcare errors in the observed IR procedures pre- and post- intervention	307
8.4.7	The distribution of the subcategories of the WHO checklist implementation according to the type of the IR procedures	309
8.4.8	Association between the total number of healthcare errors in the intraoperative phase and the implementation of the WHO checklist by the IR team	310
8.4.9	The difference in the implementation of the WHO checklist in different team group number	310
8.4.10	Comparison of the degree of implementation of the WHO checklist in pre- and post-intervention phase	310

8.4.11 Association between the degree of implementation of the WHO checklist and the duration of the IR procedures.....	311
8.5 Discussion	312
8.6 Conclusion.....	317
9 Chapter Nine: Enhancing Communication among IR and Vascular Surgery Teams in Image-guided-Procedure Pathways by developing and using a Mobile Application Technology	318
9.1 Introduction	318
9.2 Aim.....	320
9.3 Methodology	321
The design and the development of a mobile app_ FARADION (FAst RADiology InterventiON).....	321
Presentation of the mobile app to the participants of the questionnaire study:	333
Ethical considerations	333
Pilot cross sectional questionnaire study	333
9.4 Results	335
Demographics of the participants	335
9.4.1 Internal scale reliability.....	338
9.4.2 The ratings of the participants of the different aspects of the mobile app	338
9.5 Discussion	346
Introduction and quantitative analysis of the results of the questionnaire.....	346
Qualitative feedback analysis	347
Limitations	349

Generalisability and future study directions:	349
9.6 Conclusion.....	350
10 Bibliography	351
11 List of Appendices	364

List of Tables

Table 1.1 The percentage of adverse events in acute hospitals in several developed countries	47
Table 2.1 Inclusion criteria applied to the reviewed articles	61
Table 2.2 Summary of the reviewed papers (Statistical tests and Effect size points were not included as all the included studies met these criteria).....	68
Table 2.3 Total number of healthcare errors (HE) within the reviewed literature	72
Table 3.1 Healthcare error Classification System with Examples of Each Error Type.....	92
Table 3.2 Examples of minor and major healthcare errors [adapted from (Morbi et al., 2012)].	93
Table 3.3 Fieldnote description by the novice and the Expert observer	95
Table 3.4 Shows the degree of agreement between the observation of the Novice observer with the expert observer (N= 5)	96
Table 3.5 The name and frequency of observed procedures	97
Table 4.1 Severity Ratings of the FMs (source USA (2023))......	119
Table 4.2 Probability Ratings of the FMs (Source: (USA, 2023))......	120
Table 4.3 Shows the HFMEA Hazard matrix. Source: (DeRosier et al., 2002)	120
Table 4.4 Shows the rated possible healthcare errors or failure modes by the participants ..	139
Table 4.5 Shows the perception towards the importance, severity ad probability of " <i>No bed Equipment_ Room preparation</i> " FM by different roles.....	143
Table 4.6 Shows the Ratings of the participants of " Inadequate handover" FM: importance, severity, and probability.....	145
Table 4.7 Rating of the FM " Pre-procedural planning"	147
Table 4.8 Communication Rating by the Participants	150

Table 4.9 Ratings of the "Intra-operative distraction" by the participants	152
Table 4.10 Rating of the "Technical errors" by the participants.....	154
Table 4.11 Rating of the importance of the FM " Patients who present unique challenges ..	156
Table 4.12 Ratings of the participants of " Procedure-related error in a complex image-guided procedure such as (EVAR)".....	158
Table 4.13 Ratings of the participants of the failure mode " No post-procedure plan has been discussed or recorded in the patient's notes"	160
Table 4.14 Ratings of the importance of the failure modes by the IR and the vascular nurses	162
Table 4.15 The severity ratings of the failure modes by the IR and the Vascular nurses.....	163
Table 4.16 Ratings of the probability of the failure modes by the IR and the Vascular surgery nurses	165
Table 4.17 Ratings of Importance of the FMs by the IR and the Vascular Doctors.....	166
Table 4.18 Ratings of the severity of the FMs by the IR and the Vascular Doctors	167
Table 4.19 Ratings of the probability of the FMs by the IR and the Vascular Doctors	168
Table 5.1 Shows the main categories of the FERERI tool	186
Table 5.2 Clavien- Dindo Classification of Surgical Complications [source: (Dindo et al., 2004)].....	188
Table 5.3 The old SIR classification of Complications post-IR procedures.....	189
Table 5.4 Newer classification of Adverse events in IR practice (Khalilzadeh et al., 2017)	190
Table 6.1 The observed IR procedures (Total number = 40 procedures)	223
Table 6.2 Demographics of the Observed errors in all groups	224
Table 7.1 Shows the main categories and sub-categories of healthcare errors with some brief descriptions and examples	245

Table 7.2 Definition of minor, moderate, major healthcare errors and errors-caused cancellation used in this study with examples	249
Table 7.3 Statistics of healthcare errors according to the phase of the IR pathway	253
Table 7.4 Total Time of Different Phases of IR Pathway.....	258
Table 8.1 Definition of minor, moderate, major healthcare errors and errors-caused cancellation used in this study with examples	298
Table 8.2 The Essential safety measures that were needed for adherence to the WHO checklist for Radiology Interventions	300
Table 8.3 Surrogate measures of compliance	300
Table 8.4 Categories of the WHO-checklist-related Errors	301
Table 8.5 Shows examples in which the WHO checklist allowed fixing some errors	308
Table 9.1 The suggestions and the Feedback from the participants in their words.	345

List of Figures

Figure 1.1 Swiss Cheese Model on how defence- layers can be penetrated by a hazard to produce an adverse event. Adapted from(Reason, 1995).	41
Figure 2.1 Diagram shows the process of study selection.	65
Figure 3.1 The mapped-out IR pathway for this pilot study (from a focus group meeting)....	90
Figure 3.2 Shows the methodology of data collection and analysis.	91
Figure 3.3 Proportion of the female and the male patients in the study population (n:58)	98
Figure 3.4 Shows distribution of the elective, urgent and ITU procedure among the study population (n:58).....	98
Figure 3.5 The distribution of the vascular and the non-vascular IR procedure.....	99
Figure 3.6 The distribution of the case referral across the study population namely: day case, vascular and other wards.....	100
Figure 3.7 The distribution of case complexity	100
Figure 3.8 Sows the different IR team groups	101
Figure 3.9 Shows the distribution of the healthcare errors across the phases of the IR pathway	102
Figure 3.10 Frequency and percentage of the healthcare errors across the IR pathway (n:58)	103
Figure 3.11 Shows the degree of severity of the occurring healthcare errors (total number of errors:317).....	106
Figure 3.12 Shows the degree of severity of the occurring healthcare errors in Elective, urgent and ITU procedures (total number of errors:317).....	107
Figure 3.13 The distribution of the healthcare errors by the degree of interruption of the IR procedures	108

Figure 4.1 Shows a visualised model of conducting HFMEA. Source: (USA, 2023).....	116
Figure 4.2 Shows HFMEA decision tree for each failure mode [Source: (DeRosier et al., 2002)].....	121
Figure 4.3 Shows a blank HFMEA sample worksheet with illustrations(DeRosier et al., 2002)	122
Figure 4.4 Shows the QR code and the link to the final IR safety questionnaire	128
Figure 4.5 The studied Phases of the IR pathway in which the Potential Failure Modes could occur.....	129
Figure 4.6 Examples of FM process and subprocess which might occur in the Image-guided-procedure pathway.	130
Figure 4.7 Shows the subprocess of equipment FM	131
Figure 4.8 Shows the calculation of the sample size	135
Figure 4.9 The proportion of the participants by role (Total number = 80)	136
Figure 4.10 The distribution of the participants' place of work.....	137
Figure 4.11 Shows years of experience of the participants	138
Figure 5.1 ICECAP Tool (Mason et al., 2013)	184
Figure 5.2 Part 1 of the FERERI tool magnified.	191
Figure 5.3 Continuation of Part 1 of the FERERI tool magnified.	192
Figure 5.4 Part 2 of the FERERI tool magnified.	193
Figure 5.5 Continuation of Part 2 of the FERERI tool magnified.	193
Figure 5.6 Shows Dropdown menu of the main categories of healthcare errors.....	194
Figure 5.7 Breakdown of absence sub-category according to different IR team.....	195
Figure 5.8 Different types of communication errors	196

Figure 5.9 Subtypes of Equipment- related errors	197
Figure 5.10 Subtypes of Distraction error.....	199
Figure 5.11 Fatigue can be subdivided into other involved healthcare staff.	200
Figure 5.12 Different subtypes of management errors	201
Figure 5.13 Subtypes of patient-related errors.....	202
Figure 5.14 Subtypes of procedure-related errors.....	202
Figure 5.15 Planning error according to a different phase of the IR pathway	203
Figure 5.16 Subtypes of technical error	204
Figure 5.17 Subtypes of safety awareness error	204
Figure 5.18 Different staff by their title who are involved in a particular error	205
Figure 5.19 Different phase of the IR pathway.....	206
Figure 5.20 Shows a screenshot of the FERERI tool which can be accessed by following the link below : FERERI template	208
Figure 6.1 Shows the layout of the Angio suite and position of different team members.....	217
Figure 6.2 A bar chart showing the frequency of errors within each primary category of the FERERI tool. Errors identified by Expert and by Novice observers.	226
Figure 6.3 Percentage of categories of errors recorded by the Expert and the Novice group in the first batch December 2015-January 2016	227
Figure 6.4 A bar chart showing the frequency of errors within each primary category of the FERERI tool. Errors identified by Novice_one and by Novice_two observers.	228
Figure 6.5 Frequency of healthcare errors by categories recorded by the Expert and the Super-Expert observers (No. of Errors detected by Expert= 124) (No. of Errors detected by Super-Expert = 116)	229

Figure 6.6 Percentage of healthcare errors by categories recorded by the Expert and the Super-Expert observers (No. of Errors detected by Expert= 124) (No. of Errors detected by Super-Expert = 114)	230
Figure 7.1 The proportion of female and male in the studied population.....	253
Figure 7.2 Shows proportion of the different types of procedures namely: elective, urgent and ITU (total number = 132 IR procedure).....	254
Figure 7.3 A box plot shows the mean of total number of healthcare errors in the IR pathways in elective, urgent and ITU patients.....	255
Figure 7.4 Shows Degree of Case Difficulty	256
Figure 7.5 Breakdown of Healthcare Errors according to the phase of the IR pathway	259
Figure 7.6 Shows the percentage of the preventable and the non-preventable healthcare errors	260
Figure 7.7 Shows the frequency of different healthcare errors throughout the IR pathway (Total number = 1395 errors).....	261
Figure 7.8 Shows the percentage of different healthcare errors throughout the IR pathway (Total number = 1395 errors).....	262
Figure 7.9 Shows breakdown of the healthcare errors according to interruption of the flow of the IR pathway of care	263
Figure 7.10 Percentage of score of patient harm caused by healthcare errors.....	264
Figure 7.11 Shows the percentage of healthcare errors that caused cancellation of the observed IR procedures	265
Figure 7.12 Shows the percentage of different types of referral.....	266
Figure 7.13 The proportion of the vascular and non-vascular IR procedure	267
Figure 7.14 IR team composition according to the number of staff present at the start of a procedure.....	268

Figure 7.15 Shows the time of the day when the Patients admitted to the IR Department ...	269
Figure 7.16 Shows the percentage of subcategories of safety awareness error	270
Figure 7.17 Shows subcategories of communication errors	271
Figure 7.18 Shows Different forms of Distraction throughout the IR pathway	272
Figure 7.19 Classification of Equipment related errors	273
Figure 8.1 Shows the WHO checklist in Surgery	290
Figure 8.2 Shows the WHO checklist for Radiological Intervention.	291
Figure 8.3 A screenshot of the Master Microsoft Excel sheet with all the data codes	302
Figure 8.4 Shows the percentage of Elective, urgent and ITU procedures in the IR department.	303
Figure 8.5 Shows the percentage of cases where the WHO checklist performed adequately versus inadequate and not performed at all.....	304
Figure 8.6 Shows the breakdown of phases of WHO checklist during which errors occurred (Total number of IR procedures:109)	305
Figure 8.7 Shows the percentage of the different categories of WHO-checklist-related errors (N:109).	306
Figure 8.8 Shows the frequency of the severity of the healthcare errors in the intra-operative phase of the IR procedure pre- and post-intervention.....	308
Figure 8.9 Breakdown of the categories of the WHO checklist implementation across elective, urgent and ITU procedures	309
Figure 9.1 The Home screen of the app for iPhone 12 pro screen (the size is slightly decreased for demonstration).....	323
Figure 9.2 Shows the patients information screen.	324

Figure 9.3 Shows the required checklist for each patient which affect the movement of the progress bar on the previous screen.	325
Figure 9.4 Shows the task screen (all tasks on the left side of the screen versus completed tasks on the right side of the screen).....	327
Figure 9.5 Communication screen: On the left side of the screen two types of communications were shown, picture and voice communication. On the right side of the screen, it is shown how to attach a file or a document.	329
Figure 9.6 Demonstrates the Power SharePoint lists of the FARADION App in Microsoft 365	330
Figure 9.7 Demonstrates the Power SharePoint lists of the FARADION App in Microsoft 365	331
Figure 9.8 Shows Patient Information list	331
Figure 9.9 Demonstrates Task Information list	332
Figure 9.10 The number of participants by roles (n:38)	335
Figure 9.11 Bar chart shows the proportion of the experience of the participants	336
Figure 9.12 Shows locations of the participants	337
Figure 9.13 Shows the responses of the participant the statement " <i>The mobile app is user-friendly and easy to navigate</i> ".	338
Figure 9.14 Shows the responses of the participant the statement " <i>The app can enhance communication and collaboration among IR and vascular teams</i> "......	339
Figure 9.15 The app has the potential to improve the efficiency and effectiveness of patient care within the IR and the vascular department.	340
Figure 9.16 Responses of the participants regarding the statement "The app can improve task allocation and coordination among team members	341

Figure 9.17 Responses of the participants to the statement " The app can help in reducing medical errors and improving patient safety".	342
Figure 9.18 The rate of the responses to the statement " Overall, the app is satisfactory and would positively impact communication and patient care.....	343
Figure 9.19 The rating of the participants of the statement " I recommend my hospital to conduct a pilot implementation of the app"	344

The Aims of the project

The main aims of this research study are:

- To determine a pragmatic IR pathway of care in patients who undergo image-guided procedures. What is the landscape of healthcare errors in IR pathway of care?
- To evaluate the perception of the IR team of different failure modes that occur throughout the IR pathway which have the potential to pose safety challenges.
- To design a computerised tool that objectively detect and measure healthcare errors across the IR pathway of care based on views of expert multidisciplinary team members.
- To make the computerised error-capturing tool user-friendly and easy to integrate into the hospital RIS (Radiology Information System).
- To highlight the most occurring healthcare errors and their effect on patient safety and procedure delay.
- To evaluate the compliance among IR team to execute WHO checklist and to see how we can improve it.
- To develop a mobile app to enhance communication and collaboration among the IR team and beyond to improve patient safety.

The research hypotheses

The healthcare errors are frequent and diverse throughout the IR pathway of care and are comparable to surgery. Non-technical errors are more frequent than technical errors and can lead to procedure delays and infringe patient safety. These healthcare errors can be measured objectively and reliably. Outlining the scale of the safety challenges produced by these healthcare errors allow robust future intervention to decrease them or mitigate their effect to ultimately enhance patient safety and outcomes.

Specific research questions

- Can observational methods be used to map the IR pathway of care?
- What is the perception of the IR team members of the safety challenges that face them on a daily base and what is their recommendation?
- In what way the mixed methodology contributes to triangulation of a computerised error-capture tool.
- Is it feasible and reliable to devise a computerised tool to detect and estimate healthcare failures and how could be validated reliably and efficiently.
- What is the landscape of healthcare errors in IR pathway of care?
- Is the WHO checklist for radiology intervention implemented adequately in the IR realm and what is the relationship if any with the overall rate of healthcare errors in the IR operations?
- How can we design and create a mobile app to enhance patients safety and how to assess it?

Thesis outline

In the introduction chapter, I outline the foundation of the thesis by discussing the concepts around patient safety and the factors that determine safety problems. Also, I discuss the global understanding of the adverse events to get an insight about the scale of safety challenges that face the health system. Lastly, I overview methods used to measure the adverse events and medical errors. An overview about several methods used in this thesis and the theory behind them are discussed in the introductory chapter. Then I discuss the landscape of healthcare errors in the Interventional Radiology_ IR through systematic review of the literature to obtain a comprehensive idea about the prevalence of evidence in the literature about healthcare errors in the entire IR pathway of care.

Having defined the size of the problem of the safety factors in the IR, chapter three presents an observational study about mapping out the whole IR pathway of care. This will be followed by evaluation of the safety climate within the IR specialty through assessing perception of the healthcare professional regarding the possible occurring failure modes. The finding of this questionnaire study is then used to develop a computerised error- capture tool_ FERERI (Failure Estimation Record in Radiology Intervention). This tool will be validated in chapter six of this thesis. In the next chapter, an observational study will be performed to assess the entire IR pathway of care to evaluate the landscape of the healthcare errors and safety challenges throughout the IR pathway of care to plot the entire patients' journey in the IR pathway.

The WHO checklist will be assessed thoroughly in chapter eight. In the last Chapter of this thesis, I will design and develop a mobile app and present it to the IR and the vascular team to evaluate its usability and effectiveness in enhancing communication, streamlining efficacy of the daily tasks, and improving patient safety.

Chapter One: A background about patient safety

1.1 Chapter overview

This introductory chapter explores some essential concepts and definitions of patient safety, and the essential principles. A broad understanding of the concept of patient safety in healthcare settings and the specific issue in interventional specialties is required to put this thesis into context.

1.2 What is patient safety?

Patient safety has gained significant attention globally and has been a primary subject for the national bodies reporting on the quality of care in developed and the developing countries alike. According to the first report on patient safety issued in 2000 by the Committee on Quality of Health Care in America, which belongs to the Institute of Medicine in the USA, safety can be defined as "freedom from accidental injury (Institute of Medicine Committee on Quality of Health Care, 2000).

Patient safety in clinical medicine is determined to a large extent by adverse events (Angle et al., 2008). These are defined as "unintended harms to patients resulting from errors of medical staff leading to a prolonged hospital stay or a disability at the time of discharge from the hospital or even death" (Brennan and Leape, 1991, Vincent et al., 2004).

1.3 Is the Health System safe as it should be?

The health system is not as safe as it should be. There is considerable evidence that healthcare errors contribute to the rate of death and adverse event at a national level in the United States of America. In two large-sample studies in the USA involving hospitalised patients in New York and Colorado and Utah reviewing-notes in 1984 and 1992 respectively, it was found that 2.9 and 3.7 per cent of these patients experienced adverse events respectively. A considerable proportion of these adverse events were due to avoidable healthcare errors (58 per cent and 53 per cent in New York and Colorado and Utah respectively) (Brennan et al., 1991).

As a result, the estimated annual potential death toll due to preventable adverse events in the United States was between 44,000 to 98,000 when extrapolated against 33.6 million admissions to US hospitals in 1997. Even if the lowest estimate is considered, it would surpass the death

resulted from road traffic accidents (43,458), breast cancer (42,297) or AIDS (16,516) (Institute of Medicine Committee on Quality of Health Care, 2000) (Thomas and Petersen, 2003).

1.4 Why isn't there a consensus about understanding the adverse events and medical errors in general?

A growing body of literature reporting medical errors and adverse events has been developed over the last three decades with various methodology of assessing them. However, a complete picture of the epidemiology of adverse events and medical errors has not been formed. There are studies which take the patient perspective into account and report valuable figures concerning the scale of harm caused by healthcare errors. Other studies, although less in number, focus on the errors themselves whether those which have resulted in adverse events or those who have not, i.e., "near miss" or "close call". Similarly, little is known about the prevalence of healthcare errors on the broader community healthcare settings compared to hospitals (Grober and Bohnen, 2005).

Not only have synthesising and inferring data on medical errors been hindered by the non-homogeneity in the methodology and the outcome measure within the literature but also they have been complicated by the absence of a consensus about the different terminology used to describe these terms. Adverse events, near miss, or medical errors have various definitions across the literature (Institute of Medicine Committee on Quality of Health Care, 2000) (Reason, 1995). The variability in the purpose and context of the studies conducted, such as those performed as quality control research versus those conducted for or using data from insurance or legislation purposes, make this obstacle. Furthermore, this overlap of the definition of medical errors has influenced an accurate assessment of their impact on the healthcare system in general (Wilson et al., 1995) (Grober and Bohnen, 2005).

1.5 Adverse events or negligence

In their report, the Institute of Medicine (2000) defined the adverse event as "an injury caused by medical management rather than the underlying condition of the patient". What is called "preventable adverse events" can be caused by errors without negligence or negligence? A negligent adverse event is a subtype of preventable error that fulfil the criteria used by the litigant bodies to determine the activity of the negligence. In other words, negligence is deemed

to have been committed if the provided care was below the expected standard of an average qualified healthcare provider to manage the patient under question (Institute of Medicine Committee on Quality of Health Care, 2000).

1.6 Definitions of medical errors based on Outcome.

It is prudent to summarise the terms which are used to describe adverse events and medical errors. At the outset, most of the literature focused on surrogate markers to medical or healthcare errors such as patient's harm, complications, prolonged hospitalisation, disability, or death. These markers are all outcome-based approaches, as there are many errors which do not necessarily cause any of these outcomes. The reason appears to be either because of mitigating factors that fix flaws before harm could occur or because of the resilience that some patients have or just as an act of luck (Moser, 1956) (Leape, 1994, Wilson et al., 1995, Thomas and Petersen, 2003). This is stressed by Reason (1995) as well who suggests that, while adverse events could represent outcomes of medical errors, not all medical errors necessarily lead to adverse events, perhaps most of them do not. Furthermore, there is what is called near miss, which is a state resulted from an error which does not manifest into a full-blown adverse event (Reason, 1995).

To be robust, a healthcare system should highlight process- failures or errors at initial stages (Barach and Small, 2000). Therefore, a clear definition of medical error is essential to achieve this goal. Several definitions are proposed: " the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (an error of planning) (Reason, 2000). Alternatively, it could refer to an unintended act (either of omission or commission) or one that does not attain its planned outcome (Leape, 1994, Leape, 2009) . Reason's definition does not pay attention to errors of omission, while Leape's definition omits those actions that arise from wrong plans. Therefore, a more comprehensive definition would be: "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result" (Grober and Bohnen, 2005). Throughout this thesis, I use the definition by Grober and Bohnen (2005) to define healthcare errors.

1.7 Approaches of dealing with errors: Person approach versus system approach

There are two ways to approach and study errors, the person approach and the system approach, each of which targets specific areas of error causation. Similarly, each of these approaches has different viewpoints regarding error management. It is of paramount importance to understand the differences between these two approaches and their implications on day to day practice of these organisations and perhaps more specifically their frontline staff to cope with the risk of errors in clinical practice and patient management (Reason, 2000).

A person-centred approach focuses on the individuals who are involved in making an error making them the main target of investigators. These individuals are usually the frontline staff in healthcare settings such as nurses and doctors. Here in this approach, it is believed that errors are usually caused by risky acts or behaviours by these front-line staff resulted primarily from substandard mental process. Examples of these aberrant mental activities are memory lapse, lack of attention or vigilance, lack of motivation or carelessness to irresponsibility or even negligence (Reason, 2000).

Those who adopt this approach do not usually study the factors lead to healthcare errors; the environment in which these errors occur or the inherent flows within the organisation that cause these healthcare errors. This type of approach creates what is called a “blame and shame” culture where all the responsibility and consequence of a flaw or a mistake is attributed on one or several people who are usually involved in direct management of the patient (Grober and Bohnen, 2005). This approach has been said to fit with a hierarchical share of responsibility. For instance, in a hospital setting, the doctor will be seen as the main character within the team on whom most of the responsibility will fall in the case of success or failure (Grober and Bohnen, 2005).

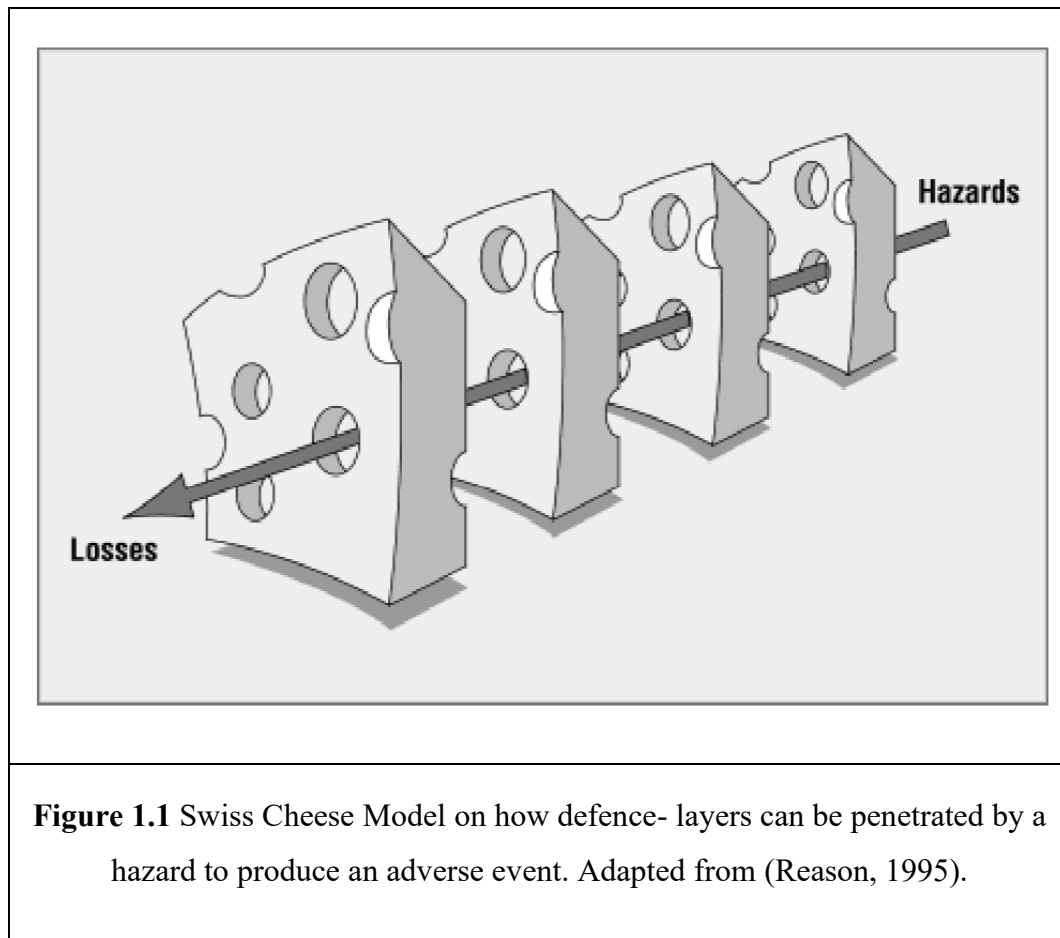
On the other hand, the system approach is a more comprehensive way of assessing errors. In the system approach, the focus is not only on the person who might have been involved in a healthcare error but also any other possible related factors. Examples of these factors might be: the team in which the questioned staff work with, the procedure in which the flaw took place, the work environment, and sometimes the whole institution (Reason, 1995). This approach is a newer concept which has become more adopted recently. The team here is the main character rather than a specific person or a role within the team. Therefore, everyone in

the multidisciplinary team regardless of their role or rank is listened to and share the responsibility when something goes wrong (Reason, 2000).

1.8 The healthcare defence _ Reason's model

The "Swiss cheese" model proposed by James Reason provides the mechanism on how a hazard can penetrate all the defences of a healthcare system and cause injury (Reason, 1990, Reason, 1995) (see Figure 1.1) . Ideally, none of the layers of the healthcare defence should contain a hole or weakness to allow a hazard to make its way to produce an incident, but in the real world, a defence layer is like a slice of a Swiss cheese which contains holes which represent weaknesses through which flaws can progress to become adverse events. The difference between the holes of a slice of the Swiss cheese and those of a defence-layer, is that, in the latter, they are continuously become open and close and change their position according to many variables. Therefore, presence of a hazard, or a mistake does not usually cause incidents as there are other layers which act as a barrier in front of the hazard. It is only when the holes of all the defence lawyers are lined-up which allows penetration by the hazard to cause damage to a patient.

According to the Swiss-cheese model, an error is handled from a system approach rather than a person approach as illustrated previously. Systems that are high-reliability systems are designed in a way that contain many layers of defence. As pointed out by Reason (1995) in his article about human error, some of these defence-layers are embedded in the construction of these systems, such as alarms, physical barriers, and automatic shutdowns. However, there are some defence layers which rely mainly on individuals such as pilots, doctors, healthcare staff or administrator staff, while there are some other defence layers which rely on procedural or administrative controls i.e., the mechanism of management of these personnel.



1.9 Active versus latent failures

Fundamentally, there are two types of failures which lead to weaknesses or holes in a defence barrier, namely active failures, and latent failures. Most of the time a combination of these two failures results in an adverse event. Active failures are any unsafe action or behaviour produced by an individual or individuals who manage patients such as a slip, an inattention, a memory lapse, a mistake, or violation of a protocol. Latent failures are usually flaws that arise primarily from the design of the whole system. The system is usually made by engineers, designers and top managers who shape all the procedures and the protocols within the system. These decisions or protocols may be inadequate and can act as precursors introducing pathogens into the system (Reason, 1995).

Although the effects of active failures are immediate, they are often direct. For instance, in the famous Chernobyl incident, the staff switched off many safety systems within the plant which led to an immediate initiation of a tragic explosion. If we were to adopt the person approach

to deal with this error, then this would be enough to look no further to establish the cause of the adverse event. However, if we were to adopt a system approach, then we should search for any latent failure within the system no matter how remote this would be to establish the root cause/s of this disaster (Reason, 2000), for example looking into the culture of organisations that led to the decisions being made to switch off the safety systems and the systems that allowed this to even happen.

Two adverse outcomes can result from the latent failure, one is an environment in which staff can easily be slipped to make mistakes (for instance, shortage of staff or equipment, inadequate training, or time pressure by the department). The other outcome is a situation which allows weaknesses carrying potentials to produce hazards on a long run such as unreliable alarms or indicators or unfeasible procedures or protocols (Reason, 1995).

Unlike the latent failures, the active failures are often hard to expect before it happens. For example, managers cannot foresee when an operator slips or makes a mistake. Whilst the latent conditions are amenable to identification and modification to prevent adverse events. For instance, short staffing or inadequate training can be pinpointed and managed before an adverse event occur. Latent failure can well be present for a good amount of time before triggering an active failure to produce an adverse event. Based on this, focusing on latent failures can create a proactive hazard management system that eradicate the precursor of any adverse event. As referred to by Reason (1995), if we consider Mosquitoes as active failures, killing them one by one cannot entirely solve the problem as they keep coming back. Whereas draining the swamps is considered a more effective way to resolve the problem. In this case, the swamp act as a latent failure on which the Mosquitoes thrive.

1.10 The global scale of Adverse Events in hospitalised patients

The first three extensive studies in the world were published in the 1990s: The Harvard Medical practice study, the Utah and Colorado Medical Practice Study and the Quality in Australian Health Care Study. These studies examined the number of adverse events (AEs) in hospitalised patients.

The three large retrospective studies were as follows: The Harvard Medical Study I and II were conducted in 1984 on 30,121 inpatient case records. Of these hospitalised patients, 3.7 per cent

developed adverse events (AE) with 2.6 per cent of these AE classified as permanently disabling injuries, while 13.6 per cent led to death. The Utah and Colorado Medical Practice Study was conducted in 1992 on 15,000 inpatients and revealed a similar result to the Harvard Medical Study. The mean rate of AEs constituted 2.9 per cent, of which death occurred in 6.6 per cent. Similarly, in 1992 in Australia, a large-scale retrospective study was performed on 14179 admissions to 28 hospitals in New South Wales and South Australia. AE occurred in 16.6% of the admissions, 13.7% and 4.9% of which caused permanent disability and death respectively (Brennan et al., 1991, Leape et al., 1991, Wilson et al., 1995, Gawande, (1999).

1.11 Adverse events in hospitalised patients in the UK

Adverse events in the inpatient population in the UK have been measured at a higher rate compared to the USA. Ten years after the Utah and Colorado study_ in 2001, Vincent et al., (2001) investigated the incidence of adverse events in hospitalised patients in UK hospitals. They performed a retrospective study on 1014 medical records in two acute- setting hospitals in Greater London to estimate the incidence of the adverse events and the associated financial burden. Eleven percent of the studied population experienced at least an adverse event. One-third of the adverse events led to moderate or more significant disability or even death. Interestingly, similar to the studies conducted in the USA and Australia, half of the adverse events are preventable despite presence of a different healthcare system (Vincent et al., 2001).

1.12 Comparison of the rate of reported adverse events among the studies across the globe.

It is worthwhile to note that there is a variation in the reported rate of adverse events between the studies performed in the United States and those performed in Australia and the United Kingdom. There are various reasons why there may be these differences.

Looking at the methodology used in each of the above studies, there is some variation in how each of these studies counted the rate of the adverse events (AEs). This could contribute to the discrepancy in the rate of the reported AEs. The Harvard Medical Study was conducted in 1984 on 30,195 inpatient records from 51 acute state hospitals in New York city of the United States. The researchers used the term index hospitalisation, during which they calculated the rate of the AEs. The index admission was defined as the period of admission which was sampled for the sake of the study. Recording AEs was restricted to the time before or during the index

admission. AEs which occurred before the index admission were only considered if they were continued or discovered during the index admission or was the cause of the patient's admission during what is defined as the index admission. The study organisers mentioned in their methodology section that to avoid overestimating the rate of AEs, they excluded recording of the AEs which occurred after the index admission or even those AEs which were originally occurred during the index admission but only discovered after it. This means that they did not record those AEs which occurred after the index admission or in subsequent admissions in 1984.

Likewise, in the other American study, the Utah, and Colorado Medical Practice Study, which was conducted in 1992 on 15,000 patient a comparable rate of AEs was recorded to that of the Harvard Medical Study I and II (2.9 per cent versus 3.7 per cent respectively). The researchers used the same methodology in calculating the annual incidence rate of AEs by counting only the events occurred during the sampled admissions. Any events which occurred later in the subsequent hospitalisations were excluded.

In contrast, recording of the AEs in the Australian study was including the index admission, those AEs which had occurred before the index admission if they deemed to be responsible for part or all the index admission, and the AEs which were detected later in the subsequent admissions. The rate then used for calculation of the annual incidence rate of the AEs. This could probably be one of the main reasons why the researchers in the Australian study recorded a higher rate of AEs_16.6 percent of hospitalised patients) (Table 1.1).

There was some other modification in the methodology of the Australian study compared to the Harvard Medical Studies. They replaced the term negligence with preventability to make the study seems more positive and considered as a quality improvement project rather than a punitive one. This, as the conductors of the study believe, would enable the study to be performed in a positive environment rather than in a negative or stressful one. It is not known fully how much this positive environment would encourage openness in the way healthcare-givers report safety incidence or acknowledge own mistakes or would encourage the health-records evaluators to attribute perceived incidents to AEs.

In the UK, there was a pilot study looking into the rate of AEs in hospitalised patients. This was a retrospective study in two acute Hospitals in London in which a review of 1014 medical and nursing records made in two stages_ screening by nurses in the first stage followed by

reviewing of these records by doctors. There was not a re-evaluation of the screened patient's records. The authors acknowledged in their conclusion that the study was small and only limited to two hospitals with a smaller sample size than its counterpart studies in the USA and Australia. Also, lesser number of specialties (four specialties across the two hospitals) were included in the patients' record screening. This might have resulted in a higher rate of AEs being recorded, as these specialties may have contained higher rate of AEs than other specialties. Therefore, in the opinion of the authors, no extrapolation of the findings was possible with accuracy. They claimed that an estimate of around 5% of yearly admitted patients to hospitals in England and Wales experience preventable AEs because half of the AEs which occurred (10 percent) in the admitted patients were deemed preventable.

Another factor that might explain the difference in the recorded rate of AEs is the difference in the time of conducting of these studies. The UK- study was done in 2001, while the Australian- study was performed in 1995, 17 years and 11 years after the Harvard Medical study (in 1984) respectively. The period of time perhaps is long enough to allow development in the healthcare system and an increase in staff awareness. It is not unusual after many years from the first studies in 1984 to see a change in the behaviour and the attitude of the medical staff. Among essential positive behaviour that healthcare personnel could possess is transparency in reporting healthcare errors and AEs. This transparency might be partly explained by a more recent system-approach to evaluate healthcare errors, in which the system, not individuals, is considered a precursor of healthcare errors.

The role of media cannot be ignored in raising awareness of the public and the government alike towards healthcare errors and the magnitude of the problem around them. After the public report by the Institute of Medicine of the USA in 2000 "To Err is Human", governments and national health bodies have become more interested in patient safety across the globe and have become more aware about the potential scale of the problem of patient safety and AEs (Institute of Medicine Committee on Quality of Health Care, 2000). One of the outcomes of this report is to encourage transparent reporting of medical errors which could be another explanation why the British study reported a slightly more AEs.

The variation in the health system across these countries might have led to differences in adverse event reporting in these studies. For instance, in America the health system is mostly private comparing to a free nationalised health system _ NHS in the UK. In Australia, the health system is copaid by people and by the government and they have what is called Medicare in

which most of the costs of health services are paid by the government through income tax money leaving a small proportion of that cost paid by Australians (Gulland, 2017). This variation in the health system across the countries could influence the culture of reporting and managing AEs. Due to the risk of getting fired from their jobs or facing litigation, some healthcare staff might be reluctant to report AEs or to attribute them to medical care.

Table 1.1 The percentage of adverse events in acute hospitals in several developed countries				
Study	Number of acute care Hospitals	Date of Study publication	Number of Hospital records studied	Rate of adverse events (% of admissions)
Harvard Medical Practice Study	51	1984	30,195	3.7
Utah-Colorado Study	28	1992	14,052	2.9
Quality in Australian Healthcare Study	28	1995	14,179	16.6
United Kingdom	2	2001	1,014	10.8
Adapted from (Leape et al., 1991) (Gawande, (1999), (Wilson et al., 1995) (Vincent et al., 2001).				

1.13 Frequency of medical errors in surgery

Seven years after the first Harvard Medical Practice study performed in 1984, the research team published the second phase of the study to analyse the adverse events in more details, specifically to design future recommendations. In a two-stage process, an evaluation of 30,195 randomly selected records in 51 hospitals across the state of New York in the United States of America was performed. Firstly, trained staff screened those records to pick up adverse events using selected criteria; then, two independent, experienced physicians evaluated the selected events. Nearly 50% of the adverse events occurred in surgical operations, and about 58% of them were deemed preventable (Leape et al., 1991). Another study conducted in Australia, where medical records of 14000 admissions in 28 hospitals were analysed, 51 % of the adverse events were considered preventable, and equally 50% of them took place in surgery (Wilson et al., 1995). Medical errors are generally largely prevalent in surgery. Several studies are performed in surgery to show this (Thomas et al., 1999), (Vincent et al., 2001) , (Lingard et al., 2004a) , (Christian et al., 2006).

1.14 The World Health Organisation Checklist and its impact on the rate of AEs and Death

Injuries related to surgery and wrong-site surgery are common problems which occur during healthcare management. The rate of errors and their serious consequences is higher in surgical theatres and ICU than other departments (Institute of Medicine Committee on Quality of Health Care, 2000). In a report by the World Bank in 2002, conditions which are treatable surgically are estimated to form 11% of the overall disease burden that affect people worldwide. Although the exact rate of complications related to surgery is not known worldwide, the rate of perioperative major complications and death in the developed countries are estimated to be 3-17% and 0.4-0.8% respectively (Haynes et al., 2009a). In their report, the Institute of Medicine of the USA pledged the government and the health system to lower the rate of adverse events and medical errors to 50% in 5 years (Institute of Medicine Committee on Quality of Health Care, 2000).

Responding to the importance of addressing these problems, the WHO developed the World Alliance in 2004 to improve patient safety. They developed "safe surgery saves life" project. The main outcome of this project was the development and application of a 19-item preoperative checklist called the WHO checklist. This checklist had been implemented from

October 2007 to September 2008 in eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) across the globe ranging from less developed countries to more developed ones.

Data was collected prospectively on clinical processes and outcomes from 3733 consecutively-enrolled patients aged 16 years or more who had undergone surgery (excluding the cardiac surgery).

3955 consecutively enrolled patients were studied after the implementation of the checklist. The checklist resulted in a reduction of the rate of death from 1.5% to 0.8% and inpatient complication from 11% to 7% ($P < 0.001$).

Since the publication of this benchmark research, many of the developed countries adopted this WHO checklist in their hospitals. Some of the countries, among which is the UK, has made this mandatory (Morbi et al., 2012).

1.15 Frequency of medical errors in Endovascular or IR procedures

Like surgery, IR is considered a speciality with significant risk and comparable rates of medical errors and adverse events to those of surgery would be expected. The evidence for the rate and type of error is growing.

Intraoperative failures are frequent in endovascular and combined vascular and endovascular procedures, the rate of the failures in latter procedures are more though (ALBAYETI et al., 2011). This high rate is because endovascular procedures rely more on complex equipment and involve more complex communication between the multidisciplinary team involving IR and the vascular team. In addition to this, reliance on modern technology and everchanging equipment make equipment problem more apparent. Therefore, the most frequent errors were equipment-related and communication errors which together constituted about 45% of the total error count. A similar pattern of errors was recorded by Morbi et al., (2012) who evaluated pure endovascular and IR procedures. 55% of errors were preventable and related to system failures (Morbi et al., 2012). Other studies in these areas found comparable results and stressed

that the medical errors are frequent in the setting of IR specialism and a significant number of them are preventable (Mason et al., 2013)

.

1.16 How to measure safety parameters such as adverse events, medical errors and to analyse failures.

There are different methodologies by which adverse events and healthcare errors are recorded. One way of finding adverse events is by reporting them. The other way is by using process measuring studies. Both have unique features (Institute of Medicine Committee on Quality of Health Care, 2000) (Grober and Bohnen, 2005).

1.1.1 Reporting adverse events and medical errors within institutions

There are two ways of reporting adverse events, mandatory or voluntary. Mandatory reporting is where organisations hold responsible by statutory bodies to report significant adverse events that lead to severe harm or death and make them available to the public. The voluntary reporting is to record those errors which did not result in adverse events to analyse the healthcare system if there is any vulnerability or weakness that predispose or could predispose to safety incidents. There is no mandate to report these errors and improvement strategies to the public, and no legal or disciplinary consequences would be incurred on staff who participated in those events in any way. Both types of reporting are encouraged to enhance patient safety and prevent negligence (Institute of Medicine Committee on Quality of Health Care, 2000).

1.1.2 Observational methodology to measure the healthcare errors in surgery and the IR.

Process- measuring studies which focus on finding healthcare errors use direct observation to estimate rate and type of medical errors (Grober and Bohnen, 2005) . These type of research are accurate in detecting most of the errors, including minor ones, near misses and full-blown adverse events (Thomas and Petersen, 2003). Examples of these methodologies are field-note observation using predefined checklists (Lingard et al., 2004a) (Catchpole et al., 2006a) (Catchpole, 2010) (Mason et al., 2013) or just field-note observation (ALBAYETI et al., 2011) (Morbi et al., 2012) .

1.1.3 Field-note- based observational methods.

There are many methods of assessing human factors in healthcare settings, including measuring healthcare errors and other interactions that occur among healthcare staff themselves and with patients. Among these methods is making field notes while observing live procedures or interaction.

The field -note-based observation is one of the early methods of scientific research where the scientist is physically present in the scene and documents notes on behaviours, interactions, and problems without having any impact on the variables or the outcome. This method has originated from research in biology and social science. It has roots back in days of Charles Darwin who published his field records in the Voyage of the Beagles in 1835. He observed birds and reptiles and annotated detailed field notes, from which he produced his comprehensive narrative “Field Notes on Science & Nature” (Schaller and Heinrich, 2011).

1.1.4 Field-note- based observational methods in surgery.

Field notes observation has been used in healthcare studies, including assessing communication, teamwork, or failures in operation theatres. Lingard et al. (2004) studied the operative theatre environment to characterise communication errors by observing 48 surgical procedures and 94 staff. They categorised communication errors under these domains: content (missing information), audience (essential personnel not addressed), purpose (problems not resolved) and occasion (poor timing). Furthermore, they measured the impact of communication errors on procedure flow, waste of resources and patient inconvenience (Lingard et al., 2004a) .

Christian et al. (2006) observed ten complex general surgery procedures using field notes and demonstrated that observational methods could expose critical system structures that impact patient safety and can form a target for patient safety initiatives. Composing a multidisciplinary team of human factor experts and surgeons, this group of researchers produced minute-by-minute field notes of these complex operations which were later coded and analysed. Qualitative analysis to find significant system features that influence team performance and safety was followed by a quantitative measure of factors that could lead to these features along with events contribute to or compensate for safety (Christian et al., 2006).

Similarly, Catchpole et al. (2008) used an observational method to study the relationship between surgical, anaesthetic, and nursing teamwork skills and technical outcomes in 26 laparoscopic cholecystectomies and 22 carotid endarterectomies. They found that non-technical skills have an impact on technical skills and duration of surgical operations, and they reiterated the concept of the possibility of improving technical performance and patient outcome by improving teamwork and communication (Catchpole et al., 2006a) (Catchpole et al., 2008).

Patel et al., (2012) assessed 15 combined open/ endovascular operations by using event logs to look at failures which were categorised later on based on their potential to cause patient harm and disruption to the flow of the procedures. They found that there is a high rate of medical errors, especially in the endovascular phase versus non-endovascular phase in combined procedure at a rate of 7.64/hour versus 3.75/hour respectively ($P = 0.05$) (Patel et al., 2012) . However, these are expensive to run, and require exhaustive resource and labour and often include several types of bias (Mason et al., 2013).

1.1.5 Fieldnote- based observational methods in IR.

Although they are not as many as in surgery, as was outlined in chapter two, observational field-note-based studies have been used in IR Morbi et al. (2012) studied the frequency and type of errors in vascular IR and designed an intervention to reduce these errors and thereby to improve patient safety and efficiency of the IR setting. They observed 88 IR procedures in total by using field notes which were analysed and categorised later by using a classification system that was modified from a system used in a previous study in paediatric cardiac surgery (Morbi et al., 2012) .

1.1.6 Questionnaire studies

1.1.6.1 Questionnaire studies in other industries such as aviation

Patient safety questionnaire-based studies in healthcare have taken guidance from questionnaire studies used in other high-risk industries such as nuclear power, NASA and aviation (Gaba et al., 2003) (Sexton et al., 2006a) (Gore et al., 2010).

The first generation of training programmes in the civil aviation of the USA _ CRM (Cockpit Resource Management) was initiated in 1981 after a conference sponsored by the National Aeronautics and Space Administration (NASA) in 1979. This training programme was an initiative to investigate the root cause of several aviation incidents in the USA in which human factors such as interpersonal communication, decision making, and leadership were found to be the main culprit. The training programme was created based on models used in corporations to increase managerial effectiveness. These models were inspired by a training method called " Managerial Grid" found by psychologists Robert Blake and Jane Mouton in 1964 (Helmreich et al., 1999) .

The programme has six generations which have evolved over two decades. The first generation started in 1981. Initially, the programme was called Cockpit Resource management which focused on pilots and cockpit then changed to Crew Resource Management to include wider members of the crew. Then CRM combined with a voluntary Advanced Qualification Program_ AQP and LOFT (Line Operational Flight Training). The main concepts of the first generation were to enhance interpersonal communication, decision making and leadership while the concepts of the second generation were focused around building effective teams, constructing team briefings, situation awareness and managing stress. The fourth generation focused on how to integrate and blend the basic CRM and voluntary AQP into the technical training programme.

The fifth generation considered the original CRM as an error reduction or containment mechanism as it has been believed that error is inevitable. Three strategies were put in place to either prevent errors or contain errors or to mitigate the complications if errors happened. The sixth generation extends the work to make the point that the crew need not only to deal with human error within the boundary of the cockpit but also need to deal with hazards originated from operational environment (Helmreich et al., 1999, Ford et al., 2014)

One question is how to make sure that this programme increases safety and decrease incidents? The answer is not straightforward. It is not feasible to draw a conclusion based on the rate of incidents before and after adopting these measures as the rate of incidents are low, and these measures are variables. Therefore, measuring surrogate markers of acceptance of these concepts is useful to improve safety. Incident's reporting is a measure to increase safety climate. However, this is voluntary, which makes the real rate uncertain, a rate which is necessary for validation. It was therefore concluded that two feasible and logical criteria to

measure are attitude and behaviour on the flight deck to show if the flight attendants accept and adopt the concept of CRM, hence the development of Flight Management Attitudes Questionnaire (FMAQ) (Helmreich et al., 1999) .

1.1.6.2 Questionnaire-based studies in medicine

Modified from the Intensive Care Unit Management Attitudes Questionnaire, which in turn modified from FMAQ, (Helmreich et al., 1999), Sexton et al. (2006) developed a Safety Attitude Questionnaire (SAQ) which is known as University of Texas SAQ. The SAQ is divided into six primary constructs or domains, containing thirty items in a double-sided-page questionnaire. The six main domains are safety climate, teamwork climate, job satisfaction, perception of management, stress recognition and working conditions (Sexton et al., 2006a).

However, the SAQ questionnaire contains only six out of thirty items which measure teamwork, and seven other items measures perception of staff of the safety climate.

1.17 Failure Mode and Effect Analysis (FMEA)

FMEA is a technique found to study new systems, new designs or new goods to proactively analyse all the steps or sub-steps of a process which might fail before they take place. Therefore, in this technique, the focus is on possible problems before they occur, not after they have occurred regardless of whether these problems lead to an adverse event. For each assumed failure, three points need to be confirmed, the severity of the outcome in case of its occurrence, probability of its occurrence, and finally the chance of its detection before it becomes a full-blown adverse event. A hazard scoring system is then formed, which is a product of multiplication of the value of each of the severity and the probability. Then a risk priority number (RPN) will be assigned to each failure mode by multiplying severity by probability and detection. Based on the hazard scoring and RPN for each failure mode, actions may or may not be taken to prevent these adverse events (Schneider, 1996).

The first industry to adopt this technique was the military sector in the United States of America in the late 1940s when the Department of Defence adopted this method across all its departments including the Engineering and weapon designing departments. In a document by the Secretary of Defence of the United States about the "Procedures for performing a failure mode effect and critical analysis" which was first published in 1949 and refined later in 1983, it is emphasised that designing and implementing a correct FMEA is vital to decision-makers

who decide about programmes in terms of practicality and suitability of design method (USA, 1949).

The FMEA technique has an additional component which was criticality analysis, making the whole technique to be called HFMEA. This determines the proactive refinement of the design, or the system based on the hazard score of each failure mode. HFMEA is regarded as one of the most helpful duties in susceptible and reliable programmes. This is because potential failures can be orderly put in a list according to their severity. In this way, each FM can be evaluated thoroughly as in what could cause it and how can be detected and what would be the direct and indirect influence on the system when it occurs and what measure should be taken to prevent its occurrence, or if occurred what would resolve it or mitigate the adverse outcome. Not only does FMEA help to authenticate the integrity of any design of any product or system, detect and measure various unwanted failure modes but also conclusions can provide substantial justification for modification in design or operating systems. Beside guiding new design procedures, FMEA is essential in maintenance planning analysis (USA, 1949).

1.1.7 Health Failure Mode and Effect Analysis (HFMEA)

The first sector in the health care system to embrace this approach was medical products and clinical engineering (Willis, 1992), while the Department of Veterans Affairs was the first who used a modified FMEA system called HFMEA (Health Failure Mode and Effect Analysis) (DeRosier et al., 2002).

The aim of this technique ideally is to enhance patient safety by preventing the occurrence of failures or planning protective measures to stop these failures to affect users (Skevington et al., 2012) or in the worst scenario by reducing the harm that can be caused by them (Joint Commission Resources/ Joint Commission International., 2010).

HFMEA is developed in the USA as a mixed model that combines ideas and tools exist in FMEA and Hazard Analysis and Critical Control Point (HACCP) and the Veterans Affairs root cause analysis (RCA). HFMEA requires a multidisciplinary team that diagrammatically present failure modes in a processes or a subprocess with their root causes and their impact on the users and the system using a hazard scoring matrix for each of these FMs. This is finalised by identifying contingency actions for any of these FMs if they occurred (Suva et al., 2014). (DeRosier et al., 2002).

Criticality is defined as the likelihood of occurrence of a failure. We have a single point weakness and a multiple-point weakness, and the former is more important to control. This is because the probability of a single- point weakness is greater than multiple-point weakness as one or more causes are required to produce a full-blown failure mode in the multiple-point weakness. While only one cause is enough to produce a single-point weakness, an example of which is electricity power cut-off which occurs suddenly and leads to a system failure. (DeRosier et al., 2002, Quality_one_International).

Lack of control measure is another factor to be considered to warrant further action. For example, a failure mode is of a single point weakness type which needs further action. However, if there is already a control measure in place, then there is no need to go further. Examples of this are anaesthetic or Oxygen gas cylinders in the operative theatres which are usually matched by colour coding. This is a potential weakness, since the colour of these cylinders might fade over time or be confused depending on the lightening of the room perception of the staff_ who might have colour blindness. Therefore, this failure mode should be addressed to prevent mixing up of different gas bottles. A simple solution would be, manufacturing unique adapters for different types of gas cylinders to prevent mixing-up gas cylinders by chance.

1.18 Conclusion

If the safety concept in medicine and surgery are in their pubescent, it would be in its infancy in the IR specialism, hence, needs further exploration. Different theories and methodologies have been tried in this area to form a comprehensive picture about the scale of the problem, each of these techniques has its own advantages and limitations. The following chapters of this thesis are going to present the works and the studies which are performed to contribute and add on what is already known and performed in patient safety arena in the IR specialism.

Chapter Two: The Healthcare Errors across the Interventional Radiology (IR) Pathway of Care: Where are we? _A Systematic Review

2.1 Introduction

Patient safety in medicine is influenced largely by adverse events (Angle et al., 2008). These are defined as unintentional injuries to patients resulting from errors of healthcare management which in turn lead to further unplanned intervention to correct those injuries (including longer unplanned hospital-stay) or lead to a disability or even death (Brennan et al., 1991, Vincent et al., 2004). The increasing rate of adverse events has been linked to both the evolution of healthcare and the presence of preventable healthcare errors (Vincent et al., 1998, Vincent, 2003). A report by the Institute of Medicine found that 13.6 percent of adverse events led to death in hospitalised patients in New York, and over 50 percent of them were caused by healthcare errors, which could have been prevented (Institute of Medicine Committee on Quality of Health Care, 2000). Ten percent of hospitalised patients experience adverse events, and half of these occur in invasive disciplines such as surgery (Weingart et al., 2000).

Interventional Radiology (IR) is accompanied by adverse events comparable to those seen in surgery. This similarity is, partly, because IR has exponentially grown since its conception, to include a wide array of therapeutic options for a myriad of pathologies (Morbi et al., 2012). Furthermore, IR reliance on equipment and complex imaging renders it particularly prone to adverse events (Koetser et al., 2013, Lutjeboer et al., 2015).

Several factors other than the skill of the interventional radiologists and the patients' characteristics are important determinants of adverse events, and these factors are called non-technical factors. These non-technical factors entail communication, teamwork, equipment and organisational. Failure of any of these technical and non-technical skills comprise what is called healthcare errors (Leape, 1994).

Unlike surgical disciplines, the exact frequency of healthcare errors and their nature in IR are not known, and their contribution to adverse events and patient safety outcome remains to be quantified. A systematic review of the literature is needed to explore this area further.

2.1.1 What are the aims of this systematic review?

This systematic review aims to identify studies that identify healthcare errors and safety issues in the IR pathway. Each of the papers were examined to determine:

- What are the frequency and nature of healthcare errors which occur throughout the IR pathway of care?
- How many of these errors are preventable?
- Which phase of the IR pathway of care is more prone to healthcare error, among others?
- How have these healthcare errors been measured? Has there been any standard tool to measure them?
- What intervention has the researchers proposed to reduce healthcare errors?
- Is there any correlation between healthcare errors and clinical outcome and patient safety?

2.2 Materials and Methods

2.2.1 Inclusion criteria:

Any quantitative study which was performed on human beings was included. These studies must assess healthcare errors in Interventional Radiology (IR) procedures which were performed solely by IR teams and written in English.

2.2.2 Exclusion criteria:

- Non- research articles, namely: editorials, conference abstracts, letters to the editor, short surveys, practice guidelines and case reports.
- Publications concerned with healthcare errors in other disciplines such as surgery or vascular surgery, including procedures which were performed jointly by IR and vascular surgery teams such as EVAR (endovascular abdominal aortic aneurysmal repair), unless specific record was made of IR procedures that could be extracted from the paper.
- Research documenting solely qualitative data.

2.2.3 Assessing the risk of biases (Quality assessment) of the included studies:

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) group and the new Cochrane review guidelines have recommended and stressed on using new terminology, "risk of bias", instead of the older one "quality assessment" in evaluating selected studies for systematic reviews (Liberati et al., 2009). This approach identifies five components as sources of bias, which have negative impacts on "estimate of effect" of intervention in RCTs. These components are: (sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting) (Altman, 2008). Regardless of what approach reviewers might adopt, they must implement and demonstrate it ahead in the protocol section of their systematic review (Angle et al., 2008).

However, this tool is not equally useful in non-RCT studies, including observational studies, in which many items of the PRISMA tool cannot be applied. Furthermore, unlike RCTs, sequence generation, allocation concealment, or blinding, are methodologically difficult or even ethically impossible in observational studies performed on specific groups of people (such as pregnant, children or elderly people). The participants in these types of studies cannot be divided into study and control groups, such as 'surgery vs no-surgery groups' (Stroup et al., 2000).

Therefore, we adopted a method used previously in our department, which in turn modified from a tool based on the recommendation by MOOSE (Meta-analysis Of Observational Studies

in Epidemiology) and QUOROM (Quality of Reporting of Meta-analyses) on quantitative studies (Weerakkody et al., 2013).

Briefly, the tool is composed of a table of seven criteria with correspondent scores in front of each criterion, namely: N/A (not applicable), 0(not met), 1(partially met) and 2(fully met) (Moher et al., 2000). Two authors (MH, CB), who were not engaged in further data extraction, performed this analysis during the full-text assessment phase of the review before the final inclusion of the selected studies. The study had to score an overall score of 1 for each item, with no individual criteria to score below 1 (provided that the item is applicable to the study). Thus, all the included studies had to partially meet the quality assessment criteria for each criteria listed on the table below (Nagpal et al., 2010b).

Table 2.1 Inclusion criteria applied to the reviewed articles				
Criteria	Score			
	N/A	0	1	2
1-Are the aims of the study clearly stated?		Aims not stated	Some aims stated clearly/ all aims stated unclearly /not in abstract	All aims clearly stated including in abstract
2-Are inclusion criteria specified?		No reference to inclusion criteria	Some inclusion criteria are given but not full	Full inclusion criteria are given
3- Are participants' characteristics given?	Criteria not applicable to paper, e.g., a study of notes, not human subjects	No reference to participants' characteristics	Some reference to participants' characteristics but not full	Participants' characteristics fully reported.
4- Ethical approval reference?		No reference to ethical approval	Ethical approval from the unnamed body	Appropriate ethical approval obtained with approving body named in the paper.
5-Are statistics appropriate?	Criteria not applicable to paper	No statistics/ inappropriate statistics	Some appropriate statistics but no justification is given	Statistics appropriate with justification for the use
6-Was effect size reported?	Criteria not applicable to paper	Effect size not reported.	Effect size reported for some but not all data	Effect size reported for all appropriate data
7-Are limitations acknowledged?		No limitations acknowledged	Some but not all limitations acknowledged	Limitations acknowledged
The scoring tool is modified from MOOSE (Stroup et al., JAMA 2000), QUOROM guidelines (Moher et al., 2000), in-house systematic review tool (Nagpal et al., 2010a) and (Weerakkody et al., 2013). The mean quality score per study is calculated by dividing the total score by the number of applicable criteria.				

2.2.4 Online Databases and utilising keywords:

On Dec 31, 2013, popular online databases were searched, such as Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)(1946 to present); Embase Classic+ Embase 1947 to 2013 Week 52; PsycINFO 1806 to December Week 4 2013; Cochrane Library - Database of Abstracts of Reviews of Effects (DARE) (Wiley) and Google Scholar . This search is supplemented by a manual cross-referencing of some of the key studies to increase the sensitivity of the search.

2.2.5 Search Strategy:

A semi-structured online search was made to look for key articles based on the question of the study. Titles, abstracts, and full texts of these papers were checked for keywords (Morbi et al., 2012b, Koetser et al., 2013) , from which basic search terms were derived. These terms then used and expanded by using medical subject headings (MeSH) to allow a broadening of the search terms and make them more reproducible. These headings aided in keeping the consistency of searching keywords across online databases such as Ovid Medline and Cochrane library. The search terms directly reflected the review question: "What is the frequency and type of healthcare errors in Interventional Radiology". These keywords were followed by US Dollar sign (\$) to be recognised by the search engine as MeSH terms.:

1) First- group terms:

From the first part of the question, "frequency of healthcare errors ", the following group of MeSH terms was retrieved.

Avoidable error\$,

Preventable errors\$,

Medical errors\$,

Healthcare error\$,

Adverse effect\$,

Malpractice\$,

Patient safety error\$,

Preoperative checklist\$,

Risk assessment\$,

Risk management\$.

2) Second-group terms:

Similarly, from the second part of the review question, "Interventional radiology\$", the following group of Mesh terms was retrieved:

Interventional Radiology Procedure\$

Interventional Radiology\$

Image-guided Intervention\$

Vascular Interventional Radiology\$

The Boolean terms 'OR' and 'AND' were used as follows: 'OR' was used to combine the "Mesh" terms within each group. While 'AND' was used to combine the "Mesh" terms of the two main groups with each other. In the search field of these databases, checkboxes "ab., kw., sh., ti., (which indicate abstract, keywords, subject headings and title of the papers respectively) were ticked to limit the search within this context.

2.2.6 The process of study selection:

A diagrammatic illustration of how studies were selected is summarised in Fig. 2-1. Two independent reviewers (FR and AA) conducted a systematic online search using the inclusion and the exclusion criteria. The search term group "medical errors" retrieved 898,888 citations, whereas the search term group "Interventional Radiology" resulted in 23,285 citations. Combination of these two groups with the Boolean character 'AND' retrieved 654 articles, from which only 487 articles were retained after removing duplicates, non- English publications, and studies not conducted on the human beings. The two reviewers then continued their independent selection of included articles, reviewing titles of the retrieved articles. From the potential 487 articles, only seven articles were relevant to be selected for full analysis. Only three articles met the inclusion criteria for the systematic review. Four articles were excluded

because of the following: Two articles were reviews, one article was about team adherence in which no healthcare- error reporting was made, and the other article studied vascular and endovascular procedures, which are not regarded as pure IR procedures (i.e., measuring healthcare errors in other disciplines).

Any disagreement in the process of selecting papers was resolved by a third assessor (MH). This work was published in Journal of Vascular and Interventional Radiology on 1st of November 2015 (Rawf et al., 2015).

2.2.1 Further search of the literature on 01/09/2021

A more recent search was performed on 01/09/2021 using the above-mentioned methodology.

Further five potential studies were found namely: Use of “Time-Out” checklist in interventional radiology procedures as a tool to enhance patient safety by Corso et al., (2014) (Corso et al., 2014); Patient-specific Rehearsal Before EVAR ; Influence on Technical and Nontechnical Operative Performance. A Randomized Controlled Trial by Desender et al., (2016) (Desender et al., 2016); Impact of Pre-procedure Time-Out Checklist for Computed Tomography–Guided Procedures on Workflow and Patient Safety by Dommaraju et al., (2019) (Dommaraju et al., 2019); Impact and Culture Change After the Implementation of a Preprocedural Checklist in an Interventional Radiology Department by Wong et al., (20219) (Wong et al., 2019) and Interventional radiology in gynaecology and obstetrics practice: Safety issues by Pinto et al., (2021) (Pinto et al., 2021).

None of the studies were included in the systematic review as they did not address the objectives of this systematic review. The studies by Corso et al, (2014), Dommaraju et al., (2019) and Wong et al., (2019) did not include measuring healthcare errors. Instead, they conducted surveys to study change in culture and team compliance with the proposed checklists. The study by Desender et al., (2016) studied EVAR procedures, which are procedures performed jointly by vascular surgery and IR teams. The other article by Pinto et al., (2021), was only a review article about the IR in gynaecology and Obstetrics practice which does not entails any data collection or observation, therefore was not deemed qualified to be included.

Although the above studies were not included in this systematic review, a short review of them will be given later in this chapter.

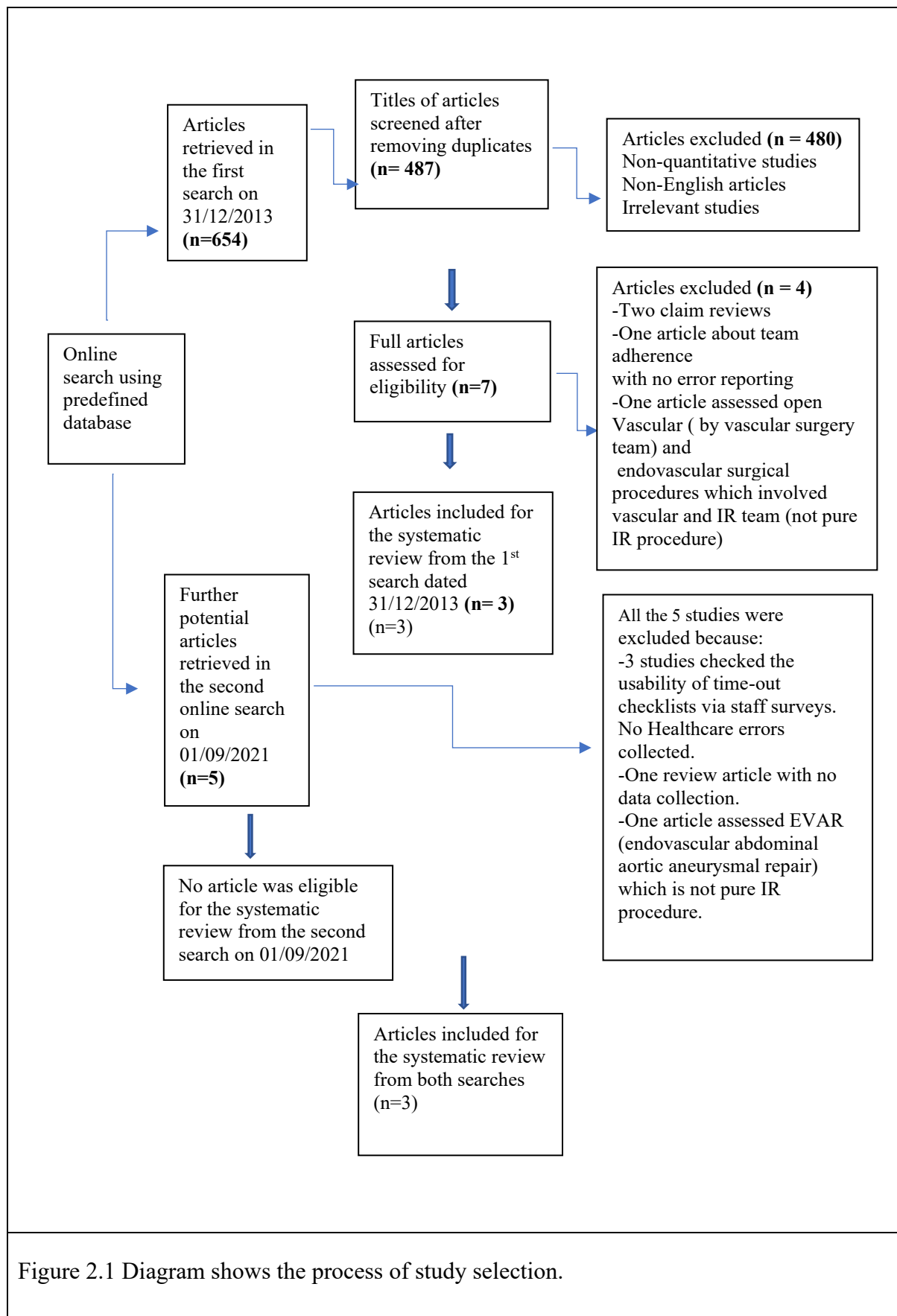


Figure 2.1 Diagram shows the process of study selection.

2.3 Results:

2.3.1 Studies included in from the first search of the literature on 31/12/2013.

From the first search dated 31/12/2013, only three studies were eligible to be included in this review which were: “Reducing Error and Improving Efficiency during Vascular Interventional Radiology: Implementation of a Preprocedural Team Rehearsal” by Morbi et al. (2012) (Morbi et al., 2012a), “A Checklist to Improve Patient Safety in Interventional Radiology” by Koetser et al., (2013) (Koetser et al., 2013), and “Impact on Patient Safety and Satisfaction of Implementation of an Outpatient Clinic in Interventional Radiology (IPSIPOLI-Study): A Quasi-Experimental Prospective Study” by Lutjeboer et al. (2015) (Lutjeboer et al., 2015). No systematic meta-analysis was feasible. The summaries of the included articles for a final review are listed in (Table 2.2).

2.3.2 Studies included from the second search of the literature on 01/09/2021.

A more recent search was performed on 01/09/2021 using the above-mentioned methodology.

Further five potential studies were found namely: Use of “Time-Out” checklist in interventional radiology procedures as a tool to enhance patient safety by Corso et al., (2014) (Corso et al., 2014); Patient-specific Rehearsal Before EVAR ; Influence on Technical and Nontechnical Operative Performance. A Randomized Controlled Trial by Desender et al., (2016) (Desender et al., 2016); Impact of Pre-procedure Time-Out Checklist for Computed Tomography–Guided Procedures on Workflow and Patient Safety by Dommaraju et al., (2019) (Dommaraju et al., 2019); Impact and Culture Change After the Implementation of a Preprocedural Checklist in an Interventional Radiology Department by Wong et al., (2021) (Wong et al., 2021) and Interventional radiology in gynaecology and obstetrics practice: Safety issues by Pinto et al., (2021) (Pinto et al., 2021).

None of the studies were included in the systematic review as they did not address the objectives of this systematic review. The studies by Corso et al, (2014), Dommaraju et al., (2019) and Wong et al., (2021) did not include measuring healthcare errors. Instead, they conducted surveys to study change in culture and team compliance with the proposed checklists. The study by Desender et al., (2016) studied EVAR procedures, which are

procedures performed jointly by vascular surgery and IR teams. The other article by Pinto et al., (2021), was only a review article about the IR in gynaecology and Obstetrics practice which does not entails any data collection or observation, therefore was not deemed qualified to be included.

Although the above studies were not included in this systematic review, a short review of them will be given later in this section.

2.3.3 Results from studies included in the systematic review.

2.3.4 Number of patients and case demographics

A total of 503 patients were studied. Morbi et al. studied 88 patients, Koetser et al. studied 195 patients, and Lutjeboer et al. studied 220 patients. A total of 259 and 244 patients were studied before and after an intervention, respectively. Morbi et al. (2012) did not collect data about patient demographics. In contrast, Koetser et al. (2013) and Lutjeboer et al. (2015) collected primary demographic data about the participated patients such as age and gender.

2.3.5 How were healthcare errors measured?

There was no standard technique to allow objective measurement of the healthcare errors across the retrieved studies. Instead, different methods used to estimate errors. One of these methods was making real-time ethnographic field notes by an observer during the intra-procedure period, which were later evaluated by different assessors to identify errors underpinning these events (Morbi et al., 2012b).

Another method of recording healthcare error was by using a structured observation form to report any deviation from a pre-set standard. These forms required no further analysis, as they were a ticking boxes process (Koetser et al., 2013, Lutjeboer et al., 2015). The process-deviation in these two studies defined as any deviation from a pre-set criterion for healthcare management or action.

Table 2.2 Summary of the reviewed papers (Statistical tests and Effect size points were not included as all the included studies met these criteria)

Study Title/ Author and year or publication	The 1st study: Reducing Error and Improving Efficiency during Vascular Interventional Radiology: Implementation of a Preprocedural Team Rehearsal. By Morbi et al. (2012).
Methods	An observational study (before and after intervention)
Country	The United Kingdom
Setting	Tertiary Hospital
Duration of the study	Ten weeks (5 weeks before intervention and five weeks after intervention).
Ethical committee approval	Sought and waived
Patient demographics	A total of 88 patients (55 before intervention and 33 after intervention) Inclusion criteria: 3.Setting: Tertiary Hospital 4.Country: The United Kingdom
Inclusion criteria:	1.Patients: Age: No data available Gender: No data available 2. Procedures: All VIR procedures that done under local anaesthesia or conscious sedation. Procedures performed during regular working hours.
Interventions	Preprocedural team rehearsal (PPTR), which characterised by: Involved all staff but led by IR consultant. Implemented immediately before the start of the IR procedures. All teams to pause until the rehearsal comes to an end. Focused on communication, teamwork, planning and availability of equipment
Outcomes	Both before and after PPTR, the following outcomes were measured: Potential failures and errors by using 22 -part classification system adapted from Catchpole et al. (Catchpole et al., 2006b). Rate of error per hour Procedure type, duration, and complexity The relation between procedure length and complexity and number of errors
Acknowledged limitations	Hawthorne effect Might not be generalised to different settings of IR
Risk of bias	Not mentioned
Conflict of interest	The authors clearly stated that no conflict of interest exists.

Study Title/ Author and year or publication	The 2nd study: A Checklist to Improve Patient Safety in Interventional Radiology. By Koetser et al., (2013)
Methods	An observational study (before and after intervention)
Country	The Netherlands
Setting	Tertiary referral centre
Duration of the study	Overall: 1 year Three weeks of pilot implementation Followed by a six month of provisional usage of a checklist by staff members, then followed by another period (no data on duration) of real-time observation post-checklist
Ethical committee approval	• Institutional review board (IRB) approval was waived, and informed consent was not obtained. This was in accordance with the Dutch Law • The study meets all requirements regarding HIPAA (Health Insurance Portability and Accountability Act) compliance
Patient demographics	Patients: Total number of patients: 195 (94 before intervention and 101 after intervention) Age (mean$\pm$ SD): 54.2 $\pm$ 18.7 (before intervention) 59.0 $\pm$ 17.5 (after intervention) Gender: male 44 (47 %) before intervention and 54 (54 %) after intervention
Inclusion criteria:	Patients who undergo vascular or non-vascular IR procedures.
Exclusion criteria	1. Patients: Patients undergoing neuro-interventional procedures Patients undergoing emergency procedures. 2. Procedures: All IR procedures except neuro-interventional and emergency ones
Interventions	A specific checklist for IR called RADiological Patient Safety System (RADPASS)
Outcomes	All process deviations Procedure postponement or cancellation
Acknowledged limitations	The authors acknowledged the effect of confounders such as time, case mix and Hawthorne effect.
Risk of bias	NA
Conflict of interest	The authors clearly stated that no conflict of interest exists.

Study Title/ Author and year or publication	The 3rd study: Impact on Patient Safety and Satisfaction of Implementation of an Outpatient Clinic in Interventional Radiology (IPSIPOLI-Study): A Quasi-Experimental Prospective Study Lutjeboer et al. (2015)
Methods	Control and experimental group study observation study (before and after intervention observation)
Country	The Netherlands
Setting	Tertiary referral centre
Duration of the study	Nine months (including 4-week duration of the intervention)
Ethical committee approval	The study was conducted in accordance with the ethical standards of the institutional review board (IRB) and with the 1964 Helsinki declaration and its later amendments. The IRB waived informed consent.
Patient demographics	Characteristic: Control group (n = 110) Age (mean $\pm$ SD) 56.6 $\pm$ 16.1 Sex (N) = Male 63, Female 47 Experimental group (n = 110) Age (mean $\pm$ SD) = 57.9 $\pm$ 14.7 Sex (N) = Male 77, Female 33
Inclusion criteria:	Patients: older than 16 years and mentally capable to fill out the Dutch questionnaire Procedures: Elective IR procedures
Exclusion criteria	Procedures: Peripheral vascular intervention , Endovascular aortic repair (EVAR), Cerebral interventions, Non-elective interventions, Change of drainage catheter or contrast injection through a drainage catheter, Combined surgical and IR procedure, Ultrasound-guided biopsy, or bone biopsy
Interventions	Outpatient IR clinic
Outcomes	Primary: measurement of the number of process deviations between the experimental group and the control group. Measured by using CIRSE- checklist (Lee et al., 2012) Secondary endpoint patient satisfaction was assessed between the two groups using a validated questionnaire based on the consumer quality index (CQI)- measurement instruments on outpatient care.
Acknowledged limitations	Yes. Hawthorne effect Regression-to-the-mean. Confounders: time-lapse after treatment Lack of generalisability because of exclusion of peripheral vascular procedures
Risk of bias	NA
Conflict of interest	The authors Jacob Lutjeboer, Mark Burgmans, Kaman Chung, Arian van Erkel stated that they have no conflict of interest.

2.3.6 Frequency of healthcare errors in retrieved studies.

A total of 3075 healthcare-errors were recorded throughout the IR pathway of care, of which 2497 before and 578 after an intervention. The breakdown of numbers of errors is summarised in Table 2.3 below. There was heterogeneity among the methodology used to record these healthcare errors. Therefore, any data synthesis might be biased and does not reflect the correct figure. Morbi et al. (2012) only studied 55 patients in the intraoperative period before the intervention, yet they recorded 2040 errors, while Koetser et al. (2013) and Lutjeboer et al. (2015) studied 94 and 110 patients in the pre- intervention phase of their studies and recorded 457 and 101 process deviations respectively.

Morbi et al. (2012) studied 55 patients in the preintervention phase of their study and recorded 1197 potential failures, which resulted in 2040 errors. However, after implementing their preprocedure team rehearsal intervention, they found 352 potential failures which resulted in a total of 477 errors.

Before implementation of their RADPASS checklist, Koetser et al. (2012) reported 190 deviations (healthcare errors) in the before-procedure stage versus 26 After implementation of the RADPASS with a mean percentage of 23 % and 3 % respectively ($P < 0.001$). Likewise, the total number of deviations during the procedure stage was 67 and 16 before and after using RADPASS respectively with a mean percentage 12 % and 2 % respectively ($P < 0.001$). Similarly, the total number of deviations in the after-procedure stage was 157 and 52 before and after RADPASS respectively with a mean percentage 39 % and 13 % respectively ($P < 0.001$).

Lutjeboer et al. (2015) demonstrated a significant decrease in the number of the total pre-procedural planning and sign in healthcare errors from 43 to 7. The number of healthcare errors (process deviations) per patient was significantly smaller in the experimental group (those who received the IR clinic intervention) 0.06 compared to the control group (who did not receive the IR clinic intervention) 0.39, ($p < 0.001$).

Table 2.3 Total number of healthcare errors (HE) within the reviewed literature

Study	Total number of HE	Number of HE in pre-intervention	Number of HE in post-intervention
Morbi et al. (2012)	2517	2040	477
Koetser et al. (2012)	508	414	94
Lutjeboer et al. (2015)	50	43	7
Total	3075	2497	578

2.3.7 The landscape of healthcare errors within the retrieved literature

Although there is some heterogeneity among the reviewed studies in their definition of healthcare errors and their methodology to record them, however, it was evident that non-technical errors were the most encountered ones. Morbi et al. (2012), in the preintervention phase, found that 65.4% of healthcare errors were non-technical and related to human factors and management inefficiency as follows: Planning errors (19.7%), staff absence (16.2%), equipment unavailability (12.2%), communication errors (11.2%), and lack of safety consciousness (6.1%). It is worthwhile that Morbi et al. observed and recorded minute by minute any perceivable omission or error in executing a task during the intra-procedure phase of IR pathway.

Koetser et al. and Lutjeboer et al. both studied the preprocedural phase and the intra-phase. However, it is not possible to group all the errors into categories.

2.3.8 The severity of healthcare errors

Although there is some variability regarding reporting of severity of healthcare errors across the reviewed studies, most of these errors were minor to moderate. However, 0.75 % of these errors or deviations were thought to be significant and have the potential to harm patients (Lutjeboer et al., 2015, Morbi et al., 2012b). Procedure postponement estimated to range from 6-15.5 % before the intervention, which decreased to 0- 2.7% after the intervention (Koetser et al., 2013) and (Lutjeboer et al., 2015).

2.3.9 Types of Intervention used in the selected studies:

Different intervention methods used to reduce healthcare errors. These were verbal pre-procedural team rehearsal, interventional radiology specific checklist (RADPASS), and implementation of a pre-procedure IR clinic used by (Morbi et al., 2012b, Koetser et al., 2013) and (Lutjeboer et al., 2015) respectively. All these interventions have resulted in reduction of healthcare- errors. They also resulted in the improvement of both patient and staff satisfaction.

There is not enough data to suggest a specific time within the IR pathway of care in which most of the errors took place. The reason is that the selected studies were different in terms of their methods, and they did not specifically look at this outcome. However, there was no specific time of intraprocedural phase where failures tend to accumulate as pointed out by Morbi et al. (2012). In contrary to this, the failures, when the procedure was split into time periods, were occurring in every decile of the procedures (Morbi et al.).

2.4 Discussion:

2.4.1 The main aim of the reviewed articles

The common aims of the reviewed literature are firstly, to improve patient safety and increase the standard of care by reducing healthcare errors, and secondly, to increase staff and patient satisfaction.

However, there was heterogeneity among the reviewed literature as to how to accomplish these aims. Some researchers tried to evaluate the magnitude of healthcare errors and what is their nature in the intra-operative phase of IR (Morbi et al., 2012b). On the other hand, other investigators studied a more extended period of IR pathway, including immediate pre-procedure, intra-procedure, and immediate post-procedure phases (Koetser et al., 2013, Lutjeboer et al., 2015). Regardless of their methods, all the researchers implemented measures to reduce these healthcare errors.

Patient safety and associated factors in healthcare have recently witnessed a growing interest in several governmental and academic schemes (Burke, 2003). The body of literature, however, remains limited, especially in specialities such as IR. In this systematic review, the quantity and the nature of the studies tackling healthcare errors have been explored. Also, the landscape of these errors and their nature have been assessed. The methodologies used to quantify these errors and interventions used to reduce them have been highlighted.

2.4.2 What is the main highlight of this systematic review?

This systematic literature review emphasises that there is a scarcity of studies within the literature which evaluate the frequency and the nature of healthcare errors across the IR pathway. Only three studies were found to deal with this issue despite two systematic searches of the online database, almost 8 years apart, on 31/12/2013 and 01/09/2021 respectively.

Patient safety is a measure or a domain by which quality of a health organisation is assessed. Healthcare errors have a direct link to patient safety as stressed in the report of Institute of Medicine of the United States of America (Institute of Medicine Committee on Quality of Health Care, 2000).

Although the notion of improving patient safety is old, but not until recently has implementing objective ways of measuring its domains been performed. In two large -scale studies conducted in the USA in the late 1980s, the rate of adverse events in hospitalised patients was measured and a breakdown of different component of these adverse events and their precursors were made (Brennan et al., 1991, Leape et al., 1991).

2.4.3 Types of studies which are included in this review.

The three studies included in this review are all before-after intervention observational studies. No Randomised Control Trial_ RCT is found across the literature to study healthcare errors and their characteristics in IR.

As previously pointed to in the methodology section of this review, RCTs are difficult to implement in specialties such as IR. It is difficult to randomise patients into two distinct groups, for example, treatment/ no treatment groups or randomising procedures to those with WHO checklist to those with no WHO checklist.

The before-and- after-intervention studies involve studying two independent cohort groups in two different time scale. It is usually the case that these two cohorts are randomly and consecutively collected by attending researchers who observe these cases.

No systematic metanalysis could be performed because of the low number of available studies. Furthermore, there was a heterogeneity among the data in terms of outcome measures and methodologies used to quantify these outcomes. For example, Morbi et al. focused on quantifying medical errors during the intraoperative period, while Koetser et al. studied the pre-procedure planning, intraoperative and immediate post-procedure period. Lutjeboer divided the operative period into planning and signing period. Morbi et al. used repetitive sample measure, thereby continuously measure for new healthcare error occurred during the intraoperative period by making field notes of what has perceived to constitute a failure inside the operative room. Different researchers later analysed these field notes to retrieve any failure and types of errors that were responsible for these failures. However, in the latter two studies by Koetser et al. and Lutjeboer et al., the researchers used some proforma to compare the actual process to an ideal one.

All three articles were a mixture of qualitative and quantitative studies. The qualitative part of these studies utilised questionnaires filled by healthcare staff to aid in the betterment of

interventions used to reduce healthcare errors. Morbi et al. (2012) used a questionnaire filled by other staff from operating IR team from nurses to consultants to evaluate the WHO checklist and how to change it in a way to be more effective in reducing most occurring preventable failures. Also, they held a round table meeting to discuss the preintervention results and to reach a consensus about an intervention to tackle these errors.

Koetser et al. (2013) also used an expert panel opinion to refine their RADPASS checklist before implementing it. Later, they asked the participating operating team members to rate the checklist and to add any comment which might aid in strengthening further their invented checklist. Similarly, Lutjeboer et al. (2015) in their study, asked all the participant patients in the experimental group to answer all questions voluntarily in a questionnaire in which the patients were allowed to rate their experience.

On the other hand, the quantitative part of these studies included measuring the rate and nature of healthcare errors and process deviation throughout distinct phases of IR pathway of care. Morbi et al. (2012) used a real-time observation to evaluate the intraoperative IR procedure, including minute to minute interaction of different team members among themselves and with the patients and their surrounding environment, including equipment preparation and usage. However, Koetser et al. and Lutjeboer et al. compared the observed process to gold standard situations where any process that was deviated from these gold standards was regarded as a failure and deviation.

Not only is patient safety evaluated using different methodologies in IR but also in other disciplines. Patient safety has been studied via different type of research methodologies over the last few decades in different healthcare specialities such as medicine, surgery, anaesthesiology, or even general practice domains (Institute of Medicine Committee on Quality of Health Care, 2000).

2.4.1 How healthcare were errors measured?

There was no standard technique to allow objective measurement of the healthcare errors across the retrieved studies. Instead, different methods used to estimate errors. One of these methods was making real-time ethnographic field notes by an observer during the intra-procedure period, which were later evaluated by different assessors to identify errors underpinning these events (Morbi et al., 2012b). This process is considered a longitudinal

repeated measurement of the same process, which is the patient's journey throughout the intraoperative stage of IR procedures to give an overview of the IR intraoperative period.

Another method of recording healthcare error was by using a structured observation form to report any deviation from a pre-set standard. These forms required no further analysis, as they were a ticking boxes process (Koetser et al., 2013, Lutjeboer et al., 2015). The process-deviation in these two studies defined as any deviation from a pre-set criterion for healthcare management or an action. Apparently, Koetser et al. (2013) used a checklist_ a gold standard form, against which the process of patient management was tested.

On the other hand, Lutjeboer et al. (2015) used a checklist adapted from the IR patient safety checklist of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) to record any process deviation. The focus of the latter two studies were just to report specific items on their form, and to see if there is any deviation or not from the standard checks. These observations were performed by independent observers attended the IR procedures.

However, these methods are not considered longitudinal repeated measures; hence, information about some healthcare errors cannot be obtained. Among these errors which cannot be revealed by these methods are communication errors, safety checks arose after the initial preprocedural check (for example, failure to notice a blood pool immediately on the ground by the circulating nurse which might represent a safety hazard for staff).

2.4.2 Frequency of Healthcare errors?

As highlighted from the reviewed studies, the frequency of healthcare errors across IR is high, and it is comparable to surgery. In a systematic review in surgery, Nagpal et al. (2010) evaluated the process of information and communication transfer (ICT) throughout the entire surgical pathway of care. They concluded that communication failures are common (Nagpal et al., 2010b). In another review in surgery by Weerakkody et al. (2013) on the frequency of equipment related errors in operative theatre, they found that the median total errors per surgical operation were 15.5 [interquartile range 2.0-17.8]. Of this total, errors related to equipment were considerable, with a median of 23.5% [IQR 15.0%–34.1]. Furthermore, they noticed that those surgical techniques that relied more on modern technology have more equipment-related errors (Weerakkody et al., 2013).

2.4.3 What is the nature of medical errors in IR?

This literature review showed that non-technical preventable failures are shared across the pre-procedure, intra-procedure, and post-procedure phase of the IR. This finding is in line with the literature in surgery. In a study, Christian et al., (2006) studied system factors that affect the safety of patients in surgical theatre in a prospective combined qualitative-quantitative study. Failure in communication and management of workload and tasks were found to be the most common factors to impact teamwork and patient safety (Christian et al., 2006).

2.4.4 IR Pathway of care:

The three studies included in this review are valuable in assessing the errors occurring during the distinct stages of the IR care pathway. However, none of which covered the entire patient's journey, these studies highlighted the need for a comprehensive analysis of pre-, intra-, and post-procedure care in IR.

2.4.5 Heterogeneity in the results of the retrieved studies

In addition to other points, there is apparent heterogeneity in the results of the retrieved studies. For instance, Morbi et al., which studied the intra-procedure phase, reported 2040 errors in 55 procedures evaluated in the preintervention phase. The setting where the study was conducted is a tertiary referral centre that is equipped with all the necessary infrastructures; from experienced consultant interventional radiologists to very well-trained medical staff forming one of the best vascular IR centres in the UK. In contrast, Koetser et al. only found a total of 67 errors during a similar phase in 94 procedures. Several reasons might explain this heterogeneity. First, the sensitivity level of recording the medical errors was different. For instance, any repetition of any request by the IR consultant to the CN was considered an error by Morbi et al. Another reason is, the difference in the number and type of predefined error items listed in each study. The reason is there were no comparable items in the list of the errors across the two studies. Also, Koetser et al. (2013) limited their error recording to immediate pre-procedure checklists and post-procedure staff actions, without observing the whole intra-procedure time. The intraoperative period is considered a critical period for medical errors to occur not only because it is a highly stressful time but also because it contains the most interaction among the operating team members (Christian et al., 2006, Catchpole et al., 2006a).

2.4.1 Was the WHO checklist being executed correctly?

All the studies performed different checklists routinely before and after the intervention. Morbi et al. performed the WHO checklist, whereas Lutjeboer et al. used CIRSE IR patient safety checklist and. It is not clear which checklist was in place in the study by Koetser et al. (2013).

It is showed in surgery that checklists or structured briefings or debriefings can reduce safety errors and enhance patient safety. This is thought to contribute to a positive outcome by improving communication among staff and decrease the chance of memory lapse. In a study in a tertiary Canadian hospital, a structured debriefing among surgeons and nurses in the preoperative stage of 172 surgical operations resulted in a significant decrease in communication errors. The mean [SD] number of communication error per procedure decreased from 3.95 (3.20) to 1.31 (1.53) before and after the intervention respectively ($P < .001$) (Lingard et al., 2008).

In another benchmark study in general surgery, implementation of a 19-item checklist is resulted in a decline of the rate of death from 1.5% to 0.8% afterward ($P = 0.003$). Likewise, the rate of inpatient complications reduced from 11.0% before the checklist to 7.0% after introduction of the checklist ($P < 0.001$) (Haynes et al., 2009). The outcome of this study was the introduction of the who checklist which has gained a wide acceptance among hospitals across the globe and even made compulsory in some countries. However, unlike in surgery, it is thought generally that the WHO checklist does not enhance information sharing or equipment check to accomplish IR procedures (Morbi et al., 2012b). The other two studies did not provide data to allow conclusion regarding the usefulness of a checklist. Therefore, none of the reviewed papers determine presence or absence of a correlation between the healthcare errors and the use of a checklist.

2.4.2 Correlation between the healthcare errors and clinical outcome (i.e., patient safety)

There is no data within the reviewed studies to highlight presence or absence of any correlation between the healthcare errors and the clinical outcome.

Morbi et al. (2012) admitted that, despite many healthcare errors and potential failures, all the observed procedures were performed successfully without any complication, allowing for few major failures, none of which led to complication. However, it was not possible to determine whether this failure could lead a complication in the future as the duration of observation was limited to the intraoperative period (Morbi et al., 2012). Koetser et al., (2013) did not encounter major adverse event during their observations apart from some process deviations which did not lead to any patient's harm. Likewise, Lutjeboer et al. (2015) encountered no major complication or major safety issues occurred to the patients.

Therefore, based on the findings of the reviewed studies, correlation between the healthcare errors and clinical outcome could not be determined. However, more research is needed to establish this among which would be looking further beyond the discharge station from the IR department.

2.4.3 Quantity of studies dealing with healthcare errors in IR versus Surgery

The number of studies which highlight healthcare error in IR are minimal compared to surgery. In a systematic review in general surgery, 28 quantitative studies were found measuring the frequency and the type of equipment related errors in the operating theatre (Weerakkody et al., 2013). In another review in surgery, 38 quantitative studies, were explicitly found evaluating the process of information and communication transfer (ICT) throughout the entire surgical pathway of care (Nagpal et al., 2010b). The reason for limited studies in IR dealing with healthcare error might be because IR is a newer subspecialty compared to surgery. Therefore, the amount of literature is realistically fewer than surgery in terms of quantity. Not only this, but surgery includes many other subspecialties such as gastrointestinal surgery, paediatrics surgery, ENT surgery, uro-surgery, vascular surgery, and many other surgical subspecialties.

2.4.4 Recent retrieved studies looking into checklist process and associated safety issues.

Three studies were found in which the authors stressed on the role of checklists in enhancing patient safety.

Corso et al., (2014) evaluated the practicality and effectiveness of a safety checklist (SC) called “Time-Out” in IR procedures to improve patient safety. A 23-item checklist, which was shortened to 20 items later, was modified from the WHO checklist for IR and the CIRSE checklist for radiology intervention. “Time-Out” SC used after 1 and 3 months on 100 out of 112 procedures and 90 out of 101 procedures respectively (approximately 89.3% of all the procedures in each of these two dates) (Corso et al., 2014).

The completion rate rose from 64.5% at 1 month to 84.4% at 3 months, allowing for only 3 omissions out of 90 (one omission related to anticoagulation medication suspension, one related to prophylaxis against contrast-induced nephropathy and one related to side of a procedure). These omissions were 13 out of 100 cases (12 Anticoagulation therapies/prophylaxis and 1 site/side) at 1 month from starting the SC. Four adverse events were recorded in the IR department prior to the commencement of the study which had decreased to no adverse event after 12 months of the study (Corso et al., 2014).

Dommaraju et al., (2019) studied the impact of Pre-procedure Time-Out Checklist for Computed Tomography–Guided Procedures on Workflow and Patient Safety. They observed.

Pre-procedure timeout in 100 CT-guided procedures (biopsies, drainages, ablations) from January 2018 to May 2018 followed by an anonymous survey of 302 radiology team members involved in these procedures about. There was a 100% compliance rate to the pre-procedure time out which lasted about 60 seconds median duration (interquartile range, 60–71 seconds).

The preprocedure time-out checklist was scripted in 52 cases (52/100, 52%) while they were verbal in the rest of the cases. Omissions from the preprocedural time-out were identified in 40 cases (40/100, 40%) and were much less frequent when scripted checklist was used (10/52 [19%] vs 30/48 [63%], $P < 0.005$) (Dommaraju et al., 2019).

Most of the safety issues raised during the time-out period were minor (14%) which were fixed in less than 30 seconds each. 3 out of 100 procedures were delayed by 3 minutes, while only one case (1/100, 1%) was postponed due to abnormal coagulation parameters discovered during the time-out.

In addition to the rate of healthcare errors or omissions in the observed cases, Corso et al., (2014) and Dommaraju et al., (2019) used anonymous surveys distributed to the managing IR team to assess the perception of the staff towards the developed checklists. In the former study

by Corso et al., (2014) anonymous surveys passed to 27 members of the IR team (composed of 10 nurses, 14 radiographers and 3 IR physicians), of which 17 completed the survey (63%). Acceptable ease of use and satisfaction rate was achieved among the staff with 73.3% and 73.4 % of them believed that the SC was “useful” and “safer for patients” respectively. Although 46.6% of the IR team saw the SC as another bureaucratic burden, 73.2% of them thought they were not burden by too much or unnecessary information and that the SC is certainly not redundant (86.6%) (Corso et al., 2014).

On the other hand, Dommaraju et al., (2019) sent out a total of 302 surveys, from which they received 137 (45%) responses from 54 radiologists (39%), 55 technologists (40%), and 28 nurses (20%). Forty-eight respondents (48/137, 35%) encountered a procedure that was.

cancelled or delayed because of information identified during time-out. Ninety-six percent (131/137) of respondents believed that time-out improves teamwork, 98% (134/137) of the surveyed staff stated that the time-out enhances communication between the team members, and 93% (127/137) stated that it identifies and resolves problems and ambiguities. They concluded that scripted preprocedure time-out is better for CT-guided procedures which takes approximately 60 seconds to complete and yet detects safety issues in 18% of cases.

2.4.5 Limitations of the included studies:

There are some limitations in the reviewed studies, among which are coverage of the IR journey and heterogeneity of methodology and outcome measures. These limitations are the Hawthorne effect, the observer bias, and the selection bias, which will be highlighted briefly.

The Hawthorne effect is when the observed members of staff behave differently, usually positively when being observed (McCarney et al., 2007). Across the reviewed studies, the authors have claimed that the Hawthorne effect might be present. Observing the operating team might make them feel that they have been singled out, so they changed their normal behaviour to a more favourable one. This effect was mitigated by allowing the observers to spend some time with the observed team to alleviate this effect. In the patient's survey performed by Lutjeboer et al., (2015), it should be noticed that having an extra time with those patients is no doubt will allow the IR consultant to prepare and plan their procedures based on more clinical information retrieved directly from patients besides the opportunity to examine them clinically.

However, this could also have some elements of the Hawthorne effect, as the patients feel more important by being given a different station of care by another consultant doctor before their procedure, hence the higher satisfaction rate.

The detection- bias, on the other hand, continues to emerge in the observational studies. Human beings might have a natural tendency to perceive things differently. In all the retrieved studies, there was only a single observer who recorded healthcare errors. Therefore, these observers might have over or under-reported some errors. Two observers could differently analyse the interaction among the operating-team. (Moher et al., 2000).

Similarly, selection bias is inherent in any non-RCT observational studies which include, for instance, choosing more straightforward cases for the post-intervention phase, which skews the results. The researchers made attempts to minimise this. For example, in both studies performed by Morbi et al. (2012) and Koetser et al., (2013) more complicated cases were studied in the postintervention phase which might show that even in the presence of more challenging procedures, their proposed interventions were capable of achieving the required purpose.

2.5 The clinical implication of this systematic review:

This systematic review emphasises and offers the opportunity for interventional radiologists to invest coordinated time and effort in reporting medical errors that ensue from their daily practice. This reporting should not be focused on one single phase of the pathway of care (for instance, the intraoperative period) out of the other phases, because there is evidence that medical misconducts could quickly happen across all of the stages of multi-destination care reasonably equally, and could have a comparable potential (as the intraoperative errors) to harm the patient (Nagpal et al., 2010b)

2.6 Conclusion

This systematic review presents a distinct lack of research concerned with healthcare errors and patient safety outcomes in the IR. It is of paramount importance to recognise this gap and to investigate further the healthcare errors across the IR pathway of care. It is also vital to have a standardised objective tool to measure these errors to guide future strategies to decrease these errors to ensure a safer IR practice as well as safer patient's experience.

Chapter Three outlining the current IR pathway of care: An observational study.

3.1 Brief Introduction

3.1.1 A brief historical background on field-note- based observational methods.

There are many ways human factors in healthcare settings is assessed to study interactions among staff themselves and study pathways of care (Catchpole et al., 2006a, ALBAYETI et al., 2011, Gradinscak et al., 2004). Among these methods is making filed notes while observing live procedures or interaction when the observer is physically present in the scene and documents notes on behaviours, interactions without having any impact on the variables or the outcome. This method has rooted back in days of Charles Darwin published in 1835. (Schaller and Heinrich, 2011).

3.1.2 Field-note-based observational methods in surgery.

Fieldnote observation has been used in healthcare studies, including assessing communication, teamwork, or failures in operation theatres. They categorised communication errors under these domains: content (missing information), audience (essential personnel not addressed), purpose (problems not resolved) and occasion (poor timing) (Lingard L, 2004).

Similarly, Catchpole et al. (2008) used an observational method to study the relationship between surgical, anaesthetic, and nursing teamwork skills and technical outcomes in general and vascular surgery. They observed technical and technical errors and found a relationship between these errors and duration of surgical operations (Catchpole et al., 2008).

3.1.3 Fieldnote-based observational methods in IR

Although they are not as many as in surgery, as was outlined in the introduction chapter and chapter two (systematic review) of. is thesis, observational field-note-based studies have been used in IR by Morbi et al. (2012) who studied the frequency and type of errors in the vascular IR. Based on their observation they designed an intervention to reduce these errors which was team rehearsal before the procedure. They observed 88 IR procedures in total by using field notes which were analysed and categorised later (Morbi et al., 2012).

3.1.4 Interventional Radiology: a multi-station pathway

The Interventional Radiology pathway can be a complicated pathway where patients are referred from different wards or as a day case. Many of the procedures that are scheduled are booked as the result of a series of consultations.

For example, an EVAR (Endovascular Abdominal Aortic Aneurysmal repair) procedure occurs after several consultations. This procedure is a joint procedure performed by the vascular and the IR team. There are several stations, but for illustrative purposes, the following pathway is followed: These patients are referred from vascular surgeons to the vascular multidisciplinary team (MDT) meeting. Those patients are first checked in the vascular clinic by a vascular surgeon who then send them for the required pre-operative laboratory screening including but not limited to blood clotting screening such as PT and INR. After discussion at the vascular MDT meeting, plans are decided upon jointly by the IR and the Vascular surgery team. Then the patients are booked by an appointment team after confirming the availability of beds in HDU (High Dependency Unit) and arrangement of other managerial preparation. Meanwhile, the required equipment is ordered from the supplier through the management team, vascular and IR chief nurse. If an anaesthetist is required, then another consultation is needed in the anaesthetic clinic where the anaesthetist's pre-operative assessment is undertaken.

3.2 Aim of the study:

The aim of this pilot study is to map out the IR pathway of care to find a feasible start and end point of the pathway for the sake of this study. Also, to understand the landscape of healthcare-errors throughout the IR-pathway.

3.3 Methods

3.3.1 Ethical approval

Application for Ethical approval is made online to the medical research council (MRC) and the local ethical committee at Charing Cross Hospital/ Imperial College London. The study was exempted from Ethical approval because it was considered a quality improvement project in the IR specialism, in which no recognisable data neither of the observed staffs nor the patients will be collected.

3.3.2 The IR- pathway

Several informal focus group meetings were held with the IR and the vascular Surgery experts to map out the IR pathway which can be seen in (Figure 3.1). The journey of patients undergoing IR procedures could start from one of shown three starting points, namely: the vascular ward, other wards or from the IR department in day cases.

However, after observing several patients from the vascular ward in the induction period, it has been found that it is non-pragmatic to define the starting point of the IR pathway from the referring vascular ward or the other wards. It was deemed a time consuming and not efficient to observe the patients from these points, as on many occasions the patients were waiting to be clerked for their procedures in the vascular ward for a long period of time. This is not to mention the preparation time by the vascular ward nurses and the time needed to send blood for clotting and other parameters tests before sending down to the IR department.

Therefore, it was decided by the research team to start the observation point from the IR ward, as it was deemed more realistic and manageable to start the journey of these patients as both inpatients and outpatients could be observed and included in the data analysis.

All communication that took place with the patients and among the healthcare staff were noted including procedure consent, handover, clerking and any other interactions in the way. I was shadowing the patients throughout their whole IR journey from the preoperative preparation at the IR ward to the intraoperative IR period back to the postoperative IR ward to the point where either the patient was sent back to the referred ward or back to home in day cases. This shadowing was to gain a comprehensive insight into nature and the frequency of healthcare errors that might happen in real-time and to make sure all the interactions between staff themselves or with the patients were observed throughout this journey.

3.3.3 Setting

This study was performed in the IR department of St Mary's Hospital under Imperial College London Healthcare NHS Trusts which is a tertiary vascular centre in the UK.

3.3.4 Induction Period

Initially, the author of this thesis (FR) received four weeks of training in the observation of intraoperative IR procedures. This induction training was given by a senior IR consultant

(MH), who is an academic and experienced Interventional radiologist with more than 10 years of experience in the field of the IR. The training was composed of one-to-one coaching on how to observe the intraoperative team and the complex interaction among them throughout the IR procedures and what possible contributing error can lead to a perceived potential failure. Also, the observer received basic training on the steps of the commonly occurring IR procedures and some basic technical theories of these procedures. During this training period, no data was collected.

Not only was this training period crucial in how to observe complex intraoperative team interaction, from a human factor perspective, but also it was essential to reduce the Hawthorne effect. The Hawthorne ef

fect, which is defined as a change in the behaviour of the observed staffs, usually positively, when being observed not because of their original attitude (Landsberger 1958a). Furthermore, this daily intraoperative attendance with the IR team provided me with the opportunity to build a good rapport with all the IR team members and build a good relationship with managing healthcare staff, many of whom were expert. This interaction allowed learning about the IR procedures and existing pathway of care and issues of patient safety and healthcare errors.

After this month of training, 5 IR pathways were observed with an IR consultant. The finding of these were analysed separately.

3.3.5 Data collection and analysis

After the induction period and the simple comparative study, 58 consecutive IR procedures were observed by a single trained observer (FR) from the point of admission to that of discharge from the IR department. These procedures were elective, urgent and ITU procedures. Minute-by-minute observation of the IR pathways was made and recorded by using ethnographic field notes which were descriptive textual notes about the pathway logs which then categorised by two senior consultants independent to each other. These two senior consultants were a vascular surgeon (CB) and an IR consultant (MH), both with more than 10 years of experience in the field of vascular surgery and the IR respectively and published many studies about patient safety in vascular and IR. The assessors used modified healthcare error classification table to categorise each textual events recorded by the observer into different categories (Table 3.1). This methodology was used previously by other researchers in both vascular Surgery and IR

(ALBAYETI et al., 2011, Morbi et al., 2012), both of which were initially adapted from methods used by Catchpole et al., (2006) (Catchpole et al., 2006a).

Complexity of cases were decided initially by the performing IR consultant which then validated by the assessors.

For each event, the delay in minutes were recorded by the observer. However, the assessors graded the delay into 5 categories namely: 0 (delay less than 1 minute), 1 (1-5 minutes), 2 (5-30 minutes), 3 (more than 30 minutes) and 4 if the procedure was deferred into another time of the same day or another day.

For the degree of harm to the patients, a scoring classification from 0 to 4 was used. 0 score was given for a failure if there was not resulted in harm or delay and did not require any further intervention, 1 for mild harm required simple measures such as monitoring or pain killers, 2 for moderate harm which requires pharmacologic intervention (such as antibiotic) or increased length of stay, 3 for severe harm (including life threatening) that required or could require further escalation of care such as further intervention or hospital admission or and 4 if the harm was not known. These classifications were modified from previous studies in surgery and IR (Dindo et al., 2004, Khalilzadeh et al., 2017) and (Morbi et al., 2012).

The main steps and methodology used for data collection and analysis can be seen in a diagrammatic flow chart Figure 3.2.

3.3.6 Inclusion criteria:

Procedures:

- Any image-guided intervention procedures, whether vascular or non-vascular, were included in this pilot study.
- Elective, semi-elective or urgent or ITU procedures were included in this pilot study.
- All IR procedures, whether performed under local or general anaesthesia, were included.

Patients:

- All Adult patients aged 18 or more were included in the study.

3.3.7 Exclusion criteria:

Procedures:

Endovascular Repair of Abdominal Aortic Aneurysm (EVAR) was excluded from this study. This procedure is performed jointly by the vascular and the IR team. This exclusion serves multiple purposes including ensuring a focused study of pure IR challenges and characteristics, retaining a homogenous data, and eliminating confounders unique to EVAR. This ultimately strengthens the analysis and maintains feasibility and practicality of the study.

Patients:

- Paediatrics patients, as the hospital is not a paediatrics hospital and there was no paediatric procedure performed throughout the period of the data collection.

3.3.8 Outcome

- Defining the IR Pathway.
- Frequency and types of medical errors in the entire IR pathway.
- Correlation between different variables.

3.4 Definition of minor and major healthcare errors

It is not usually possible to define what could constitute a minor or a significant error, especially when trying to estimate behaviours, interaction or teamwork which are non-quantitative actions or behaviours. (Helmreich et al.) Kline et al. (1999). Major failures were described as events that came close to an incident or accident (Kline et al., 1999). Minor failures are events where lead to no adverse effect or cause no or a short pause to the procedures. Examples of minor failures can be found in (Table 3.2).

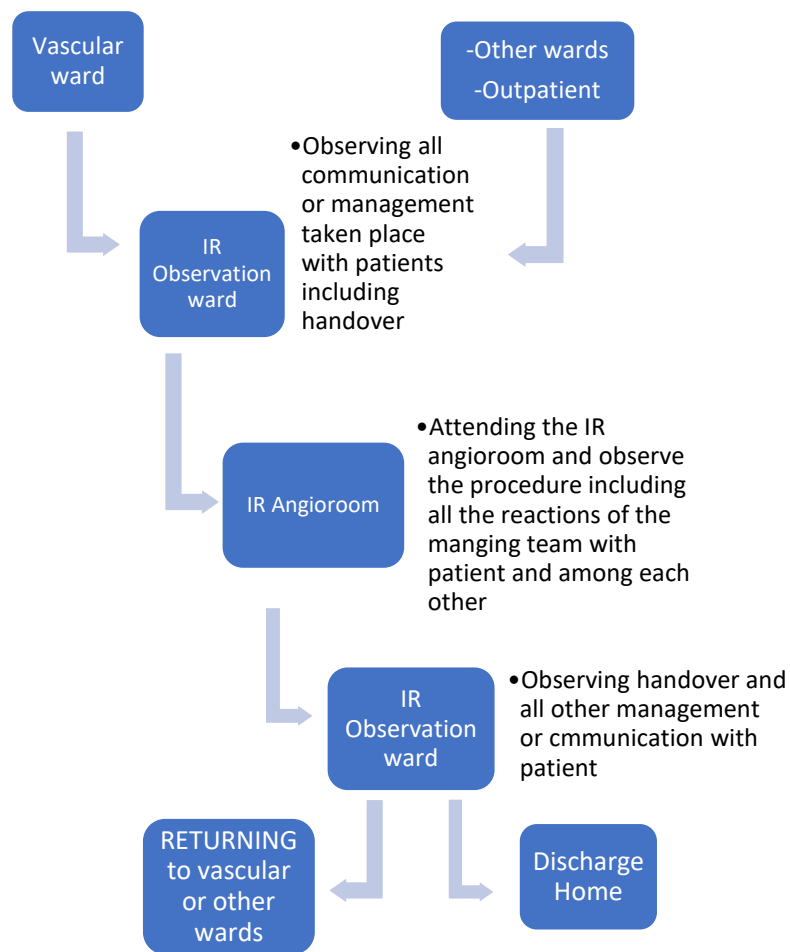


Figure 3.1 The mapped-out IR pathway for this pilot study (from a focus group meeting)

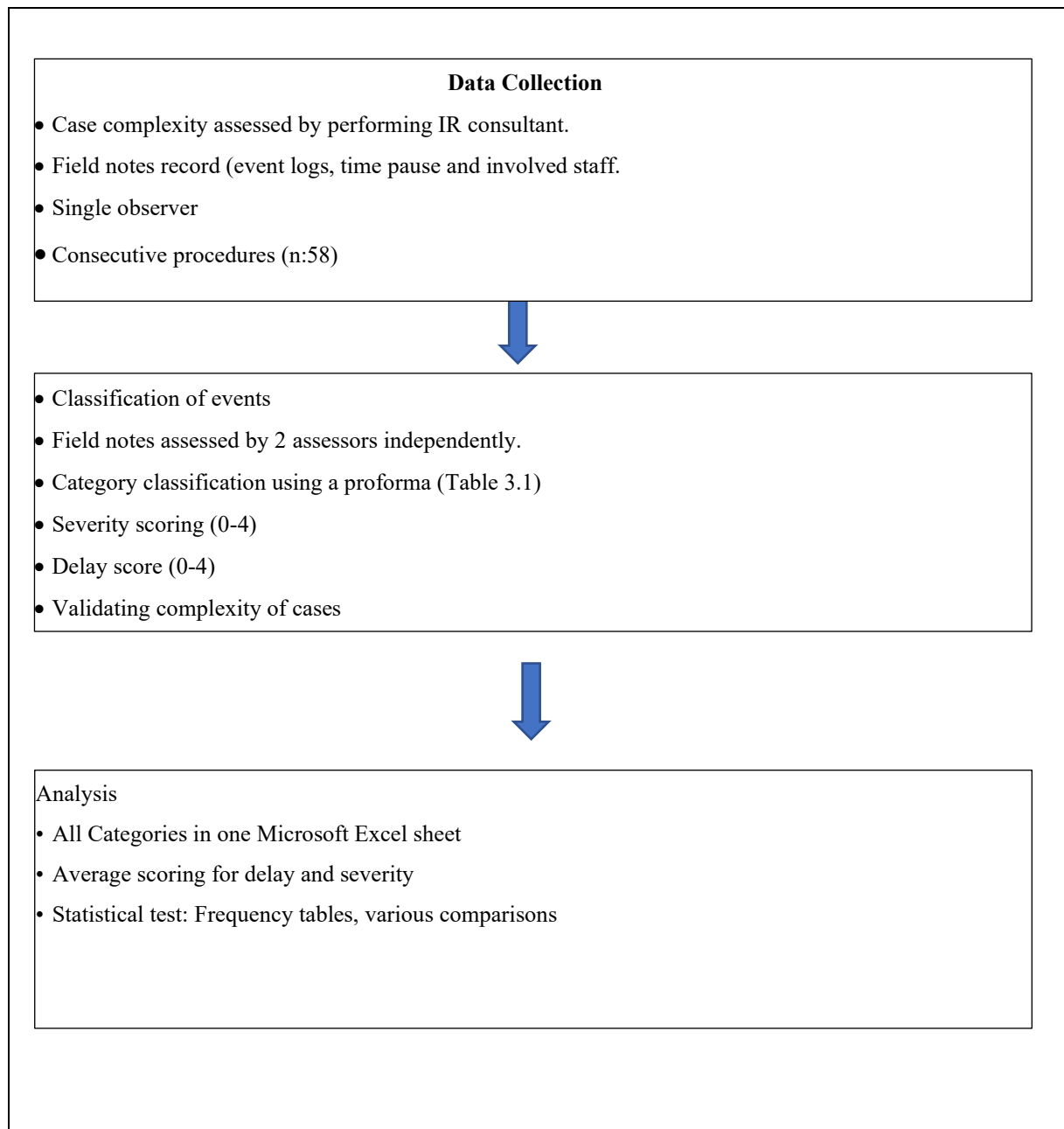


Figure 3.2 Shows the methodology of data collection and analysis.

Table 3.1 Healthcare error Classification System with Examples of Each Error Type

Healthcare error	Description
Absence	Lack of personnel when required (e.g., CN is absent when the IR team requests a stent to be opened).
Communication error	Errors in communication and information transfer (e.g., IR requests guidewire but CN not sure which size to bring because IR initially nonspecific, prompting staff)
Equipment unavailability	Equipment required is not available for use when requested. (e.g., specific stent-graft size requested by IR is not immediately available)
Workspace management error	Errors in the organisation of workspace and equipment (e.g., infusion lines become caught on fluoroscopic C-arm)
Equipment configuration error	Failure to prepare or operate equipment appropriately (e.g., stent-graft catheter not flushed before deployment)
Equipment failure	Intraoperative equipment failure (e.g., Stent-graft catheter becomes kinked)
Distraction	Distraction by phone call, external staff, or departmental (Example: Requirements of an external organisation affect the procedure (e.g., team rushes to complete the current procedure to start the next procedure, team member distracted by entering staff or phone ringing).
Fatigue	The indication that individuals are tired or lack sleep. (e.g., staff falling asleep during procedure, CN sitting on the chair with head on table)
Patient-related procedural difficulties	Characteristics of the patient that make the procedure more difficult (e.g., tortuous iliac arteries cause difficulty in the deployment of a catheter)
Planning error	Failure to anticipate or discuss task requirements before the start of the procedure (e.g., IRs debate stent-graft size to use during the procedure) Procedure-related error Procedural errors by IR, radiographer, anaesthesiologist, SN, and CN (e.g., SN is slow to give equipment to IR.)
Psychomotor error (general)	Handling errors (e.g., an IR handheld is dropped)
Safety consciousness (awareness) or Vigilance	Failures to observe essential elements of patient safety (e.g., mask violations, chewing gum in theatre). Failure to notice immediately essential aspects in the procedure. (e.g., CN fails to spot instrument or pool of blood on the floor, IR fails to request heparin or antibiotic administration) (memory-related)
Team conflict	Team members have contrasting opinions or give conflicting commands. (e.g., IR wants to stop patient breathing from allowing the performance of fluoroscopic run but anaesthesiologist refuses)
Technical error	The error associated with lack of expertise or skill (usually in trainees) (e.g., consultant IR captures error made by trainee IR.)
Modified from (Catchpole et al., 2006a)	

Table 3.2 Examples of minor and major healthcare errors [adapted from (Morbi et al., 2012)].

Minor Healthcare Errors	Major Healthcare Errors
Interventional radiology consultant asks for a piece of equipment, but a circulating nurse does not hear, so the request must be repeated.	Technical error during a uterine artery embolisation, resulting in a dissection, which led to emergency angiography and stent placement (safety)
Scrub nurse drops a syringe onto the floor. This is a general psychomotor error.	The nurse tries to give the wrong drug (safety)
Radiographer and Interventional radiologist disagree about the screening position that is required. This is a type of communication error called "team conflict"	The interventional radiologist is about to use ultrasound, but the old cover and blood are still on the probe from the previous case (safety and delay)
Circulating nurse enters the room without wearing any lead protection. This is a type of safety awareness error called "Vigilance or awareness error"	Patient tries to get off the table and almost fails (safety)
The phone of the IR consultant rang while he was in a middle of a procedure. This caused distraction but no patient's harm or delay in the procedure.	Safety awareness error during an ultrasound-guided liver biopsy. One box of dry ice contained two tube samples for two patients and the research staff who handed over this box to the IR nurses did not mention that there are two separate tube samples for two separate patients. The name on the sample tube, which was about to be used for the patient on the table was for a different patients. The IR nurse checked the sample just before handing it to the IR doctor. Then the team changed the tube. This error would have posed a severe adverse event had it not been recognised by the IR team.
The circulating nurse was not putting surgical cap and mask. This is called safety awareness error of subtype violation of safety guidelines.	In a procedure: "Embolisation of Hepatic artery dissection pseudoaneurysm of Ehlers Danlos syndrome". Difficult procedure, with difficult angle of the hepatic artery and fragile hepatic artery branches which were easily bled because of the nature of the disease. This led to development of few bleeding spots required coiling. This was a planning error in addition to patient-related-error.
The C arm could not be moved as it was stuck by the ultrasound machine.	A technical error occurred in which the IR assistant doctor incorrectly applied an Angioseal, which is a tool used to seal the hole created at the puncture site during an IR procedure. This led to bleeding from the puncture site which resulted in the IR consultant to apply manual pressure on the puncture site for about an hour and the patient's recovery delayed. This was a communication errors as well as the IR assistant did not hear the IR consultant well regarding the exact steps of deploying this tool.
	In a procedure called femoral line insertion, the patient was sent by the general surgical ward. During the preoperative check by the IR nurse, the patient stated he is allergic to some antibiotic without knowing the name of it. This error occurred in the referring ward where the ward nurse did not check for Drug Allergy.

3.5 Results

3.5.1 Comparison of the novice and the expert observations

In five intraoperative IR procedures, the observation of the trained observer (FR) was compared to an IR consultant (BP) to measure the agreement between their records. Fieldnote description of the perceived healthcare failures were created by each observer which were later analysed by two independent senior assessors (MH) and (CB). The starting point of the observations were from the point where the WHO checklist was read out to the point where the sign-out of the WHO was done. No attempt was made from the observers to intervene to prompt the IR team to rectify any error. Each observer was positioned in a different corner of the IR angio-room to make sure they can observe all the objects in the room and to make sure that their observations remain independent to each other. The textual description of the healthcare errors is shown in Table 3.3.

The novice observer recorded 26 healthcare errors while the IR consultant recorded 29 healthcare errors. There was generally a good agreement between the measurement of the two observers. There was a perfect agreement between the observers for the Absence, communication, and planning with the Kappa coefficient value = 1 ($p = 0.025$). A very good interrater agreement was found for the technical errors (Kappa = .727, $P = .023$), while substantial interrater agreement was demonstrated for Equipment_related_error (Kappa = .667), Distraction (Kappa = .545), Patient_related_error (Kappa = .545). However, there was a weak interrater agreement for safety awareness (Kappa = .308) (Table 3.4).

Table 3.3 Fieldnote description by the novice and the Expert observer

Name of the IR procedure	Novice observation	Expert Observation
1. Left nephrostomy insertion	• RDG not present during the WHO check. • The nephrostomy tube was not flushed by the IR assistant but prompted by the IR consultant who was observing the case to flush it before use. • Patient was experiencing pain, reassured, and given pain killer.	• Radiographer not available for WHO • Team members talking during who checklist. • Nephrostomy not flushed or prepped. • Patient in pain
2. Porta Cath insertion	• The IR assistant Dr did not put the wire into the tip hub. • The light was not optimum in the room, so the performing IR fellow asked for a spotlight, short pause. • The SN was not sure about what to put on the operating table (for e.g., heparin, suture stiches needle not available • The CN was about to trip over the sharp bin, but the bin was moved promptly by the observing IRC. • The SN did not count the needle before and after the procedure. • The SN counted the metal tools before the monitoring nurse bring the paper to list the sharps, gausses, and metal tools. • WHO checklist sign-out was not verbalised	• Assistant not aware how to use equipment. • Light source inadequate - needs adjustment • Nurse not aware not the next step and needle promoting for equipment. • Access needle not available • Student nurses tripping on the equipment bin asking for dressings. • Counting equipment before assistant was ready to do count. • Needle count not done. • Sign-out not verbalised.
3. Right uretero-nephrostomy insertion	• The trolley was not prepared before the procedure. • The RDG did not collimate early enough, the hands of the IRF were shown in the field, quickly collimated the field • The wire was not hold securely by the IR assistant Dr was about to unfold and get unsterilised, promptly put back in place by the IRF who was performing the procedure and the observing consultant.	• Trolley not set up prior procedure. • Lead shield not used until it was requested by operator. • Airgap not reduced - should be done as standard. • Hands in X-ray beam Radiographer did not cone hands out of imaging
4. Porta Cath removal	• Distraction by external staff • The RDG was not present for the sign-out	• A nurse from next door distracted the team asking for a tool. • Radiographer went out during the sign-out.
5. Left Nephrostomy	• The WHO checklist form was requested by the IRF but there was not one in the room, pause for 30 seconds. • Scrub nurse was not involved in the WHO. • the IRF requested the Inco pad. • The same previous error • The X ray tube shield dropped. • Wire was not available.	• Who checklist not available • During WHO checklist nurse initially not involved • Nurses distracted and not listening to IRF. • Nephrostomy set not available in the room. • IRF asked for signal needle - not given. • Assistant not familiar and therefore not prepping. • Asked for wire, said unavailable but was in the room - lack.
	• Non-familial IR assistant doctor, not engaging. • Patient tried to move off the bed in pain, being warned by the operating team to stay still	• Patient in pain, nursing staff slow to respond

Table 3.4 Shows the degree of agreement between the observation of the Novice observer with the expert observer (N= 5)

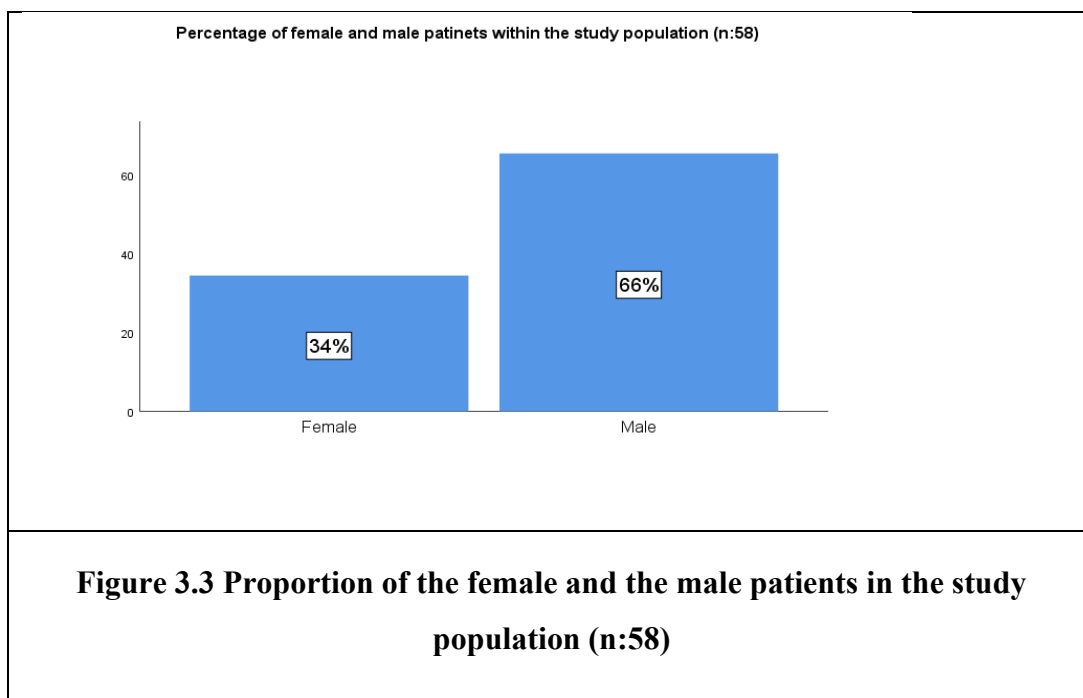
Category of healthcare error recorded by the Novice and the Expert	Measure of Agreement (Kappa)	Approximate Significance (P value)
Absence	1.000	.025
Communication	1.000	.025
Equipment_related_error	.667	.083
Distraction	.545	.171
Patient_related_error	.545	.171
Planning	1.000	.025
Safety_awareness	.308	.140
Technical	.727	.023

3.5.2 Demographics of the study population and the observed IR procedures

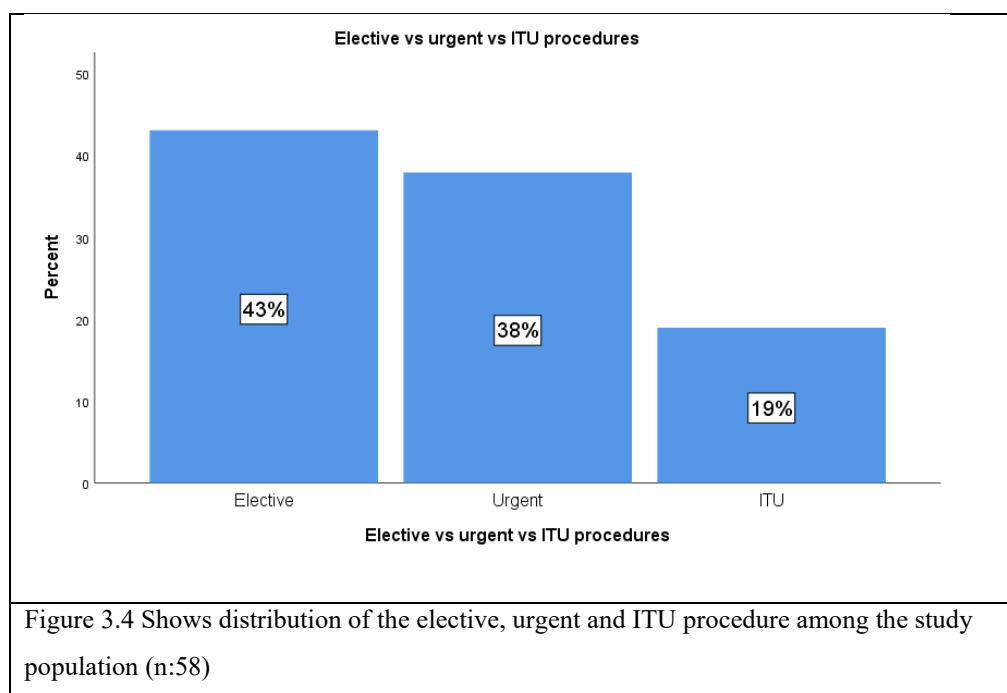
After the comparison study, the trained observer (FR) observed the whole IR pathway from the point of admission of the patients to the IR department to their discharge from the IR department to home or back to the referring ward. However, three cancellation affected eight IR procedures and three whole IR pathways. These cases were excluded from the analysis of the duration of the pathways and the procedures to exclude the extreme outliers in the data. A total of 148 hours and 22 minutes of work was observed, of which 55 hours and 22 minutes were intraoperative. The median duration of the IR pathways was 127 minutes [Std. Deviation = 102.875] while the median duration of the IR procedures was 54 minutes [Std. Deviation= 47.824]. The observed IR procedures were shown in Table 3.5. The highest frequency of these procedures was lower limb angioplasty constituting 23 cases, followed by 11 US-guided liver biopsy, 4 of which were transjugular. The number of men were more than women in our study population at a frequency of 38 (66%) versus 20 (34%) (Figure 3.3).

Table 3.5 The name and frequency of observed procedures

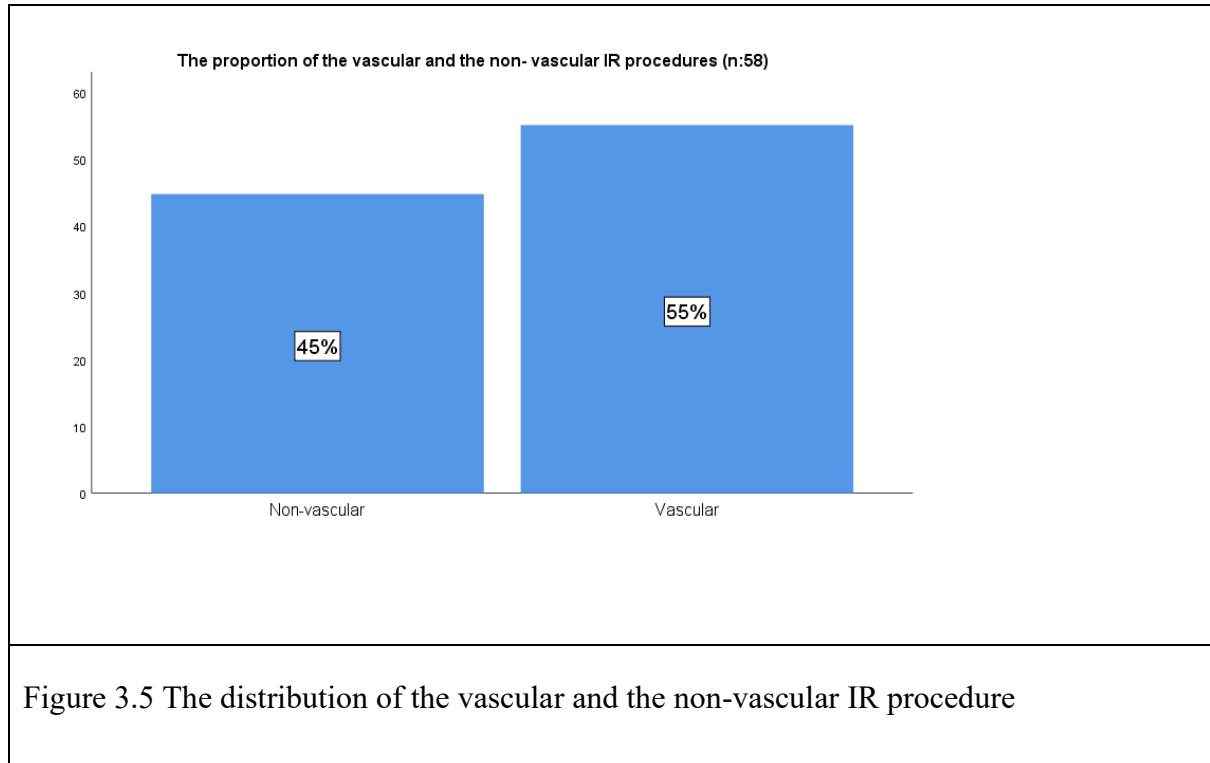
Name of the IR Procedure	Number of observations
TESIO exchange	1
Lower limb Angioplasty	23
Transjugular liver biopsy	4
Ultrasound_ guided Liver ablation (microwave)	2
US-guided liver biopsy	7
Femoral line insertion	1
Hickman line insertion	1
IVC filter removal	1
Fistuologram upper limb	1
US drainage Ascites	1
NJ tube insertion	3
SIRT (Selective internal radiation therapy)	1
SMA branch aneurysm embolisation	1
Iliac Angioplasty right_ plus/ minus stent	2
TIPS (Transjugular intrahepatic portosystemic shunt)	1
PAE (Prostatic Artery Embolisation)	1
Left leg venogram.	1
Ultrasound-guided biopsy (Lymph Node)	1
US guided left Tubo-ovarian abscess	1
US Guided aspiration	1
US drain of Psoas muscle collection	1
UAE	1
Hepatic artery dissection pseud- aneurysm embolisation (Ehlers Danlos syndrome)	1
Total	58



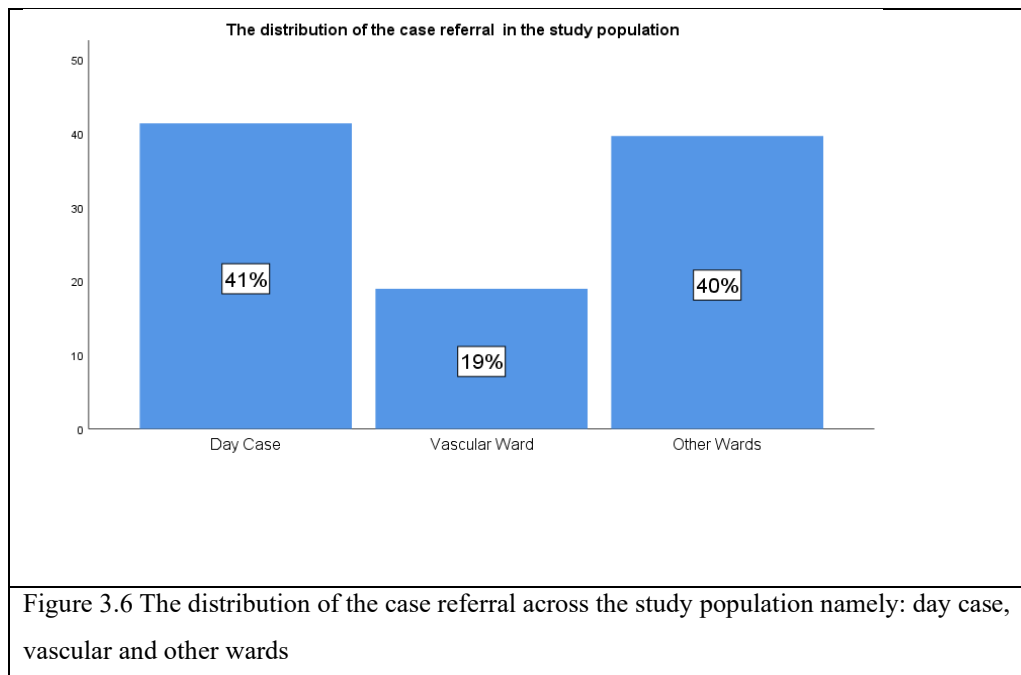
The highest proportion of the IR procedures was elective procedures at a rate of 25 (43%) followed by urgent procedures 22 (38%) and ITU 11 (19%) (Figure 3.4).



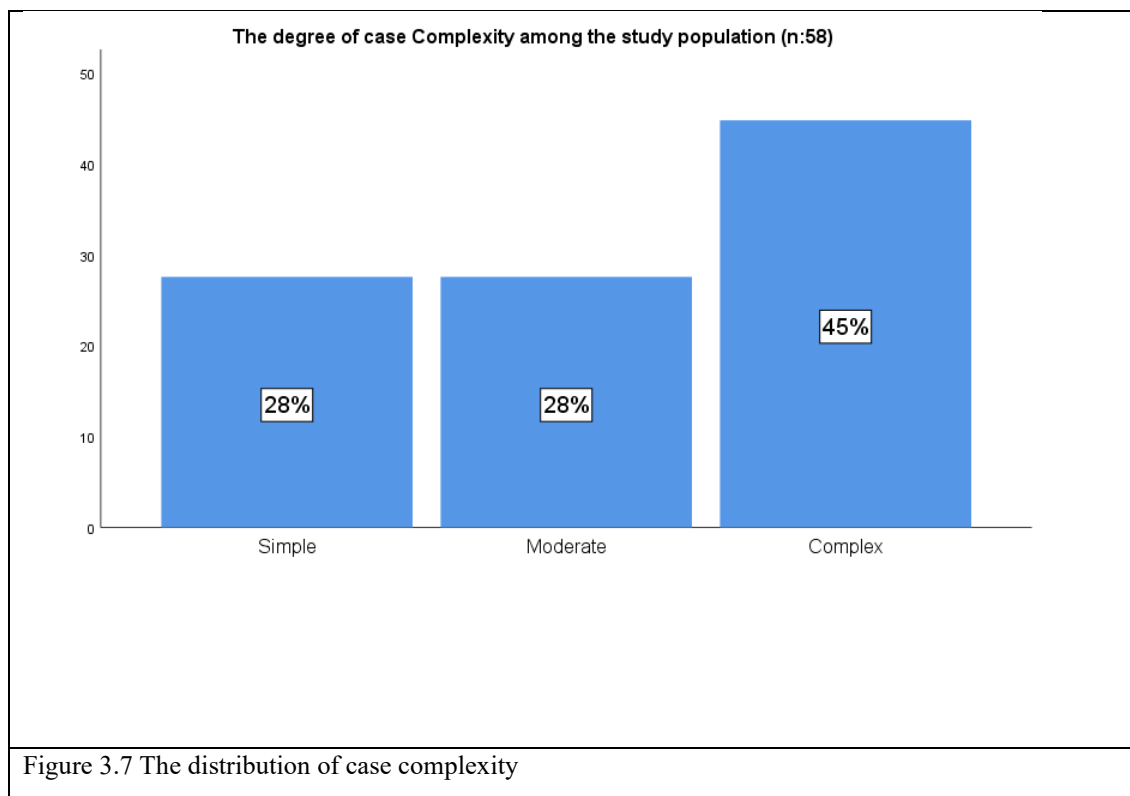
The vascular procedures constituted the highest proportion of the IR procedures versus the non-vascular procedures at a frequency of 32 (55%) and 26 (45%) respectively (Figure 3.5).



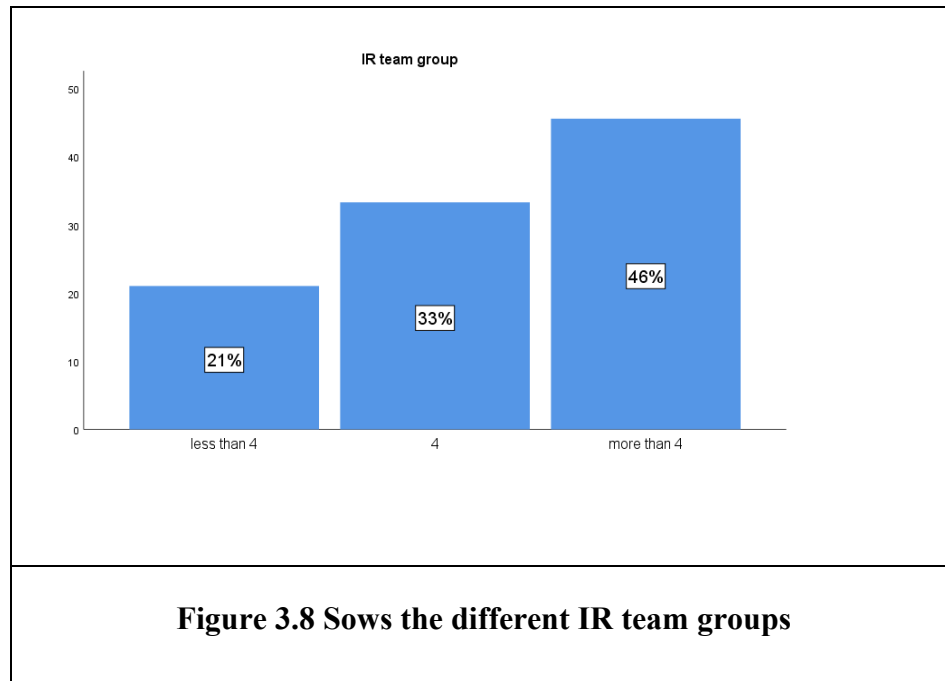
Day cases and referral from other wards formed the most frequent case referral at 41% and 40% respectively. On the other hand, procedures referred from the vascular wards formed 19 % (Figure 3.6).



Most of the IR procedures were complex (45%) in comparison with the simple and moderately difficult procedures which constituted 28% each (Figure 3.7).



In 46% of the procedures, the IR team was composed of more than 4 members, whereas in 33% of the procedures, the IR team was composed of 4 members versus 21% of the procedures where the IR team was formed by less than 4 members (Figure 3.8).



3.5.3 The frequency of the recorded healthcare errors in the IR pathway

Of the fifty-eight observed IR pathways, a total number of 317 healthcare errors were recorded. The median total number of healthcare errors across the entire IR pathway was 4 [Std. Deviation= 4.776] while the median total number of healthcare errors in the intra-procedure IR procedure was 5 [Std. Deviation= 5.124]. From the total number of healthcare errors 53 (17%) of which were in the preoperative phase, 261 (82%) in the intraoperative phase, and only 3 (1%) in the postoperative phase (Figure 3.9).

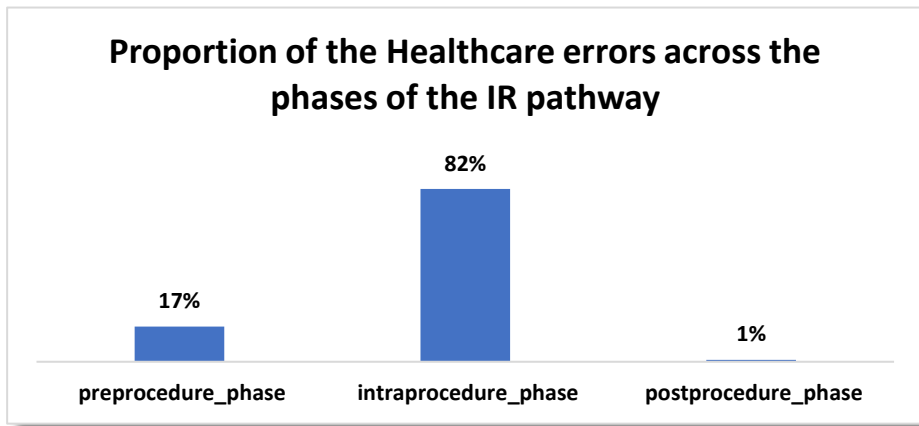


Figure 3.9 Shows the distribution of the healthcare errors across the phases of the IR pathway

3.5.4 The landscape of healthcare errors across the IR pathway

The most frequent healthcare errors were communication [81(26%)], equipment-related-error [49(15%)] and safety awareness [34(11%)]. Technical errors were the fourth frequently encountered errors at a rate of [30(9%)] followed immediately by planning [27(9%)]. Patient-related-errors [25(8%)] and Distraction and [24(8%)] were less frequently recorded. The least recorded errors in order from higher to lower were absence [20(6%)], management [14(4%)], procedure-related-errors [10(3%)] and others [2(1%)] (Figure 3.10).

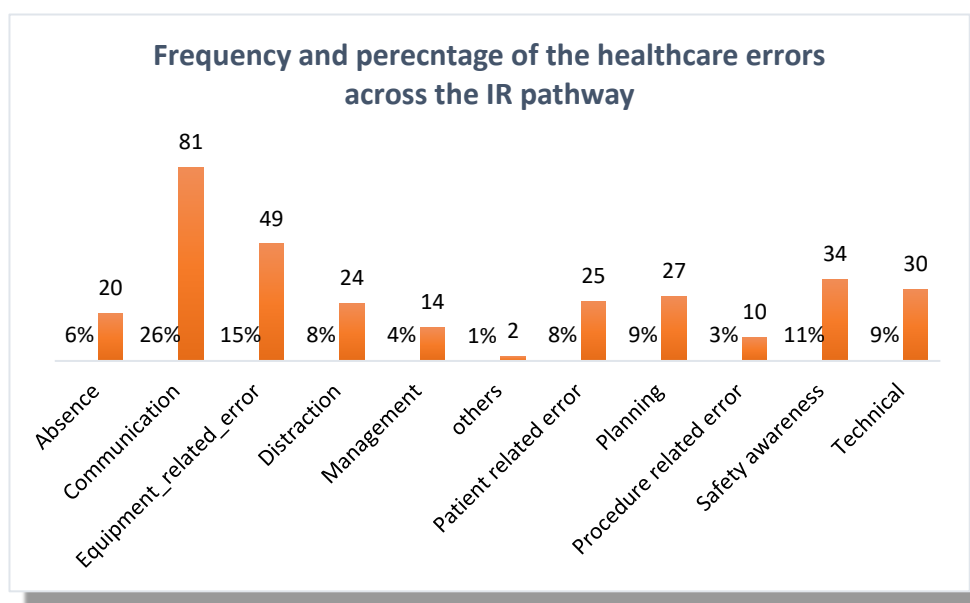


Figure 3.10 Frequency and percentage of the healthcare errors across the IR pathway (n:58)

3.5.5 The degree of severity of the healthcare errors

Most of the healthcare errors did not cause patients harm (75%). Mild and moderate patient harms occurred in 7% and 6% respectively. On the other hand, on 1% of the healthcare errors deemed to have caused or have the potential to cause severe patient's harm. Furthermore, in 11% of the healthcare errors, the severity of the patient's harm or the potential for a harm could not be established (Figure 3.11).

Using Independent Samples Kruskal Wallis Test, the distribution of the different degrees of severity of the occurring healthcare errors was the same among the elective, urgent and ITU procedures ($P = .368$). Only three severe healthcare errors occurred within these 58 IR procedures, one in each type of procedures namely: elective, urgent and ITU. The breakdown of the severity of healthcare errors across elective, urgent and ITU procedures are shown in Figure 3.12.

Three errors were deemed severe or could have severe damage to the patients. Two of them were safety awareness and the other resulted from two components: patient-related and planning errors.

During an ultrasound-guided liver biopsy. One box of dry ice was handed over by two staff from the referring ward to the IR nurse. However, they did not mention that there were two separate tube samples for two different patients. The name on the sample tube, which was about to be used for the patient on the table was for a different patients. The IR nurse checked the sample just before handing it over to the IR doctor. Then the team realised that this was a wrong tube and changed the tube. This error would have posed a severe adverse event had it not been recognised by the IR team.

In a procedure "Embolisation of Hepatic artery dissection pseudoaneurysm of Ehlers Danlos syndrome". The procedure was difficult, and the anatomy of the patient was difficult with difficult angle of the hepatic artery and fragile hepatic artery branches. The arteries easily bled because of the nature of the disease. This led to development of few bleeding spots required coiling. This was a planning error in addition to patient-related-error.

In a procedure called femoral line insertion, the patient was sent by the general surgical ward. During the preoperative check by the IR nurse, the patient stated he is allergic to some antibiotic without knowing the name of it. This error occurred in the referring ward where the ward nurse did not check for Drug Allergy.

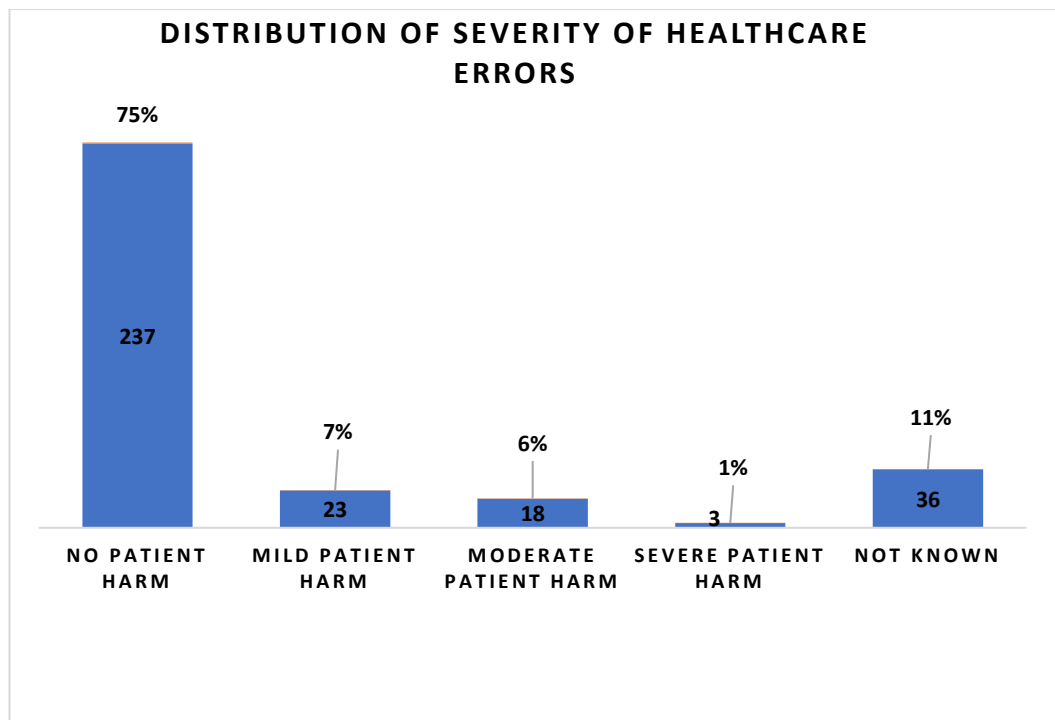


Figure 3.11 Shows the degree of severity of the occurring healthcare errors (total number of errors:317)

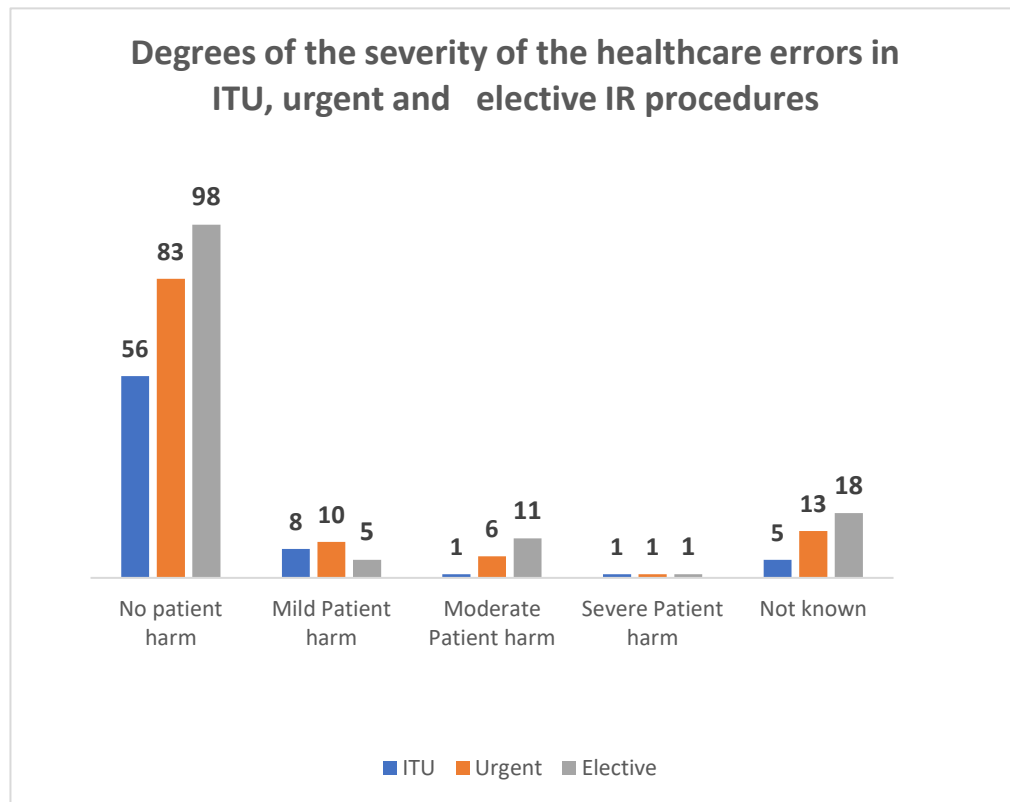
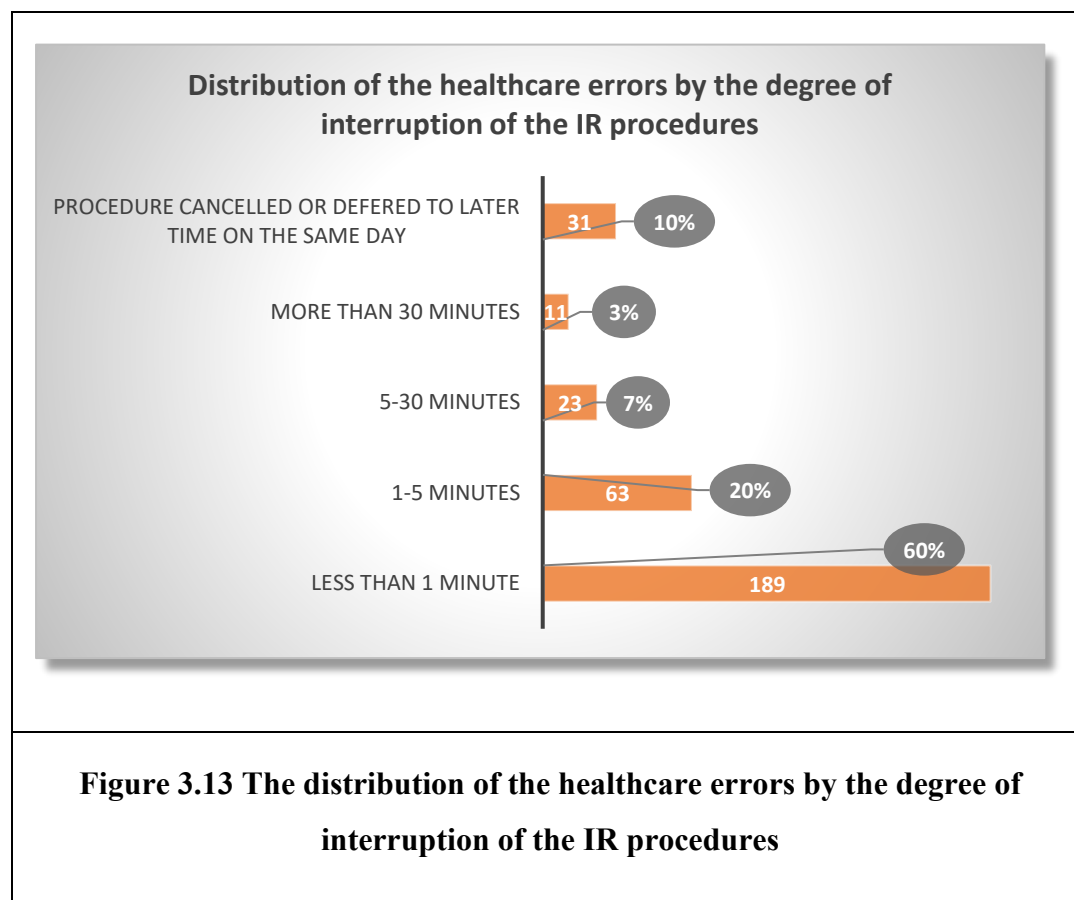


Figure 3.12 Shows the degree of severity of the occurring healthcare errors in Elective, urgent and ITU procedures (total number of errors:317)



3.5.6 The degree of interruption caused by the healthcare errors.

In 60% of cases, the healthcare errors resulted in less than 1 minute pause. 20 percent of the healthcare errors caused mild or 1-5 minute pause to the IR procedures while 7% caused moderate pause of 5-30 minute to the IR procedures. Only 3% of the errors cause severe pause to the IR procedures. However, 10 % of the errors resulted in cancellation of the IR procedures (Figure 3.13).

3.5.7 Correlation of the age of the patients with the mean total number of healthcare errors throughout the IR pathway

No correlation between the age of the patients with the mean total number of healthcare errors in the IR pathway was found (Spearman's rho = .022, P value, .872).

3.6 Discussion

This pilot study revealed that there is a defined pathway for IR procedures which can be mapped out. The result of the current study also shows that healthcare errors are frequent in the IR pathway of care and that these errors can be detected and analysed using ethnographic field notes.

The current method used to observe pathways was validated previously in the literature. Catchpole et al. (2006) found that it is insufficient to rely solely on explicit error-capture technique for data collection as these errors need to be examined against the time and context of the clinical scenario at the time of occurrence. Therefore, they added a direct field-note observation to their study, and they stressed that this way of error analysis form a rich source of information, on which the subsequent analysis heavily relied (Catchpole et al., 2006b). Ethnographic fieldnote observation method was also used in other studies in the vascular/endovascular and IR environment (ALBAYETI et al., 2011) (Morbi et al., 2012).

However, this methodology encompasses some limitations such as inconvenience to be used for large scale studies as it is a labour-reliance method requires at least 3 to 4 researchers to conduct. Not only do these studies require data collection by at least one person actively but they also require analysis of data by at least two- three more people. Furthermore, the time needed is considerable from data collection to data classification and then data analysis (Mason et al., 2013).

Most (75%) of the classified healthcare errors in the current study were minor causing no patient harm versus 13% mild-moderate harm. Only 1% of the errors were classified to cause or have the potential to cause severe patient's harm. Having said that, the severity of errors could not be determined in 11% of the errors. The low rate of severe errors in the current study reflects the nature of the IR specialism being a minimum invasive intervention versus classic surgery.

This agrees with the previous literature. Gradinscak et al., (2004) studied 2,436 aorto-femoral, cerebral, and other IR procedures. No deaths or major complication was detected attributable to the procedures. 561 complications in total were identified in those 2,436 procedures (23%). Most complications were related to either puncture site hematoma/ bruising or localized puncture site pain at a rate of 9.7 and 7% respectively (Gradinscak et al., 2004). In another

large study, the rate of the complications in 5000 catheter-cerebral angiograms performed at 4 hospitals, 2 of which were training hospitals was analysed by computer. The analysis revealed only 68 (1.4%) complications in total, 8 (0.16%) of which were major (Mani et al., 1978). Similar rates were found in other studies (Lewis et al., 1999). (Tuong et al., 2009)

The percentage of preventable healthcare errors is considerable formed 80% in this study, which is comparable to the result of the previous studies. Gawande et al. (1999), reported that preventable adverse events among surgical ones are 54% (Gawande, (1999). Morbi et al. (2012) found that 65.4% of healthcare errors were non-technical and preventable (Morbi et al., 2012). Other studies in the literature concluded similar results (Armour Forse et al., 2011) (Catchpole et al., 2006b).

The findings of this observational study suggest that non-technical healthcare errors are frequent across the IR pathway of care. Communication, equipment-related-error, and safety awareness were the most frequent reported healthcare errors. Technical errors came fourth in the rate of occurrence. The results of the current study are comparable to the literature (Lingard et al., 2005) (Lear et al., 2017, Lingard et al., 2004a, ALBAYETI et al., 2011) (Morbi et al., 2012).

The most frequent healthcare errors in the current study were communication [81(26%)] and equipment-related-error [49(15%)]. This agrees with the previous study by Albayati M.A et al., (2011) who observed 66 intraoperative cases of vascular and endovascular surgery and reported equipment-related errors at a rate of (23.5%) followed by communication errors (21%) (ALBAYETI et al., 2011). Morbi et al., (2012) studied the IR procedures in eighty-three patients in a pre- and post-intervention phase. In the preintervention phase, they found equipment unavailability (12.2%) and communication errors (11.2%) among the commonly encountered errors (Morbi et al., 2012).

Technical errors on the other hands were the fourth frequently encountered errors at a rate of [30(9%)]. It is worthwhile that this is slightly higher the rate by Al-Bayeti et al., (2011) who reported 3.6% of the errors secondary to technical errors. However, we included psychomotor error as a subtype within the technical error, unlike Al-Bayeti et al., (2011) who considered psychomotor errors as a standalone error which constituted 5.4%. Therefore, combining these errors together it becomes 9% which is exactly the percent we found in the current study.

The current study highlights that minor errors constitute most occurring healthcare errors. This finding agrees with previous literature in both Surgery and IR. Morbi et al. (2012) concluded that only 2.17% of the failures were major safety failures, the rest were minor safety failures, whereas severe safety failures in the study by Albayati et al. (2011) were 5.2%. It is worthwhile to note that although isolated minor errors are harmless or perceived as harmless, however, aggregation of these errors might have a detrimental effect on the patient's condition. A suggestion to this conclusion is that minor errors are unnoticeable to the operating team and that they pass their recognition ending up exerting substantial impact. In a study in paediatric cardiac surgery, the researchers investigated the role of human factors as sources of errors. They found that multiple factors such as those related to culture, environment or organisation could play roles in the type of non-technical errors. Their study demonstrated a high rate of these system or non-technical errors, example of which included distraction, lack of safety consciousness, equipment failure and communication (de Leval et al., 2000).

There are some limitations to the current study which needed to be acknowledged. Like any other observational study, selection bias, observational or measurement bias are inherent biases.

Selection bias is one of the intrinsic biases in any observational study, whereby the selected sample does not represent the target population. This bias is resulted from non-randomisation of the included cases (Tripepi et al., 2010) . I observed consecutive patients who were pre-booked for their procedure without having a prior knowledge of the details of the cases or a prior knowledge of the patient characteristics or type of the procedures as I was not part of the clinical team who involve with these data. Nevertheless, selection bias remains a source of systematic error of observational studies.

Observational measurement bias is another bias that can occur in observational studies in which the observer might miss some events or errors, especially minor ones. This may be the case in novice observers who are inexperienced in interpreting or conceptualising various complex interactions among different team members (Catchpole et al., 2006b) (Paul Barach MD, 2008) (ALBAYETI et al., 2011, Morbi et al., 2012). The observer received four-week training on how to conduct ethnographic filed record by senior IR consultant who has experience in both technical aspects of the IR procedures and human factor with several

publication under the topic of patient safety and healthcare errors. Furthermore, a comparative study was conducted on patients by the trained observer and a consultant IR physician, the result of which showed good to perfect interrater agreement in most of the items (see section 3.5.1 of the results).

Furthermore, no attempt was made by the observer to interpret the perceived events or the collected scenarios. The observer restricted his observations to make descriptive notes in a pure textual format which then analysed by two expert academics (MH and CB) to extract possible errors. Both analysers were blinded to the interpretation of each other. Despite this, the results of these type studies need to be carefully interpreted. Future research would need to focus on the development of more objective ways to collect data.

The Hawthorn effect is one of the biases that accompanies observation studies. This is a phenomenon in which the observed people would behave differently, usually more productive, or ideal by the effect of psychological stimulus of being focused on and made to feel worthy (LANDSBERGER 1958b) (McCarney et al., 2007a). However, the IR team have been observed numerous time as the hospital is a tertiary teaching hospital with the vascular and IR department receive referrals across the UK. Therefore, the team are used to be observed daily. Furthermore, the training in the induction period was aimed to reduce this Hawthorne effect beside the training.

Performing a pilot study is considered beneficial before one can perform the main project. This type of study allows a critical review of the methodology used to invite further improvement, while more research is underway (Hammer et al., 2009). This point was one of the intentions of this study.

3.7 Conclusions

This observational pilot study demonstrates that the IR pathway is versatile but can be mapped out to allow characterisation of these patients and their requirements. It appears that field-note observation can act as a method to detect errors throughout this pathway. Both technical and non-technical errors occur throughout the patient's journey in the IR, most of which are minor. However, this method of data collection is labour intensive and require allocation of time and resource and would not be feasible in large scale studies. This would invite further research in this area to develop further methods of data collection throughout the IR pathway to allow future solution to address this gap.

Chapter Four : Evaluating the Safety Climate through Perception of Potential Failure Modes in image-guided-intervention pathways such as Interventional Radiology

4.1 Chapter outline

This chapter aims to analyse the potential failure modes within the pathway of care in Interventional Radiology (IR) by examining the perceptions of the multidisciplinary team responsible for managing patients undergoing image-guided interventional procedures. Initially, an overview of Failure Mode and Effect Analysis (FMEA) and Health Failure Mode and Effect Analysis (HFMEA). The research utilizes a mixed-method approach that integrates a modified version of HFMEA into a self-response questionnaire. The justification for employing this method will be presented, and the reliability and consistency of the questionnaire will be assessed. The participants' perceptions regarding various aspects of failure modes throughout the IR patients' journey will be investigated. Finally, the study's implications and future directions will be addressed.

4.2 Background

With increasing attention given to patient safety, systems have become more adaptive in understanding its fundamental aspects. Adverse events are considered crucial in-patient safety and are targeted by various systems to comprehend their nature and underlying causes. Systems focusing on near-miss events, which have not yet resulted in adverse events, have also been developed. These robust systems detect weaknesses or flaws that may potentially lead to near-miss or adverse events. One such methodology is Failure Mode and Effect Analysis (FMEA) (DeRosier et al., 2002).

Failure Mode and Effect Analysis (FMEA)

FMEA is a technique employed to proactively analyse all steps or sub-steps of a process in new systems, designs, or products, in order to identify potential failures before they occur. It prioritizes addressing problems before their manifestation, irrespective of whether they lead to adverse events. For each assumed failure, three aspects need to be confirmed: the severity of the outcome if it occurs, the probability of its occurrence, and the chance of its detection before evolving into an adverse event. A hazard scoring system is then established by multiplying the

severity and probability values, resulting in a Risk Priority Number (RPN) assigned to each failure mode. Based on the hazard scoring and RPN, preventive actions may be taken to mitigate adverse events (Schneider, 1996).

Initially introduced in the military sector in the late 1940s, FMEA was adopted by the United States Department of Defence across all departments, including engineering and weapon design. A document published by the Secretary of Defence emphasized the significance of implementing a correct FMEA in decision-making processes related to program feasibility and design suitability (USA, 1949).

FMECA, an extension of FMEA, incorporates criticality analysis to further refine the design or system based on the hazard score of each failure mode. However, even without the criticality analysis, FMEA is considered an invaluable tool in reliable and susceptible programs, as it organizes potential failures according to their severity. FMEA facilitates comprehensive evaluations of failure modes, including their causes, detection methods, direct and indirect impacts on the system, and appropriate preventive measures. Moreover, FMEA not only ensures the integrity of product design or system implementation but also provides justifications for modifications in design and operational systems. Additionally, FMEA is essential in maintenance planning and analysis (Willis, 1992) (DeRosier et al., 2002).

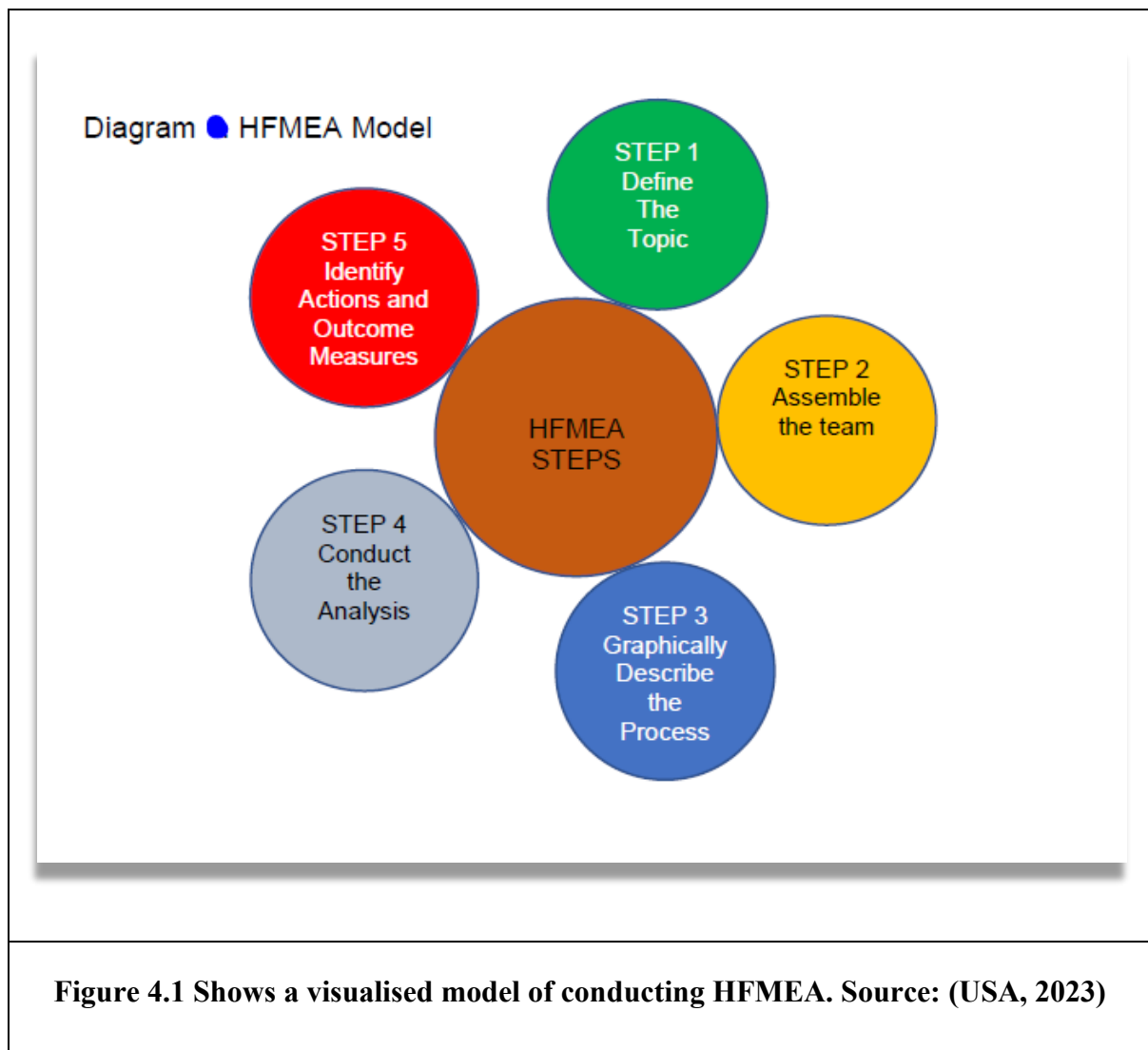
Health Failure Mode and Effect Analysis (HFMEA)

The healthcare sector, particularly medical products and clinical engineering, was the first to adopt this approach (Willis, 1992). The Veterans Affairs (VA) National Centre for Patient Safety in the United States implemented a modified FMEA system known as Health Failure Mode and Effect Analysis (HFMEA) (DeRosier et al., 2002). HFMEA aims to enhance patient safety by preventing failures or implementing protective measures to minimize their impact on users (Skevington et al., 2012) ; (Joint_Commission_Resources, 2010).

HFMEA incorporates ideas and tools from FMEA, Hazard Analysis and Critical Control Point (HACCP), and Veterans Affairs' root cause analysis (RCA). It requires a multidisciplinary team to diagrammatically present failure modes, processes, subprocesses, causes, and their impact on users and the system using a hazard scoring matrix. Contingency actions are identified for each failure mode (Suva et al., 2014).

4.3 The methodology used in an ordinary HFMEA.

In an ordinary HFMEA study, the following steps are used as summarised graphically in Figure 4.1 (USA, 2023).



Step 1. Identify the Topic or the Process which needs evaluation.

HFMEA is usually recommended for high-risk areas or processes to justify the time and the resources which are needed (Burgmeier, 2002). Information from other root cause analysis procedures, such as sentinel event reports, can be utilized for conducting HFMEA. However, failure modes can also be brainstormed by a multidisciplinary expert team (JCAHO, 2002) (DeRosier et al., 2002).

Step 2. Assemble a Team to conduct the HFMEA process.

The team should comprise of subject-matter experts who possess knowledge about the studied process and members without prior knowledge to provide critical perspectives on meeting accepted standards. A team leader coordinates meetings, ensures consistency, and encourages active participation (DeRosier et al., 2002).

Step 3. Create a graphical flow chart of the process.

To facilitate comprehension and prevent loss of interest, the HFMEA process can be represented visually using flowcharts rather than text. Each step or subprocess can be numbered and labelled with letters respectively. For instance, step 1,2, and 3 or Step 1A, 1B, 1C, etc. Or phase I, II, III, etc. Figure 4.5 and Figure 4.6 shows the examples of the possible FMs in the IR pathway. Breaking down a lengthy process into manageable sections can enhance feasibility (Figure 4.7).

Step 4. Perform risk (Hazard) analysis.

The scoring process is heavily reliant on expert opinions, as they gauge the severity, probability, and detectability associated with each potential failure. Severity ratings are determined based on the anticipated impact on patients, categorized into four levels: catastrophic, major, moderate, and minor (**Table 4.1**).

Probability scores range from 4 to 1, representing the frequency of events: 4 indicates frequent occurrences within a year, 3 denotes occasional incidents over a two-year period, 2 signifies uncommon events spanning 2 to 5 years, while remote implies rare events happening between 5 and 30 years (Table 4.2).

The hazard score is calculated by multiplying the severity score by the probability score. The resulting score falls between 1 and 16, with higher scores indicating more severe scenarios. Notably, any failure mode that obtains a score of 8 or above is deemed to possess sufficient severity and probability, thus warranting the implementation of appropriate control measures. For instance, a catastrophic FM _ with a severity score of 4 would result in a severe scenario even if it were uncommon (with a score 2 probability) as the net result would be ($4 \times 2 = 8$ Hazard score number). The HFMEA hazard matrix is shown in (Table 4.3).

Step 5. Actions and Outcome Measures

Regarding the outcomes associated with failure modes, three possibilities exist: 1_ elimination, 2_ control, and 3_ acceptance, which implies halting further analysis. The first two outcomes necessitate additional actions to be taken. The course of action depends on further exploration of the failure mode, considering three key factors: the identification of single-point weaknesses (criticality), the absence of existing control measures, and the level of detectability. These actions and decision-making processes are visually represented in a dedicated HFMEA decision tree (Figure 4.2). A whole HFMEA worksheet can be seen in Figure 4.3 (DeRosier et al., 2002).

Table 4.1 Severity Ratings of the FMs (source USA (2023)).

Severity Rating				
	Patient Outcome	Visitor Outcome	Staff Outcome	Equipment or Facility
Catastrophic Event (4)	^{a, b} Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; or hospitalization of 3 or more visitors	A death or hospitalization of 3 or more staff	Damage equal to or more than \$250,000. Any fire that grows larger than an incipient stage
Major Event (3)	^a Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	^c Damage equal to or more than \$100,000.
Moderate Event (2)	Increased length of stay or increased level of care for 1 or 2 patients	Evaluation and treatment for 1-2 visitors (less than hospitalization)	Medical expenses, lost time or restricted duty injuries or illness for 1-2 staff	Damage more than \$10,000 but less than \$100,000. A fire at incipient stage or smaller
Minor Event (1)	No injury, nor increased length of stay nor increased level of care	Visitor evaluated (no treatment or treatment refused)	First aid only (no lost time, restricted duty injuries or illnesses)	^{c, d} Damage less than \$10,000. Loss of utility system with no adverse outcome.

Table 4.2 Probability Ratings of the FMs (Source: (USA, 2023).

HFMEA Probability Ratings	
Frequent Event (4)	Likely to occur immediately or within a short period (may happen several times in one year)
Occasional Event (3)	Probably will occur (may happen several times in 1 to 2 years)
Uncommon Event (2)	Possible to occur (may happen sometime in 2 to 5 years)
Remote Event (1)	Unlikely to occur (may happen sometime in 5 to 30 years)

Table 4.3 Shows the HFMEA Hazard matrix. Source: (DeRosier et al., 2002)

HFMEA Hazard Matrix					
Probability	Severity of Effect				
		Minor (1)	Moderate (2)	Major (3)	Catastrophic (4)
	Frequent (4)	4	8	12	16
	Occasional (3)	3	6	9	12
	Uncommon (2)	2	4	6	8
	Remote (1)	1	2	3	4

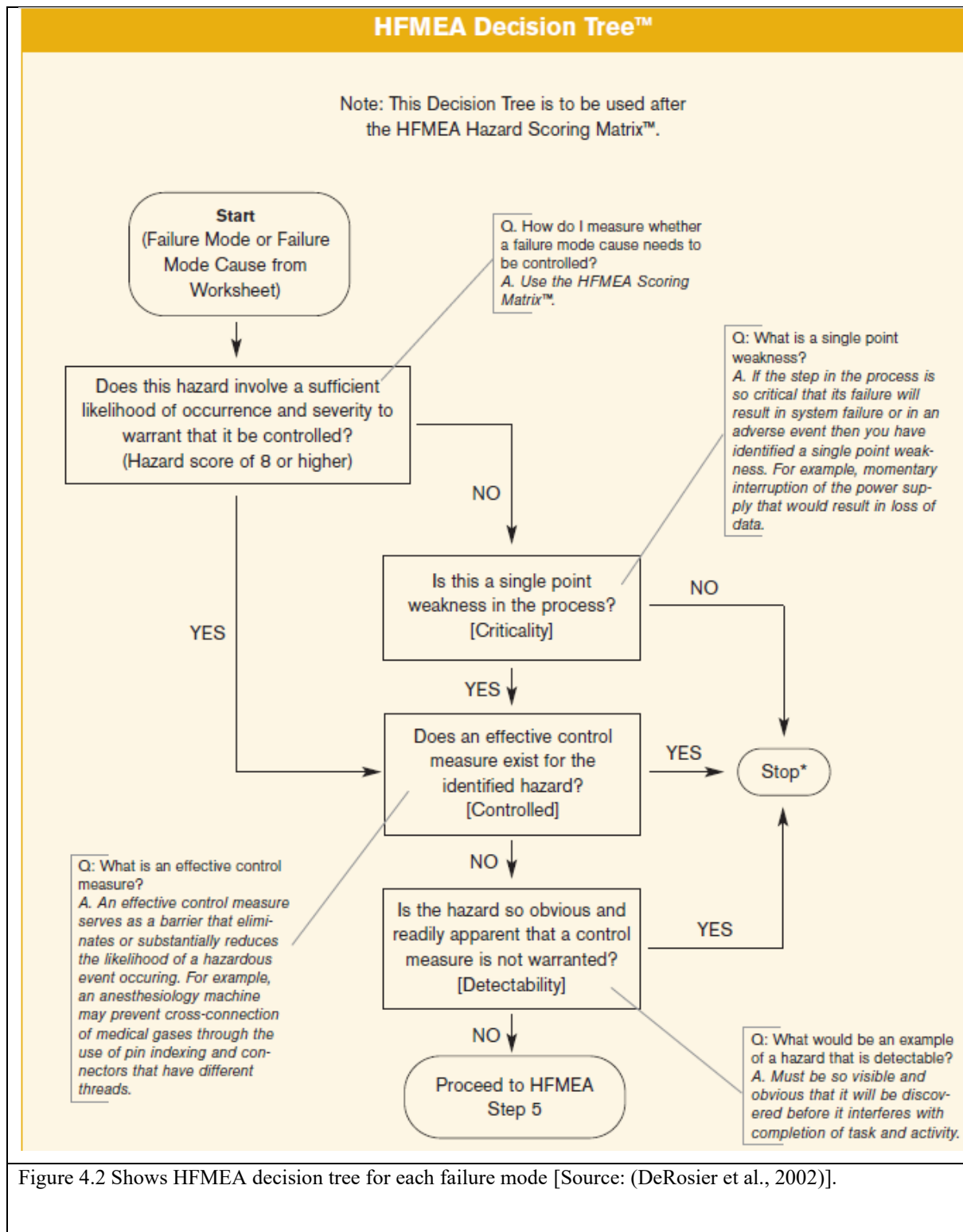


Figure 4.2 Shows HFMEA decision tree for each failure mode [Source: (DeRosier et al., 2002)].

HFMEA Worksheet™

Decoding the HFMEA™ Worksheet

Failure mode number
(eg, 1A1)

Always evaluate the failure mode first to determine if causes need to be identified.

Subprocess Step number

Subprocess description

Worksheet for Subprocess step 1A Hit Snooze Button

HFMEA Step 4—Hazard Analysis

HFMEA Step 5—Identify Actions and Outcomes

Failure Mode: First evaluate failure mode before determining potential causes		Scoring						Decision Tree Analysis				Action Type (Cont, Accept, Eliminate)				Outcome Measure	Person Responsible	Management Concurrence
		Potential Causes	Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?									

List failure mode, such as wrong speed for equipment

Subprocess number + Failure Mode number + Cause Identifier

Failure Mode

This space should be left blank, unless your hazard analysis determined a stop action. In that case, you would list the rationale for stopping.

Figure 4.3 Shows a blank HFMEA sample worksheet with illustrations (DeRosier et al., 2002)

Rationale of the current study

Healthcare Failure Mode and Effect Analysis (HFMEA) has been implemented in various medical fields, including medication administration (Fletcher, 1997), drug distribution systems (McNally et al., 1997), I.V drug infusion (Adachi and Lodolce, 2005) I.V pump infusion (Wetterneck et al., 2006) , epidemiology (Linkin et al., 2005), and surgery (Nagpal et al., 2010a). However, as far as the author of this thesis is aware, there has been no application of HFMEA or any comprehensive questionnaire to investigate the patient's journey within the IR pathway of care and identify potential failure modes that may occur during this process.

Despite the proven effectiveness of Healthcare Failure Mode and Effect Analysis (HFMEA) in mitigating system failures, there are significant challenges to its successful implementation. Healthcare systems have a legal obligation to prioritize patient safety and adhere to regulatory requirements. However, they must also balance these responsibilities with workload management, staff education and professional development, and administrative needs. These factors create four main barriers that impede certain steps of the conventional HFMEA process, particularly the assembly of a focus group meeting.

Hierarchy-related barrier: The IR pathway involves a diverse range of team members with varying levels of skills, education, professional grades, and backgrounds. This diversity in authority and expertise creates a hierarchical dynamic where lower-ranked members may feel unheard and influenced by their own skill biases. Additionally, there is a risk of succumbing to the "Bandwagon" phenomenon, as noted by Southard et al. (2011) (Southard et al., 2011).

Horizontal-dimension barrier: Patients in the IR pathway receive care from multiple departments, such as vascular wards, other wards, laboratories, and various other departments. Coordinating teams representing all these departments presents a significant challenge and may not be feasible.

Time-dimension barrier: Hospital operations run around the clock, requiring careful scheduling to ensure the full participation of all staff members. Assembling teams for comprehensive participation becomes a complex task.

Severity of patients' health condition: The critical health conditions of patients can hinder the organization of team meetings for quality improvement projects, as noted by Southard et al. (2011).

Considering these challenges, the author of this thesis adopted a mixed-method approach that combines elements of HFMEA with a questionnaire to target a diverse group of expert healthcare professionals in pathways where there are image-guided procedures such as IR, cardiac intervention, and vascular surgery to assess their perception and input about these failure modes.

4.4 Aim of the study

The aim of this study is to assess the perception of different groups of healthcare professionals towards different healthcare errors or scenarios that occur throughout the journey of patients who undergo image-guided procedures or interventions. The conclusion from the finding of this study is hoped to contribute to guide further studies about the healthcare errors, especially about the way to objectively assess them.

4.5 Outcome measure

The current study aims to measure the following variables:

- The degree importance, severity, and frequency of each healthcare event of failure mode from the perspective of the healthcare staff.
- What failure modes are perceived to have higher importance, severity, and probability?
- The consistency of the items of the questionnaire which measure specific domain.
- Correlation among different groups of healthcare professionals in terms of their perception of each domain.

4.6 Methodology

Setting

The study was performed at St Mary Hospital, Imperial College London NHS trusts teaching hospitals from March 2015 to November 2015. Further data were collected from July 2022 to June 2023. No ethical approval was required as this was a quality improvement project where no patient or staff identifiable information were collected.

Determining the sample size

A pilot study was conducted on 22 participants to assess the feasibility of the main study and provide preliminary data for sample size calculation. The significance level (alpha) is set at 0.05 throughout the thesis, indicating a 5% chance of a Type I error (which means rejecting the null hypothesis when it is true). The statistical power was set at 0.80 (80%). Statistical power is the probability of correctly detecting a true effect, or in other words, avoiding a Type II error (which means accepting the null hypothesis when it is false) (Jones et al., 2003).

Statistical Test: Based on the nature of the data in the pilot study, t-tests, and analysis of variance (ANOVA) were conducted to determine the difference between groups in their perception of the occurring healthcare errors during the image-guided procedure pathways. I used G Power software (version 3.1.9.7) to determine the appropriate sample size to ensure statistical power and validity in the subsequent data analysis.

Mixed methodology used in the current study.

In the current study, a mixed methodology was used to evaluate the perception of the healthcare experts about the healthcare failure modes that occur during the pathway of patients undergoing image-guided procedures. Using ideas from HFMEA, a cross sectional expert questionnaire was created and sent to different groups of professionals managing patients who undergo image-guided procedures (DeRosier et al., 2002). The studied pathway is shown in (Figure 4.5).

Methodology used to create the IR safety questionnaire in the pilot study.

A focus group of experts conducted a round-table discussion to formulate the possible failure modes to be included in the questionnaire. The team was comprised two consultant

Interventional radiologists_ with experience of 6 and 11years each, one consultant vascular surgeon with more than 10 years' experience in vascular surgery and a trained PhD fellow (the author of this thesis). Each of the IR and the vascular consultants had experience of more than 5 years in patient safety with several articles published about healthcare errors and patient safety. The coordinator of this study (FR) organised the meetings among the team and ensured the delivery and analysis of the questionnaire.

4.6.1.1 Content of the questionnaire initially

The themes emerged from the ethnographic data from the observational study in chapter 3 were utilised to create a bank of failure mode events or scenarios to be used in this study. Other items were added by brainstorming of possible events by the main research coordinator and the focus group. The list of the items was finalised from the literature for completion (Catchpole et al., 2006) (Catchpole et al., 2008), (Morbi et al., 2012).

Initially, the questionnaire in the pilot study contained 44 questions distributed across the pathway of care in the studied image-guided procedures. The questionnaire was created by a Microsoft Excel Sheet. Both paper format and electronic copy were used to target the healthcare professionals. A sample of the questionnaire is attached in ([Appendix Failure Modes_ Healthcare errors during the IR pathway of care](#)).

Six phases were identified in the IR pathway of care where failure modes or healthcare errors could happen.

- Phase I (in the ward): 7 failure modes or healthcare errors could occur in this phase, almost all of which fall under clerking of the patients.
- Phase II (handover to IR Nurse): 7 failure modes could occur in this phase, all of which are related to inadequate handover.
- Phase III (Immediate pre-procedure care): 4 FMs could occur which are related to consenting of the patients for their procedures, preparation of the room, equipment and planning of the procedures.

- Phase IV (procedural intervention): This phase contains 15 possible FMs exploring the domains of communication, planning, safety guideline adherence, leadership, and management.
- Phase V (handover to post procedure nursing staff): 4 FMs could occur, most of which are related to handover process.
- Phase VI (handover to ward or discharge to home): 7 FMs could happen, all of which are related to post-procedural plan.

4.6.1.2 The number and the characteristics of the participants in the pilot study

From 54 questionnaires sent to the healthcare professionals, 24 (44.4%) of which were completed. Seven Vascular Surgeons, Seven IR doctors, five radiographers, and five IR nurses participated in this cross-sectional study.

The sample size was calculated based on the difference in the means of the score ratings of the participated healthcare professionals of the possible occurring healthcare errors throughout the image-guided-procedure pathway of care. Using ANOVA (Analysis of variance), the effect size was measured. The finding of this test was used to calculate the sample size of the required participants in the actual study.

Modification of the initial questionnaire

The pilot study showed that the items of the questionnaire are too many and requires length time to complete. This would prevent the participants to complete them effectively as they get demotivated to continue through the whole questionnaire. Furthermore, the required participant number would not be achieved without modifications to the content and the way of delivery of the questionnaire.

Therefore, the questionnaire shortened from 44 items to only 12 items after grouping of some of the items under wider concepts and omitting of some other items which deemed unnecessary. For example, the items of the initial phase I (in the ward) were grouped together under the umbrella of inadequate clerking. Furthermore, the Phase V (handover to post procedure nursing staff) and Phase VI A (Handover to the referring ward) were merged with the Phase II (handover to IR Nurse) under a general category named handover. The proposed

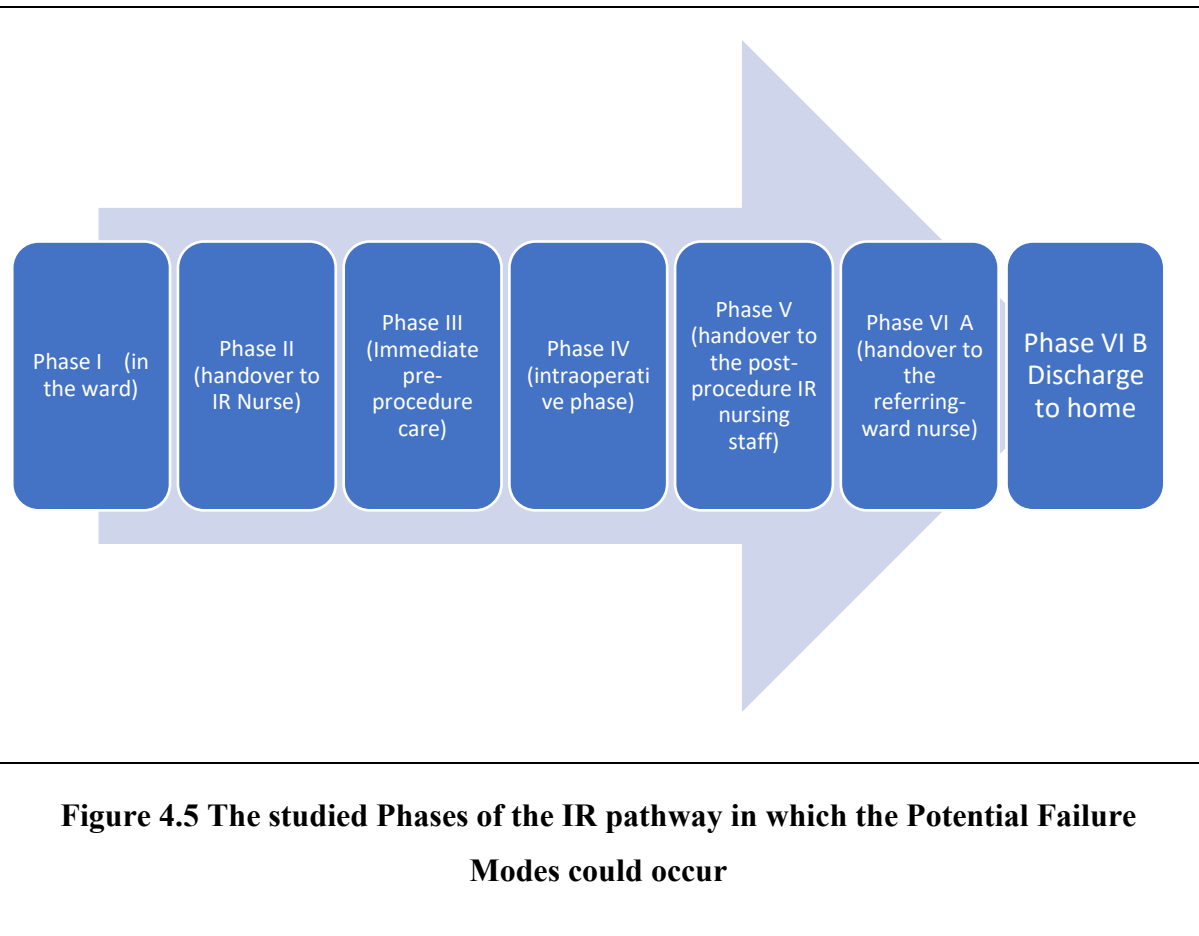
groups of healthcare errors or failure modes were summarized in (Figure 4.6). An example of a failure mode would be the Phase IV_ Intraoperative phase of the IR pathway. Equipment failures are assigned number 4D, which can manifest in various subtypes: 4D _1 refers to situations where the equipment becomes unavailable, 4D_2 denotes instances of equipment malfunctioning, and 4D_3 signifies calibration faults (Figure 4.7).

However, after consultation with the research team, the final prototype of the questionnaire was eventually more concise to ensure maximum completion rate. The final prototype of the questionnaire can be accessed through scanning the QR code or copy and paste the URL in one of the online search engines provided in Figure 4.4:



https://imperial.eu.qualtrics.com/jfe/form/SV_3EugjdS0PsBJrYG

Figure 4.4 Shows the QR code and the link to the final IR safety questionnaire



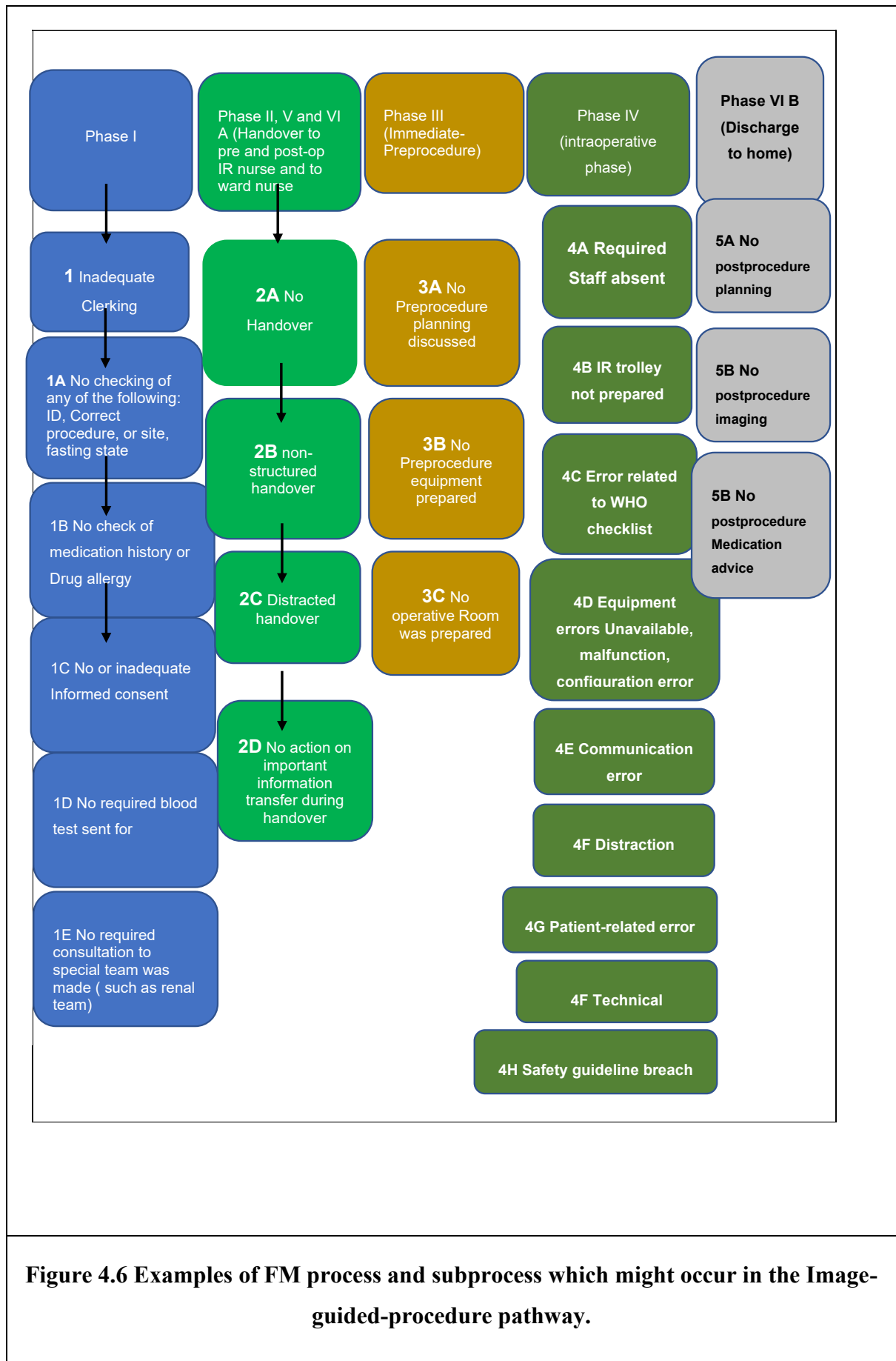
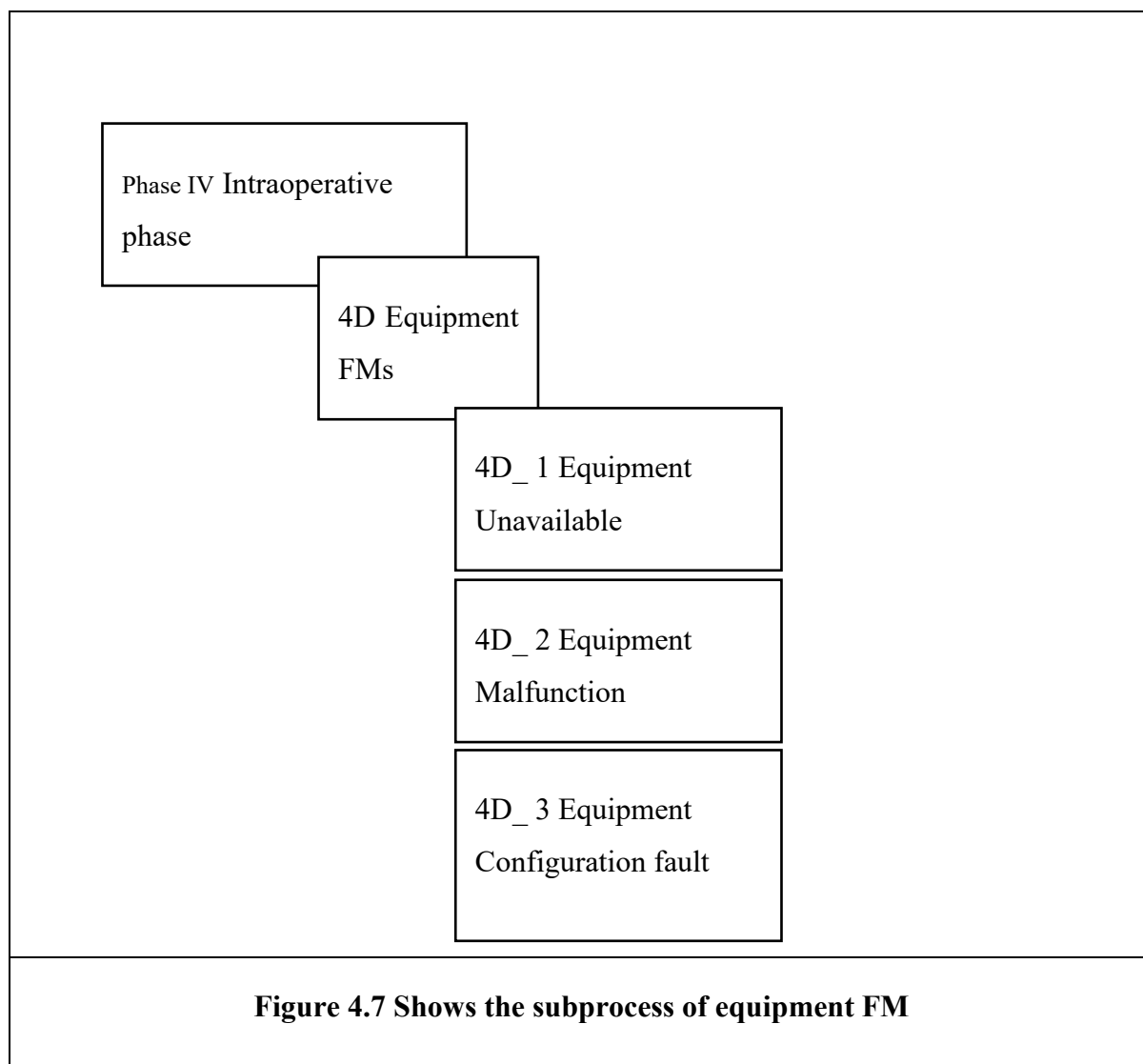


Figure 4.6 Examples of FM process and subprocess which might occur in the Image-guided-procedure pathway.



The method of delivering the questionnaire

The final version of the questionnaire is an online questionnaire which can be completed quickly, as it is a self-explanatory and contains a brief introduction.

The Statistical test used in validation of the questionnaire.

Analysis of Variance (ANOVA) in the pilot study was used to detect the effect size. Power analysis test using G Power test version 3.1.9.7 was used to calculate the sample size.

To assess the internal reliability of the questionnaire, Cronbach's Alpha reliability test was used. Non-parametric Independent-Samples Kruskal-Wallis Test was used to compare the rankings of different roles (IR Nurse, Vascular Surgery Nurse, Radiographer, IR doctors,

Vascular doctors) regarding the perception of different failure modes occurred in the pathway of care of the image-guided procedures. The Kruskal-Wallis test is used to find the difference of means among different groups when the dependent variable is ordinal or continuous and the independent variable is categorical.

To conduct pairs of groups, Mann Whitney U test was used. P value of 0.05 or less was considered statistically significant.

Different frequency tables were made using the SPSS version 24, from which various tables were transferred to Microsoft Excel spreadsheet. The individual items of the scale were grouped to form seven main domains, namely: Safety, planning, communication, equipment-related, coordination/leadership, external pressure and technical.

4.7 Results

The results of the pilot study used in the power calculation of the study sample.

Results of from the Analysis of Variance (ANOVA) in the pilot study revealed significant differences among the groups for the variables of Communication, Planning, Distraction, and Safety Check failures ($p < .001$).

For the variable Communication, there was a significant difference observed between the groups ($F(3, 116) = 7.128, P = <.001$). Further examination of the mean squares suggests that the variance between the groups (Mean Square = 5.634) is larger than the variance within the groups (Mean Square = 0.790).

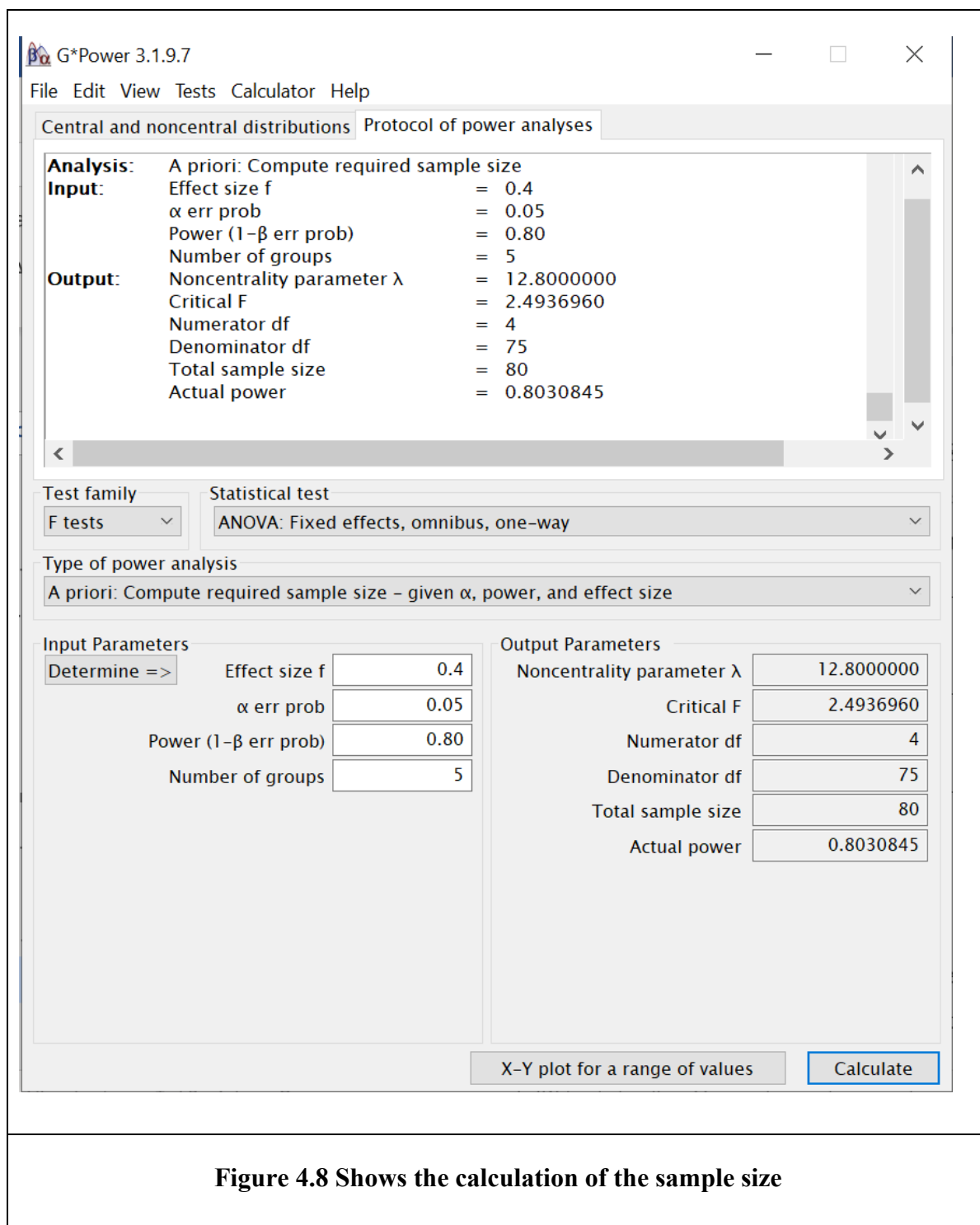
Similarly, for the variable Planning, a significant difference was found among the groups ($F(3, 196) = 8.268, P, < .001$). Regarding External Pressure/Patients/Departmental, a significant difference was observed between the groups ($F(3, 80) = 4.320, p = .007$). Lastly, for the variable Safety Checks/Issues, significant differences were found among the groups ($F(3, 261) = 11.908, P, < .001$).

These findings indicate that there are substantial variations in the perception of healthcare errors throughout the image-guided procedure pathways among different healthcare professional groups. Therefore, in calculating the sample size, we assumed a large effect size among the five groups of healthcare professionals participated in the study.

Rate of participation

Invitations to 200 participants across were sent by emails followed up by reminder emails and phone calls of some of the contacts. The targeted healthcare professionals were not restricted to the IR department of St Mary's Hospital, but also across all the hospitals under Imperial College London NHS trusts. Furthermore, requests were sent to the Radiology and the Neuroradiology departments of Queen Elizabeth Teaching Hospital NHS trust in Birmingham and the Radiology, Cardiac and Vascular Surgery Departments at St Helens and Knowsley Teaching Hospitals NHS trust in the Northwest of England. Requests were also sent to IR and vascular Consultants in Sweden, the UAE, and the Republic of Iraq. This is to ensure as many as healthcare experts participate in this questionnaire study.

The power analysis calculation revealed that a sample of 80 participants is needed to show a large effect size between the groups as assumed previously in the pilot study. The alpha level (P value) was set at 0.05, the power of the study was set at 80% and the targeted groups were 5 (Figure 4.8). Out of these 200 invitations, 106 (53%) recorded responses were received, from which only 80 (40%) questionnaires were completed correctly and included in the analysis. The rest were incomplete and excluded from the analysis. Once, the required number of responses was obtained, the potential respondents were not chased up to ask them to complete the questionnaire. The responses were anonymous making targeting individuals to urge them to complete the questionnaire extremely difficult if not impossible.

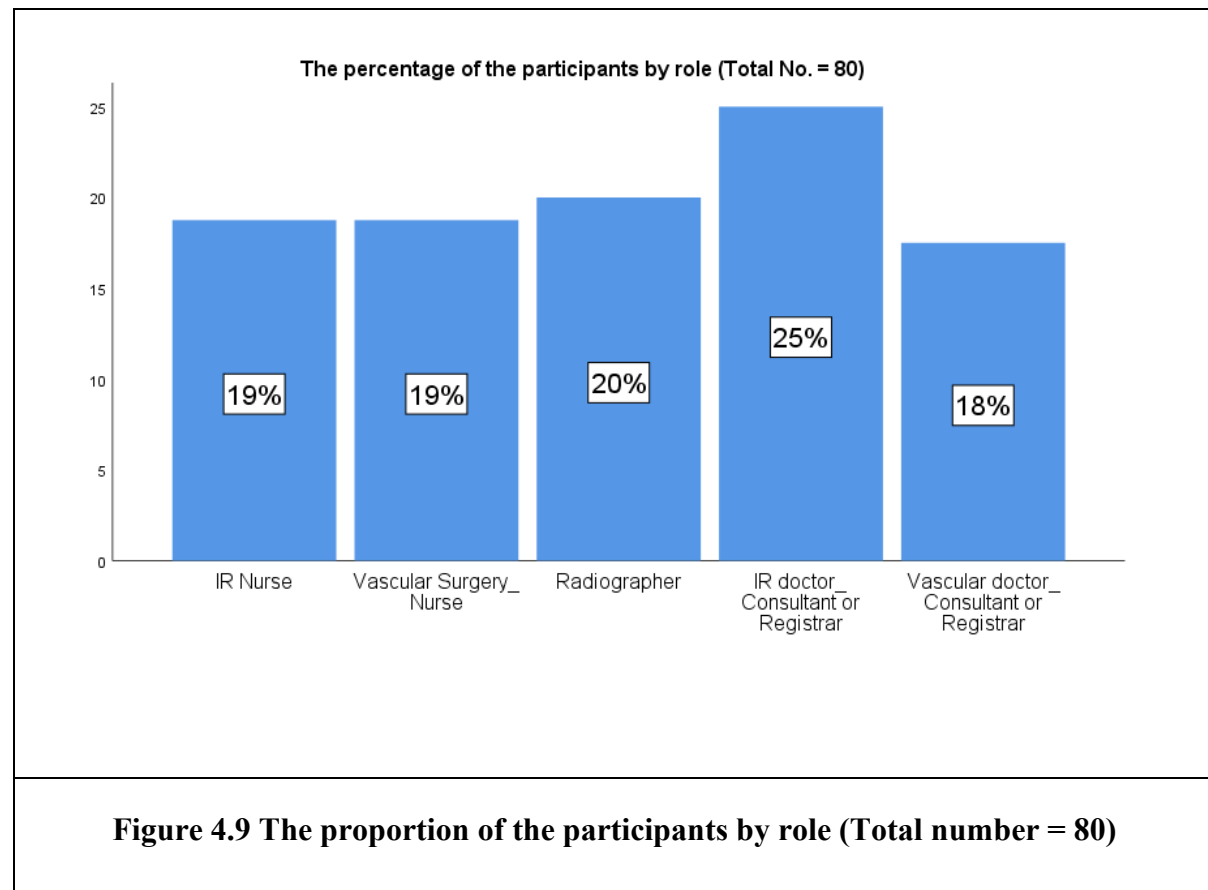


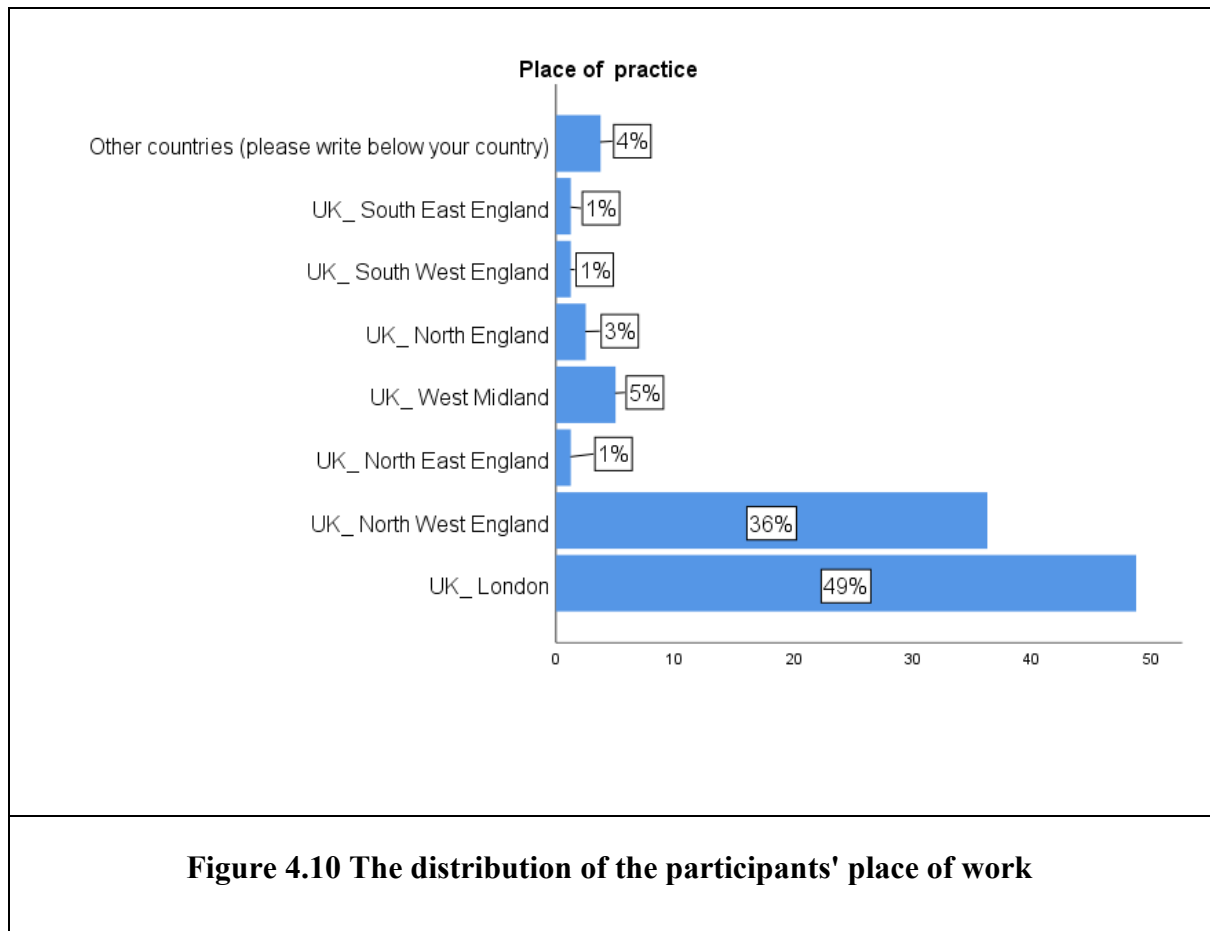
Measuring the internal reliability of the scale the individual items under different main domains

Using Cronbach's Alpha, the degree internal reliability of the questionnaire was measured. The Cronbach's Alpha coefficient of 0.887, and the Cronbach's Alpha based on standardized items of 0.894 indicated a very good level of internal reliability for the questionnaire.

The proportion of the participants by role

The participants were grouped into five groups namely: IR nurses _15 (19% of the total) , Vascular Surgery nurses 15 (19%), Radiographers_16 (20%), IR doctors_ Consultants or Registrars 20 (25%) and Vascular doctors_ Consultants or Registrars 14 (18%) (Figure 4.9).

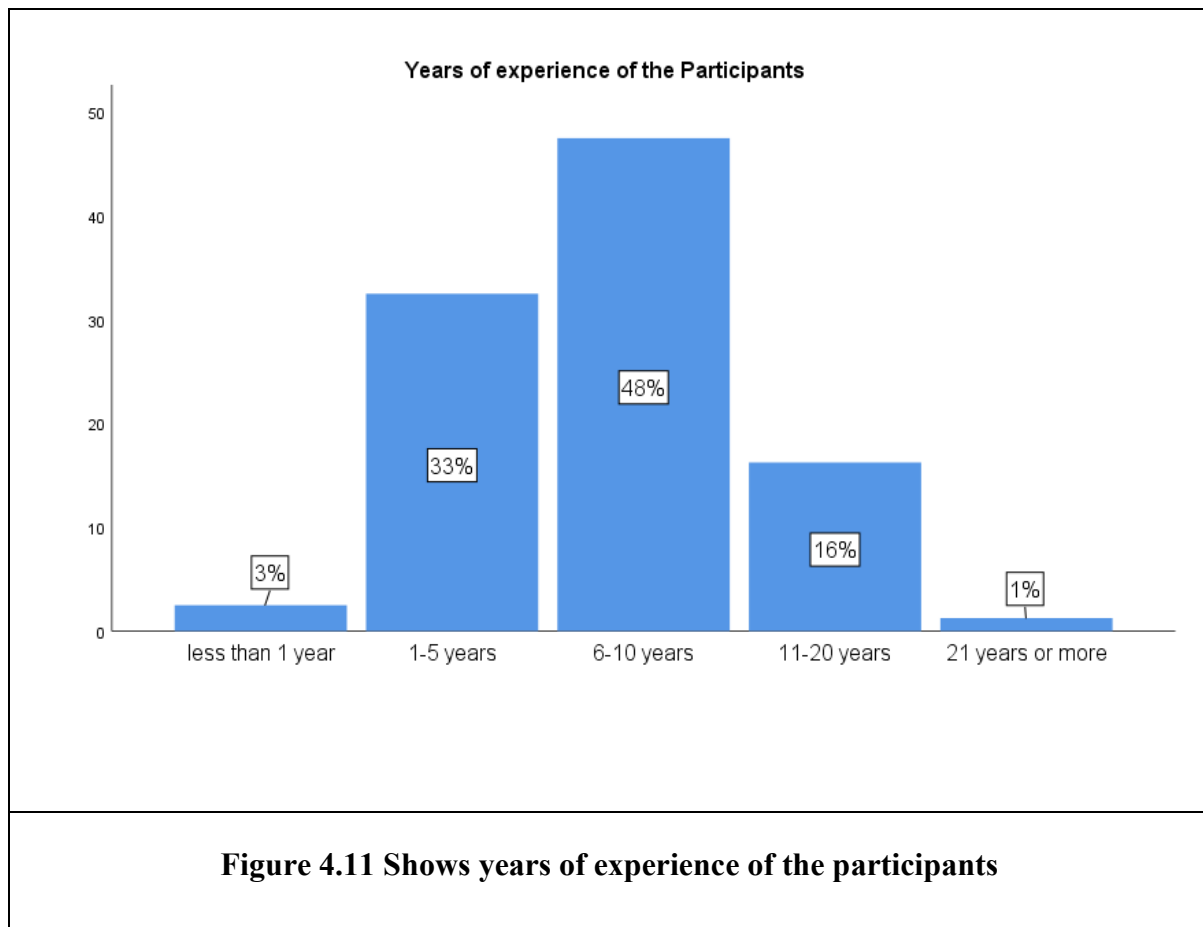




Location of the participants' place of work

Most of the participants were in the UK (96%) versus 4% located overseas (Middle East_ Iraq). Within the UK, most of the participants are located in London (49%) followed by Northwest England (36%) (Figure 4.10).

The years of experience of the participants



The categories of the Healthcare errors or Failure modes and their ratings

Twelve categories of healthcare errors or Failure modes were included in the final prototype of the questionnaire, four of them were in the preprocedure phase, seven of them were in the intraoperative phase and one of them was in the post-procedure phase.

Most of the healthcare errors or failure modes were believed to be extremely important, except Distraction and patient-related-errors which received a rating of moderate importance (a rate 3 out of 4).

Table 4.4 Shows the rated possible healthcare errors or failure modes by the participants												
Healthcare errors or failure modes	Importance				Severity				Probability			
	Not important	Mildly	Moderately important	Extremely	Mild n (%)	Moderate n(%)	Severe n (%)	Catastrophic	Remote	Uncommon	Occasional	Frequent
Inadequate patient clerking including incorrect informed consent.	1 (1.3)	7 (8.8)	17 (21.3)	55 (68.8)	8 (10)	41 (51.2)	19 (23.8)	12 (15)	9 (11.3)	28 (35)	27 (33.8)	16 (20)
No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure.	3 (3.8)	6 (7.5)	18 (22.5)	53 (66.3)	8 (10)	54 (67.5)	15 (8.8)	3 (3.8)	4 (5)	23 (28.8)	19 (23.8)	34 (42.5)
Inadequate handover	2 (2.5)	8 (10)	17 (21.3)	53 (66.3)	6 (7.5)	41 (51.3)	25 (31.3)	8 (10)	3 (3.8)	25 (31.3)	37 (46.3)	15 (18.8)
Pre-procedural planning	2 (2.5)	2 (2.5)	22 (27.5)	54 (67.5)	8 (10)	23 (28.8)	34 (42.5)	15 (18.8)	6 (7.5)	38 (47.5)	23 (28.8)	13 (16.3)
A team member is absent when needed	2 (2.5)	10 (12.5)	24 (30)	44 (55)	5 (6.3)	45 (56.3)	23 (28.8)	7 (8.8)	11 (13.8)	28 (35)	23 (28.8)	18 (22.5)
Violation of safety guideline (not wearing mask) incorrect WHO checklist	2 (2.5)	7 (8.8)	18 (22.5)	53 (66.3)	7 (8.8)	27 (33.8)	34 (42.5)	12 (15)	24 (30)	30 (37.4)	21 (26.3)	5 (6.3)
Communication errors	2 (2.5)	7 (8.8)	19 (23.8)	52 (65)	7 (8.8)	44 (55)	20 (25)	9 (11.3)	9 (11.3)	33 (41.3)	28 (35)	10 (12.5)

Distraction (mobile phone ringing, irrelevant talks, or external staff)	2 (2.5)	19 (23.8)	36 (45)	23 (28.8)	21 (26.3)	46 (57.5)	8 (10)	5 (6.3)	8 (10)	21 (26.3)	20 (25)	31 (38.8)
Technical errors _ by performing team or member	2 (2.5)	7 (8.8)	22 (27.5)	49 (61.3)	7 (8.8)	20 (25)	42 (52.5)	11 (13.8)	7 (8.8)	47 (58.8)	17 (21.3)	9 (11.3)
Patients _related errors(uncooperative or restless during the procedure, or anatomical or physiological characteristics, such as overweight, high BP, or calcified arteries	2 (2.5)	6 (7.5)	39 (48.8)	33 (41.3)	3 (3.8)	45 (56.3)	27 (33.8)	5 (6.3)	5 (6.3)	27 (33.8)	36 (45)	12 (15)
Procedure-related errors. Example: During an (EVAR), a complex nature of the aneurysm, requiring advanced technical skills and careful decision-making	1 (1.3)	8 (10)	27 (33.8)	44 (55)	5 (6.3)	16 (20)	44 (55)	15 (18.7)	15 (18.8)	47 (58.8)	10 (12.5)	8 (10)
No post-procedure plan discussed or recorded in the patient's notes.	2 (2.5)	14 (17.5)	20 (25)	44 (55)	4 (5)	40 (50)	29 (36.3)	7 (8.8)	17 (21.3)	38 (47.5)	20 (25)	5 (6.3)

None of the errors were rated catastrophic by most participants. However, the following healthcare errors received a rating of severe from higher to lower percentage:

Procedure-related errors 44 (55%), Technical errors 42(52.5%), Violation of safety guideline and Inadequate Handover each at rates of 34(42.5%).

Only "No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation and " Distraction" were rated frequently occurring errors by the majority of the participants at rates of 34(42.5%) and 31(38.8%) respectively. There was a consensus that no errors of included in the questionnaire were rare or remote (Table 4.4).

How different team members perceive importance of the main domains of the failure modes throughout the IR pathway of care.

Kruskal-Wallis test was used to compare the rankings of different roles (IR Nurse, Vascular Surgery Nurse, Radiographer, IR doctor - Consultant or Registrar, Vascular doctor - Consultant or Registrar) regarding the perception of different healthcare errors or failure modes.

1. Inadequate patient clerking:

The perception of the importance of *"inadequate patient clerking and informed consent for a vascular operation or an Interventional IR or cardiac procedure"* was assessed and revealed a statistically significant differences between the groups in their rankings (P-value = 0.023).

To further investigate the differences between the groups, we conducted Mann-Whitney U test. There was a statistically significant difference between the IR Nurses (mean Rank = 19.60) and the Vascular Surgery_ Nurses (mean Rank= 11.40) in their rating of the above-mentioned error (P = .002). There was also a significant difference between the rating of the vascular surgery nurses (Mean Rank =12.70) and the radiographers (mean Rank= 19.09) in rating the importance of the inadequate clerking (P = .049). However, the other groups' rankings were similar.

No statistically significant differences were found in the perception of the severity of *"inadequate patient clerking including informed consent for a vascular operation or an Interventional IR or cardiac procedure"* among different roles (H (4) = 6.336, p = .175).

However, there was a significant difference in the perception of the probability of the same error among different roles ($H(4) = 16.367, p = .003$).

Using Mann-Whitney U test, a statistically significant difference was found in the rating of the probability of the above-mentioned error between the Vascular Surgery_ Nurses and the IR Nurses ($P = .001$), the Vascular Doctors ($P = 0.008$), the IR doctors ($P = .012$) and the Radiographers ($P = .001$) respectively.

No difference between the IR Nurse with the radiographers, the IR doctors, and the vascular doctors in their perception of the above error ($P = .528$), ($P = 0.297$) and ($P = 0.395$) respectively.

2. No bed- Equipment-Room preparation:

The perception of the participants was statistically significantly different regarding the importance and severity of the failure mode-healthcare errors: "*No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure*" [with ($P, <.0001$) and ($P = 0.047$) respectively]. However, the probability of the above FMs were rated similarly ($P = .446$) (Table 4.5).

The lowest mean ranking was given by the Vascular doctors to the importance of the above errors (Mean Rank = 16.11). The second lowest importance rating was given by the IR doctors (Mean Rank = 38.98). The ratings from the highest were given by the radiographers, Vascular Surgery nurses and the IR nurses with the mean ranks of (51.78), (51.63) and (42.13) respectively.

Comparison between groups using Mann-Whitney U test revealed a statistically significant difference in the rating of the importance of the above errors between the Vascular Doctors on one side and the Vascular surgery nurses, the IR nurses, the Radiographers, and the IR doctors on the other side ($P = <.001$) and ($P = 0.004$), ($P, <0.001$), ($P = 0.001$) respectively.

The IR doctors recorded less scores to the importance of the above errors "*No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure*" than the IR nurses and the Radiographers ($P = 0.027$ and 0.021 respectively). No difference between the IR doctors and the Vascular surgery nurses

was found ($P=0.648$). On the other hand, the ratings among other groups (IR nurses, Vascular Surgery nurses and the Radiographers) were similar.

Table 4.5 Shows the perception towards the importance, severity and probability of "No bed Equipment_ Room preparation" FM by different roles

	No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure. - Importance	No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure. - Severity	No bed arrangement for an inpatient case or no pre-procedure room or Equipment preparation for a vascular operation or an IR/ cardiac procedure. - Probability
Kruskal-Wallis H	32.690	9.653	3.716
df	4	4	4
Asymp. Sig.	.000	.047	.446
a. Kruskal Wallis Test			
b. Grouping Variable: Role - Selected Choice			

3. Inadequate handover:

There was a statistically significant difference among the participants in the rating of importance of the FM_ Healthcare error "Inadequate handover". The Vascular doctors scored the lowest rating ($M=22.93$) followed by the IR doctors ($M=31.75$). The highest score was given by the IR nurses ($M=54.00$) ($P, < .001$). Similarly, the probability score shows differences in the ratings among the healthcare participants, in which the IR doctors scored the lowest ratings ($M=25.45$) ($P=.009$) (Table 4.6).

However, similar ratings were observed among the participants in the severity scoring of the above-mentioned error ($P=0.136$).

The Mann-Whitney U test showed a similar rating between the Vascular doctors and the IR doctors in terms of importance of the above error ($P = 0.280$). However, the Vascular doctors' rating was different with the rest of the participants [with the Vascular surgery nurses ($P = .001$), with the IR nurses ($P, <.001$), and with the Radiographers ($P=.002$).

The rest of the participants (IR nurses, Vascular surgery nurses, Radiographers, and the IR doctors) were similar.

Table 4.6 Shows the Ratings of the participants of " Inadequate handover" FM: importance, severity, and probability

FM_ Healthcare error	Role	N	Mean Rank		
Inadequate handover - Importance	IR Nurse	15	54.00	Kruskal-Wallis H	26.911
	Vascular Surgery_ Nurse	15	48.50	df	4
	Radiographer	16	46.66	Asymp. Sig.	.000
	IR doctor_ Consultant or Registrar	20	31.75		
	Vascular doctor_ Consultant or Registrar	14	22.93		
	Total	80			
Inadequate handover_ Severity	IR Nurse	15	45.23	Kruskal-Wallis H	6.998
	Vascular Surgery_ Nurse	15	35.80	df	4
	Radiographer	16	50.72	Asymp. Sig.	.136
	IR doctor_ Consultant or Registrar	20	35.03		
	Vascular doctor_ Consultant or Registrar	14	36.61		
	Total	80			
Inadequate handover _ Probability	IR Nurse	15	48.80	Kruskal-Wallis H	13.473
	Vascular Surgery_ Nurse	15	43.60	df	4
	Radiographer	16	45.50	Asymp. Sig.	.009
	IR doctor_ Consultant or Registrar	20	25.45		
	Vascular doctor_ Consultant or Registrar	14	44.07		
	Total	80			

4. Pre-procedural planning

There was a significant difference among the roles in rating the importance of the "pre-procedural planning" ($H(4) = 12.417$, $P = .015$). The mean ranks indicate that IR Nurses rated the importance the highest ($M = 53.50$), followed by Radiographers ($M = 44.00$), IR Doctors - Consultant or Registrar ($M = 36.90$), Vascular Doctors - Consultant or Registrar ($M = 38.21$), and Vascular Surgery Nurses ($M = 30.70$) (**Table 4.7**).

In contrast, for the Severity of the above error, the Kruskal-Wallis test did not indicate a significant difference among the roles ($H(4) = .989$, $P = .911$). The mean ranks suggest that the perceived severity of the failure mode was relatively consistent across all roles, with IR Nurses having the highest mean rank ($M = 38.63$), followed by IR Doctors - Consultant or Registrar ($M = 40.90$), Vascular Doctors - Consultant or Registrar ($M = 43.00$), Radiographers ($M = 43.16$), and Vascular Surgery Nurses ($M = 36.67$).

For the Probability, the Kruskal-Wallis test revealed a significant difference among the roles ($H(4) = 14.921$, $P = .005$). IR Nurses rated the probability the highest ($M = 53.87$), followed by Vascular Doctors - Consultant or Registrar ($M = 45.50$), Radiographers ($M = 26.56$), IR Doctors - Consultant or Registrar ($M = 35.10$), and Vascular Surgery Nurses ($M = 44.53$).

Table 4.7 Rating of the FM " Pre-procedural planning"

	Role - Selected Choice	N	Mean Rank		
Pre-procedural planning_Importance	IR Nurse	15	53.50	Kruskal-Wallis H	12.417
	Vascular Surgery_ Nurse	15	30.70	df	4
	Radiographer	16	44.00	Asymp. Sig.	.015
	IR doctor_ Consultant or Registrar	20	36.90		
	Vascular doctor_ Consultant or Registrar	14	38.21		
	Total	80			
Pre-procedural planning_Severity	IR Nurse	15	38.63	Kruskal-Wallis H	.989
	Vascular Surgery_ Nurse	15	36.67	df	4
	Radiographer	16	43.16	Asymp. Sig.	.911
	IR doctor_ Consultant or Registrar	20	40.90		
	Vascular doctor_ Consultant or Registrar	14	43.00		
	Total	80			
Pre-procedural planning_Probability	IR Nurse	15	53.87	Kruskal-Wallis H	14.921
	Vascular Surgery_ Nurse	15	44.53	df	4
	Radiographer	16	26.56	Asymp. Sig.	.005
	IR doctor_ Consultant or Registrar	20	35.10		
	Vascular doctor_ Consultant or Registrar	14	45.50		
	Total	80			

5. A team member is absent when needed.

The rating of the importance of the variable "A team member is absent when needed" by using Kruskal-Wallis test revealed a significant difference among the roles ($H(4) = 13.377$, $p = .010$). The mean ranks indicate that IR Nurses rated the importance the highest ($M = 53.97$), followed by Radiographers ($M = 46.81$), Vascular Surgery Nurses ($M = 39.23$), IR Doctors - Consultant or Registrar ($M = 33.25$), and Vascular Doctors - Consultant or Registrar ($M = 30.57$).

In terms of the severity of the above error the Kruskal-Wallis test did not indicate a significant difference among the roles ($H(4) = 3.803$, $p = .433$). The mean ranks suggest that the perceived severity of the failure mode was relatively consistent across all roles, with Vascular Surgery Nurses having the highest mean rank ($M = 45.87$), followed by Radiographers ($M = 42.88$), IR Doctors - Consultant or Registrar ($M = 42.30$), Vascular Doctors - Consultant or Registrar ($M = 38.07$), and IR Nurses ($M = 32.47$).

Regarding the ratings of the probability of the above healthcare error a marginally but no statistically significant difference among the roles was found ($H(4) = 9.132$, $P = .058$). The mean ranks indicate that IR Nurses rated the probability the highest ($M = 49.80$), followed by Vascular Surgery Nurses ($M = 46.60$), IR Doctors - Consultant or Registrar ($M = 42.80$), Radiographers ($M = 31.94$), and Vascular Doctors - Consultant or Registrar ($M = 30.50$).

6. Violation of safety guideline (not wearing mask) or the WHO checklist was incorrect:

The ratings of the Importance of the "Violation of safety guideline " revealed a significant difference among the roles ($H(4) = 17.736$, $p = .001$). The mean ranks indicate that IR Nurses rated the importance the highest ($M = 51.63$), followed by Radiographers ($M = 46.56$), Vascular Surgery Nurses ($M = 42.03$), IR Doctors - Consultant or Registrar ($M = 38.10$), and Vascular Doctors - Consultant or Registrar ($M = 23.43$).

In terms of its Severity, the Kruskal-Wallis test did not indicate a significant difference among the roles ($H(4) = 5.939$, $p = .204$). The mean ranks suggest that the perceived severity of the failure mode was relatively consistent across all roles, with IR Nurses having the highest mean rank ($M = 45.83$), followed by Radiographers ($M = 45.31$), Vascular Surgery Nurses ($M = 44.40$), IR Doctors - Consultant or Registrar ($M = 37.15$), and Vascular Doctors - Consultant or Registrar ($M = 29.89$).

Regarding the Probability of occurrence of the above failure mode, the Kruskal-Wallis test revealed a significant difference among the roles ($H(4) = 12.655$, $p = .013$). The mean ranks indicate that Radiographers rated the probability the highest ($M = 54.38$), followed by IR Nurses ($M = 46.13$), Vascular Surgery Nurses ($M = 39.20$), IR Doctors - Consultant or Registrar ($M = 33.88$), and Vascular Doctors - Consultant or Registrar ($M = 29.46$).

These findings suggest the perceived severity remains relatively consistent across the roles, indicating a shared understanding of the effect of this failure mode.

7. Communication errors among the team:

Using the Kruskal-Wallis test, a significant difference among the roles was revealed in the rating of "Communication errors among the team" in all aspects namely: importance, severity, and probability. In terms of importance, the results were ($H(4) = 14.459$, $p = .006$). The mean ranks indicate that IR Nurses rated the importance the highest ($M = 54.50$), followed by Radiographers ($M = 46.75$), IR Doctors - Consultant or Registrar ($M = 35.05$), Vascular Surgery Nurses ($M = 33.83$), and Vascular Doctors - Consultant or Registrar ($M = 33.29$).

In terms of Severity of the "Communication errors among the team", the Kruskal-Wallis test also indicated a significant difference among the roles ($H(4) = 11.247$, $p = .024$). The mean ranks suggest that Vascular Doctors - Consultant or Registrar rated the severity the highest ($M = 52.61$), followed by IR Nurses ($M = 46.07$), IR Doctors - Consultant or Registrar ($M = 41.20$), Vascular Surgery Nurses ($M = 34.00$), and Radiographers ($M = 29.91$).

In terms of the Probability of the same error, the Kruskal-Wallis test revealed a significant difference among the roles ($H(4) = 11.989$, $p = .017$). The mean ranks indicate that IR Nurses rated the probability the highest ($M = 48.73$), followed by Vascular Doctors - Consultant or Registrar ($M = 49.82$), Vascular Surgery Nurses ($M = 45.57$), IR Doctors - Consultant or Registrar ($M = 32.65$), and Radiographers ($M = 29.69$)(**Table 4.8**).

Table 4.8 Communication Rating by the Participants					
	Role - Selected Choice	N	Mean Rank		
Communication errors_ Importance	IR Nurse	15	54.50	Kruskal- Wallis H	14.45 9
	Vascular Surgery_ Nurse	15	33.83	df	4
	Radiographer	16	46.75	Asymp. Sig.	.006
	IR doctor_ Consultant or Registrar	20	35.05		
	Vascular doctor_ Consultant or Registrar	14	33.29		
	Total	80			
Communication errors among the team for example lack/ misleading or misheard communication_ Severity	IR Nurse	15	46.07	Kruskal- Wallis H	11.24 7
	Vascular Surgery_ Nurse	15	34.00	df	4
	Radiographer	16	29.91	Asymp. Sig.	.024
	IR doctor_ Consultant or Registrar	20	41.20		
	Vascular doctor_ Consultant or Registrar	14	52.61		
	Total	80			
Communication errors among the team for example lack/ misleading or misheard communication_ Probability	IR Nurse	15	48.73	Kruskal- Wallis H	11.98 9
	Vascular Surgery_ Nurse	15	45.57	df	4
	Radiographer	16	29.69	Asymp. Sig.	.017
	IR doctor_ Consultant or Registrar	20	32.65		
	Vascular doctor_ Consultant or Registrar	14	49.82		
	Total	80			

8. "Intra-operative distraction" Failure mode/healthcare error

The ratings of the importance of "Intra-operative distraction" using Kruskal-Wallis test indicated a significant difference among the roles ($H(4) = 23.292, p < .001$). The mean ranks suggest that Radiographers rated the importance the highest ($M = 60.03$), followed by Vascular Surgery Nurses ($M = 43.83$), IR Doctors - Consultant or Registrar ($M = 37.90$), IR Nurses ($M = 36.10$), and Vascular Doctors - Consultant or Registrar ($M = 23.04$)(Table 4.9).

Regarding the severity of "Intra-operative distraction" the Kruskal-Wallis test did not reveal a significant difference among the roles ($H(4) = 3.332, p = .504$). The mean ranks indicate similar severity ratings across the roles, with Radiographers having the highest mean rank ($M = 44.50$), followed by IR Nurses ($M = 45.00$), Vascular Surgery Nurses ($M = 42.27$), IR Doctors - Consultant or Registrar ($M = 37.15$), and Vascular Doctors - Consultant or Registrar ($M = 34.00$).

Regarding the probability of the "Intra-operative distraction", the Kruskal-Wallis test indicated a significant difference among the roles ($H(4) = 9.769, p = .044$). The mean ranks suggest that Vascular Surgery Nurses rated the probability the highest ($M = 53.43$), followed by IR Doctors - Consultant or Registrar ($M = 40.65$), IR Nurses ($M = 39.80$), Vascular Doctors - Consultant or Registrar ($M = 40.79$), and Radiographers ($M = 28.59$).

Table 4.9 Ratings of the "Intra-operative distraction" by the participants

Failure mode/Healthcare error	Role - Selected Choice	N	Mean Rank		
Intra-operative distraction by anything including mobile phone ringing, irrelevant talks, or external staff_Importance	IR Nurse	15	36.10	Kruskal-Wallis H	23.292
	Vascular Surgery_ Nurse	15	43.83	df	4
	Radiographer	16	60.03	Asymp. Sig.	.000
	IR doctor_ Consultant or Registrar	20	37.90		
	Vascular doctor_ Consultant or Registrar	14	23.04		
	Total	80			
Intra-operative distraction by anything including mobile phone ringing, irrelevant talks, or external staff_Severity.	IR Nurse	15	45.00	Kruskal-Wallis H	3.332
	Vascular Surgery_ Nurse	15	42.27	df	4
	Radiographer	16	44.50	Asymp. Sig.	.504
	IR doctor_ Consultant or Registrar	20	37.15		
	Vascular doctor_ Consultant or Registrar	14	34.00		
	Total	80			
Intra-operative distraction by anything including mobile phone ringing, irrelevant talks, or external staff_Probability	IR Nurse	15	39.80	Kruskal-Wallis H	9.769
	Vascular Surgery_ Nurse	15	53.43	df	4
	Radiographer	16	28.59	Asymp. Sig.	.044
	IR doctor_ Consultant or Registrar	20	40.65		
	Vascular doctor_ Consultant or Registrar	14	40.79		
	Total	80			

9. Technical errors by the performing team

The ranks presented in (Table 4.10) illustrate the perceptions of different roles regarding "Technical errors by the performing team or member."

Importance of the above error, the Kruskal-Wallis test did not reveal a significant difference among the roles ($H(4) = 5.477$, $p = .242$). The mean ranks suggest that Radiographers had the highest rank ($M = 48.16$) in perceiving the importance of technical errors, followed by Vascular Doctors - Consultant or Registrar ($M = 43.32$), IR Doctors - Consultant or Registrar ($M = 39.40$), IR Nurses ($M = 39.87$), and Vascular Surgery Nurses ($M = 31.80$).

Regarding the Severity, the test also did not indicate a significant difference among the roles ($H(4) = 2.594$, $p = .628$). The mean ranks show similar severity perceptions across the roles, with Vascular Doctors - Consultant or Registrar having the highest rank ($M = 45.96$), followed by IR Doctors - Consultant or Registrar ($M = 42.70$), Radiographers ($M = 39.91$), Vascular Surgery Nurses ($M = 39.63$), and IR Nurses ($M = 33.97$).

For the Probability, no significant difference was found among the roles ($H(4) = 3.996$, $p = .407$). The mean ranks suggest that IR Nurses had the highest rank ($M = 46.73$) in perceiving the probability of technical errors, followed by Vascular Doctors - Consultant or Registrar ($M = 43.29$), IR Doctors - Consultant or Registrar ($M = 38.10$), Vascular Surgery Nurses ($M = 42.53$), and Radiographers ($M = 33.31$).

Table 4.10 Rating of the "Technical errors" by the participants					
Healthcare error	Role - Selected Choice	N	Mean Rank		
Technical errors by the performing team or member_Importance	IR Nurse	15	39.87	Kruskal-Wallis H	5.477
	Vascular Surgery_ Nurse	15	31.80	df	4
	Radiographer	16	48.16	Asymp. Sig.	.242
	IR doctor_ Consultant or Registrar	20	39.40		
	Vascular doctor_ Consultant or Registrar	14	43.32		
	Total	80			
Technical errors by the performing team or member_Severity	IR Nurse	15	33.97	Kruskal-Wallis H	2.594
	Vascular Surgery_ Nurse	15	39.63	df	4
	Radiographer	16	39.91	Asymp. Sig.	.628
	IR doctor_ Consultant or Registrar	20	42.70		
	Vascular doctor_ Consultant or Registrar	14	45.96		
	Total	80			
Technical errors by the performing team or member_Probability	IR Nurse	15	46.73	Kruskal-Wallis H	3.996
	Vascular Surgery_ Nurse	15	42.53	df	4
	Radiographer	16	33.31	Asymp. Sig.	.407
	IR doctor_ Consultant or Registrar	20	38.10		
	Vascular doctor_ Consultant or Registrar	14	43.29		
	Total	80			

10. Patients with unique challenges

The provided table (Table 4.11) presents the ranks for different roles in terms of their perceptions of patients who present unique challenges during procedures. These challenges may include patient uncooperativeness, restlessness, or specific anatomical/physiological characteristics such as obesity, high blood pressure, or calcified arteries.

For the importance of this error, the Kruskal-Wallis test did not indicate a significant difference among the roles ($H(4) = 8.798$, $p = .066$). However, the mean ranks suggest that IR Nurses had the highest rank ($M = 50.50$) in perceiving the importance of these unique challenges, followed by Radiographers ($M = 47.44$), IR Doctors - Consultant or Registrar ($M = 37.03$), Vascular Doctors - Consultant or Registrar ($M = 35.71$), and Vascular Surgery Nurses ($M = 32.20$).

Regarding the Severity of the above error, the Kruskal-Wallis test again did not show a significant difference among the roles ($H(4) = 6.514$, $p = .164$). The mean ranks indicate that Vascular Doctors - Consultant or Registrar had the highest rank ($M = 51.71$) in perceiving the severity of these challenges, followed by IR Nurses ($M = 42.00$), Radiographers ($M = 39.50$), IR Doctors - Consultant or Registrar ($M = 37.80$), and Vascular Surgery Nurses ($M = 33.20$).

While the perception Probability of the above failure mode, the Kruskal-Wallis test found a significant difference among the roles ($H(4) = 12.224$, $p = .016$). The mean ranks suggest that IR Nurses had the highest rank ($M = 54.30$) in perceiving the probability of encountering these unique challenges, followed by Vascular Doctors - Consultant or Registrar ($M = 42.61$), IR Doctors - Consultant or Registrar ($M = 39.55$), Radiographers ($M = 39.66$), and Vascular Surgery Nurses ($M = 26.90$).

Table 4.11 Rating of the importance of the FM " Patients who present unique challenges

Failure Mode	Role - Selected Choice	N	Mean Rank		
Patients who present unique challenges_ Importance	IR Nurse	15	50.50	Kruskal-Wallis H	8.798
	Vascular Surgery_ Nurse	15	32.20	df	4
	Radiographer	16	47.44	Asymp. Sig.	.066
	IR doctor_ Consultant or Registrar	20	37.03		
	Vascular doctor_ Consultant or Registrar	14	35.71		
	Total	80			
Patients who present unique challenges_ Severity	IR Nurse	15	42.00	Kruskal-Wallis H	6.514
	Vascular Surgery_ Nurse	15	33.20	df	4
	Radiographer	16	39.50	Asymp. Sig.	.164
	IR doctor_ Consultant or Registrar	20	37.80		
	Vascular doctor_ Consultant or Registrar	14	51.71		
	Total	80			
Patients who present unique challenges_ Probability	IR Nurse	15	54.30	Kruskal-Wallis H	12.224
	Vascular Surgery_ Nurse	15	26.90	df	4
	Radiographer	16	39.66	Asymp. Sig.	.016
	IR doctor_ Consultant or Registrar	20	39.55		
	Vascular doctor_ Consultant or Registrar	14	42.61		
	Total	80			

11. Procedure-related errors during complex

The provided (**Table 4.12**) presents the ranks for different roles in terms of their perceptions of procedure-related errors during, for example, an intricate image-guided procedure such as endovascular aneurysm repair (EVAR). These errors arise due to the complex nature of the aneurysm, requiring advanced technical skills and careful decision-making.

For the "Importance" of this event, a significant difference among the roles was found ($H(4) = 14.502, p = .006$). The mean ranks suggest that IR Nurses had the highest rank ($M = 52.60$) in perceiving the importance of these errors, followed by Radiographers ($M = 49.63$), IR Doctors - Consultant or Registrar ($M = 36.13$), Vascular Doctors - Consultant or Registrar ($M = 35.68$), and Vascular Surgery Nurses ($M = 29.00$).

Regarding "Severity" of the above event, similar perception among the roles was revealed ($H(4) = .476, p = .976$). The mean ranks indicate that Vascular Doctors - Consultant or Registrar had the highest rank ($M = 43.43$) in perceiving the severity of these errors, followed by IR Doctors - Consultant or Registrar ($M = 41.28$), Radiographers ($M = 39.72$), IR Nurses ($M = 38.67$), and Vascular Surgery Nurses ($M = 39.40$).

However, for "Probability" of such events, again a significant difference among the roles was revealed ($H(4) = 13.288, p = .010$). The mean ranks suggest that IR Nurses had the highest rank ($M = 55.13$) in perceiving the probability of these errors, followed by Vascular Doctors - Consultant or Registrar ($M = 46.86$), Radiographers ($M = 34.97$), IR Doctors - Consultant or Registrar ($M = 33.98$), and Vascular Surgery Nurses ($M = 34.53$).

Table 4.12 Ratings of the participants of " Procedure-related error in a complex image-guided procedure such as (EVAR)"					
	Role - Selected Choice	N	Mean Rank		
Procedure-related error in a complex image-guided procedure such as (EVAR). Importance	IR Nurse	15	52.60	Kruskal-Wallis H	14.502
	Vascular Surgery_ Nurse	15	29.00	df	4
	Radiographer	16	49.63	Asymp. Sig.	.006
	IR doctor_ Consultant or Registrar	20	36.13		
	Vascular doctor_ Consultant or Registrar	14	35.68		
	Total	80			
Procedure-related error in a complex image-guided procedure such as (EVAR). Severity	IR Nurse	15	38.67	Kruskal-Wallis H	.476
	Vascular Surgery_ Nurse	15	39.40	df	4
	Radiographer	16	39.72	Asymp. Sig.	.976
	IR doctor_ Consultant or Registrar	20	41.28		
	Vascular doctor_ Consultant or Registrar	14	43.43		
	Total	80			
Procedure-related error in a complex image-guided procedure such as (EVAR). Probability	IR Nurse	15	55.13	Kruskal-Wallis H	13.288
	Vascular Surgery_ Nurse	15	34.53	df	4
	Radiographer	16	34.97	Asymp. Sig.	.010
	IR doctor_ Consultant or Registrar	20	33.98		
	Vascular doctor_ Consultant or Registrar	14	46.86		
	Total	80			

12. Lack of post-procedure plan being discussed or recorded in the patient's notes.

The provided (**Table 4.13**) presents the ranks for different roles in terms of their perceptions of errors related to "the absence of a post-procedure plan being discussed or recorded in the patient's notes".

For the "Importance" of the above error, a significant difference among the roles was found ($H(4) = 17.263, p = .002$). The mean ranks suggest that IR Nurses had the highest rank ($M = 52.10$) in perceiving the importance of this error, followed by Radiographers ($M = 51.44$), IR Doctors - Consultant or Registrar ($M = 37.85$), Vascular Surgery Nurses ($M = 34.23$), and Vascular Doctors - Consultant or Registrar ($M = 26.07$).

However, for the "Severity" aspect of the above error, no significant difference among the roles was revealed ($H(4) = 4.035, p = .401$). The mean ranks indicate that Vascular Surgery Nurses had the highest rank ($M = 47.60$) in perceiving the severity of this error, followed by IR Nurses ($M = 42.73$), Vascular Doctors - Consultant or Registrar ($M = 41.75$), IR Doctors - Consultant or Registrar ($M = 38.53$), and Radiographers ($M = 33.13$).

Regarding "Probability" of such failure mode, the test found a significant difference among the roles ($H(4) = 31.054, P, <.001$). The mean ranks suggest that Vascular Doctors - Consultant or Registrar had the highest rank ($M = 57.21$) in perceiving the probability of this error, followed by IR Nurses ($M = 52.53$), IR Doctors - Consultant or Registrar ($M = 38.88$), Vascular Surgery Nurses ($M = 39.47$), and Radiographers ($M = 17.59$).

Table 4.13 Ratings of the participants of the failure mode " No post-procedure plan has been discussed or recorded in the patient's notes"					
	Role - Selected Choice	N	Mean Rank		
No post-procedure plan has been discussed or recorded in the patient's notes_ Importance	IR Nurse	15	52.10	Kruskal-Wallis H	17.263
	Vascular Surgery_ Nurse	15	34.23	df	4
	Radiographer	16	51.44	Asymp. Sig.	.002
	IR doctor_ Consultant or Registrar	20	37.85		
	Vascular doctor_ Consultant or Registrar	14	26.07		
	Total	80			
No post-procedure plan has been discussed or recorded in the patient's notes_ Severity	IR Nurse	15	42.73	Kruskal-Wallis H	4.035
	Vascular Surgery_ Nurse	15	47.60	df	4
	Radiographer	16	33.13	Asymp. Sig.	.401
	IR doctor_ Consultant or Registrar	20	38.53		
	Vascular doctor_ Consultant or Registrar	14	41.75		
	Total	80			
No post-procedure plan has been discussed or recorded in the patient's notes_ Probability	IR Nurse	15	52.53	Kruskal-Wallis H	31.054
	Vascular Surgery_ Nurse	15	39.47	df	4
	Radiographer	16	17.59	Asymp. Sig.	.000
	IR doctor_ Consultant or Registrar	20	38.88		
	Vascular doctor_ Consultant or Registrar	14	57.21		
	Total	80			

Perception of the importance of the failure modes by the IR nurses and the vascular nurses

The ratings of the IR nurses and the Vascular surgery nurses regarding the importance of the failure modes/ healthcare errors presented in the questionnaire were different in 7 out of 12 failure modes, namely: "Inadequate patient clerking", " pre-procedural planning", "A team member is absent when needed", "Communication errors", "Patients who present unique challenges", "Procedure-related error", and " No post-procedure plan". In all these occasions, the ratings of the IR nurses were higher than the vascular nurses **Table 4.14**.

Table 4.14 Ratings of the importance of the failure modes by the IR and the vascular nurses				
	Role - Selected Choice	N	Mean Rank	P value
Inadequate patient clerking	IR Nurse	15	19.60	.002
	Vascular Surgery Nurse	15	11.40	
	Total	30		
No bed_Equipment__ Room arrangement	IR Nurse	15	17.10	.125
	Vascular Surgery Nurse	15	13.90	
	Total	30		
Inadequate handover - Importance	IR Nurse	15	16.50	.150
	Vascular Surgery Nurse	15	14.50	
	Total	30		
Pre-procedural planning_ Importance	IR Nurse	15	20.00	.000
	Vascular Surgery Nurse	15	11.00	
	Total	30		
A team member is absent when needed _ Importance	IR Nurse	15	18.57	.020
	Vascular Surgery Nurse	15	12.43	
	Total	30		
Violation of safety guideline	IR Nurse	15	17.10	.125
	Vascular Surgery Nurse	15	13.90	
	Total	30		
Communication errors_ Importance	IR Nurse	15	19.50	.001
	Vascular Surgery Nurse	15	11.50	
	Total	30		
Intra-operative distraction	IR Nurse	15	13.97	.293
	Vascular Surgery Nurse	15	17.03	
	Total	30		
Technical errors	IR Nurse	15	17.00	.307
	Vascular Surgery Nurse	15	14.00	
	Total	30		
Patients who present unique challenges.	IR Nurse	15	18.93	.018
	Vascular Surgery Nurse	15	12.07	
	Total	30		
Procedure-related error_	IR Nurse	15	19.50	.005
	Vascular Surgery Nurse	15	11.50	
	Total	30		
No post-procedure plan	IR Nurse	15	18.90	.016
	Vascular Surgery Nurse	15	12.10	
	Total	30		

Comparison of the severity ratings of the failure modes by the IR nurses and the vascular nurses

Both groups show similar perception regarding the severity of the failure modes **Table 4.15**.

Table 4.15 The severity ratings of the failure modes by the IR and the Vascular nurses				
	Role	N	Mean Rank	P value
Inadequate patient clerking including informed consent_	IR Nurse	15	13.07	.115
	Vascular Surgery_ Nurse	15	17.93	
No bed_Equipment_Room arrangement	IR Nurse	15	13.20	.108
	Vascular Surgery_ Nurse	15	17.80	
Inadequate handover_ Severity	IR Nurse	15	17.03	.266
	Vascular Surgery_ Nurse	15	13.97	
Pre-procedural planning_ Severity	IR Nurse	15	15.80	.845
	Vascular Surgery_ Nurse	15	15.20	
A team member is absent when needed_ Severity	IR Nurse	15	13.00	.076
	Vascular Surgery_ Nurse	15	18.00	
Violation of safety guideline	IR Nurse	15	15.90	.792
	Vascular Surgery_ Nurse	15	15.10	
Communication errors	IR Nurse	15	17.53	.159
	Vascular Surgery_ Nurse	15	13.47	
Intra-operative distraction	IR Nurse	15	15.80	.844
	Vascular Surgery_ Nurse	15	15.20	
Technical errors	IR Nurse	15	14.27	.415
	Vascular Surgery_ Nurse	15	16.73	
Patients who present unique challenges.	IR Nurse	15	16.90	.296
	Vascular Surgery_ Nurse	15	14.10	
Procedure-related error_ Severity	IR Nurse	15	15.27	.878
	Vascular Surgery_ Nurse	15	15.73	
	Total	30		
No post-procedure plan has been discussed or recorded in the patient's notes	IR Nurse	15	14.73	.608
	Vascular Surgery_ Nurse	15	16.27	

Comparison of the probability ratings of the failure modes between the IR and the vascular nurses

The probability ratings of IR and the vascular surgery nurses were similar in most of the failure modes, except for the failure modes: " Inadequate patient clerking", " Patients who present unique challenges." And " Procedure-related error_ Probability" where they were different (Table 4.16).

Table 4.16 Ratings of the probability of the failure modes by the IR and the Vascular surgery nurses

	Role - Selected Choice	N	Mean Rank	P value
Inadequate patient clerking_	IR Nurse	15	20.40	.001
	Vascular Surgery_ Nurse	15	10.60	
No bed_Equipment_Room arrangement	IR Nurse	15	18.17	.080
	Vascular Surgery_ Nurse	15	12.83	
Inadequate handover	IR Nurse	15	16.50	.509
	Vascular Surgery_ Nurse	15	14.50	
Pre-procedural planning_	IR Nurse	15	17.20	.260
	Vascular Surgery_ Nurse	15	13.80	
A team member is absent when needed	IR Nurse	15	16.57	.483
	Vascular Surgery_ Nurse	15	14.43	
Violation of safety guideline	IR Nurse	15	16.90	.332
	Vascular Surgery_ Nurse	15	14.10	
Communication errors among the team	IR Nurse	15	16.37	.555
	Vascular Surgery_ Nurse	15	14.63	
Intra-operative distraction	IR Nurse	15	12.63	.054
	Vascular Surgery_ Nurse	15	18.37	
Technical errors	IR Nurse	15	16.43	.516
	Vascular Surgery_ Nurse	15	14.57	
Patients who present unique challenges.	IR Nurse	15	20.57	.001
	Vascular Surgery_ Nurse	15	10.43	
Procedure-related error_Probability	IR Nurse	15	19.33	.010
	Vascular Surgery_ Nurse	15	11.67	
No post-procedure plan has been discussed or recorded in the patient's notes_Probability	IR Nurse	15	18.10	.066
	Vascular Surgery_ Nurse	15	12.90	

Comparison of the perception of the importance of the failure modes between the IR consultants and the vascular consultants

The IR doctors and the vascular doctors agrees on the importance of most of the failure modes. However, the IR doctors rated the following failure modes higher the vascular doctors: " No bed_Equipment_Room arrangement" [P value = .001], " Violation of safety guideline" [P value = .048] and " Intra-operative distraction" [P value = .021] (**Table 4.17**).

Table 4.17 Ratings of Importance of the FMs by the IR and the Vascular Doctors				
	Role - Selected Choice	N	Mean Rank	P value
Inadequate patient clerking	IR doctors	20	17.05	.710
	Vascular doctors	14	18.14	
No bed_Equipment_Room arrangement	IR doctor_ Consultant or Registrar	20	21.80	.001
	Vascular doctors	14	11.36	
Inadequate handover - Importance	IR doctors	20	18.95	.280
	Vascular doctors	14	15.43	
Pre-procedural planning_ Importance	IR doctors	20	17.25	.839
	Vascular doctors	14	17.86	
A team member is absent when needed _ Importance	IR doctors	20	17.93	.754
	Vascular doctors	14	16.89	
Violation of safety guideline	IR doctors	20	20.10	.048
	Vascular doctors	14	13.79	
Communication errors_ Importance	IR doctors	20	17.55	.970
	Vascular doctors	14	17.43	
Intra-operative distraction	IR doctors	20	20.45	.021
	Vascular doctors	14	13.29	
Technical errors	IR doctors	20	16.83	.583
	Vascular doctors	14	18.46	
Patients who present unique challenges.	IR doctors	20	17.63	.919
	Vascular doctors	14	17.32	
Procedure-related error_	IR doctors	20	17.48	.984
	Vascular doctors	14	17.54	
No post-procedure plan	IR doctors	20	19.48	.144
	Vascular doctors	14	14.68	

Comparison of the perception of the severity of the failure modes between the IR Doctors and the vascular surgery doctors

The IR doctors and the vascular doctors were similar in their ratings in regards of the severity of the failure modes **Table 4.18**.

Table 4.18 Ratings of the severity of the FMs by the IR and the Vascular Doctors				
	Role - Selected Choice	N	Mean Rank	P value
Inadequate patient clerking	IR doctors	20	16.70	.535
	Vascular doctors	14	18.64	
No bed_Equipment_Room arrangement	IR doctors	20	18.98	.198
	Vascular doctors	14	15.39	
Inadequate handover - Importance	IR doctors	20	17.25	.848
	Vascular doctors	14	17.86	
Pre-procedural planning_Importance	IR doctors	20	17.05	.742
	Vascular doctors	14	18.14	
A team member is absent when needed _ Importance	IR doctors	20	18.18	.604
	Vascular doctors	14	16.54	
Violation of safety guideline	IR doctors	20	18.70	.377
	Vascular doctors	14	15.79	
Communication errors_Importance	IR doctors	20	15.50	.134
	Vascular doctors	14	20.36	
Intra-operative distraction	IR doctors	20	18.10	.640
	Vascular doctors	14	16.64	
Technical errors	IR doctors	20	17.10	.762
	Vascular doctors	14	18.07	
Patients who present unique challenges.	IR doctors	20	15.25	.084
	Vascular doctors	14	20.71	
Procedure-related error_	IR doctors	20	17.30	.875
	Vascular doctors	14	17.79	
No post-procedure plan	IR doctors	20	16.98	.689
	Vascular doctors	14	18.25	

Comparison of the perception of the probability of the failure modes between the IR consultants and the vascular consultants

Most of the failure modes were rated similarly by the IR and the vascular doctors, except for " Inadequate handover - Importance" and " No post-procedure plan" were the vascular doctors recorded significantly higher scores with P value of .006 and .010 respectively (**Table 4.19**).

Table 4.19 Ratings of the probability of the FMs by the IR and the Vascular Doctors				
	Role - Selected Choice	N	Mean Rank	P value
Inadequate patient clerking	IR doctors	20	17.23	.836
	Vascular doctors	14	17.89	
No bed_Equipment_Room arrangement	IR doctors	20	18.15	.625
	Vascular doctors	14	16.57	
Inadequate handover - Importance	IR doctors	20	13.95	.006
	Vascular doctors	14	22.57	
Pre-procedural planning_Importance	IR doctors	20	15.70	.180
	Vascular doctors	14	20.07	
A team member is absent when needed _ Importance	IR doctors	20	19.45	.158
	Vascular doctors	14	14.71	
Violation of safety guideline	IR doctors	20	18.80	.324
	Vascular doctors	14	15.64	
Communication errors _Importance	IR doctors	20	14.95	.063
	Vascular doctors	14	21.14	
Intra-operative distraction	IR doctors	20	17.35	.911
	Vascular doctors	14	17.71	
Technical errors	IR doctors	20	16.60	.497
	Vascular doctors	14	18.79	
Patients who present unique challenges.	IR doctors	20	17.18	.809
	Vascular doctors	14	17.96	
Procedure-related error_	IR doctors	20	15.25	.076
	Vascular doctors	14	20.71	
No post-procedure plan	IR doctors	20	14.10	.010
	Vascular doctors	14	22.36	

4.8 Discussion

Introduction

The aim of the current study is to assess the perception of participated healthcare professionals in regards of different healthcare errors or failure modes (FMs) that could influence patient safety during image-guided procedures. The current study is conducted by using a mixed model approach by utilizing elements from HFMEA and applying them to an online questionnaire sent out to various experts within the field of interventional radiology, vascular surgery, and cardiac intervention. We assessed the perception of importance, severity, and probability ratings of different failure modes or healthcare errors among different groups of healthcare professionals. The results highlighted keys areas that needs to be addressed to enhance safety of patients who undergo image-guided procedures.

To the knowledge of the author of this thesis, this is the first study of its kind to assess the perception of various groups of healthcare professionals, who are involved directly with the management of patients undergoing image-guided procedures, towards the possible failure mode/ healthcare errors that occur during these procedures.

A pilot study was conducted before the main study on twenty-two participants to evaluate the practicality and validity of a preliminary questionnaire and to help to estimate the sample size of the main study. A significant variation among the participants was revealed.

However, several modifications were made to the initial questionnaire. Being a Microsoft Excel sheet with 44-items, each with four parameters to score, the initial questionnaire was too long to complete and did not gain enough compliance rate from the invited professionals.

Modification of the questionnaire was made to make it more concise and an online questionnaire, the required sample of eighty people was feasibly collected.

Another modification was to add another group of healthcare professionals to the participants which is the vascular surgery nurses. Initially, the participants comprised of four groups namely (IR nurses, Radiographers, IR doctors, and vascular doctors). By adding an important group_ the vascular surgery nurses, a more comprehensive evaluation of the degree of perception of the healthcare errors has been achieved.

Internal reliability of the questionnaire

The questionnaire used in the current study shows a very good internal reliability (Cronbach's Alpha coefficient of 0.887) which indicates that the questionnaire is consistently measuring the items having similar construct. Having a robust, consistent and reliable questionnaire can act as valuable tool to detect areas that need attention (Sexton et al., 2006a).

The perceived importance of the failure modes/healthcare errors by the participants

The vast majority (ten out of twelve) failure modes/healthcare errors rated extremely important by the participants. This demonstrates a consensus among various group of experts about the factors that are related to patient safety. Regular assessment of safety climate is essential not only among the caregivers in one department but also across different departments of a hospitals. This assessment allow identification of areas of weakness and strength in a clinical setting through comparison data among different roles and different department (Sexton et al., 2006a). For instance lack of teamwork in a department or between departments would invite multidisciplinary rounds, while lack of safety climate warrants arrangement of empowerment or leadership rounds (Jensen and Rakovan, 1995, Thomas et al., 2005).

The perceived severity of the failure modes/ healthcare errors by the participants

No failure mode or healthcare error received a score of 4 (catastrophic) under severity parameters, which means the image-guided procedures are less risky procedures. This aligns with the literature which highlight the low rate of adverse events in IR despite seriousness of the occurred adverse events which might require corrective surgical intervention (Mellouk Aid et al., 2017). However, "preprocedural planning", "technical errors", "safety guideline errors", and "procedural errors" received scores of 3/4 in terms of severity by most of the participants. This demonstrates that these errors might have potential to severely impact the safety of the patients during the image-guided procedures. The literature supports the importance of these failure modes in regards of procedural outcome and safety of patients (Nagpal et al., 2010b, Nagpal et al., 2010a, Thomas et al., 2005).

Inadequate preprocedural planning can result in the failure of proper decision-making process, inadequate equipment preparation or breakdown of critical communication among the team. Although most of the literature focus on the intraoperative phase of the surgical care, it is stressed that preoperative phase can pose risks that can extends into the other phases of the

surgical care (Nagpal et al., 2010b). Nagpal et al., (2010a) conducted a HFMEA study on the lack of communication in surgical Care and found that seventeen out of 45 failure modes within the preoperative phase are critical. Some examples of the preoperative preparation were lack of proper medication prescriptions, inadequate preoperative investigations. The researchers attributed this to the blurring of the responsibilities among the healthcare professionals which can be addressed by assigning tasks to specific roles. Patterson et al.,(2004) stressed that maintain transparent responsibility among the surgical caregivers is crucial to prevent adverse events (Patterson et al., 2004). Adherence to protocols, following checklists and automating some task are among the proposed solutions to address these flaws (Nagpal et al., 2010a).

Hospitals should put emphasis on standardised protocols to allow teams to follow them without reliance on personal judgment and memory. However, access to these protocols needs to be facilitated such as integrating them into mobile applications and make them available and to some extent compulsory to the targeted caregivers.

Enhancing communication among different teams can be achieved by regular multidisciplinary rounds or meetings to bring a generalised perception of the risks associated with the inadequate planning of the image-guided procedures.

Technical errors imply mistakes occurred by the performing team members in the technical points of the procedures such as improper handling or use of tools or mistakes in executing the required techniques. Procedure related errors imply errors that are resulted from difficult procedures. These errors are associated with technical errors as more complex procedures require higher level of technical abilities to deal with them. The high rating by the participant to these technical and procedure related errors emphasise the seriousness of the outcome from these errors.

The literature contains many studies that have shown the effect of the technical errors on the short-, mid- and long-term outcome of the procedures. In a retrospective study on 377 patients underwent EVAR, 18% of the cases showed technical intraoperative errors which results in increase in the midterm complications (Vacirca et al., 2019). Similarly, technical errors from inadvertent clot induction during an EVAR procedure or misplacement of the EVAR stent which obstruct the side branches of the aorta can have detrimental effects on patients safety. Bowel ischaemia is a notable complication of EVAR which leads to 50% death after 1 one month from EVAR (Becquemin et al., 2008, Maleux et al., 2009).

To reduce technical errors, continuous training including regular simulation-based training, standardised protocols, or continuous education for healthcare staff. Simulation training has been proven to decrease complication in cardiac intervention. Gurm et al., (2016) assessed the impact of simulation training on success rate of the femoral access in cardiac interventions among trainees and found that those who attended simulation training had lower complication rates than those who undertaken standard non-simulation training (Gurm et al., 2016)

Safety guideline errors was another error that received a consensus high severity rating by most of the participants. These safety guideline errors comprised violations of the established safety guidelines imposed by the hospitals such as failure to adhere to infection control measures, or personal protective equipment (PPE), or non-compliance with the established checklists such as the WHO checklist. These errors can impose patients to significant harm including risks of infection, procedural complications and increased hospital stay.

There are myriads of studies emphasise on the importance of following safety guidelines to decrease adverse events and death. A bench mark study by Haynes et al., (2009) on the use of the WHO checklist showed a significant decrease in both postoperative complication and death after the use of this 19-itmes checklist (Haynes et al., 2009a). The use of PPE has been emphasised globally during the latest COVID pandemic in 2019 with numerous publication stress on this point (Brooks et al., 2021) (Haldane et al., 2021) (Srivastav et al., 2022).

The current study revealed significant understandings into several factors that are related to patient safety during image-guided procedures. Important themes emerged from the analysis are preprocedural planning, communication errors, absence of staff when needed, technical errors and lack of post-procedure planning.

Communication errors appeared to be one of the main theme emerged with more than half of the participants believed that communication errors are extremely important. These findings agrees with the previous studies (Reason, 1995) (Barach and Small, 2000) (Institute of Medicine Committee on Quality of Health Care, 2000) (Sexton et al., 2000) (Mishra et al., 2008). Therefore, enhancing communication among the team within the same department and with other departments should be one of the priorities for any hospital to improve patient safety.

One of these solutions could be team training, standard protocols to decrease communication errors.

Comparison of the ratings of various failure modes/ healthcare errors among different roles

4.8.1.1 IR nurses versus Vascular surgery nurses

- **Importance of the Failure Modes**

The ratings of the IR nurses and the Vascular surgery nurses regarding the importance of the failure modes/ healthcare errors presented in the questionnaire were different in 7 out of 12 failure modes, namely: "Inadequate patient clerking", " pre-procedural planning", "A team member is absent when needed", "Communication errors", "Patients who present unique challenges", "Procedure-related error", and " No post-procedure plan". In all these occasions, the ratings of the IR nurses were higher than the vascular nurses. This analysis indicates that the IR nurses perceive the importance of these healthcare errors differently from the Vascular surgery nurses.

This finding agrees with the previous studies which emphasize that different perspectives regarding the safety aspects and priorities are shown by different roles (Sexton et al., 2006b, Gore et al., 2010). IR nurses who are involved in IR procedures which are not restricted to vascular intervention may have broader perception of a wider spectrum of healthcare errors across different settings and referrals. On the other hand, Vascular surgery nurses are more specialise in dealing with vascular procedures which results in assigning more importance to failure modes that are related to their subspecialty and areas of care.

This variation in the ratings of the importance of some of the failure modes between the IR nurses and the vascular nurses highlights the importance of identifying role-specific perception to guarantee efficient and consistent care across different health settings. It also warrants the need for more communication and collaboration among multidisciplinary teams. Enhancing communication among these two important roles, IR nurses and Vascular nurses, and understanding the concerns of each group regarding different aspects of patientcare, leading to better outcome and improve patient safety.

- **Probability of the Failure Modes**

The perception of the IR nurses and the Vascular nurses were different for some of the failure modes namely: "inadequate patient clerking", "patients who present unique challenges", and "procedure-related errors". In all the above failure modes, the IR nurses rated with higher probabilities those errors compared to the vascular surgery nurses. In contrary, the rest of the other failure (the majority) were perceived similarly by the two groups.

While the above differences between the two groups of healthcare professionals indicate some important implications for outcome and patient safety, they suggest potential variation in risk awareness and risk mitigation. The higher ratings of probability assigned by the IR nurses to certain failure modes such as inadequate clerking or patients with unique challenges or procedural errors may reflect the unique complexities related to the IR procedures which needs increased awareness of the related risks. Identifying and addressing these higher probability failure modes are vital to allow bespoke intervention to mitigate these risks and improve patient safety.

On the other hand, the similar perception among the IR nurses and the Vascular surgery nurses emphasises the common understandings of these healthcare professionals which promote introducing standardised approach to decrease miscommunication and improve patient safety.

These findings agree with the literature studying the different perception among different healthcare roles and their implication on patient safety. Several studies highlight the gap in communication across multidisciplinary teams. Nagpal et al., (2010) systematically assessed the communication transfer in the surgical care and found numerous flows across the quantum of surgical care which need addressing. Many of these flows were related to the lack of transparent communication among different staff. They emphasises that these failure modes are common across the preoperative, the operative and the postoperative phases alike (Nagpal et al., 2010a). A study by Lingard et al., (2002) assessed the communication among the operative team and found that various understandings of these failure pose a risk into the patient care. They also stressed that a gap in the communication among these healthcare professionals leads to more adverse events (Lingard et al., 2002). Similarly, previous studies conducted in vascular and IR specialism stressed on the importance of the acknowledgement of the multidisciplinary team to the risks associated with these failure modes to improve patient

safety through decreasing medical errors (ALBAYETI et al., 2011), (Morbi et al., 2012), and (Koetser et al., 2013)

- **Severity of the Failure Modes**

While the IR nurse and the vascular surgery nurses were different in some of their perceptions in terms of the importance and the probability of the possible failure modes in the pathway of the image-guided procedures, both groups show similar perception regarding the severity of the failure modes (see **Table 4.15**).

This similar ratings among the IR nurses and the vascular surgery nurses highlights a common understandings among these groups of the possible healthcare errors throughout the image-guided procedure pathway and stresses on a mutual awareness of these risks. This is promising and allows targeted interventions in the future to be directed towards these threats which have common ground of agreement among different groups to mitigate the associated risks and to improve patient safety.

The finding aligns with the literature, in which many studies praise the importance of recognition and identification of the healthcare errors across the healthcare settings to prevent their occurrence or mitigate their implication before harming patients (Catchpole et al., 2007a, Catchpole and Wiegmann, 2012, Higgins and Herpy, 2021b).

4.8.1.2 The IR doctors and the Vascular surgery doctors

- **Importance of the Failure Modes**

There is similar perception among the IR doctors and the Vascular surgery doctors about the importance of the failure modes in the image-guided procedure pathways which is promising in terms of the similar approach to deal with these failure modes and mitigate them to enhance patient safety. Having similar safety culture among different specialties is important to provide a consistent safe care to patients. This concept has been promoted by numerous studies in the literature (Sexton et al., 2000, Thomas et al., 2005), (Sexton et al., 2006a).

Despite thus, there are some noted difference in the importance attributed to some of the failure modes by these two groups of doctors. The IR doctors assigned a significantly higher rank to the " No Bed-Equipment_Room arrangement" failure mode than the vascular doctors. This

finding may be caused by the difference in the perspective and expertise of these two groups regarding the necessity of arrangement of beds, equipment, and room to safely complete the IR procedures. This implies that the IR doctors rank a high importance towards the need of beds for some of the procedures that might need admission to hospitals after being scheduled as day cases. This could be because the IR department has no facility for inpatient admission and their patients need to be admitted to other wards such as the general or vascular surgery wards, and prior allocation of would obviously be one of the priority of the IR doctors to secure before starting the procedures. Similarly, the IR procedures are heavily relied on equipment which becomes increasingly complex in features and varieties. Without these IR equipment, it is difficult to ensure safe and successful IR procedures. In the same way, the IR procedures are conducted using X ray fluoroscopy, different tools, and equipment, such as ultrasound machine for the puncture site visualisation. All these factors demand a meticulous organisation of the Angio suite.

The failure mode "Violation of safety guideline" also rated differently by these two groups with the IR doctors ranked them higher in importance than their counterparts. A possible explanation would be that the IR procedures might become more complex as the field expands exponentially to include wider arrays of procedures on wider age groups, some of which have comorbidities. These factors make these procedures particularly exposed to safety weaknesses in absence of strict safety guidelines. As the IR doctors are involved directly in these procedures, they are aware of the risks and consequences of safety guidelines hazards.

Similarly, the intra-operative distraction receives a higher score by the IR doctors (P value, 0.02). The reason might be related to the sensitivity of the intraoperative period from the IR perspective as these procedures require a high level of attention and focus. Distraction would create a safety hazard to the patients. This is in agreement with the literature which stress on the unique requirements of the IR procedures with the associated challenges (Mellouk Aid et al., 2017, Higgins and Herpy, 2021b).

- **Probability of the Failure Modes**

No significant variation is revealed in the rating of the probability of the failure modes between the IR doctors and the Vascular surgery doctors in most of the failure modes, except the "Inadequate handover" and the " No post-procedure plan" failure modes. This indicates that both groups attribute similar importance to the possible failure modes occurs in the image-guided procedure pathways. This could be the outcome of regular MDT meetings which are in place between the IR and the vascular surgery doctors prior to many difficult procedures. Also, many procedures such as EVAR are jointly performed by these doctors which highlight the importance of the shared acknowledgment of these failure modes.

On the other hand, the rating of the vascular doctors was significantly higher than the IR doctors regarding the probability of " Inadequate handover" (M rank of 22.57 vs 13.95, P value), and " No post-procedure plan" (Mean rank of 22.3 vs 14.10, P value, .010). This could highlight the different perspective of different roles of certain types of healthcare errors. The vascular surgery or the combined endovascular procedures needs consistent knowledge about the patients care from the admission to the discharge. Therefore, assuring consistent transfer of information between different care groups through handover processes is important. Furthermore, ensuring the minimum adverse events during the post-procedure period is to stress on the post procedure plan. This is aligned with the previous literature which assessed the quantum of healthcare service in the surgical environment (Nagpal et al., 2010b).

- **Severity of the Failure Modes**

It is important to note that despite some variation among the ratings of the IR doctors and the vascular surgery doctors in terms of importance and probability of some of the failure modes, there were no substantial difference in the perceived severity between the two groups. This agreement highlights the shared consideration and recognition of the possible harms and consequences that are associated with these failure modes, while reveal presence of a common aim of prevention of adverse events and enhancement of patient safety.

The literature supports the findings of the current study in emphasizing the importance of adherence to the safety guidelines, better communication and standard protocols (Sorra et al., 2012, Lingard et al., 2004b).

Limitations

While this study presents important understandings about the perception of the importance, severity, and probability of different failure modes in the IR and image-guide procedures pathway of care, it is prudent to acknowledge its limitations.

While the study sample was enough to show the required effect size using power calculation, the study sample is limited in comparing individual groups of participants. Therefore, the findings are needed to be interpreted cautiously. Further studies should include larger individual samples to allow more powerful effect size estimate.

Another constraint is a limited number of group of professionals who participated in the study who were five groups. Future studies should focus on involving more roles within the healthcare settings to allow more understandings of the importance and characteristics of these failure modes.

The current study is considered a cross sectional questionnaire study which assess the perception of the healthcare professionals at a specific time. There are some inherent limitations into these cross-sectional evaluations as it lacks demonstration of the cause and effect. Also, the perception of people might change by time and by acquiring experience and different exposure. It is important for the future studies to include these factors. Therefore, other types of studies such as observational studies by independent observers to analyse and quantify these failure modes. Other qualitative studies such focus group interview could reveal in-depth the factors that lead people to have different perspectives.

Generalisability

It is worthwhile to mention that these findings are based on a limited sample of participants, allowing for the power calculation conducted to determine the sample size of the current study. The individual comparison between groups were conducted on lower number of participants. For example, 15 IR nurses and fifteen vascular surgery nurses, or 20 IR doctors and 14 vascular doctors. Further research is needed on larger individual samples to generalise these findings on wider groups of healthcare professionals.

It is also imperative to assess other factors that might influence the perception of these individuals such as years of experience, geographic locations, and type of healthcare settings,

such as small or large hospitals or district or teaching hospitals. Furthermore, including other professionals who are involved in the care of these patients such as Anaesthetists and other specialties allow better understanding of the perspective of a broader population of healthcare professionals about these failure modes to reach a consensus about the general understanding about the importance, severity, and frequency of these failure modes.

Limitations related to the content of the questionnaire may be a possibility as the items of the questionnaire were constructed based on a focus group of people and a previous pilot observational study. There may be some other related elements in the care of these patients which were not included in the study. However, the questionnaire allowed the participants to include other information when relevant such as other areas or failures. Future studies might consider wider populations to allow inclusion of more items that might influence the safety of patient in the image-guided procedure pathways.

4.9 Conclusion

This questionnaire study aimed to assess the perception of the participant healthcare professionals from the IR and the vascular surgery departments who are involved in direct management of the patients who undergo image-guided procedures. The study analysed different aspects of the possible failure mode or healthcare errors, namely importance, severity, and probability, in the pathway of care in image-guided procedures.

The findings of the current study allow valuable insights to be drawn in regards of the perception of different groups of healthcare professionals in Interventional radiology and Vascular Surgery departments into these failure modes. The results demonstrated differences and similarities among these experts in their understandings of these failure modes.

It is notable to conclude that all the participants share similar understandings and insights about the severity of the failure modes presented in this questionnaire which emphasises a common ground understanding among the participants about the safety implications and outcome of these failures.

The findings of the current study support the existing literature, which signify effective communication, proper planning of procedures, adequate provision of infrastructure, following safety guidelines to enhance patient safety.

However, it is important to accept the limitations of this study as mentioned earlier. The results are based on a single cross sectional questionnaire study on a limited sample and group of people.

To address the above limitations and enhance the findings, future studies should attract larger and more diverse sample to include other stakeholder involved in management of these patients. In addition, other types of studies such as longitudinal observational studies or qualitative studies such as interview studies to explore the underlying causes of these perceptions.

Overall, the current study provides valuable insights to the understandings and awareness of the healthcare staff in Interventional radiology and vascular surgery. The findings underscore the need of multidisciplinary communication and collaboration to target these areas to promote patient safety.

Chapter Five: Design and Development of a Computerised Error - Capture Tool in Interventional Radiology Entire Pathway of Care

5.1 Introduction:

Adverse events were recognised more than thousand years ago by Hippocrates in his famous Oath, in which he vowed to prescribe treatment for the best interest of his patients and never do harm to them (Jacques, 2012). However, not until the 1990s were adverse events and their impact on patient safety quantified (Institute of Medicine Committee on Quality of Health Care, 2000). The adverse events are defined as non-intentional harms to patients by healthcare staff that result in their damage or an increase in the critical care or a delay in the discharge from the hospital or leading to a disability or even death. These events occur in 10% of hospitalised patients in the United Kingdom (Vincent et al., 2001). The healthcare errors are inadvertent mistakes either in the planning or the execution of treatment that contribute or could contribute to unintended results (Grober and Bohnen, 2005). Healthcare- errors contribute to half adverse events.

There has been a new perception aetiology of healthcare- errors that constitute a shift from a vision of blaming individuals as the leading cause of errors to a vision which contributes these errors into a failure in the whole care system. The new vision encourages more self-reporting of incidents to enable healthcare staff to identify the root causes of these incidents or adverse events (Vincent et al., 2001, Vincent et al., 2004). Underpinning the new vision, a more comprehensive array of factors can cause errors which are complex interaction among the multi-disciplinary team, work atmosphere and utilisation of continuously evolving equipment (Wiegmann et al., 2007).

Gawande A.A. et al. (1999) found that surgical errors are commonly associated with teamwork ineffectiveness and communication failures resulting in a poor surgical outcome. Surgical discipline, as a complex environment, contributes to more than half of adverse events; vascular surgery is even more vulnerable to adverse events. For instance, abdominal aortic aneurysm repair procedure has been top-ranked in terms of adverse events at a rate of 18.9%, compared to other major abdominal procedures such as colon resection, which has a rate of only 5.9% (Gawande, (1999). Endovascular procedures are types of IR procedures which can be performed either as standalone procedures or as combined procedures such as EVAR (endovascular aortic aneurysmal repair). A previous study in vascular surgery has identified

that medical errors occur more frequently in the endovascular part of combined vascular-endovascular procedures (ALBAYETI et al., 2011).

As previously highlighted in chapter 2 of this thesis (see chapter 2), there is a shortage of literature about the adverse events and healthcare errors in the IR, and there is limited evidence about tools to estimate them objectively.

Many different techniques or methods have been used previously in surgery to estimate healthcare errors. However, these are labour-intensive, inefficient and less feasible in more exhaustive range studies (Haynes et al., 2009a).

Hence, in response to the necessity of devising a tool to objectively capture errors in vascular and endovascular surgery, in a pilot study, a group of researchers at Imperial College London developed the ICECAP (Imperial College Error CAPture tool). This tool is an error -record sheet in a paper format which covers the intraoperative phase of vascular and endovascular surgery (Mason et al., 2013).

However, this tool does not exist in the IR specialism currently. Since all the hospitals in the United Kingdom like other developed countries have been maintaining their records and files electronically, where information can easily be stored, retrieved, or viewed by healthcare personnel, it is essential to devise an error-capture tool that integrates into this system. Besides being electronic, an ideal tool should also be efficient in capturing healthcare errors, feasible and applicable to everyday use in the IR including the whole pathway of the pre-and post-operative journey.

Therefore, this study aims to devise a computer-based error-capture tool that is easy, efficient, cover the entire IR pathway of care and integrates easily into the current N.H.S. electronic information system.

5.2 Aim of the chapter

- To use Microsoft Excel programme to develop an automated error-capture tool.
- The tool can cover the whole IR pathway of care.
- To produce a computer-based tool to integrate into Hospitals' database.

5.3 Methods

Study venue

The study conducted at St Mary's Hospital/ Imperial College N.H.S. trusts, which is a tertiary vascular centre.

Software used.

Microsoft Excel version 2013.

The approach used to design of FERERI (Failure Estimation REcord in Radiology Intervention)

A multimodal approach was implemented in designing the FERERI error-capture tool. The tool is a Microsoft Excel sheet created using Microsoft Excel version 2013. This tool is modified from a previous error capture tool called ICECAP_ Imperial College Error capture tool used by Mason et al., (2013) to capture errors in the intraoperative phase of vascular surgeries (Mason et al., 2013). A copy of this tool is found in (Figure 5.1)

However, other healthcare subcategories were added based on the literature (Catchpole et al., 2006a, Morbi et al., 2012) and findings of chapter 4 of this thesis.

The features of FERERI Error-capture Tool

While the ICECAP tool is designed to capture errors during the intraoperative phase of vascular and endovascular surgeries, the FERERI tool is designed to cover the whole IR pathway of care from the patients' admission to their discharge point. Furthermore, this is an electronic form that can be stored easily into any hospital's electronic patient's file. Not only can this tool be used by researchers to observe different phases of IR or the whole IR pathway for research or auditing purpose, but it can arguably be used as a self-reporting tool in quality improvement projects in IR department when looking into how to improve the care of patients and enhance patient safety.

ICECAP (Imperial College Error CAPture) Record for Vascular Surgery								OBSERVER		Imperial College London	
Date:		Start time:		End time:		Total time:		Hospital:		No. team members present:	
Surgery:		Completed by:									
Error Category	Equipment Radiological, Surgical Anaesthetic, Drugs /Medication, Other	Communication	Procedure – Indep Pressures	Technical	Safety	Patient	Other	Details	Delay	Resol	
	U-Unavailable F-Failure/Fault C-Configuration D-De-sterilised	M-Misleading L-Lack of D-Discord H-Does not hear/ misheard	A-Absence D-Distracted E-External pressures	Psy-Psychomotor Unf-Unfamiliar with - Procedure - Equipment - Technique	C-Checks not done V-Violation	A-Anatomy P-Physiology C-Compliance		Provide further information including people, item involved and/or circumstance	(1-5)	(1-5)	
Time	☐ Ra ☐ S ☐ An ☐ Dr /Med ☐ Oth	☐ U ☐ F ☐ C ☐ D	☐ M ☐ L ☐ D ☐ H	☐ A ☐ D ☐ E	☐ Psy ☐ Unf ☐ Proc ☐ Equip ☐ Tech	☐ C ☐ V	☐ A ☐ P ☐ C	☐			
:	☐ Ra ☐ S ☐ An ☐ Dr /Med ☐ Oth	☐ U ☐ F ☐ C ☐ D	☐ M ☐ L ☐ D ☐ H	☐ A ☐ D ☐ E	☐ Psy ☐ Unf ☐ Proc ☐ Equip ☐ Tech	☐ C ☐ V	☐ A ☐ P ☐ C	☐			

Figure 5.1 ICECAP Tool (Mason et al., 2013)

Using Microsoft Excel 2013 to build FERERI Error-capture Tool.

By using the Microsoft Office Excel Program (version 2013), I created the FERERI tool. The main steps will be explained in the following subsections. However, the main feature of the tool is to use dependent drop menus for the main and the sub-categories. To achieve this feature, I utilised features such as the data set definition and data validation and a function called [Indirect] to make the sub-category lists dependent on the main category list. There are many online tutorials or YouTube channels which explain how to use Microsoft Excel to create dropdown menus.

Content of the FERERI Tool

A multimodal approach was used to design the FERERI tool. Ideas were taken from a previously developed error capture tool by the vascular department of our hospital called ICECAP tool (Mason et al., 2013). Other items extracted from the results of the questionnaire study performed in chapter 4 of this thesis (please see chapter 3 and 4 for details). The literature was used to get some items and for the completeness (Catchpole et al., 2006a) (ALBAYETI et al., 2011, Morbi et al., 2012). The main categories of the FERERI tool are shown in Table 5.1. Most of the items which were labelled important by the experts in the questionnaire study of the chapter 4 of this thesis were imported to this checklist. A focus group meeting conducted by the author of this thesis with two senior consultants in IR and vascular surgery to finalise the items that need to be included in the final prototype.

Table 5.1 Shows the main categories of the FERERI tool

Category	Definition
Absence	A team member is absent when required
Communication	Any form of communication error among the IR team members such as lack of communication that resulted in an error, or misleading communication or misheard communication.
Equipment_related_error	Unavailable equipment. Faulty equipment or equipment with configuration error.
Distraction	Any distraction to the procedure by factors non-related to the procedure such as phone call, external staff, or irrelevant talks.
Patient_related_error	Errors occurred because of patient's characteristic such as abnormal anatomy_ tortuous arteries. Non-cooperative patients who move excessively during the procedure.
Planning	The team did not anticipate or discuss task requirements prior to start of procedure.
Procedure_related_error	Failures related to difficult procedures or unusual ones.
Safety_awareness	Failure to adhere to safety guidelines such as wearing masks or lack of anticipation of safety violations such as failure to spot pool of blood on the floor.
Technical	Any error related to experience or knowledge or handling errors such as psychomotor (in which tools are dropped from the hand of the operator).

Definition of minor and major complications in the IR speciality

Although IR is generally less invasive and have less complication, it is considered comparable to surgery in the context of adverse events (Mafeld et al., 2020) (Higgins and Herpy, 2021a).

The literature in surgery showed that there was no consensus about the definition and grading of post-surgical complications which hampered retrieval of data among different hospitals (Dindo et al., 2004). An initial classification of complications in surgery was published in 1992 (Clavien et al., 1992) which was revised in 2004 by Dindo et al., (2004). The new classification is composed of five and two subgrades based on treatment or intervention used to mitigate the complication. Grade I includes any deviation from the normal postoperative outcome that requires no further medical, surgical, or other forms of intervention all the to grade V in which the outcome is death of the patient (Table 5.2). Ever since Clavien–Dindo Complication Classification has become a most widely used and accepted surgical classification to grade postoperative complication.

The differences in invasiveness between the surgical operations and the IR procedures have suggested the creation of a classification system of the adverse events or complications that is distinctive to IR. Therefore, the Society of Interventional Radiology (SIR) of the USA developed a classification between 1997 and 2003 to be used widely by the IR society (Saad et al., 2010, Sacks et al., 2003). This classification lacks objectivity and detailing in providing further classification of the degree of severity of AE. For instance, an AE requiring minor hospitalisation is classified as major complication along with other complications such as death (Degirmenci et al., 2013) (Khalilzadeh et al., 2017). Therefore, a modified classification of AE in IR was proposed by Khalilzadeh et al., (2017) (Table 5.4).

This modified classification has been acquired a higher rating compared to the older SIR classification (Khalilzadeh et al., 2017). It is composed of two parts, A and B. Part A contains description of the AE which can be used for research or publications, etc, whereas part B (not included in the table 5.4) contains confidential description of the causality of these complications which can be used internally by the IR department. The newer classification allows more details than the older SIR classification. For example, both short hospitalisation less than 48 hours or long hospitalisation more than 48 hours classed as major AE in the older system (Table 5.3). In contrast, the grades 2 and 3 in the newer system denotes moderate

to severe AE depending on more specific information regarding the case, such as grade IIIa if no general anaesthesia used but IIIb if intervention is required under GA (Table 5.4).

Table 5.2 Clavien- Dindo Classification of Surgical Complications [source: (Dindo et al., 2004)]

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment, surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolyte replacement, physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complication Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

Table 5.3 The old SIR classification of Complications post-IR procedures

Category/Class	Definition
Minor complications	
A	No therapy, no consequences
B	Nominal therapy, no consequence; includes overnight admission for observation only
Major complications	
C	Requires therapy, minor hospitalization (< 48 h)
D	Requires major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h)
E	Permanent adverse sequelae
F	Death
AE = adverse event.	

Table 5.4 Newer classification of Adverse events in IR practice (Khalilzadeh et al., 2017)

1. Mild AE: No therapy or nominal (non-substantial) therapy (post-procedural imaging performed and fails to show manifestation of AE); near miss (e.g., wrong site of patient prepared, recognized, and corrected before procedure, wrong patient information entered for procedure).
2. Moderate AE: moderate escalation of care, requiring substantial treatment, e.g., intervention (description of intervention and result of intervention) under conscious sedation, blood product administration, extremely prolonged outpatient observation, or overnight admission after outpatient procedure not typical for the procedure (Excludes admission or hospital days unrelated to AE).
3. Severe AE: marked escalation of care, i.e., hospital admission or prolongation of existing hospital admission for > 24 hours, hospital admission that is atypical for the procedure, inpatient transfer from regular floor/telemetry to intensive care unit, or complex intervention performed requiring general anaesthesia in previously non-intubated patient (generally excludes paediatrics or in circumstances in which general anaesthesia would primarily be used in lieu of conscious sedation, e.g. in mentally challenged or severely uncooperative patients);
4. Life-threatening or disabling event: e.g., cardiopulmonary arrest, shock, organ failure, unanticipated dialysis, paralysis, loss of limb or organ.
5. Patient death or unexpected pregnancy abortion.

Parts of the FERERI Tool

The FERERI tool is divided into two main parts. Part 1 and Part 2 as described below:

- **Part 1**

In part one, the patient's demographic data are displayed, such as name, gender, age, hospital number, pathway, procedure name type of the procedure and the side (Figure 5.2 and Figure 5.3).

Three pathways are: 0 = day-case, 1 = referral from vascular, and 2= referral from any other ward.

Procedure type is coded as follows: zero if the procedure is non-vascular, and 1, if the procedure is vascular. Laterality is coded as follows: 0= left side, 1 for the right side, and N.A. if the side is non-applicable such as liver biopsy for instance.

How to calculate age in Microsoft Excel?

Step 1: In our example (Figure 5.2): In the first row, we enter the following headers in:

Cell G25: Date of Birth

Cell H25: Today's Date and

Cell I25: Age.

Step 2: In the second row, we input the corresponding values:

Cell G26: the date of birth (e.g., 18/05/2003).

Cell H26: We enter the TODAY () function to display the current date automatically.

Cell I26: We enter the formula to calculate the age in years, months, and days. The following formula can be used: =DATEDIF (G26, H26,"Y") &" years, "&DATEDIF (G26, H26,"YM") &" months, "&DATEDIF(G26,H26,"MD")&" days"

FERERI (Failure Estimation REcord in Radiology Intervention)							
Patient Name	Op	Gender	1		DOB	Today's date	Age
Pathway	1	Hospital No.	0= Non-vascular 1= Vascular		18/05/2003	08/06/2023	20 years, 0 months, 0 days
Procedure	Lt lower limb angio +- plasty	Type of procedure	1	Side			0
							0= LT 1= RT 2= NA

Figure 5.2 Part 1 of the FERERI tool magnified.

Figure 5.3 shows the other items of part 1 of the tool which entails the following items: T.O.A. (Time of Admission) which is the admission time to the IR or to the Vascular ward (if pathway No.2 was selected), time of calling to the IR department, which is the time when the IR department rang the vascular or the other departments to send the already booked patient for

their procedure. T.O.D. is a time of discharge to the referring ward or home. time to arrive at IR is the actual time when the patient has arrived at the IR Department. By knowing these two times, the time of calling to the IR and the time to arrive at IR, we know how much delay from the referring ward was there, which is regarded as an inefficiency in the system sometimes. Total Pathway time is calculated by subtracting the time of admission from the time of discharge. This time was calculated by using the function subtraction.

There is another cell which is case complexity in which three grades exist, grade 1, 2 and 3. The case complexity is decided by the IR consultant and the IR team according to their experience. The IR team is another item that can be recorded. The value of the field is entered manually. For example, (1 I.R.C., 1 S.N., 1CN, 1 R.D.G.) means that the team is composed of an IR consultant, a scrub nurse, a circulating nurse, and a radiographer). Lastly, how the filled was filled in is another item. Here, zero means the form was self-reported by the operating staff, one by a novice independent observer and two by an experienced independent observer.

Admission time To IR or to Vascular ward (if pathway No.2 selected)		Time of Discharge to ward or to home		1= Easy grade 1 2= Moderate grade 2 3= Difficult grade 3 "Decided by IR consultant"		0= Self-reported by the op staff after the procedure 1= by a novice observer 2= by an experienced observer	
D.O.A		03/12/2018		0= LA 1= Regional Anaesthesia 2= GA		Imperial College London	
Time of Calling to IR		11:00:00		Time to arrive to IR		00:30:00	
T.O.A		11:30:00		Total pathway time		05:20:00	
T.O.D		16:50:00		Case no.23		Page 1 out of 1	
2		Type of Anaesthesia		0		Who filled in this form	
		Case Complexity		2		IR Team	

Figure 5.3 Continuation of Part 1 of the FERERI tool magnified.

5.3.1.1 Part 2

As shown in Figure 5.4 and Figure 5.5 below part 2 of the FERERI Tool is comprised of 13 fields, almost all of which are related to healthcare errors. These errors can occur throughout the IR pathway from the start point, which is the time of admission to the endpoint, which is the time of discharge from the IR department. These fields in order of consequence are Time,

Failure, Category of error causing the failure, Mechanism, Staffs involved, during which phase of IR pathway the error occurred, Interruption Time, Score of Patient Harm, Resolution Score, could have been preventable by the current care, Brief description in text format, other errors/Notes, Pathway Log (Main steps).

Time	Failure	Category of error causing the failure	Mechanism	Staffs involved	During which phase of IR Pathway the error occurred?	Interruption Time
		1= Vascular or other ward 2= Preop. IR ward 3= Operative IR room 4= Postop. IR room 5= Handover to ward or discharge to home			0= less than 1 min 1= 1-5 min 2= 5-30 min 3= more than 30 min 4= procedure cancelled or deferred to later time on the same day	

Figure 5.4 Part 2 of the FERERI tool magnified.

Score of Patient Harm	Resolution Score	Could have been preventable by the current care	Brief description in text format	Other errors/Notes	Pathway Log (Main steps)
☐ 0 = No Pt harm ☐ 1= Mild Pt harm ☐ 2= Moderate Pt harm ☐ 3= Severe Pt harm ☐ 4= NOT KNOWN	☐ 0= No need to resolve ☐ 1= Easy to resolve ☐ 2= Moderately difficult to resolve ☐ 3= Extremely difficult to resolve				

Figure 5.5 Continuation of Part 2 of the FERERI tool magnified.

Time is the time of occurrence of a particular healthcare error. In the field failure, we just enter the number of error/s at that time. If one error happened, we just put number 1 and then elaborate that error further in the following fields as will be explained below.

Under the dropdown menu "Category of error", there are eleven main categories. If the error does not fall into any category, others would be chosen. The dropdown menu contains the following categories (as shown in Figure 5.6) which are Absence, Communication, Equipment_related_error, Distraction, Fatigue, Management, Patient_related_error, others, Planning, Procedure_related_error, Safety_awareness and Technical.

B	C	D	E
Time	Failure	Category of error causing the failure	Mechanism
	1		
		Absence Communication Equipment_related_error Distraction Fatigue Management Patient_related_error others	

Figure 5.6 Shows Dropdown menu of the main categories of healthcare errors.

Absence (see Figure 5.7) means the absence of any member of the IR team that was needed at a particular time, which led to some delay of the procedure or led to undermining of patient safety. For instance, when the IR consultant needed a projection to know the updated position

of a wire or a stent, the radiographer was outside, as he or she was asked to do another task by another staff outside the operating IR team. As a result, the IR consultant must wait until the radiographer comes back and put the C- arm fluoroscopy into the required position. This task is specific to the radiographer and cannot be performed by other members of the IR team; therefore, their absence would undoubtedly cause delay and subsequently, patient safety issue.

	A	B	C	D	E	F	G
1		Category	Absence	Communication	Equipment_related_error	Distraction	Fatigue
2		Absence	Circulating Nurse		Unavailable	Departmental	CN
3		Communication	IR Consultant Dr	Lack	Configuration error	By Team member/ non-relevant talk	Scrub Nurse
4		Equipment_related_error	IR Fellow	Misleading	Default equipment	By External staff	IRC
5		Distraction	Radiographer	Misheard/non-heard		Due to Phone or Bleep	IRF
6		Fatigue	Scrub Nurse	Team conflict			RDG
7		Management					Vascular Consultant D
8		Patient_related_error					Anaesthesia Nurse
9		others					Anaesthesia D
10		Planning					
11							

Figure 5.7 Breakdown of absence sub-category according to different IR team

Communication (see Figure 5.8) is another healthcare error which means any communication error that causes a delay or undermines patient safety. It has four sub-categories, which are Lack, Misleading, Misheard/non-heard, Team conflict. Lack of communication means that an error happened because there was no communication between the IR team to prevent it. For instance, the IR consultant gave a dose of anticoagulant and did not communicate this action

with the circulating nurse to document it on the procedure log. This error would pose safety harm as might lead to an overdose of the anticoagulant been given. Misleading communication means a request by a member of the IR team was not made correctly and did not achieve their aim. For instance, the IR consultant requested a type of a stent but with no exact name or specification or size which made the circulating nurse wonder and ask for clarification about the exact equipment he or she needs. Making this failure results in a delay and a safety problem as the faulty equipment was used. Besides this is a waste of resource.

	A	B	C	D	E	F	G
1		Category	Absence	Communication	Equipment_related_error	Distraction	Fatigue
2		Absence	Circulating Nurse		Unavailable	Departmental	CN
3		Communication	IR Consultant Dr	Lack	Configuration error	By Team member/ non-relevant talk	Scrub Nurse
4		Equipment_related_error	IR Fellow	Misleading	Default equipment	By External staff	IRC
5		Distraction	Radiographer	Misheard/non-heard		Due to Phone or Bleep	IRF
6		Fatigue	Scrub Nurse	Team conflict			RDG
7		Management					Vascular Consultant Dr
8		Patient_related_error					Anaesthesia Nurse
9		others					Anaesthesia Dr

Figure 5.8 Different types of communication errors

On the other hand, Misheard/non-heard means that communication was heard wrongly or not at all by the receiver. An example of this could be when a circulating nurse brings a wrong device because she or he did not hear accurately what the IR consultant requested. The error may result because the voice of the IR consultant was low, or there was a distraction from another member of staff during the request. This error also results from a problem from the

recipient side; either did not hear it properly because he or she was not close to the IR consultant or being busy with another task or did not understand what is meant due to lack of knowledge or experience. Team conflict is another communication error, which occurs when two or more members of the IR team do not agree about a step or more of the procedure, because of which the procedure paused. For instance, there is a dispute between the IR consultant and the radiographer about how to position the C-arm. This dispute might lead to a delay or repetition of the C- arm position and an increase in radiation dose.

Equipment_ related_ error is another error that has sub-categories which are: Unavailable, Configuration error, Default equipment (see Figure 5.9). Unavailable means that a piece of specific equipment was not available when was needed, which led the IR team to get around the issue and change their approach, which might mean delay or patient safety threat. Configuration error is another sub-category which denotes that the equipment is not faulty but because it was not tuned enough to achieve the task. For instance, the Doppler setting of the ultrasound machine was not correctly set up by the IR team, which did not clearly show the interrogated vessels. This error might lead to a delay. Default equipment means that the equipment was not working in the first place due to manufacturing error. This error leads to both delay and patient safety issue in addition to wasted resource and extra-cost to the N.H.S.

	A	B	C	D	E	F	G
1							
2		Category	Absence	Communication	Equipment_related_error	Distraction	Fatigue
3		Absence	Circulating Nurse		Unavailable	Departmental	CN
4		Communication	IR Consultant Dr	Lack	Configuration error	By Team member/ non-relevant talk	Scrub Nurse
5		Equipment_related_error	IR Fellow	Misleading	Default equipment	By External staff	IRC
6		Distraction	Radiographer	Misheard/non-heard		to Phone or Bleep	IRF
7		Fatigue	Scrub Nurse	Team conflict			RDG

Figure 5.9 Subtypes of Equipment- related errors

Distraction is one of the significant categories of healthcare errors. This error can be subdivided into the following: Departmental, By Team member (non-relevant talk), By External staff, Due to Phone or Bleep (see Figure 5.10). Departmental distraction is the pressure that the department put on the IR team to finish procedures on time to achieve the scheduled workload. This error might cause different other categories of errors, such as communication or psychomotor. Another type of distraction is by the operating IR team members themselves.

An example of this would be " The IR consultant in the middle of the procedure, while other team members engage in other talks". This error not only would distract the concentration of the IR consultant away from the procedure but also may predispose to another type of errors such as communication or psychomotor errors. Another type of distraction is made by a staff member outside the operation room asks the IR team about another case or a piece of equipment or an irrelevant subject. Another form of distraction is phone calls or bleep. It happens that during the middle of a procedure, one of the staff members get a call to distract them from what they were doing. For instance, an IR consultant while he was in the middle of a critical step during a vascular procedure gets a call from another doctor asking him or her about another patient.

AutoSave Off						
File Home Insert Page Layout Formulas Data Review View Help						
Distraction		Departmental				
	A	B	C	D	E	
1		Category	Absence	Communication	Equipment_related_error	Distraction
2		Absence	Circulating Nurse	Lack	Unavailable	Departmental
3		Communication	IR Consultant Dr		Configuration error	By Team member
4		Equipment_related_error	IR Fellow		Default equipment	By External
5		Distraction	Radiographer			Due to BL
6		Fatigue	Scrub Nurse			
7		Management				
8		Patient_related_error				
9		others				
10						

Figure 5.10 Subtypes of Distraction error

Fatigue can result in healthcare error. For instance, a circulatory nurse is seen about to fall asleep after having a long day (see Figure 5.11).

FERERI Form - Excel		
View	Help	Tell me what you want to
E	F	G
Equipment_related_error	Distraction	Fatigue
Unavailable	Departmental	CN
Configuration error	By Team member/ non-relevant talk	Scrub Nurse
Default equipment	By External staff	IRC
	Due to Phone or Bleep	IRF
		RDG
		Vascular Consultant Dr
		Anaesthesia Nurse
		Anaesthesia Dr

Figure 5.11 Fatigue can be subdivided into other involved healthcare staff.

Management error is another form of an error where there is mismanagement of either workspace or resource or human resource. An example of this could be placing of the scrub table in a way that prevents free movement of staff, which could cause destabilisation of equipment or delay in handing over various equipment (see Figure 5.12).

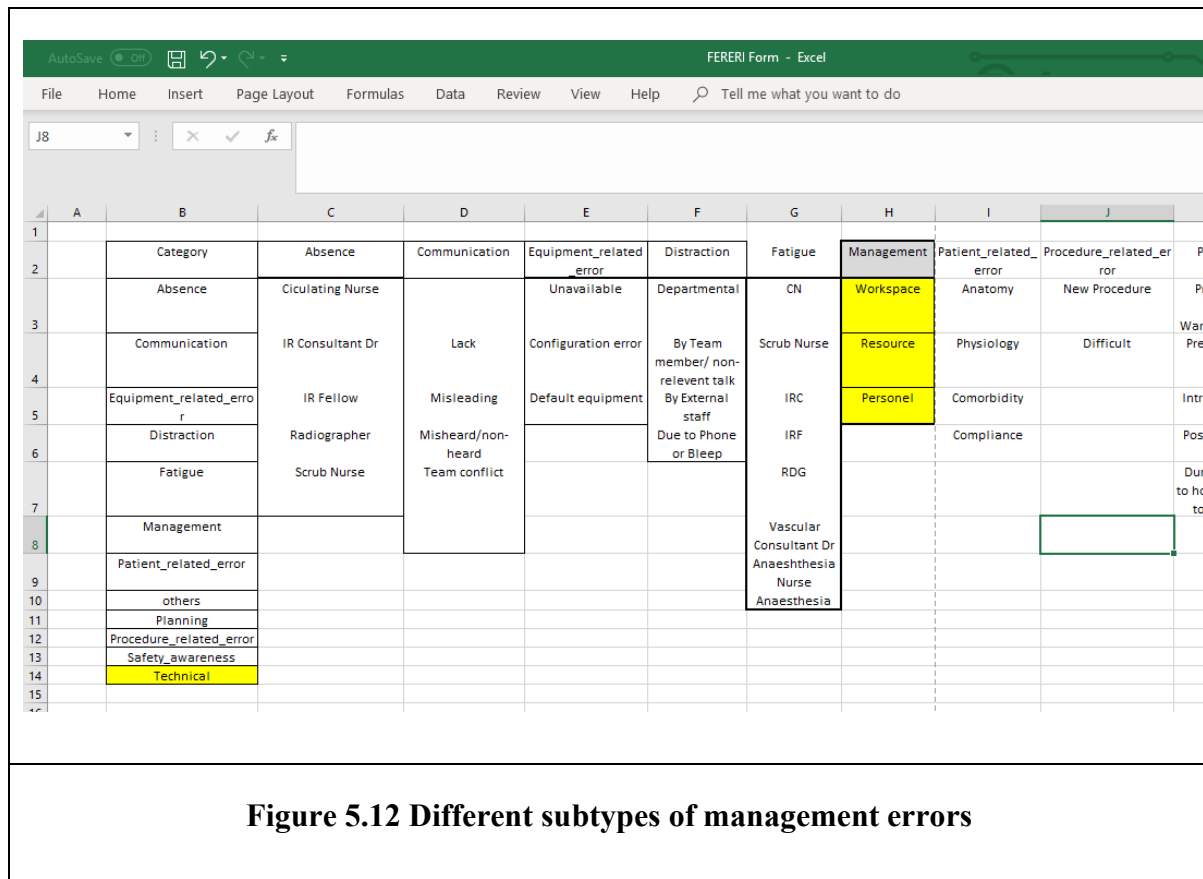
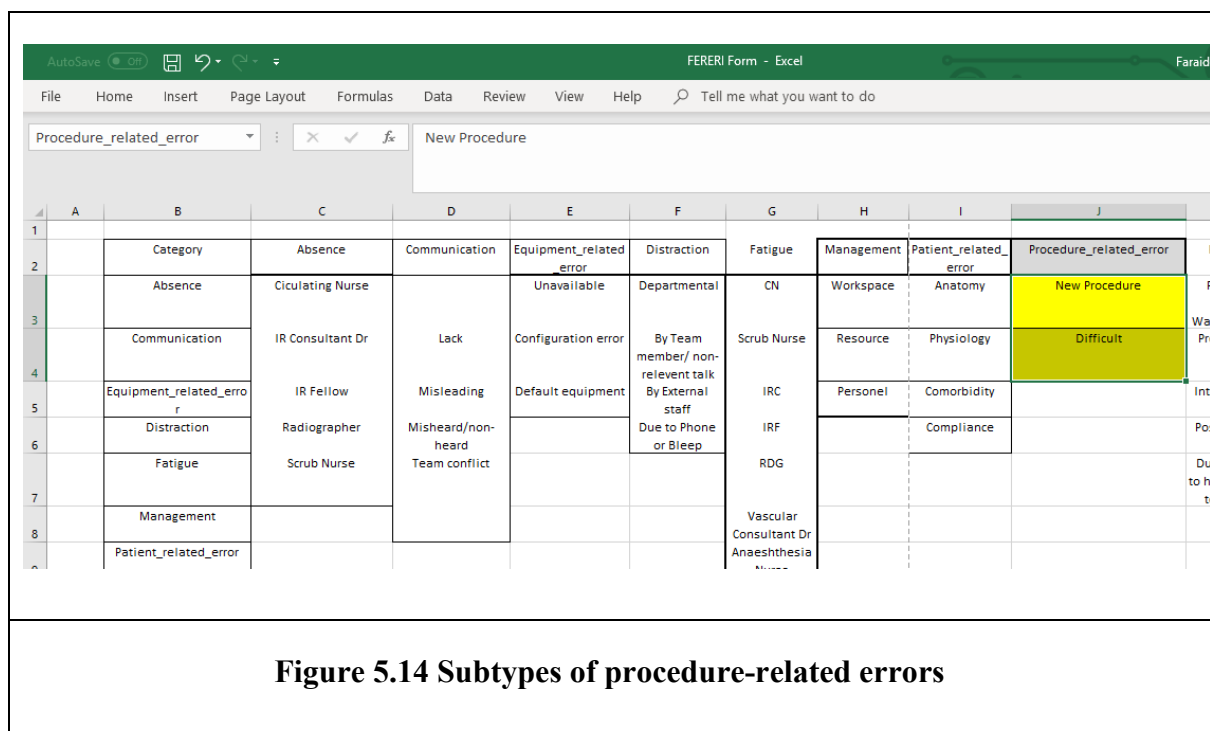
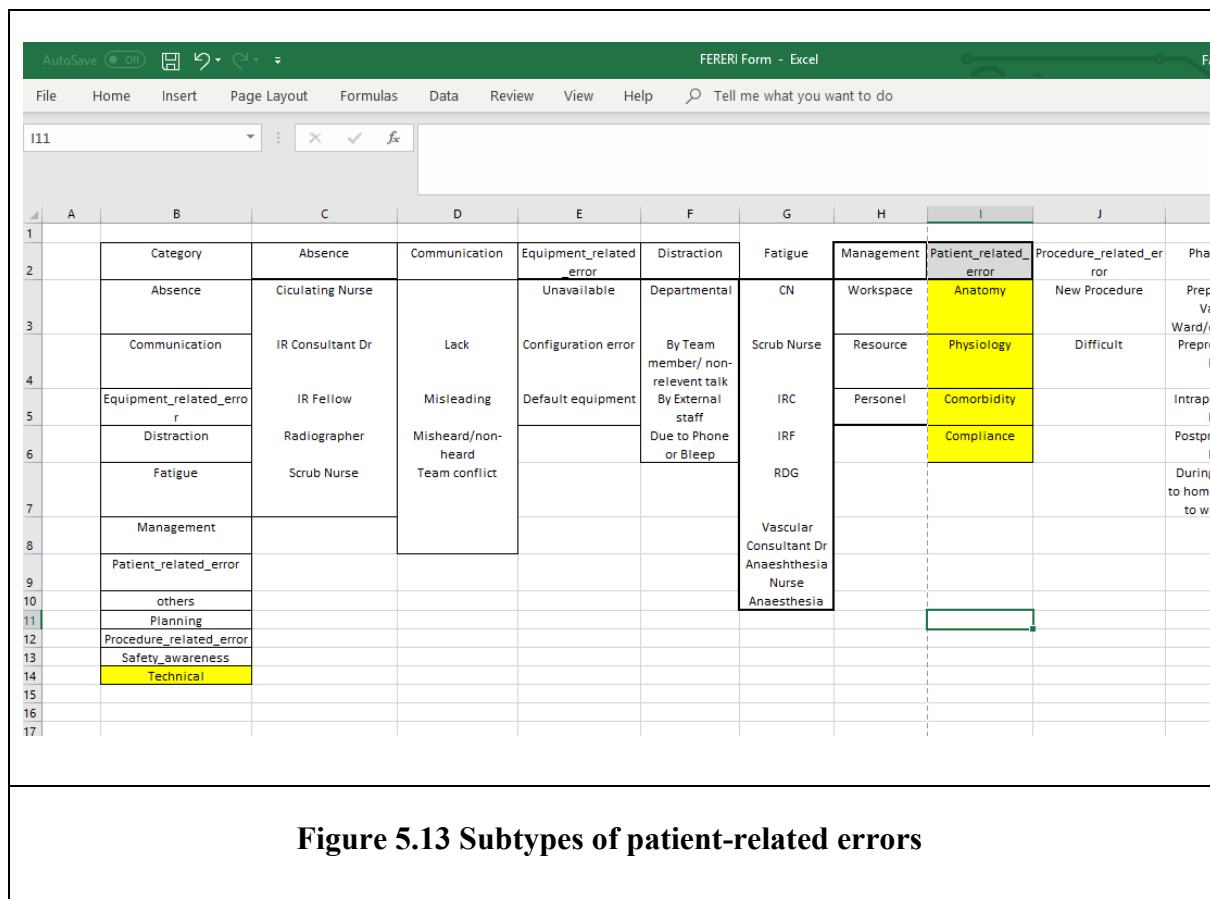


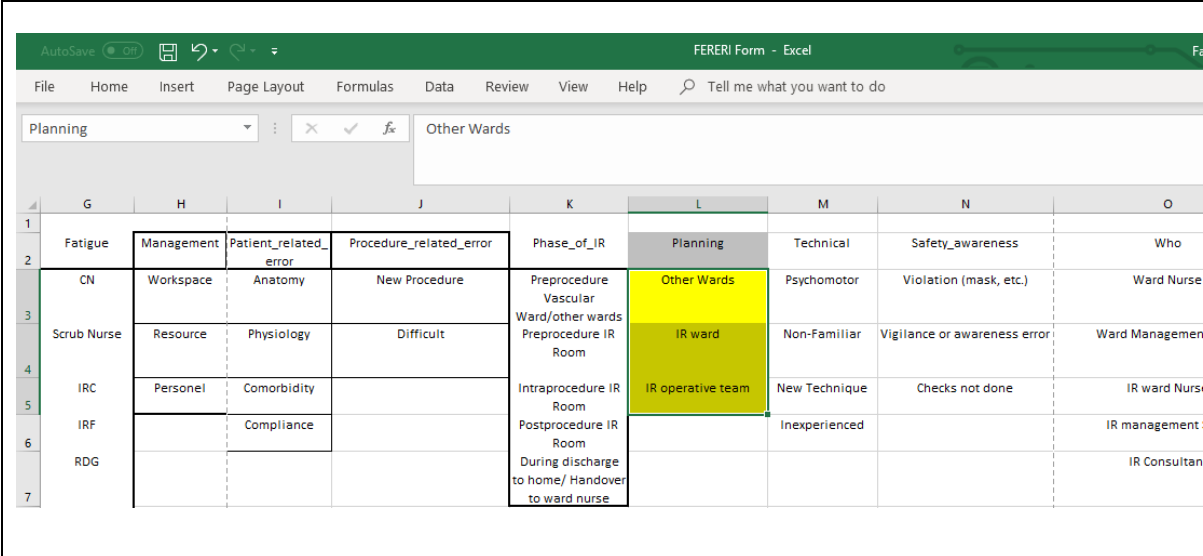
Figure 5.12 Different subtypes of management errors

Sometimes there is some failure which occurs due to factors related to patients such as abnormal vascular anatomy like tortuous arteries which cause difficult catheterisation or having comorbidity which prone the patient to particular complication such as diabetes or hypertension (see Figure 5.13). Sometimes it happens that the patient is not compliant and continuously move and about to fall on the operation table.

Whereas procedure-related-error is any error that is related to the procedure itself such as new procedure in which the operating staff is unfamiliar with or inherently difficult complicated procedure such as fenestrated thoracic endovascular vascular aortic aneurysmal repair_ TEVAR.



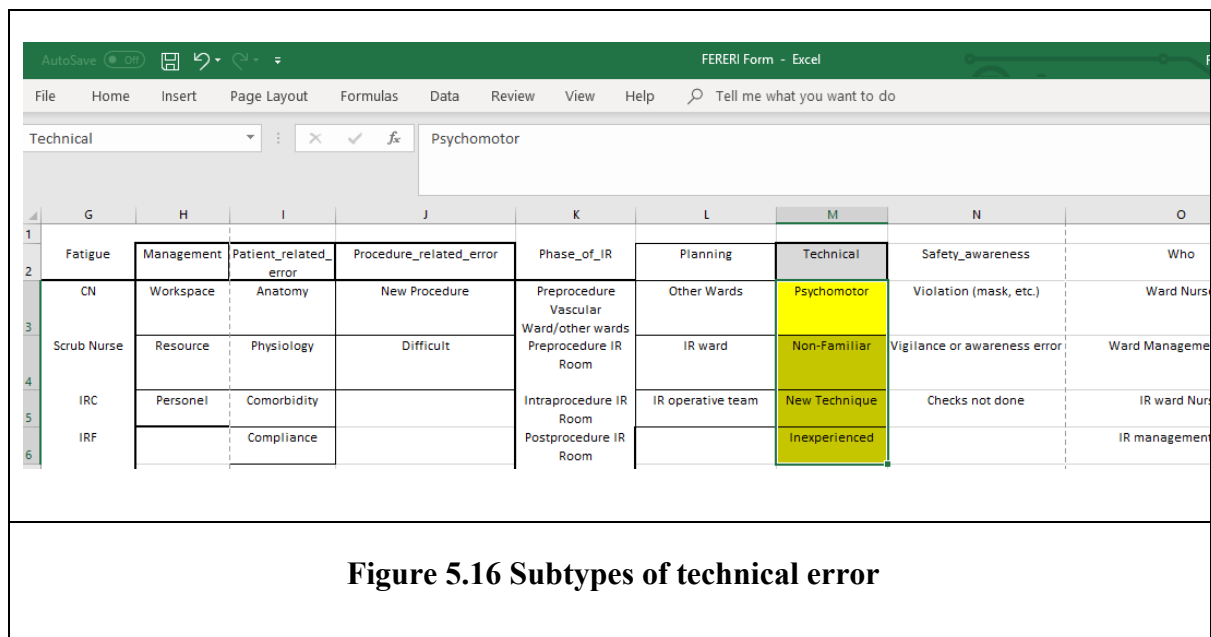
Planning error is a critical error which is a base of many other errors either directly or indirectly. The inappropriate planning can be found early in the preparation phase for procedures or management of patients in the vascular ward or other referring wards or inside the operation room (see Figure 5.15).



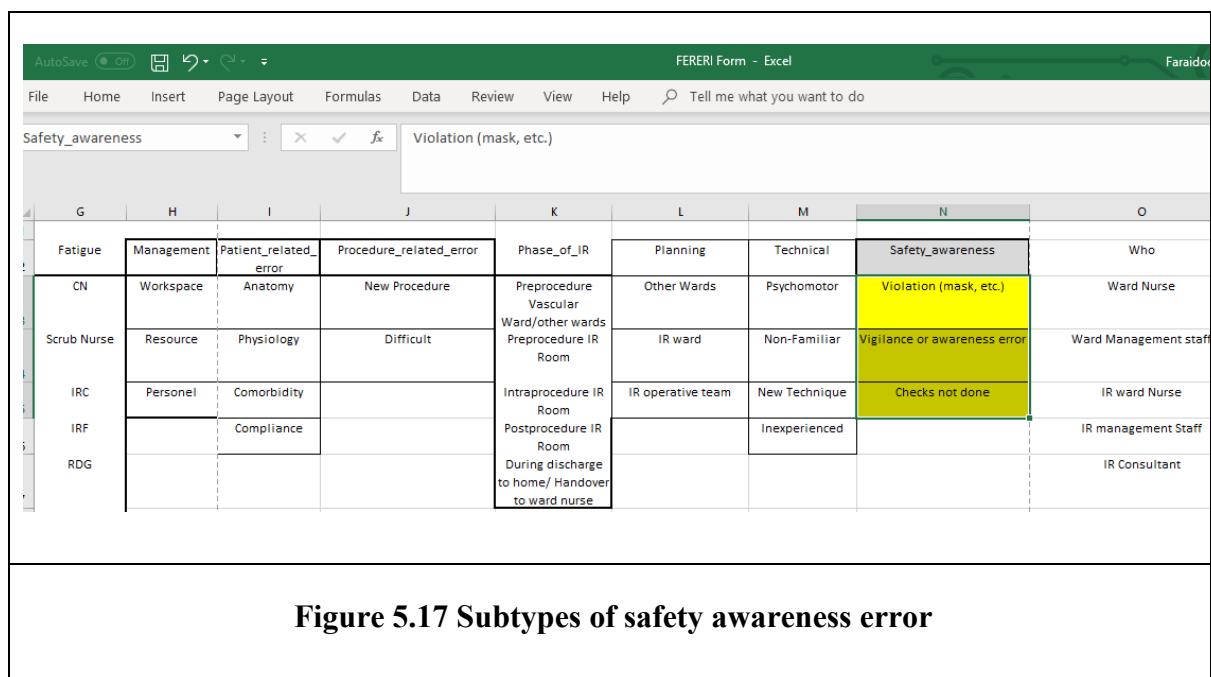
	G	H	I	J	K	L	M	N	O
1						Planning	Technical	Safety_awareness	Who
2	Fatigue	Management	Patient_related_error	Procedure_related_error	Phase_of_IR	Other Wards	Psychomotor	Violation (mask, etc.)	Ward Nurse
3	CN	Workspace	Anatomy	New Procedure	Preprocedure Vascular				
4	Scrub Nurse	Resource	Physiology	Difficult	Ward/other wards	IR ward	Non-Familiar	Vigilance or awareness error	Ward Management
5	IRC	Personel	Comorbidity		Intraprocedure IR Room	IR operative team	New Technique	Checks not done	IR ward Nurse
6	IRF		Compliance		Postprocedure IR Room		Inexperienced		IR management
7	RDG				During discharge to home/ Handover to ward nurse				IR Consultan

Figure 5.15 Planning error according to a different phase of the IR pathway

On the other hand, technical errors are still can happen, especially by IR trainee doctors or trainee nurses when they are unfamiliar with the procedures. The senior IR staff usually rectify these errors. The psychomotor error can fall into this category as well. Dropping a handheld IR equipment is an example that reflects psychomotor error.



Safety_awareness is found to be a significant category of error which is subdivided into the following: violation of safety by not wearing a surgical mask or having chewing gum (see Figure 5.17). Vigilance or awareness error occurs when staff, for example, fails to spot a blood pool on the ground, which pose a safety hazard. Sometimes healthcare staff fail to do checks such as various checks for blood levels of essential substances such as INR plasma creatinine, or pre-procedure antibiotic check.



There is another field in the tool which demonstrates the operational staff that involved in the occurred failure (see Figure 5.18). This failure does not mean to blame an individual staff in the involved failure. Instead, this would determine which group of specialisms need to be worked on in the future. This piece of information also gives an idea of what training goals should focus on a lure in the future.

After characterising the healthcare error, the tool allows recording the phase in which it occurs namely Pre-procedure Vascular Ward/other wards, Pre-procedure IR Room, Intra-procedure IR Room, Post-procedure IR Room, and during discharge to home/ Handover to ward nurse (see Figure 5.19).

FERERI Form - Excel								
File Home Insert Page Layout Formulas Data Review View Help Tell me what you want to do								
N10								
	H	I	J	K	L	M	N	O
1	Management	Patient_related_error	Procedure_related_error	Phase_of_IR	Planning	Technical	Safety_awareness	Staff_involved
2	Workspace	Anatomy	New Procedure	Preprocedure Vascular Ward/other wards	Other Wards	Psychomotor	Violation (mask, etc.)	Ward Nurse
3	Resource	Physiology	Difficult	Preprocedure IR Room	IR ward	Non-Familiar	Vigilance or awareness error	Ward Management staff
4	Personel	Comorbidity		Intraprocedure IR Room	IR operative team	New Technique	Checks not done	IR ward Nurse
5		Compliance		Postprocedure IR Room		Inexperienced		IR management Staff
6				During discharge to home/ Handover to ward nurse				IR Consultant
7								IR Dr Assistant
8								CN
9								SN
10								RDG
11								Anaesthesia Dr
12								Anaesthesia Nurse
13								IR healthcare Assistant
14								External staff
15								
16								

Figure 5.18 Different staff by their title who are involved in a particular error

FERERI Form - Excel									
File Home Insert Page Layout Formulas Data Review View Help Tell me what you want to do									
Phase_of_IR				Preprocedure Vascular Ward/other wards					
	G	H	I	J	K	L	M	N	O
1									
2	Fatigue	Management	Patient_related_error	Procedure_related_error	Phase_of_IR	Planning	Technical	Safety_awareness	Who
3	CN	Workspace	Anatomy	New Procedure	Preprocedure Vascular Ward/other wards	Other Wards	Psychomotor	Violation (mask, etc.)	Ward Nurse
4	Scrub Nurse	Resource	Physiology	Difficult	Preprocedure IR Room	IR ward	Non-Familiar	Vigilance or awareness error	Ward Management s
5	IRC	Personel	Comorbidity		Intraprocedure IR Room	IR operative team	New Technique	Checks not done	IR ward Nurse
6	IRF		Compliance		Postprocedure IR Room		Inexperienced		IR management Sta
7	RDG				During discharge to home/ Handover to ward nurse				IR Consultant
8	Vascular Consultant Dr								IR Dr Assistant
9	Anaesthesia Nurse								CN

Figure 5.19 Different phase of the IR pathway

5.3.1.2 Healthcare errors analysis in terms of delay score, patient harm score, resolution score and preventability

Healthcare errors can be further analysed using the delay score. The delay-score would take zero if no delay or a delay of fewer than 1 minutes happened, one for a delay of 1-5 minutes, 2 for a delay of 5-30 minutes and three if there was more than 30 minutes delay. Furthermore, four is used if the procedure was cancelled or deferred to a later time on the same day.

Also, patient harm is divided into the following scores: zero, which means there was no patient harm with the healthcare error in question. For mild harm, we put number 1 and 2 if moderate harm occurred. For example, if more delay or more harm can be resulted by an error such as when the patient might develop pain or potentially needs a more increased level of care to rectify the failure. Another example is when the IR consultant warned the radiographer that the patient's name on the screen is wrong. This error might have a very detriment consequence if it did not pick up early and resolved but might be moderately significant in terms of harming the patient if it was picked up early. Similarly, number 3 is when there is severe patient harm.

Sometimes we do not know by having an error whether there would be any patient harm or not, in which case we put number 4 to refer to this.

To know how easy, it is to fix a healthcare error, the following rating is used: zero if no need to resolve. If the error is easy to resolve, we put two, or two if moderately difficult to resolve, three if extremely difficult to resolve. For preventability, zero is put if the error is preventable or one, if not. For instance, there is no reason communication errors are not preventable. On the other hand, there are specific errors which cannot be prevented, such as psychomotor error or default equipment at least by the current practice.

The other parts of the FERERI are self-explanatory. In the short description field, one can describe any further elaboration of the healthcare error or staff involved, and the way occurred descriptively. This field would document the observation in more detail and would invite further analysis or audit as to whether the objective characters of a particular healthcare error were correctly addressed.

There is a field where any other error or note can be reported or observed. The last field of the FERERI form is chronologically documenting the procedure log. For instance, the start time of the procedure, when did the WHO checklist begin, and when did it finish. This field is significant to know how every pathway began and how it ended.

The whole FERERI tool screenshot is shown in Figure 5.20 and the Microsoft Excel sheet can be opened by clicking the following link: [FERERI template](#)

FERERI (Failure Estimation REcord in Radiology Intervention)										Imperial College London		
Patient Name		Op	Gender	I	DOB	Today's date	Age	D.O.A	21/09/2022	Time of Calling		
Pathway		1	Hospital No	18/05/2003	08/06/2023	20 years, 0 months, 21 days	T.O.A	08:30	Time to arrive to IR	Case no.2	Page 1 out	
Procedure		Li lower limb angio +- plasty	Type of procedure	1	Side	0	T.O.D	15:00	Total pathway time	Who filled in this form	IR Team	
Time	Failure	Category of error causing the failure	Mechanism	Staffs involved	During which phase of IR Pathway the error occurred?	Interruption Time	Score of Patient Harm	Resolution Score	Could have been preventable by the current care	Brief description in text format	Other errors/Notes	Pathway L
09:44:00		Technical	Psychomotor	IR Dr Assistant	3	0	0	1	0	The IR assistant Dr inadvertently sterilised the glove by touching the ultrasound probe, changed the glove.		9.26 VHO checked
09:50:00		Equipment-related error	Configuration error	IR Consultant	3	1	0	1	0	The configuration of the ultrasound machine wasn't clearly showing the puncture site. The IPC		
09:56:00		Distraction	By Team member/ non relevant talk	CN	3	0	0	0	1	During the IR procedures in general for two student		
10:03:00		Communication	Misheard/no n-heard	RDG	3	0	0	1	1	IPC requested table down, the RDG asked whether meant moving table south or north. The		
												10:19 diagnosed left lower limb

Figure 5.20 Shows a screenshot of the FERERI tool which can be accessed by following the link below :

[FERERI template](#)

5.4 Discussion:

In this chapter, I explained how FERERI_ a computerised error-capture tool by using is developed by using the Microsoft Excel programme. Due to several features and functions described in the methodology section that is unique to Microsoft Excel software, it is considered a convenient program to design the error-capture tool to measure healthcare errors across the IR pathway of care. Being one of the prevalent and available programs in any computer, selecting the Microsoft Excel spreadsheet to design FERERI tool allows this tool to be included into the online I.T. system of any hospital or department to measure human factors.

The FERERI tool allows to detect and characterise healthcare errors from different angles to form a three-dimensional picture of these errors. Not only this but also their implication on patient safety in the IR pathway of care. We might ask why detecting healthcare errors is essential at all?

It was acknowledged more than two decades ago that the focus should be on tackling medical or healthcare errors if the quality of care is ever needed to be improved. The Institute of Medicine, in their report "To Err is Human: Building a safer Health System" in 2000, stated that making an error is natural, but finding a solution for it should also be an instinct. Everyone approves that medical errors should not happen (Institute of Medicine Committee on Quality of Health Care, 2000). This report came after the publication of the two extensive studies, one in Colorado and Utah and the other in New York, in which adverse events occurred in 2.9 and 3.7 per cent of hospital admissions, respectively. In Colorado and Utah hospital, 6.6% of adverse events caused death in comparison to 13.6 % in New York hospitals. Interestingly, half of these adverse events occur due to preventable medical errors with an estimate that as minimum as 44,000 and as high as 98,000 Americans dies each year as a consequence of medical errors (Gawande, (1999) and (Brennan et al., 1991).

Looking at the U.K. data, the rate of adverse events in hospitalised patients is comparable to the U.S.A. Vincent et al., (2001) found that about 10% of patients admitted to acute hospitals experienced an adverse event, half of which were avoidable with current N.H.S. standards of care. The annual cost of medical errors in the U.K. is £1 billion which is comparable to that of the U.S.A., considering the population, which is \$17 billion and \$29 billion (Vincent et al.,

2001) (Institute of Medicine Committee on Quality of Health Care, 2000) . Therefore, estimating these healthcare errors has been the priority of any patient safety initiative.

There have been various methods of estimating healthcare errors in surgery. Understanding the healthcare errors depend on the context within which they happen, hence measuring healthcare errors and adverse events are more complicated than other healthcare parameters (Thomas and Petersen, 2003).

In a review article, eight methods were found common to be used to measure adverse events, and medical errors, each of them has its strengths and weaknesses. These methods are morbidity and Mortality conferences and autopsy, malpractice claims analysis, error reporting system, administrative data analysis, chart review, electronic medical record, observation of patient care and clinical surveillance. The first three methods can detect latent errors, which will be explained in the next paragraph. However, the only method to detect dynamic errors, which will be explained below, is the observation of patient care (Thomas and Petersen, 2003).

Not only is the observation of patient care, the only method in which observers can detect active errors but also it provides information otherwise unavailable. The dynamic errors, which we are interested in detecting and measuring by the FERERI tool, are defined as those errors which occur at the level of healthcare providers such as wrong techniques, or wrong patients or wrong sites or administration of incorrect doses of medication. In contrast, latent errors are related to a preliminary system design like defects in installation or maintenance or insufficient staffing, all of which are not accessible or impossible to be measured because of inability to predict the time before any error can result from them (Thomas and Petersen, 2003).

Interestingly, within the direct observation method, we have a different way of observing patient care. Field-note-based observation has been one of the established methods used in surgery. Lingard et al. (2004) used this method in the operation room to characterise communication errors, while Christian et al. (2006) used this type of observation in ten complex general surgery procedures. Similarly, Catchpole et al. (2008) studied teamwork skills among different operative teams. Field-note-based studies are also found in the IR literature. Morbi et al. (2012) studied the vascular IR by using field notes. I also used Field-note-based method in chapter 3 of this thesis to observe thirty consecutive patients throughout the whole IR pathway of care.

However, these methods have some limitations. Field-Note- Observation is regarded as a time-consuming method. Not only does it entail writing what was happened during an observation descriptively, it also needs time to analyse these field notes later. Besides this limitation, more people are needed in this type of studies as there are usually two or more other observers who are needed to analyse further the descriptive field notes to differentiate errors from normal behaviour. Sometimes, we need a third person to resolve any disagreement between the initial assessors. As a result of these and other factors, the Field-Note-Observation studies are usually expensive to conduct as they involve adequate training of observers and analysers to undertake reliable observation and analysis, respectively. Not only this, but also large-scale studies can be challenging to this type of observational methods.

To tackle the above limitations, a group of researchers at Imperial College London developed the ICECAP (Mason et al., 2013), which is a paper format error-capture tool. I used this tool as one of the sources to design the FERERI tool. Mason et al., (2013) thought the tool is reliable in detecting significant errors at a rate of 100 per cent interobserver' agreement. However, it deemed to be less effective for minor errors. Not only can ICECAP be used as an error-capture tool but also considered as a tool as a self-report document to be used by the operating staff themselves. It showed improvement of error recall by teams across different categories by 40%. Mason et al. (2013) admitted that ICECAP has a significant limitation in terms of errors falling outside the operation room. Whereas there are errors across the whole patient's journey either preoperatively, operatively, or postoperatively (Nagpal et al., 2010a), it has been considered a necessity to design a tool to cover these stages of care.

One of the limitations of the ICECAP tool is being a paper document which cannot be integrated easily into the current N.H.S. system database. It must be scanned and then uploaded into the system. Not to mention that it would be extremely difficult to retrieve data from the tool for the purpose of audit or research to guide departmental policy and protocols in quality assurance projects.

In comparison to the ICECAP, the FERERI tool is a Microsoft Excel sheet which can be easily integrated into the system of any hospital. To the knowledge of the writer of this thesis, FERERI is the first computerised error-capture tool to be developed for use in I.R., and it is a novel tool to cover the whole patient's journey from admission to discharge from the IR department. The tool contains additional items and might have the potential to discover more dimensions to the healthcare errors throughout the IR pathway. Since Microsoft Excel

programme is a readily available programme in all the current N.H.S. computers, making the FERERI tool out of it is a bonus to use the current programme without the need to invest in expensive software or programmes. The ease of integration of the tool into the hospital's software is essential in my view as this can be a useful annexe to the current programmes used by the IR department as a self-awareness programme to decrease medical errors.

The content of the FERERI is different from the ICECAP. For example, the procedure independent pressure in the ICECAP tool contains the following items: Absence, Distraction, Departmental, External pressure. However, Absence is a standalone error in the FERERI tool which has further subcategories depending on who was absent (for e.g. IR consultant, Radiographer, etc). Also, distraction is an error on its own which has subcategories such as phone, external, irrelevant talks, departmental. Each of the errors in the FERERI tool has other parameters such as the staff involved directly with the error, the phase during which the error occurred, the degree of interruption and severity of the error. Also, the resolution score and whether the error is preventable. There is no scoring for the severity of the error in the ICECAP tool. Therefore, the FERERI tool covers in more detail the landscape of healthcare errors during the IR pathway of care.

The tool needs only one person to fill it out, and there is no need to categorise further or analyse the detected errors. The tool is hoped to be as user-friendly as it should be. However, like any other methodology, there are several limitations.

5.5 Limitation of the tool

Admittedly, there are several limitations. As the FERERI tool is regarded as one of the methods of direct care observation, it would bear all the limitations that are specific to this type of healthcare error assessment.

Firstly, to use the tool as useful as it should be, there must be a reasonable amount of training of the observer or the user. The items contained in the tool are self-explanatory. However, the interpretation of different interaction among the IR team or other communication or technical moves need an observer to be familiar with the basics of these procedures and how should the ideal procedure pathways be.

To know whether the tool is reliable (which means it consistently detects the occurring errors throughout the IR pathway), we need to validate it across the IR pathway of care. One of doing

so is by presenting the tool to different observers and measure inter-rater variability or agreement. This process would be a future project that measures the usability and validity of the tool before it is used as a tool to observe large scale studies.

5.6 Conclusion

The development of FERERI is feasible by using Microsoft Excel program. This tool can be easily used as a form of electronic document alongside the other electronic programs used by any N.H.S. trusts in the U.K. Future work should focus on validation FERERI tool by assessing interobserver variability and agreement.

Chapter Six: Validation of a Computerised Error -Capture Tool for Quality Assessment in Interventional Radiology Entire Pathway of Care”

6.1 Introduction:

As previously mentioned in chapter five, there have been several ways to measure healthcare errors across the healthcare management pathways including surgical and IR pathways. Each of these methods has their own strength and weakness. Mason et al. (2013) created the ICECAP_ Imperial College Error CAPture tool to estimate and categorise errors that occur during the intraoperative phase of vascular and endovascular surgery. However, developing an error capture tool to cover the whole patient’s journey from admission to discharge has been a challenge and was highlighted by the previous researchers at Imperial College London as a gap which should be addressed (Mason et al., 2013).

In response to the necessity of devising a computerised tool that cover the whole IR pathway, the FERERI tool has been developed which was discussed in detail in chapter five of this thesis. The tool is meant to be integrated into any hospital IT patient-care software or system. This tool is composed of a Microsoft Excel spreadsheet.

Since many hospitals in the United Kingdom like other developed countries have been maintaining an electronic form of records where patient files or information can easily be stored, retrieved, or shared by healthcare personnel.

Therefore, it is essential to devise a tool which is electronic. Besides being electronic, an ideal tool should also be efficient in capturing healthcare errors, feasible and applicable to everyday use within a wider set of IR throughout the pre- and post-operative stage.

For any tool to be used safely and confidently within the healthcare system or any other sector, it should be validated. The FERERI as any other measurement tool should be precise, which is a synonym of reliable (with no random measurement error) and accurate_ a synonym of valid (i.e. has no systematic measurement error) (Thomas and Petersen, 2003).

6.2 Aim

The aim of this study therefore is to evaluate the reliability and validity of the FERERI tool: to test if it can detect and measure what is meant to measure if it was used within the IR suite.

6.3 Methods

Setting:

The project was undertaken at the Interventional Radiology unit of a tertiary Hospital_ St. Mary's Hospital, Imperial College NHS trusts/London. The hospital is one of the nationwide tertiary vascular and IR referral centres within the UK.

Ethical approval

Ethical approval was sought by filling an online application to the medical research council (MRC) and the local ethical committee at Charing Cross Hospital/ Imperial College London. The approval was waived as the study deemed a quality project, in which no recognizable data neither of the observed staff nor the patients were collected.

Training Induction period

This study is composed of two stages of data collection. The first stage started from December 2015 to January 2016. The first stage constituted validation of the FERERI tool between the study conductor (FR_ PhD fellow) and two medical students who acted as complete novice-users of the FERERI error capturing tool.

Before this, there was a 4-week induction period in the IR department in which the FERERI tool was used in the first two weeks by the study conductor to evaluate the potential healthcare errors which might occur during the intraoperative phase of IR pathways. No data were collected at this stage. The tool was tested against the ethnographic field notes collected in the free-text field_ called notes that is located at the end of the tool. These field notes were descriptive terms entered by the attending observer to describe a situation occurred which can be a potential failure or error. These notes were shown to a senior IR consultant (with more 15-year experience in the field of IR) and who is the supervisor of this project. The categories of the collected errors and their subtypes using the FERERI tool were assessed against the assessment of the expert IR consultant of the descriptive notes collected by the study conductor to see if they match the FERERI tool classification.

This period was used as a training session where the IR consultant taught the observer how to use the tool, what different potential failure would consider true error or not and how each of them could be categorised and subcategorised using the tool. Furthermore, this period of live

application of the FERERI allowed some final refinement of the prototype to be ready to use in the IR environment. No data were collected at this stage.

Later, for further two weeks, two medical students (VB and SR), who were in the final year of their MBBS degree, trained by the main coordinator of the study (FR) on how to use the tool. The overall 4-week period was also thought essential in decreasing the ‘Hawthorne effect’ (McCarney et al., 2007b).

The second stage of FERERI validation was performed by involving two IR doctors to observe IR procedures with the main conductor of this study (FR). Each of these doctors had at least three years of experience in performing IR procedures. One of these doctors was a newly appointed IR consultant (BP) and the other doctor was an IR fellow in his final year of IR fellowship (AR). Each of these doctors performed more than 200 IR procedures either independently or under supervision.

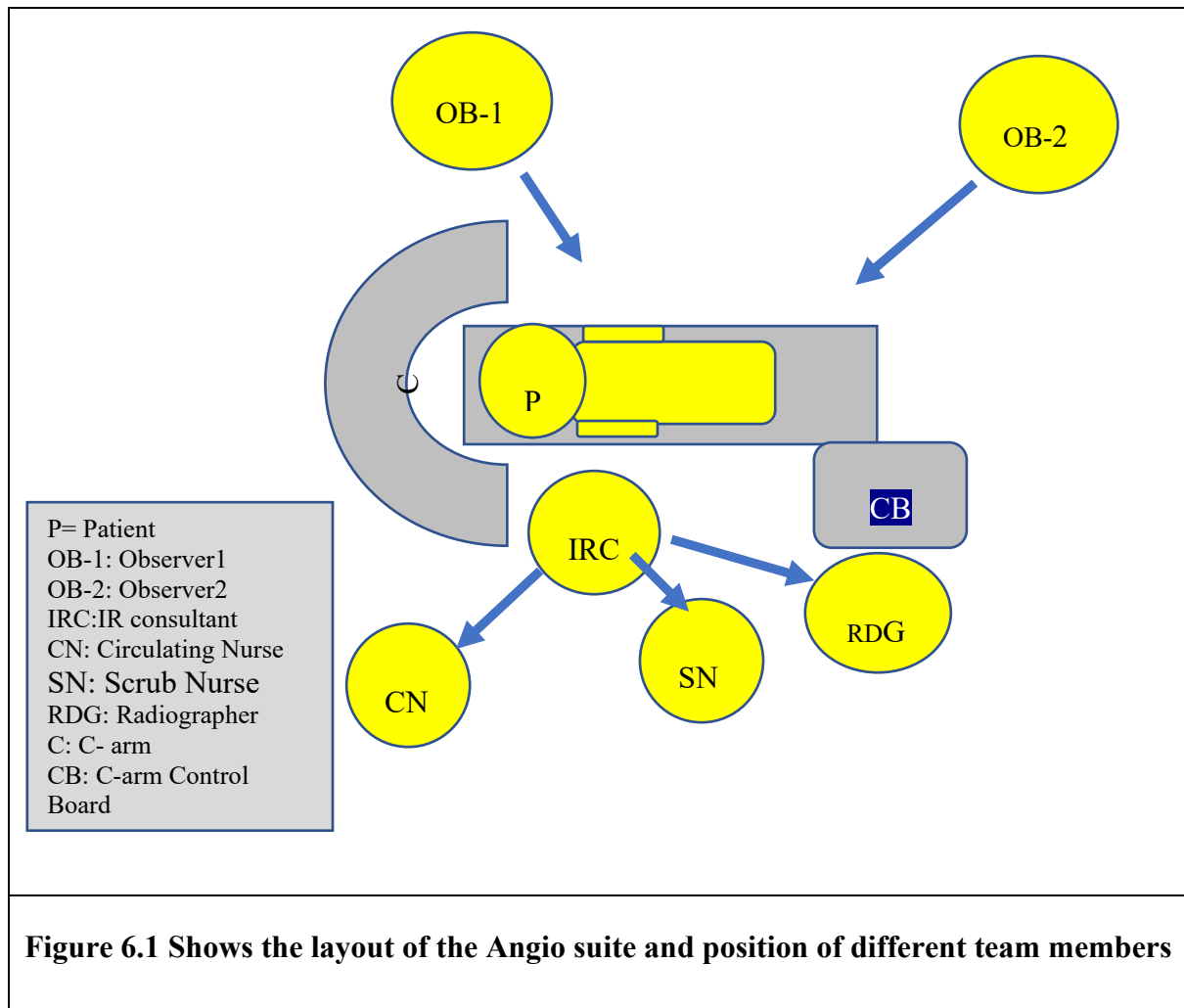
In November 2022, a week of test-usage of the FERERI tool was performed by the observers FR, BP, and AR to be familiar with the items included in the tool and how to use it to record healthcare errors with all the subclassification of each error. No data were collected. Once the two IR doctors became familiar how to use the tool, the next phase started which was official data collection.

Validation of FERERI tool

The real-time observation was conducted in 40 IR cases using the FERERI tool to estimate the ability of the tool to cover all errors and to check the feasibility of the tool in the IR setting. Ten cases were observed by the writer of this thesis (FR), as an expert versus one of the novice-observers (VB, SR) on an alternate case-mix. The other ten cases were observed by the two novices (VB and SR). The other 20 IR cases were observed by the study conductor (FR) against the two IR doctors (who are regarded as experts in the field of IR).

For each IR procedures, two real time observers were present who were independently observing the procedure to maintain the integrity of the study and eliminate bias.

The layout of the Angio suite and the position of different team members and the observers are shown in Figure 6.1 below.



Twenty consecutive IR procedures were observed within the study venue over a 6- week period (December 2015- late January 2016). A further twenty consecutive IR procedures were observed in late November 2022.

The IR team was informed that the observer(s) were conducting research on patient safety and that no information led to identification of patients or staff would be recorded. Observations were only documented in procedures in which all the IR team provided verbal consent for the presence of the observers.

Patients

6.3.1.1 Inclusion criteria

- Adult patients over 18-year-old

6.3.1.2 Exclusion Criteria

- Paediatric patients under 18-year-old

Procedures:

6.3.1.3 Inclusion criteria

- Any IR procedures within this period.

Tools used for observation:

An Apple iPad mini [version 9.3.1], containing Microsoft Excel Spread Sheet program, was given to each observer. The FERERI form was stored in the Microsoft office application of each iPad so as each observer got the chance to store their data. Each case was stored in a new spread sheet within the Microsoft Excel spread sheet. The date and case number were recorded by an observer to be matched later with the corresponding date and number of the other observer. Instructions on how to open and store the data using the FERERI tool on these iPads were given in the induction period.

During the observation time

The observers had no access to each other's observation during the data collection phase and did not communicate their findings among themselves or with the operating team members during the collection period. Both observers were positioned to guarantee that all the observed targets including the patient, the team members and the other observable objects were clearly visible throughout the observation time. The observers did not obstruct or communicate with the team members, and they did not try to intervene even if there was a healthcare error.

Interobserver variability

The FERERI tool was validated prospectively and independently at three-level validation as follows: between two novices (two medical students_ VB and SR) in ten IR procedures , between the study conductor (FR) and a novice (either VB or SR) in another ten IR procedures and between the study conductor (FR) and the IR doctors_ experts (BP and AR_ each of which observed 10 IR procedures) in the other 20 IR procedures.

Definitions

Errors were defined as acts of omission or commission in the planning or the execution that contribute or could contribute to an unintended result (Grober and Bohnen, 2005). An adverse event is defined as “an injury caused by medical management rather than the underlying condition of the patient” (Institute of Medicine Committee on Quality of Health Care, 2000).

Data Collection

Errors were recorded and categorised (using the FERERI tool) from the time of reading out of the WHO checklist for radiology Interventions to the time where the IR team announce the end of the procedure when no more physical contact remained between IR team members and the patient. For instance, when an IR consultant announces a procedure as finished and he or she withdrawn the last piece of IR handheld from the puncture site but still needed to press the puncture site with his or her hands, the procedure would not be regarded as finished unless he or she lifted his or her hand away from the patient’s puncture site.

Each error was categorised and sub-categorised and assessed using a drop menu scale according to an interruption might cause, or a harm to the patient might cause, or how easy could be resolved. A note of the preventability of the errors and the staff (by role) involved in each error without referring to their identifiable data.

In terms of procedural interruption caused by errors, grades 0 to 4 were used. For instance, grade 0 is given if a healthcare error does not cause disruption of the flow of the procedure or cause less than 1 minute disruption; 1 for those errors causing disruption of 1-5 minutes delay; 2 for 5-30 minutes disruption, 3 for errors with severe disruption of more than 30-minute; and 4 for those errors that cause either postponement of the procedure to a later time within the same day or cancellation of the procedure to another day.

For ease of resolution, a score of zero was assigned to errors that required no resolution, 1 for those which were easy to resolve using standard care, 2 for those that were moderately difficult to resolve requiring the involvement of more than one team members, 3 for those errors that were almost impossible to resolve requiring involvement of multiple team members, and 4 for errors were either the team members were not of aware of or did not attempt to resolve it or indeterminate as to whether it is easy or not to resolve. These scores were used to determine whether the most important errors were captured by the observers using this tool.

In terms of preventability of each error, scores of 0 and 1 are used. Number 0 was assigned to errors which were non-preventable whereas number 1 was assigned to preventable errors by current standard of care.

Data recording and statistical analysis

Confidentiality and data protection were maintained according to data collection act (Parliament, 1998). The data which were recorded on the FERERI Microsoft Excel Sheet was entered into another Microsoft Excel sheet which then analysed. The number and category of healthcare errors were analysed. Statistical analysis was conducted using Statistical Package for the Social Sciences version 25.0 (SPSS, Chicago, IL, USA). Intra-class Correlation Coefficient correlation was used to compare the total numbers of errors between the observers, while for internal consistency and reproducibility of FERERI, Cronbach's alpha reliability test was used. This was regarded as having a particularly good correlation with any figure at or above 0.8 within 95% confidence interval, and a P value of 0.05 or less was regarded as statistically significant.

Furthermore, inter-rater agreement was measured at three levels, Novice-Novice, Novice_Expert and Expert_super Expert level, by using Cohen's Kappa statistics. In the first batch, 20 IR procedures were evaluated, ten of which were studied by Novice1_ Novice 2 and the other ten cases were studied by Expert_ Novice. In the second batch, 20 IR procedures were studied by the Expert (conductor of this study) and the super-experts (the IR doctors). This is to measure the agreement between the two observers in each group namely: Novice- Novice, Expert-Novice, and Expert_ Super Expert.

It was not possible to ensure that the same exact error was recorded by each observer at an exact time. However, a 5-minute-time window of flexibility was given to allow matched errors to be considered if the brief description of the errors in the note field were matched. For instance, a communication error recorded by one observer at 9:00 am would match a communication error recorded by the other observer in the same IR procedure even if it were recorded at 9:03 am if the context were similar by the description of the error. Furthermore, some errors did not need to be recorded at the same time to be regarded as matched. For instance, an error such as "Violation of safety by not wearing a fascial mask", which comes under the main category of "Safety awareness" does not need to be recorded exactly at the same time by the two observers to be regarded as matched. This is because this type of error is

only recorded once during a procedure. Therefore, it might be recorded by one observer at the start of the procedure or later by the other observer and still regarded as matched- error between the two observers.

6.4 Results:

Real-time observation of forty consecutive IR procedures was performed in two separate occasions. Ten cases were observed by the Expert-Novice group and the other ten observed by the Novice-Novice group in the first 20-case batch in December 2015-January 2016 while the other 20 IR procedures were observed in late November 2022 between the expert observer (FR) and the super-expert observers. These procedures are shown in (Table 6.1below).

The total observation time was 38 hours and 13 minutes (Average of 57.3 minutes per procedure). The observers observed 22 hours and 14 minutes during the first 20 IR procedures whilst 15 hours 59 minutes of work were observed in the second batch of 20 IR procedures (Table 6.2).

Table 6.1 The observed IR procedures (Total number = 40 procedures)	
Procedure	Number
Lower limb angiography with or without angioplasty	16
TPA check	2
U/S Guided Chest drainage	1
Thrombolysis	1
UAE	1
Lumbar Puncture	1
Trans-Jugular Liver biopsy	1
RIG (Radiologically Inserted Gastrostomy)	1
IVC Filter Removal	1
IVC Filter Insertion	1
NJ tub insertion	2
Hepatic artery Embolisation	2
Nephrostomy	6
Port-a-Cath insertion	2
Port-a-Cath removal	2

Table 6.2 Demographics of the Observed errors in all groups	
The total observation time (40 IR procedures)	38 hours and 13 minutes
First batch of 20 IR procedures	22 hours and 14 minutes (
Second batch of 20 IR procedures	15 hours and 59 minutes (second batch of twenty cases)
Average time per IR procedure	57.3 minutes
Mean total error/procedure (Combined Expert_ Novice and Novice1_ Novice2 groups)	19.7

During the first ten cases in the Expert _ Novice group, the observer 1(Expert) detected 249 medical errors and the observer 2 (Novice) detected 222 medical errors. The other group_ Novice-Novice observed 10 IR procedures, in which the observer 1 (Novice1) detected 162 healthcare errors while the observer 2 (Novice 2) detected 161 healthcare errors. Further 20 IR procedures were observed by the conductor of this research (FR) and two other IR doctors (BP and AR) where 124 and 118 healthcare errors were recorded respectively.

Safety awareness errors were the most dominant errors across all groups. In the Expert_ Observer group, from a total of 249 healthcare error reported by the Expert observer, 46 (18%) of them were safety awareness errors, while from a total 222 healthcare errors reported by the Novice, 43 (19%) were safety awareness errors (Figure 6.2, Figure 6.3). In the Super-Expert_ Expert group, the Super-Expert observers reported 28 (24%) safety awareness from a total of 118 errors reported by them whereas the expert observer reported 22 (18%) safety awareness errors from a total of 124 errors (Figure 6.5 and Figure 6.6).

Communication errors formed the second most common occurring errors in both Expert_Novice and Novice1_Novice 2 groups. The expert observer reported 46 (18 %) communication errors versus 47 (21%) communication errors reported by the Novice group. Likewise, the communication errors formed 29 % and 35% of the total reported errors by the Novice 1 and the Novice 2 observers respectively. However, the communication errors were the third most frequent occurring errors recorded by the super_expert observers whereas they were the fourth errors in terms of frequency recorded by the expert observer.

The other errors reported by the expert observer in the Expert_Novice group from higher to lower frequency were as follows: Absence (41, 16 %), Distraction (39, 15%), Patient- error (20, 8%), Equipment-error (19, 7 %), Technical (16, 6%), Planning (10, 4 %), Management (8 , 4 %), Fatigue (2, 1%), Procedure-error (1, 0.4%) and others (1, 0.4%) . On the other hand, the other errors are recorded by the Novice from higher to lower frequency were : Distraction (35, 16 %), Absence (30, 12 %), Technical (21, 9%), Planning (14, 6 %), Equipment-error (12, 6%), Patient-error (10 , 4.1%), Management (7, 3 %), Procedure-error (3, 1 %) and others (1, 0.4%) (

Technical errors constituted the second most common occurring errors in the second batch by the Super-expert and Expert group unlike the Expert_Novice and the Novice1_Novice 2 groups, in which the technical errors came the seventh in frequency only before planning and management (Figure 6.2).

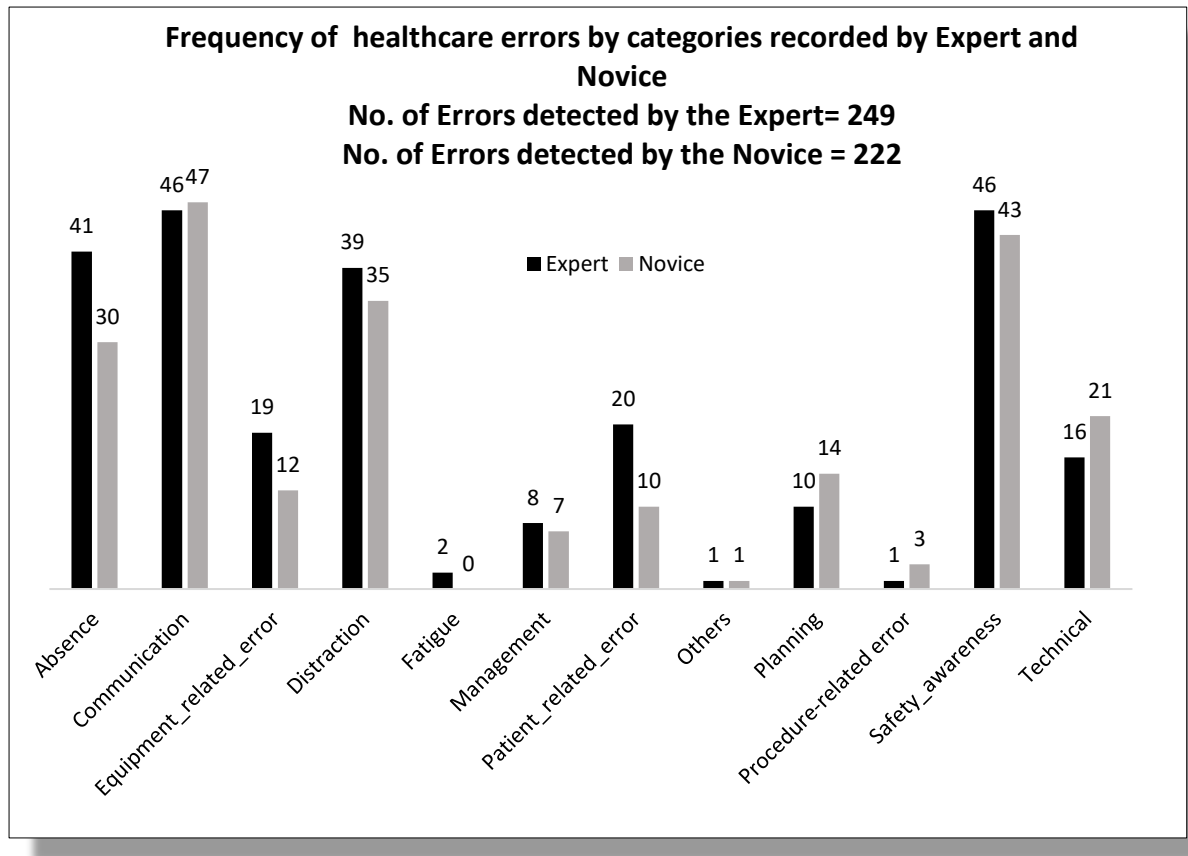


Figure 6.2 A bar chart showing the frequency of errors within each primary category of the FERERI tool. Errors identified by Expert and by Novice observers.

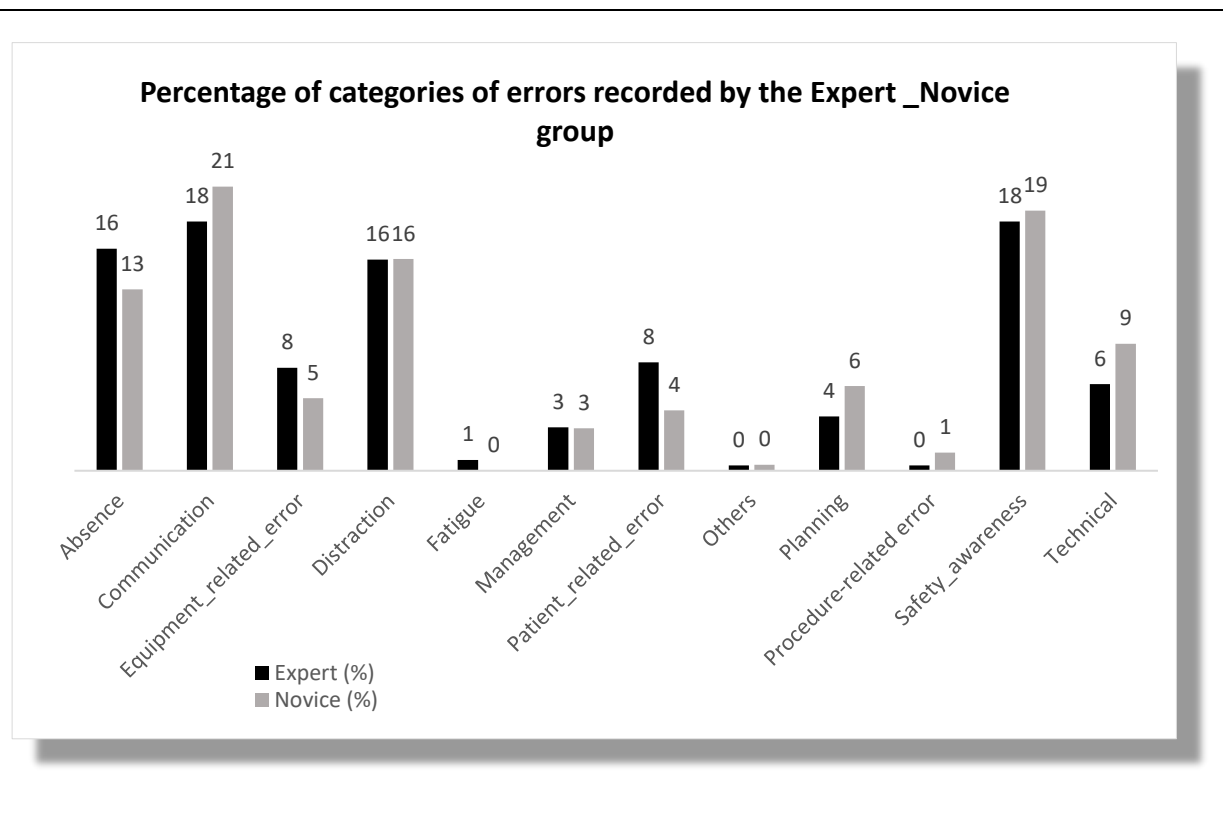


Figure 6.3 Percentage of categories of errors recorded by the Expert and the Novice group in the first batch December 2015-January 2016

The following errors in order from high to low are detected by the Novice1 (in the Novice1-Novice2 group): Distraction (27, 17 %), Absence (16, 10 %), Equipment-error (15, 9%), Planning (15, 9%), Patient- related error (11, 6.8 %), Technical (10, 6%), Management (3, 2%) and Procedure-error (2, 1%).

On the other hand, the following other errors are recorded by the Novice2 from higher to lower frequency: Distraction (24 , 15 %), Absence (18, 11 %), Equipment- related error (11, 7 %), Patient-related error (11, 7%), Planning (9, 5.6%), Management (8, 5%), Technical (3, 2 %) and Procedure-error (2, 1 %) (Figure 6.4).

In the second batch of patient observation between the conductor of this study (Expert) with two more experienced IR doctors (Super_ Expert), the second most frequent occurring error is technical at a frequency of 28 (23 %) and 22 (19 %) respectively.

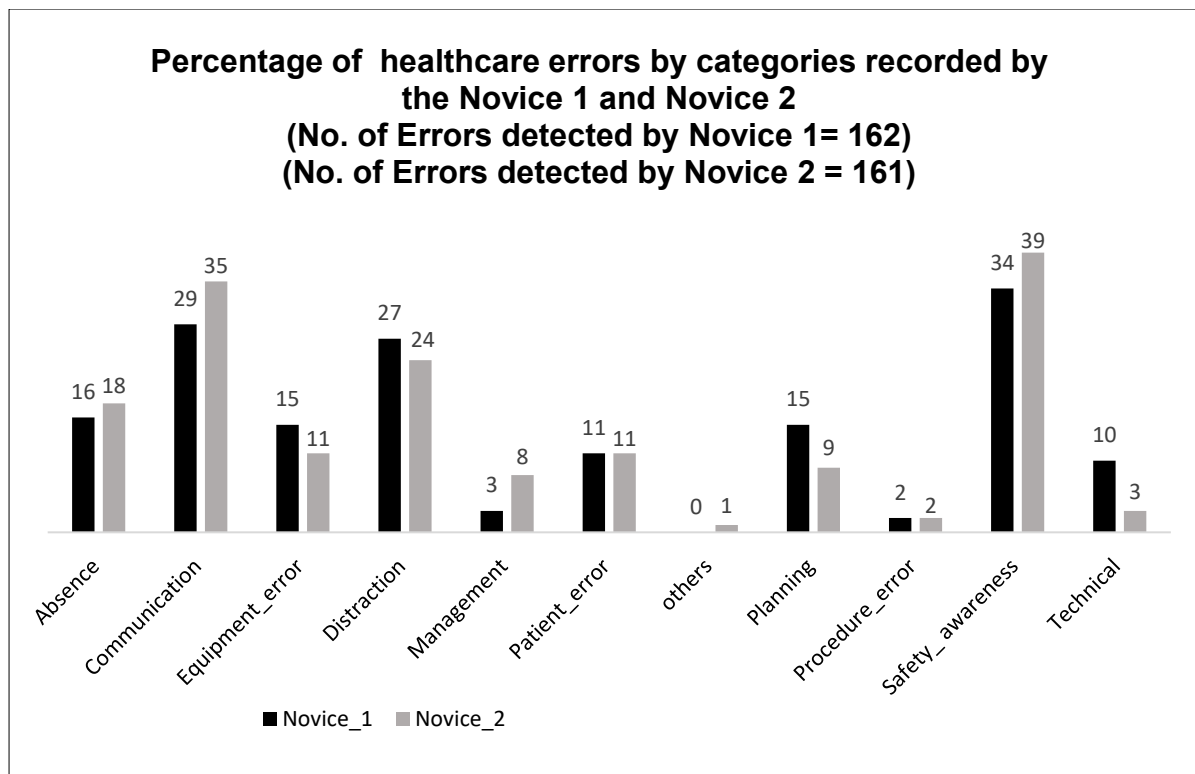


Figure 6.4 A bar chart showing the frequency of errors within each primary category of the FERERI tool. Errors identified by Novice_one and by Novice_two observers.

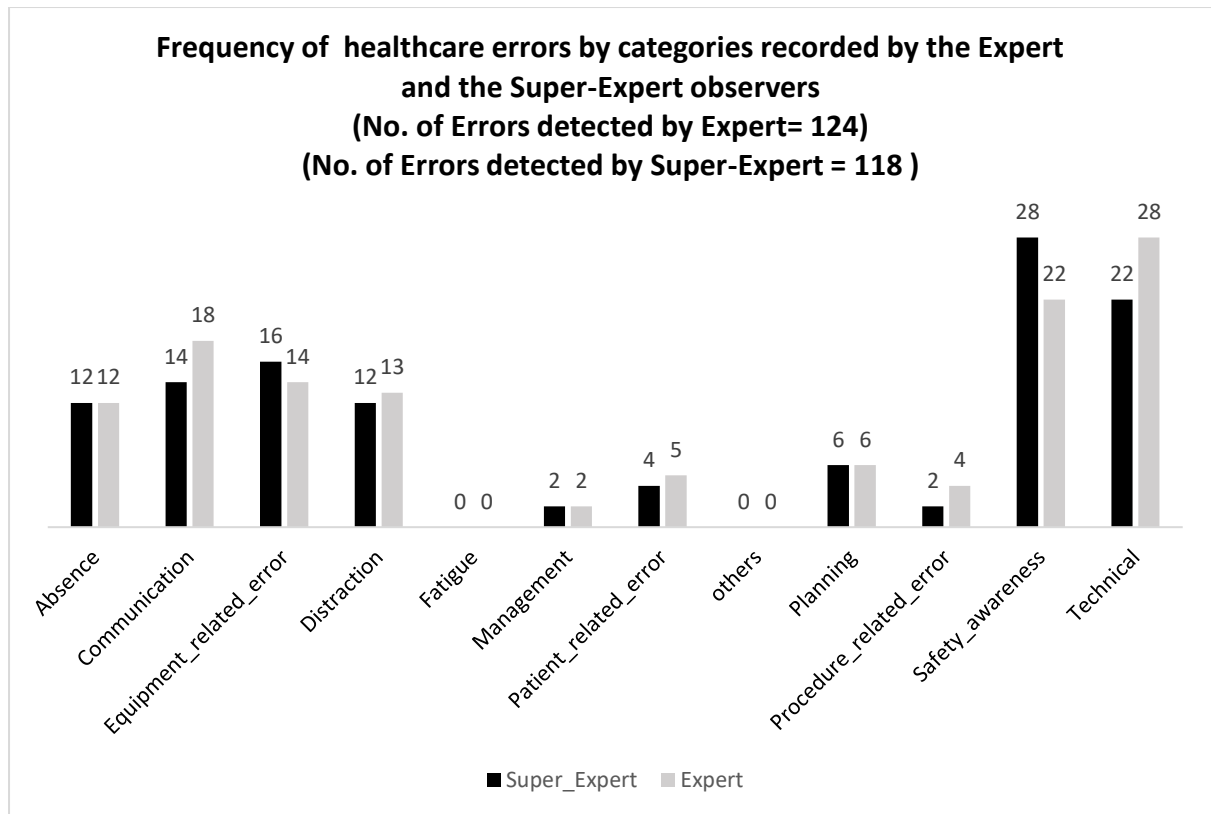


Figure 6.5 Frequency of healthcare errors by categories recorded by the Expert and the Super-Expert observers (No. of Errors detected by Expert= 124) (No. of Errors detected by Super-Expert = 116)

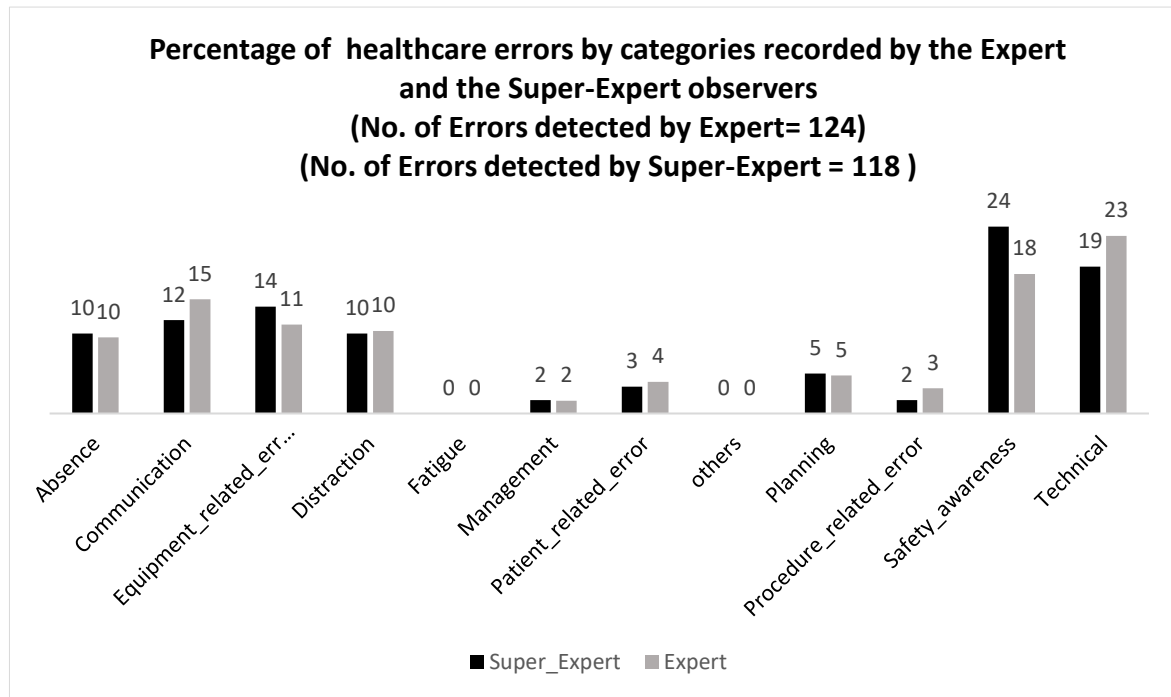


Figure 6.6 Percentage of healthcare errors by categories recorded by the Expert and the Super-Expert observers (No. of Errors detected by Expert= 124) (No. of Errors detected by Super-Expert = 114)

FERERI Validation:

For assessing internal consistency of the items and reproducibility of FERERI tool, we utilized Cronbach's alpha reliability test which demonstrated a strong scale reliability with a coefficient value of 0.878 for Expert_ Novice agreement, 0.996 for Novice1_ Novice2, and 0.912 for the Expert_ Super Expert groups. Furthermore, Intra-class Correlation Coefficient was used to compare categories of errors between the observers in different groups. A strong correlation was found with a coefficient figure of 0.878 (P-value <0.001) for the Expert_ Novice group, 0.990 (P-value < 0.001) for the Novice1_ Novice 2 group, and 0.839 (P-value <0.001) for the Expert_ Super Expert group respectively.

The inter-rater agreement to compare the reported categories of healthcare errors across different groups was measured using Cohen's Kappa statistic. This measurement was recorded

down to a level of a single error event category at a specific point of time to see how well the observers arrived at their different rating. Cohen Kappa's coefficient value was substantially high with a rate of 0.6 for the Expert_ Novice group (P-value < 0.001), substantial- good with a rate of 0.68 for the Expert_ Super expert group (P-value < 0.001), and strong at a rate of 0.8 for the Novice-Novice group (P-value < 0.001).

6.5 Discussion:

It has been highlighted in the literature that patient safety is influenced by healthcare errors. Exploring and categorising these errors could enhance safety of patients. There has been development of different studies with different methodologies to categorise and measure healthcare errors in various healthcare sectors including surgery and IR. However, these methods are resource and labour-intensive and not easy to be conducted on large-scale based studies.

Recently, the researchers at Imperial College London have developed an error capture tool called ICECAP_ Imperial College Error Capture tool to study the intraoperative phase of vascular and endovascular surgeries (Mason et al., 2013). This was a paper-based checklist-like record with several categories of errors were put on it which could be ticked according to the type of an error an observer might consider.

However, being a paper record, the tool would not be practical considering the present direction towards digitalising the healthcare system in the UK and the other developed healthcare systems around the world alike. Furthermore, this tool was developed to cover the intraoperative period of the vascular surgical operations. The researchers in this pilot have recognised the need to develop a tool that is more comprehensive and can be used to cover the whole patient's journey from admission to discharge.

In the previous chapter of this thesis, the FERERI healthcare error-capture tool has been developed which is proposed to be an electronic tool that cover the whole IR pathway.

In this chapter, the FERERI tool has been assessed to study its reliability and validity. The FERERI tool is validated by measuring inter-observer agreement in three groups of observers namely: the Expert_ Novice, the Novice1-Novice 2, and the Expert_ Super-Expert groups. Different statistical testes are used in this validation namely Cronbach's alpha reliability test, intra-class Correlation Coefficient and Kohen kappa test. The researchers of the study have shown that the FERERI tool is reliable and valid.

There is some variation in the degree of agreement among different groups of this study. The Cohen Kappa agreement test was substantial in the Expert-Novice group (between the main coordinator of this study and two novice users_ medical students) with the Cohen Kappa Coefficient was estimated to 0.6. The degree of agreement is higher between the main

conductor of this study (FR) and the two IR doctors (BP and AR) who have enough IR experience to be considered super- experts among the observers of the current study. There was an upper-level substantial degree of agreement with a Cohen Kappa coefficient value of 0.68. However, a significant increase in the degree of agreement is shown when the observations of the Novice 1 and Novice 2 observers were studied as it shows a strong agreement between them with the value of Cohen Kappa coefficient factor was 0.8. There might be reasons which explain this variation.

One of these reasons is the difference in the knowledge and the experience between the novice users and the expert user around patient safety and error categorisation. This could explain why the novice observers recorded a smaller total number of errors than the expert (218 versus 248). Some of the behaviours or observations might have not been perceived by the novices as true errors. It has been confirmed in the literature that there is a substantial discrepancy between observers who have different level of experience. In a previous study, a group of researchers studied the teamwork behaviour in twelve urosurgical operations by using OTAS (Observational Teamwork Assessment for Surgery). They assessed the preoperative, operative, and postoperative period and found that there was a significant discrepancy between the observations of the expert and the novice observers compared to the findings of the Expert-Expert group (Sevdalis et al., 2009). These researchers proposed that the intricacy of human behaviour makes it difficult for the observers with different background and experience to arrive at similar conclusion or contemplation regarding these behaviours. This was also proposed by other studies (Mason et al., 2013).

Although there is a degree of similarity in the Expert's and the Novice's rating of the most commonly occurring healthcare errors, there is some difference about some other errors namely Equipment-related errors and Patient-related errors with a smaller number of errors were recorded by the novice- observer in both categories.

Training in the induction period might have an impact on why there is some variation in the strength of agreement between the Expert and the Novice observer. The Novice observers received two weeks training on how to use FERERI tool. To my knowledge, there is no correct answer to how much period of training is required for these tools to be used reliably and accurately by Novice observers. However, logically, the more training the more accurate should their observation become.

Mishra, Catchpole, & McCulloch (2009) developed and evaluated a method for measuring operating-theatre teamwork quality_ The Oxford Non-Technical Skills (NOTECHS) scale (Mishra et al., 2009). This scale was developed from an aviation instrument for assessment of non-technical skills. Two of the three observers of this study received 9.5 hours of lectures and interactive training by two experienced pilots followed by 12 sessions of intraoperative coaching over a 3 month-period. They achieved an excellent interobserver reliability in 24 operations independently assessed by two observers. Not only was there a thorough induction period but also the observers were received a prior training in anatomical, technical and non-technical skills needed to study the behaviour of the operative team. One of the observers was a surgical trainee and the other observer was a human-factors practitioner. Furthermore, they only observed one type of operation which is pretty much standard in terms of technical and non-technical skill requirement (Mishra et al., 2009).

On the other hand, the Novice-Novice observers in our study achieved a very good interrater agreement even though they conducted a relatively short period of training on how to use the FERERI tool. This gives a bonus to the FERERI tool in terms of easiness to use. This would possibly provide the opportunity in future researches to assess the feasibility of the FERERI to be used as a self-reporting tool since it requires a reasonably short-period of time to train team members including the nurses on how to use the tool.

Another explanation is geographical position of the two observers, where each of them placed in a different corner within the IR operative room. Although, care was taken prior to each case to ensure that both observers can observe all the operating team and other observable objects. Mason et al, (2013) reported that there is inconsistency in the rate of detection of minor errors between the observers who have different clinical experience as both having different views on what constituted a minor error. As minor errors are those which are more frequent and needs a thorough and swift pickup by observers, position of the observers might influence the rate of spotting these minor errors.

The total observation time was 38 hours and 13 minutes (Average of 57.3 minutes per procedure). This agrees with the previous studies performed in IR specialty. Morbi et al, (2012) reported that the mean duration of the IR procedures is 62 minutes prior to intervention.

In this study, there was an average of twenty errors per operation and eighteen errors per an hour operation time were recorded. This is in accordance with the literature. Morbi et al, (2012)

recorded an approximately twenty-two failures per procedure in the pre-interventional phase. Al- Bayati et al, (2011) studied sixty-six open -vascular and endovascular procedures and identified a total of 1145 failures which results in an approximately seventeen failure per procedure. If we count the endovascular procedure only_ which is comparable to IR procedures, the rate of failure per hour procedure would be 18 failures per hour (ALBAYETI et al., 2011). This is the identical to our results.

The conductor of this research (FR) recorded a total of 249 healthcare errors in the first 20 IR procedures with the novice observers while the same observer (FR) recorded a total of 124 errors in the second batch of IR procedures (20 cases) with the super-expert observers. There are several reasons for this:

Firstly, the first 20-case batch took more time than the second 20-case batch (22 hours and 13 minutes versus 15 hours and 59 minutes) which is equivalent to six more IR procedures. This would probably increase the chance of exploring more errors. This would probably explain partly this difference as the average length of the IR procedures was 57.3 minutes and the average number of healthcare errors was 19.7 per IR procedure. This agrees with the previous studies. In a previous study conducted by the IR team in our department, the researchers found that there is a strong correlation between the number of healthcare errors and the length of the procedures (Morbi et al., 2012).

Secondly, there is a time lapse of 7 years between the first and the second batches of observed procedures which may contribute to this difference. Among other possible factors, there has been a better adherence to the implementation of the WHO checklist than before (Please refer to chapter eight of this thesis). This probably have contributed to the overall lower number of healthcare errors as the errors related to the WHO checklist were also reported.

Safety awareness errors were the most dominant errors in both Expert_ Novice and Novice 1_Novice 2 groups followed by communication errors, absence, and distraction. This is probably because of the demanding nature of IR procedures in terms of techniques and ever evolving equipment used which make the learning curve of these procedures higher for the IR team and hence the resultant communication hierarchy produced by them. For instance, the requirement of a particular procedure in terms of different wires and catheters is not standard among different IR consultants or institutions, hence various approaches, or options to treat the

same pathology, unlike open surgical procedures which requires a predefined set of steps known to most of the surgical team.

In a previous research by our group at Imperial College London, it is found that there is a prominent risky period during combined open and endovascular procedures, especially in the endovascular period, which involves the IR team. Communication and equipment errors contributed to the biggest share of the total errors, and they were rooted from planning errors. This is because IR has been well known to be reliant on the ever-changing technology, which is resulted in equipment unfamiliarity and even depletion due to failure to anticipate the procedure's need. This is a conundrum which needs rectification, probably by more effective team training and communication. Previous studies highlighted the need for effective information transmission among surgical teams and effective team assembly (Lingard et al., 2004b).

The pattern of errors identified in this study were not only like the errors shown in IR or open-vascular/ endo-vascular procedures (Morbi et al, 2012) (Al- Bayati et al) but also to other disciplines such as cardiac surgery and orthopaedics. Catchpole et al, (2007), found Communication and coordination the most frequent occurring errors leading to problems in the operative theatre, especially in paediatric cardiac operation. This is because of complicated inter-related tasks that requires multi-disciplinary- team involvement at the same time.

This study has a number of limitations that need to be acknowledged. Being an observational study it has some inherited weaknesses such as selection bias, information bias and interobserver reliability (Thomas et al., 2000) (Thomas and Petersen, 2003) (Carthy, 2003) (Catchpole et al., 2006b) (Barach et al., 2008) (Tripepi et al., 2010). In this chapter, selection and information biases are less noticeable as the objective of this study is validation of the FERERI tool thereby measuring the inter-observer variability and internal consistency. Instead, the selection and information biases are more important to account when the study aims at measuring the pre- and post-intervention studies, especially the selection bias where a group of cases are selected with more outcome of interest (Tripepi et al., 2010).

Limitations that could arise from inter-observer reliability would be the focus of this study. The study by J, Carthy (2003) has made an important contribution to our understanding of factors that limit the inter-rater reliability marker. J, Carthy (2003) studied Structured observational research and how it is used by experts to record errors, adverse events, near

misses, team performance and culture of organizations. In his study he evaluated pros and cons and future lessons drawn from studying human factors in Arterial Switch Operation_ a complex operation performed on newly born neonates to fix transposition of the great arteries attached to the heart. The study evaluated the inter-rater variability of two human factors specialists who observed paediatric cardiac surgical operations in 16 UK centres (Carthy, 2003) .

In their study they identified four main limitations related to observational studies due to inter-observer reliability issues, which can be true for all other observational studies evaluation surgical teams. These limitations are 1- Observer training and capability, since there is no structured training of observers to conduct observational studies, neither is there any written or verbal examination to objectively evaluate their capability to observe surgical teams. In their study, the expert observer observes red several cases and read a number of surgical textbooks to have an insight about the anatomy and the main steps in these cardiac surgeries. Not before the consultant surgeon responsible for the study evaluated the observational reports presented by the observer, they allowed the observer to collect data. Therefore, it was down to the judgement of the expert surgeon who satisfied that the observer can reliably collect data (Carthy, 2003).

2- Absence of objective inter-rater reliability measures 3- Total reliance on observational data collection without having other source of validation such as video recording. 4- Problems related to transference of knowledge from the more expert observer to more novice one. These drawbacks might be mitigated by having more structured training of observers in different conditions such as simulation-based circumstances or by receiving direct coaching from experts in human factors along with expert in specific areas such as IR in our example. Having said that, it can be argued that these limitations are true when comparing two observers of comparable level of experience (Hull et al., 2011).

However, it is still unclear what could or how much would skill variation affect the data collection process. This variation is at least more pronounced when it comes to minor errors or more technical errors where it is hard to pick unless the observers are domain-expert ones (Mason, 2013, Design and validation of an error capture tool for quality evaluation in the vascular and endovascular surgical theatre). This shortcoming continues to face observational studies as more senior staff are usually key-workers in their subspecialty and have tremendous

clinical duties that prevent them to be free-up for error-capturing observation. It would be of paramount importance to have inter-observer rating among observers who are already experienced IR consultants which thought to add more strength to error capturing procedure. Videotaping methodology might be an alternative as those experts can observe the operations in their free time where more observations can be picked up while rewinding the videos.

Another limitation is what is called the Hawthorn effect which has a well-known perceivable influence on any observational study. This phenomenon refers to modification of the observed persons of their behaviour not because of their real characters but because they are being watched by others (LANDSBERGER 1958b). However, the IR staff in this study have previously participated in many studies where they were observed. Also, the main study coordinator (FR) had been conducting several other observational studies within the same department. Moreover, the 2- week induction period was aimed also to reduce this effect. It has become a norm in our institution to have an observer within the IR suite as it is a tertiary hospital involving in numerous research on regular base.

It is not certain whether the finding of this study could be generalised to other departments or even all phases of the IR pathway of care as we only studied the intraoperative period. However, it is argued that the intraoperative stage would comprise the most challenging phase of the whole IR pathway. This phase entails a myriad fast-paced interaction among the IR team with themselves and their surroundings. The surrounding objects include the patient, the tools, and the machines beside the pressures from outside the operative room such as workload and departmental pressures. It has been highlighted in the previous studies that the operative period pose a safety hazard for adverse effect and medical errors (Lingard et al., 2004b) (Catchpole et al., 2006b) (Barach et al., 2008).

One of the applications of this study is the possibility of introducing this tool as a valid tool for studying the whole IR pathway of care in the future to discover the landscape of healthcare errors across the wholistic pathway. It is hoped that this tool would be included as a routine document as a self-reporting file by the operating staff to be used as a complimentary document to enhance team performance and improve patient safety as it is a Microsoft Excel file which deemed to be easily integrated into the IR department file system.

From the results of the current study, it is suggesting the FERERI tool to be validated by combining the current method of observation to self-reporting method by the operating team.

This will allow validation of the tool to be used as a self-reporting computerised error-reporting tool. Further studies are needed to evaluate this.

6.6 Conclusion:

This study concludes that the FERERI tool is a valid tool which can be used to study the healthcare error that occur throughout the IR pathway of care. However, it is not clear based on this study whether this tool is usable to cover all the phases of the IR. Further studies need to evaluate this point. This will be discussed in the following chapter of this thesis.

Chapter Seven: Landscape of Medical Errors across the entire IR pathway of care.

7.1 Introduction

Patient safety has recently gained significant attention across the globe and has been a primary issue for the institutes which deal with quality improvement in the healthcare in many countries. According to the first report on patient safety issued in 2000 by the Committee on Quality of Health Care in America, of the Institute of Medicine in the USA, safety can be defined as "freedom from accidental injury. (Institute of Medicine Committee on Quality of Health Care, 2000).

7.2 The need for a study to systematically assess the healthcare errors across the whole IR pathway of care.

It has been highlighted in the systematic review chapter of this thesis that there is a scarcity of research in IR specialism evaluating healthcare errors. Currently, almost all of these studies focused solely on the intraoperative period (ALBAYETI et al., 2011, Morbi et al., 2012, Koetser et al., 2013, Lutjeboer et al., 2015). It is vital to understand the number of errors in the IR pathway, including the preoperative, operative, and post-operative period. Previous work in vascular and IR speciality specifically highlighted the importance of evaluating the whole pathway of care (Morbi et al., 2012, Mason et al., 2013).

7.3 The aim of the chapter

At the time the research was conducted. There was no study which evaluated healthcare errors throughout the whole IR pathway of care. Therefore, it is essential to study this area in detail to understand the rate and types of errors that occur not only in the operative period but also in the preoperative admission stage and the post-operative care. This would allow an in depth understanding of the picture of the landscape of healthcare errors in the IR pathway of care. In addition, and as highlighted in the previous chapter (see chapter 6), there is a need to use a valid and reliable tool to record healthcare errors across the IR pathway. Therefore, this study aimed to document the landscape of healthcare errors throughout the IR pathway of care using the previously validated FERERI tool.

7.4 Hypothesis

- Healthcare errors are frequent across the entire IR pathway.

7.5 Methods

This prospective longitudinal observational study was conducted in a tertiary hospital in London in two periods between 03/11/2015 to 21/06/2016 and 26/07/2022 to 24/11/2022.

Ethical approval

Application for Ethical approval is made online to the medical research council (MRC) and the local ethical committee at Charing Cross Hospital/ Imperial College London. The study was exempted from Ethical approval because it was considered a quality improvement project in the IR. No recognisable data neither of the observed staffs nor the patients were collected.

Setting

The study was conducted at St Mary Hospital, which is part of the Imperial College Healthcare NHS Trust in London, UK. This hospital is a tertiary vascular surgery referral unit at a national level where cases are referred from primary or secondary NHS settings or other hospitals. The IR team were composed of experienced IR consultants, radiographers and nurses who perform IR procedures of various complexity on a daily base and participate in complex endovascular procedures that require involvement of a multidisciplinary team of IR, vascular surgery, and anaesthetic team. These teams have been frequently engaged in research, many of which required the presence of one or more than one observer during the procedures. Also, these teams have been involved in teaching medical students and junior staff, including nurses, radiographers, and IR registrars and fellows.

Definition of healthcare errors in this study.

The healthcare errors throughout this thesis are defined as "acts of omission or commission in planning or execution that contribute or could contribute to unintended results" (Grober and Bohnen, 2005).

Inclusion criteria

- 1- Procedures: The following procedures were studied:
 - All the image-guided intervention procedures, whether vascular or non-vascular, were included in this study.
 - All elective, urgent, or intensive unit (ITU) procedures were included.
- 2- Patients: The following patients were studied
 - Adult patients aged 18-year-old, or more were included in the study.

Exclusion criteria:

- 1- Procedures: The following procedures were excluded:
 - Combined vascular procedures are requiring multiple teams such as vascular surgery such as EVAR (endovascular aortic aneurysmal repair).
- 2- Patients: The following patients were excluded
 - Paediatrics patients.

7.6 Outcome measure

- Frequency of healthcare errors throughout the IR pathway of care.
- Categories of healthcare errors.
- Breakdown of healthcare errors according to the degree of procedure pause or severity score.
- The phase of the IR, during which the errors occurred.
- Preventability of these errors.
- Relationship of healthcare errors across the entire IR pathway according to different procedure or patient demographic characteristics.
- Team composition and its relationship to the total number of healthcare errors.
- The effect of various independent factors on the total number of healthcare errors.

Data collection methods and privacy

Data was collected using the FERERI tool designed by the author of this thesis in chapter four of this thesis (refer to chapter four). The data then transferred into a master Microsoft Excel

spreadsheet. Anonymised data was collected with no identifiable information neither on patients nor on staff was recorded. Furthermore, data was encrypted to prevent unauthorised access.

Sample size

There is scarcity of data in the literature which estimates the frequency of the healthcare errors in the IR specialty (see chapter two of this thesis) which makes performing power analysis difficult if not impossible. There is no data about the mean of total number of healthcare errors in the IR specialty with standard deviation, both of which are needed to calculate the sample size.

However, the mean of the total healthcare errors per hour of endovascular procedures in two previous studies by Al-Bayati et al. (2011) and Morbi et al. (2012) was used (ALBAYETI et al., 2011) and (Morbi et al., 2012) was used which was 12.25. This mean was combined with a hypothetical standard deviation of four and a null hypothesis value of 11.25 to calculate the sample size. a Power-analysis was performed using MedCalc Version 20.218; Medcalc software to calculate the sample size. The calculation was based on a type 1 error of 0.05 (Alpha value or P value) and a power of 80 % (Beta value). This resulted in a calculated minimum sample size of 128 patients.

Statistical tests used.

Statistical Package for Social Sciences version 24.0 (SPSS, Chicago, IL, USA) was used to analyse the data. The following tests were used:

- Descriptive statistics to show the frequency or proportion of different characteristics of the studied population by using tables, charts, and box plots to display numbers, percentages, mean, median, standard deviation and interquartile ranges (IQR).
- Spearman Correlation.
- Independent Samples Kruskal-Wallis Test to compare the mean of total healthcare errors across different categories of IR procedures such as elective, urgent and ITU.

- Linear and multiple regression to test the difference among multiple categorical variables and the total number of healthcare errors.
- Alpha value (P value) of 0.05 or less were considered significant throughout the thesis.

Definition of different categories of healthcare errors used in this study:

The following main categories of healthcare errors were used which were included in the FERERI error-capture tool (see chapter 5 and 6 of this thesis). The categories are Absence, communication, equipment- related error, distraction, fatigue, management patient_ related error, procedure_ related error, planning, technical, safety awareness. All of the above main categories are subdivided into different subcategories. Table 7.1 shows different error categories with their sub-categories and some examples.

Table 7.1 Shows the main categories and sub-categories of healthcare errors with some brief descriptions and examples			
Main error categories	Definition	Subcategories	Examples
Absence	Absent of an IR team member when required	Circulating nurse IR Consultant Doctor IR Fellow, Radiographer	A circulating nurse was absent inside the operative room when required because he or she was outside to bring an IR tool.
Communication	Lack of or failure of proper sharing / transferring or receiving information among the involved parties	Lack Misleading Misheard/non-heard. Team conflict	A procedure is cancelled because of lack of communication between the referring ward and the IR department. Misleading: A non-clear or incorrect piece of information is shared by an IR team member which leads to a pause or wrong action. For example: the IR doctor requested a wrong piece of equipment resulted in a pause in the procedure flow or resulted in opening a wrong tool. Non-heard/ misheard: An IR consultant had to repeat a request twice or got a wrong tool from the circulating nurse as they did not hear it or misunderstood it. Team conflict: contrasted opinion among the IR team members.
Equipment_ related error	Any error related to the used equipment	Unavailable Configuration error Default equipment	An equipment is requested by the IR team but is not available. Or the IR team member configured a tool incorrectly. For example, wrong calibration of the automatic power injector. Or an equipment was not working as it should such as the remote control of the C arm is not working which needs replacement or replacement of its battery.

Distraction	Any distraction to the flow of the IR procedure	Departmental By Team member/ non-relevant talk By External staff Due to Phone or Bleep	Departmental: there is a departmental pressure on the IR team beyond the procedure itself to finish it in time as there are other procedures booked on the same day. Distraction can be resulted from some IR team members themselves having irrelevant talks not engaged or on their phones or by external staff trying to discuss other matters or other patients with the IR team while they are in the middle of the IR procedure. Or the IR team might be distracted by phone or bleep
Management	Errors related to improper management	Workspace Resource Personnel	Examples of workspace management failures are: Suboptimum lightening of the angio-room, improper position of the operative table which in a way that decrease spaces for free movement of the IR team. Examples of errors related to management of personnel is inadequate allocation of team members for each day or list of IR procedures.
Patient_ related error	Any failure or error that is secondary to factors related to the patient	Anatomy Physiology Comorbidity Compliance	Tortuous vessels are example of anatomical variance which leads to difficult access or catheterisation. Low blood pressure can result in procedure difficulty. Comorbidity such as diabetes, renal failure, etc can cause procedural difficulty or complication. Non-compliance due to patient's movement can cause errors or safety hazard such as desterilising tools or even body injury as there are always guidewires, catheters, or tools attached to the patients which need not to move unintentionally.

Procedure_related error		New Procedure Difficult	
Planning	Errors which are secondary to improper planning	Other Wards IR ward IR operative team	An example of an improper planning is A patient sent for ultrasound-guided drain of Psoas muscle collection under general anaesthesia with ascites drainage. However, the IR consultant was not sure about what to drain as there was no loculated fluid to be drained during the ultrasound check on the operative table, while the patient on GA. The IR doctor had to call the surgeon to clarify what is it they need them to drain. Beside a pause for about 5 minutes, there was a safety risk to the patient from general anaesthesia.
Technical	Errors related to technical abilities of the treating IR team members	Psychomotor Non-Familiar New Technique Inexperienced	Dropping of an IR tool leading to desterilising it is an example of a psychomotor error. The rest of the technical errors are more common in trainee doctors or nurses and are usually rare in IR consultant doctors.
Safety_awareness		Violation (mask, etc.) Vigilance or awareness error Checks not done.	Violation of infection control guidelines such no wearing of masks considered errors. Omitting or forgetting to do some check such as WHO checklist is regarded as safety awareness errors. Sometimes failure to proactively prevent or remove some safety hazards are examples of safety awareness error such as failure of cleaning a blood pocket or pool on the ground from the puncture site as this can cause safety hazards.

Definition of degree of severity of healthcare errors used in this study.

Using the data from the literature (Catchpole, 2010, ALBAYETI et al., 2011, Morbi et al., 2012, Mason et al., 2013) with the previous studies in the previous chapters of this study (see chapter 3, 4 and 6), a classification healthcare errors according to their degree of severity is performed (see Table 7.2).

Table 7.2 Definition of minor, moderate, major healthcare errors and errors-caused cancellation used in this study with examples

Terms	Definition
Minor Healthcare errors	Any errors that cause no pause to the IR pathway or procedure or a pause for up to 5 minutes or cause no or minor patient harm or no need to resolve or easy to resolve. Examples: In a lumbar puncture procedure: Communication error occurred under the subcategory “Misleading” where the IR Consultant asked the radiographer for AP (anterolateral) projection when she meant lateral. This error did cause only several seconds pause of the procedure without patient harm. The error is easily fixed. In a procedure called Hickman line insertion, while the IR consultant tried to locate the vessel for the puncture site “The ultrasound machine switched off suddenly as the wire unplugged because the machine was too far from the wall socket. The CN changed the location of the plug”. This error causes a pause of less than a minute and did not cause any patient damage. In a procedure called Iliac Angiography with angioplasty there was an Equipment_ related error under the subcategory “Unavailable” in which the circulating nurse had to leave room to obtain a particular stent not available in the IR Angio-room. This error caused a pause for less than a minute with no potential to cause patient harm. The resolution was easy.
Moderate Healthcare errors	Any errors that cause pause to the IR pathway or procedure or a pause between 5- 30 minutes or cause moderate patient harm or moderately difficult to resolve. Examples: In a lower limb angioplasty procedure, there was a communication error under the subcategory of “non-heard misheard”, The IR consultant requested a 180cm long Terumo wire, but the CN opened a 150cm long wire and IR consultant had to replace it again after deployment into the target artery. This error is regarded as moderate as it caused a wasted time of more than 5minutes but less than 30 minutes. Also, it had still a potential to harm the patient as the wrong stent was deployed into the targeted artery when realised it is short. Although the error could have been easily fixed had the circulating nurse communicated well with the IR consultant. In a procedure which was “Left antegrade lower limb angioplasty” there was a planning error that caused a delay of 25 minutes. The context of the error was as follow: “While the team finished the procedure and transferred the patient back on to his bed the IR consultant called the IR fellow to do a diagnostic angiography run for the whole left leg. Therefore, the IR team had to transfer the patient back on the angio-room table and do another angiography run. In another IR procedure_ IVC filter insertion, the IR Consultant was absent as the consultant was outside seeing another patient in the ultrasound room. The patient was on the operative table and the IR team had to wait for the IR consultant for 20 minutes to

	start the procedure. Although there was no patient harm in this case, but the pause was more than the time window for a minor error.
Major healthcare errors	Any errors that cause a pause to the IR pathway or procedure for more than 30 minutes or cause severe patient harm, such as bleeding for example, or very difficult to resolve. Examples: The patient's position was not straight, and the IR team could not figure out the reason, so while the needle was in the artery of the puncture site, they manoeuvred the patient to get a straight position which would pose a safety hazard as this might cause bleeding of the punctured artery". In a liver biopsy procedure, the box of dry ice samples contained two tube samples for two different patients and the referring ward staff who handed over this box to the IR nurses did not mention that there are two separate tube samples for two different patients. The IR nurse did a check and just found out the name on the tube does not match with the name of the patient before handing over the tube sample to the IR operative team to transfer the liver biopsy sample. This was rectified and the correct sample tube handed over ultimately". In an IR procedure_ femoral line insertion, the referring ward nurse did not check whether the patient has allergy to any medication. However, during clerking of the patient by the IR nurse in the preoperative stage, the stated he is allergic to some antibiotic without knowing the name of it. The main category of the error is safety awareness" and the subcategory is "checks not done".
Errors led to cancellation of the scheduled IR procedure	Any error, because of which the IR procedure was cancelled. Examples: A prostate artery Embolisation procedure was cancelled because there were two other long complex cases namely Endovascular aortic aneurysm repair (EVAR) and Thoracic endovascular aortic aneurysm repair (TEVAR) booked on the same day and there was only one IR consultant available in the I department on that day without IR assistant doctor". This failure is considered secondary to a planning error in which no proper planning was made when IR procedures were booked by the IR department. When booking IR procedures, the complexity and the projected length of each procedure should be considered to make the list feasible as well as the IR team availability on that day. Also, this failure could be secondary to management error under the subcategory of "personnel". An Angioplasty procedure of the right lower limb was cancelled because of lack of communication between the appointment team of the referring ward and the patient. The patient did not turn up for his appointment. There should have been a better communication with the patient at different stages after booking had been made to ensure the patient is compliant or to allocate the slot to another patient in advance if that was not the case. Although this error could be labelled patient-related error as well with a subcategory "compliance".

	A procedure for” Iliac artery stenting” was cancelled because there was no bed available in the destination ward. This was regarded as both planning error and lack of Communication error.

7.7 Results

Demographics of studied patients and healthcare errors

The total number of studied IR pathways were 132. The mean age of the patients was 62 [St. Deviation = 16.252]. The median age of the studied patients was 64 years [Interquartile Range = 20]. The age of the patients ranged from 18-93 years (range = 75). Males formed 56% of the studied population versus 44% females (Figure 7.1).

The total number of healthcare errors across the whole IR pathway was 1395, 132 of which was in the pre-procedure phase, 1206 in the intra-procedure phase and fifty-six in the post-procedure phase. Of the 132 observed IR pathways, the mean of the total number of errors per IR pathway is 10.57 [Std. Deviation = 10.006] versus 10.96 [Std. Deviation = 9.707] per procedure (Table 7.3).

Pearson Correlation test was used to see the correlation between ages of the patients and the total number of healthcare errors in the entire IR pathway of care. No correlation is found between these two variables (correlation coefficient number= 0.130, P value = 0.138).

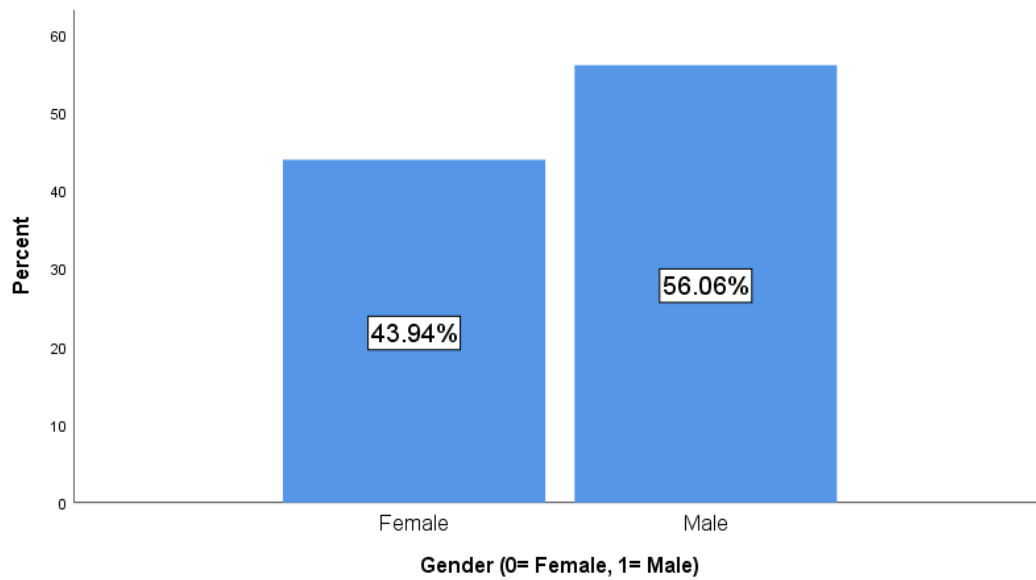


Figure 7.1 The proportion of female and male in the studied population

	N	Sum	Mean	Std. Deviation
Total number of ME (entire pathway)	132	1395	10.57	10.006
No. of ME in pre-procedure phase	132	132	1.00	1.284
No. of ME in intra-procedure phase	110	1206	10.96	9.707
No. of ME in post-procedure phase	110	56	.51	.832
Valid N (listwise)	110			

The proportion of elective, urgent and ITU patients

Elective procedures constituted the biggest proportion of the patient's population of this study followed by urgent and ITU procedures at rates of 43 percent, 32 percent, and 25 percent respectively (Figure 7.2).

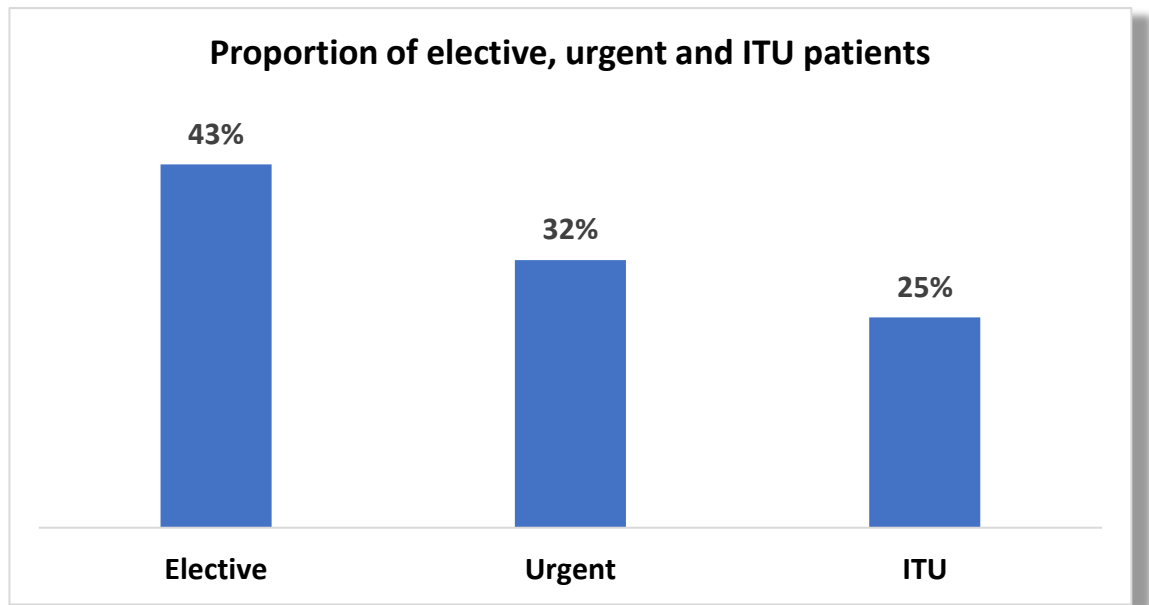
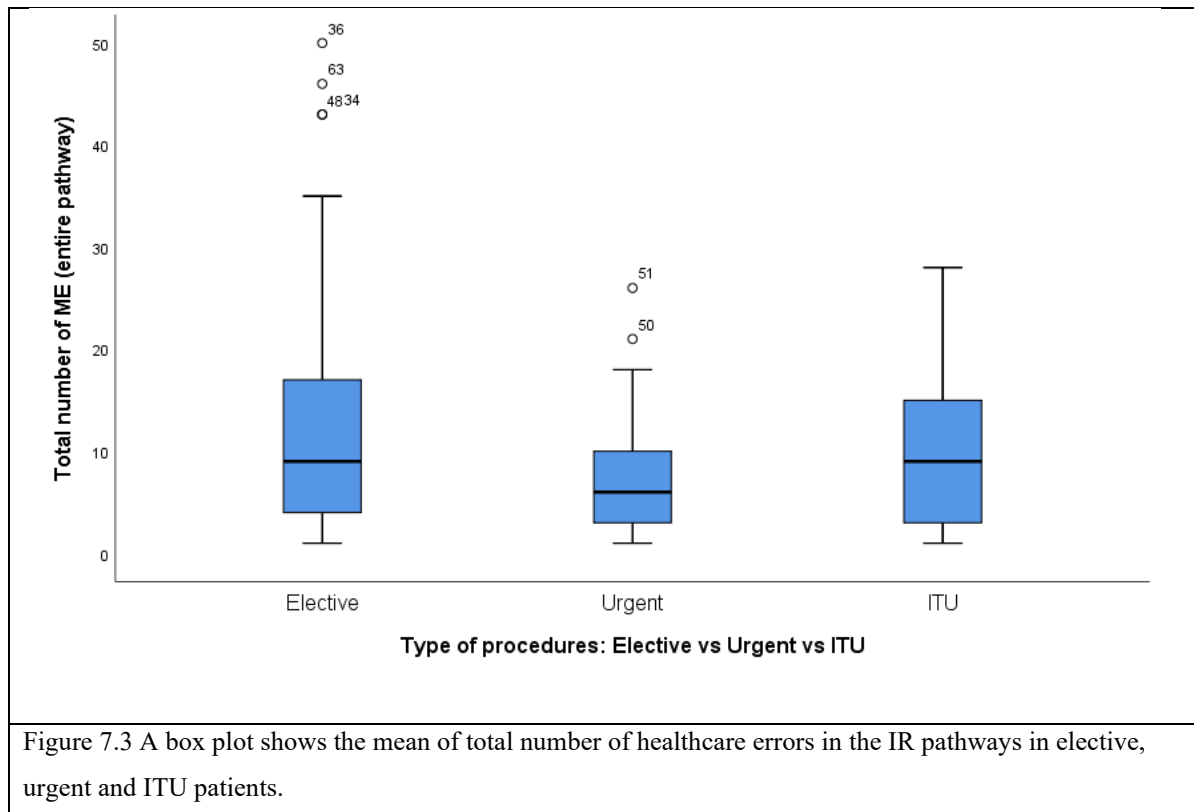


Figure 7.2 Shows proportion of the different types of procedures namely: elective, urgent and ITU (total number = 132 IR procedure).

The total number healthcare errors in elective, urgent and ITU patients and the difference in their means.

The highest average number of healthcare errors per IR pathway was found in elective IR procedures followed by ITU and urgent procedures. The mean total number of healthcare errors in elective IR procedures was 13.6 [95% Confidence Interval for Mean = 10.25 - 16.94] [Std. Deviation =12.594, Interquartile Range (IQR) =14] with a median of 9. While the mean total number of healthcare errors in ITU IR procedures was 9.76 [95% Confidence Interval for Mean= 6.92-12.60] [Std. Deviation 8.016, IQR=12] with a median of 9. On the other hand, the mean total number of healthcare errors in urgent IR procedure was 7.24[95% Confidence Interval for Mean=5.55-8.92] [Std. Deviation =5.405, IQR= 7] with a median of 6 (Figure 7.3).

Independent Samples Kruskal-Wallis Test was used to study the difference of the mean total number of healthcare errors across elective, urgent and ITU procedures. The distribution of the mean total number of healthcare errors in the IR pathway was not statistically different across these different groups ($P = 0.062$).



The association between IR procedure category (elective, urgent and ITU) with the case complexity category (simple, moderate, and complex).

A Chi-square test was conducted to assess whether there was a significant association between case IR procedure category (elective, urgent, ITU) and the level of case complexity (simple, moderate, complex). The results of the Chi-square test revealed a significant association between IR procedure category and case complexity, $\chi^2 (4) = 19.100, p = .001$.

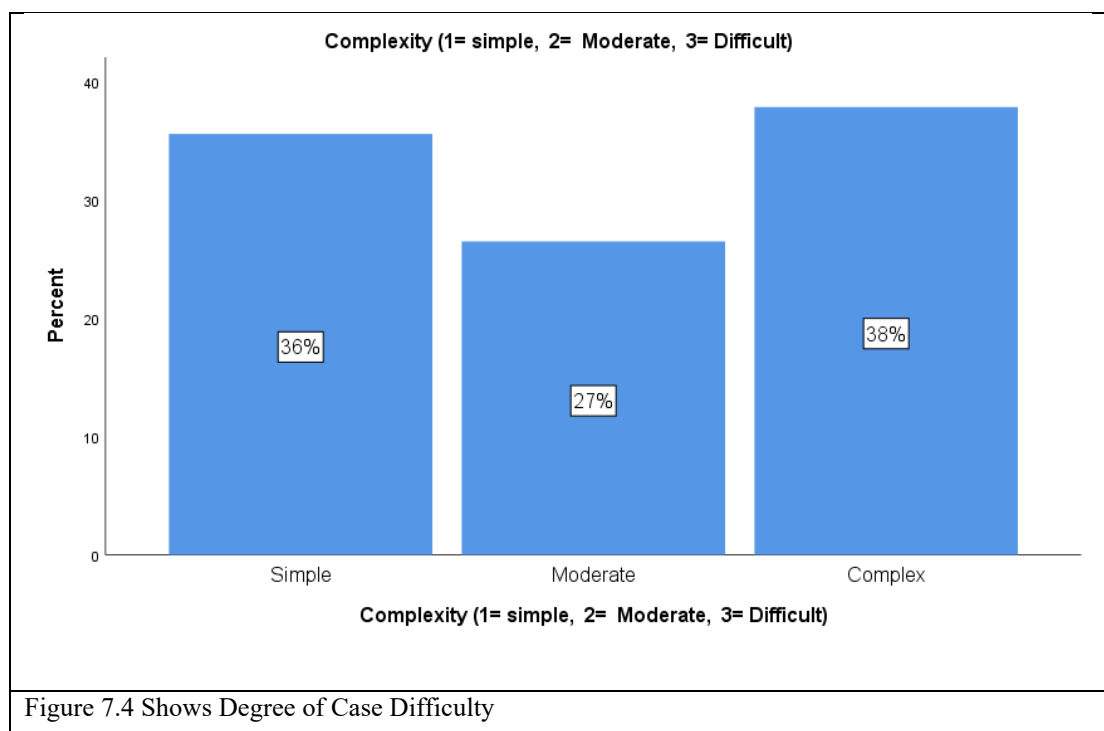
An examination of the contingency table shows that a higher number of elective cases were classified as complex (24/57), while a higher number of urgent cases were classified as simple (25/42). It is noted that the highest number of ITU cases was complex (17/33).

Complexity of the IR Procedures and the mean total number of healthcare errors across the IR pathway.

The highest proportion of the IR procedures was comprised of complex procedures at a rate of 38% followed by simple procedures and moderate procedure at rates of 36% and 27%

respectively (Figure 7.4). There was a significant difference in the mean total number of healthcare errors among these different groups (using Univariate Analysis of Variance, $F = 59.185$, $P \text{ value} = <.001$).

However, when we compared individual groups with each other, we found that the mean total of healthcare errors in complex procedures is significantly higher than simple procedures [mean difference = 7.42 (Std. Error 1.937), $P \text{ value} = .001$]. Also, the mean total of healthcare errors in moderate procedures is slightly significantly higher than simple procedures [mean difference = 5.35 (Std. Error 2.128), $P \text{ value} = .046$]. On the other hand, there was no statistically significant difference between the mean total healthcare errors between the complex and the moderate procedures [mean difference = 2.07 (Std. Error 2.101), $P \text{ value} = .615$].



The difference in the mean total number healthcare errors in elective, urgent and ITU patients when controlling for the complexity of IR procedures.

Using Quade's test in SPSS, the difference of the mean total number of healthcare errors across the IR pathway of care was assessed across the groups of elective, urgent and ITU procedures

while adjusting for the case complexity variable. There was no difference in the mean total number of healthcare errors in the IR pathway of care among these groups ($F= 1.192$; P value = 0.315).

Different time durations of the IR pathway

The total observation time of this study was 373 hours and 5 minutes from the beginning of the IR pathway (i.e., the time of the admission of the patients to the IR department) to the end (the time of the discharge of the patients from the IR department). Observation of minute by minute of the whole IR pathway of care was conducted by a single trained observer (FR_ author of this thesis). The whole IR pathway time is comprised of 123 hours and 43 minutes pre-procedure phase, 118 hours and 46 minutes intraoperative phase and 130 hours 38 minutes post-procedures phase. The total time delay of the patients before attending the IR department was 88 hours (Table 7.4). This time delay was calculated by subtracting the time when the patients sent for by the IR department from the time of arrival or admission of the patients to the IR department.

The mean duration of a whole IR pathway was 2 hours 48 minutes [STD= 118.516], while the mean duration of an IR procedure was 1 hour and 7 minutes [STD = 44.634]. The mean delay before admission to the IR department was 44 minutes (Table 7.4).

Table 7.4 Total Time of Different Phases of IR Pathway

Total time (Different Phase of IR Pathway	Time (hh: mm)
Total Time of the Whole IR Pathway	373:05
Total Pre-procedure Time	123:43
Total Procedure Time	118:46
Total Post-procedure Time (hh:mm)	130:38
Average time per IR pathway (hh:mm)	02:48
Average time per IR procedure (hh:mm)	1:07
Total Time Delay Before Admission	88:00
Average time delay before admission (hh:mm)	00:44

Healthcare errors according to the phases of the IR pathway

Most of the healthcare errors occurred in the intraoperative phase, followed by preoperative and post-operative phase at rates of 86%, 9.5 % and 4% respectively (Figure 7.5).

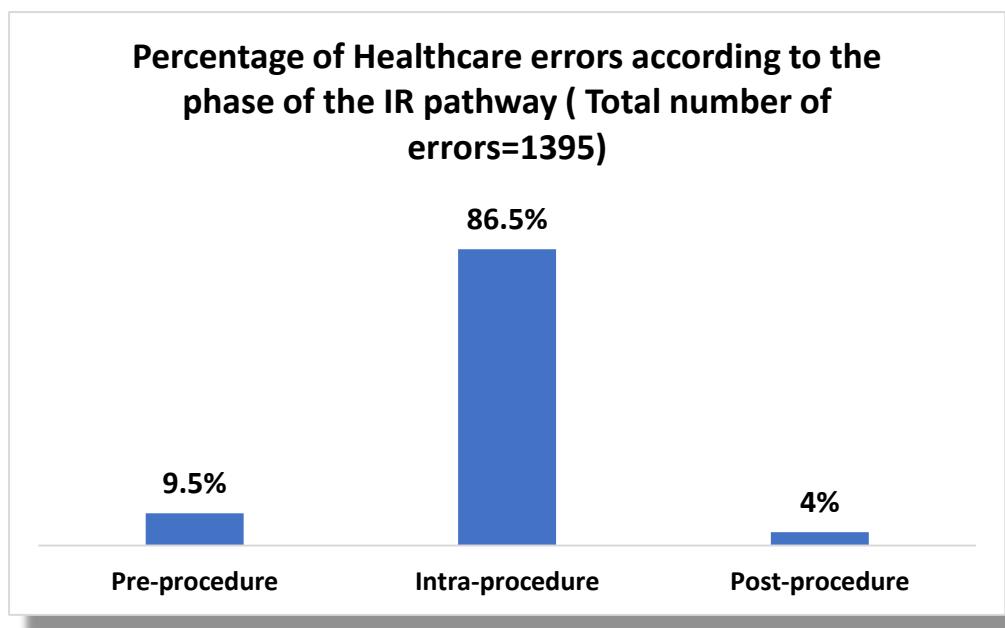
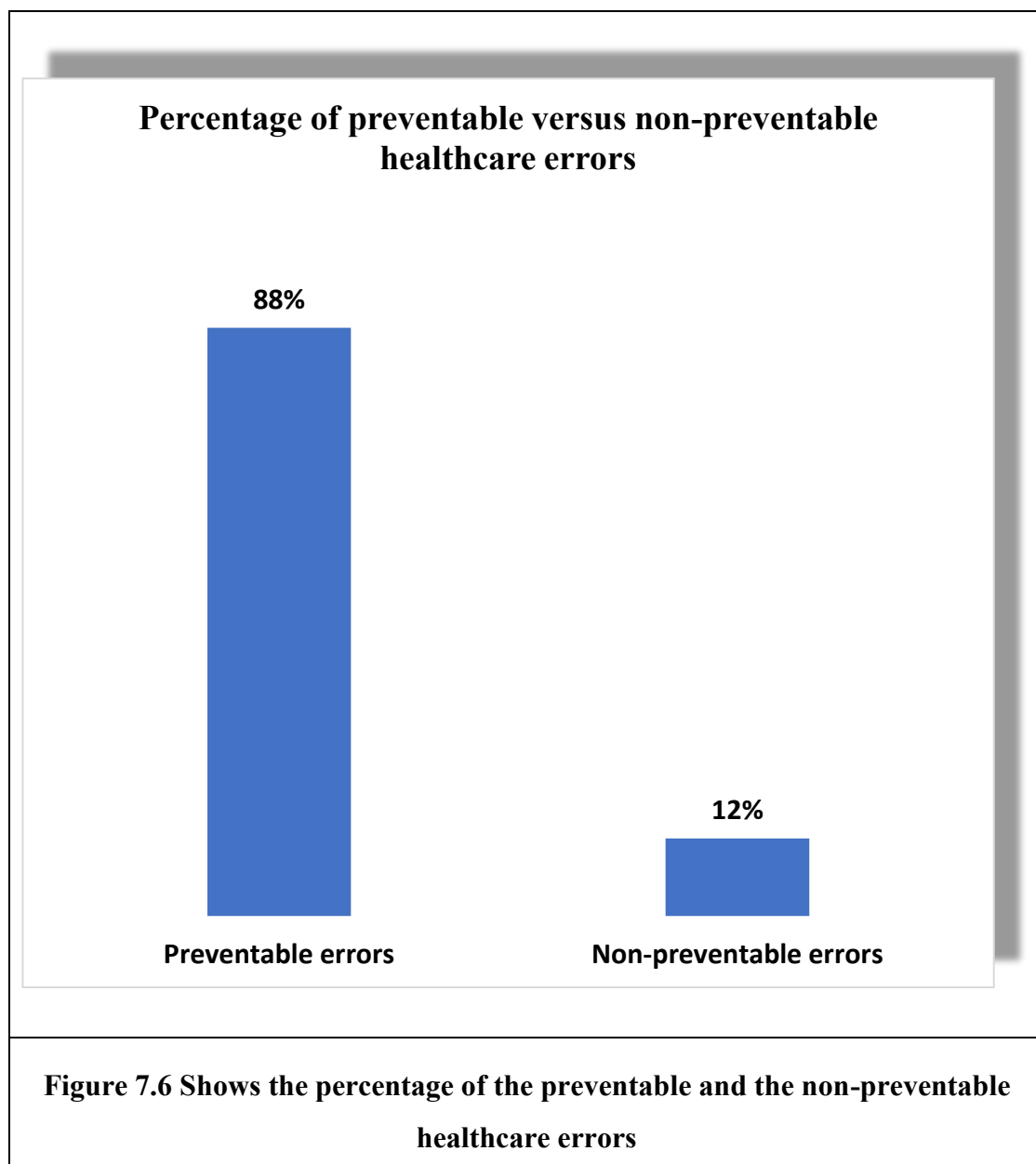


Figure 7.5 Breakdown of Healthcare Errors according to the phase of the IR pathway

Preventability of Healthcare errors

Out of the total 1395 recorded healthcare errors, 1232 (88%) were preventable while 163 (12%) were non-preventable (Figure 7.6).



Categories of Healthcare Errors Throughout the IR Pathway

There were twelve major categories of healthcare errors encountered in the studied 132 IR pathways. From the total 1395 healthcare errors, the most frequent error was safety awareness at a rate of 336 (24%) followed by communication error, equipment-related errors, and distraction at rates of 274 (20%) and 145 (10 %) and 137 (10%) respectively.

The rest of the healthcare errors were as follows (in order from high to low): Technical 121(9%), Absence 113 (8%), Planning 98 (7%), Patient-related errors 93 (7%), Management 52 (4%), Procedure-related errors 18 (1%), Others 6 (0%) and Fatigue 2(0%) (Figure 7.7 and Figure 7.8).

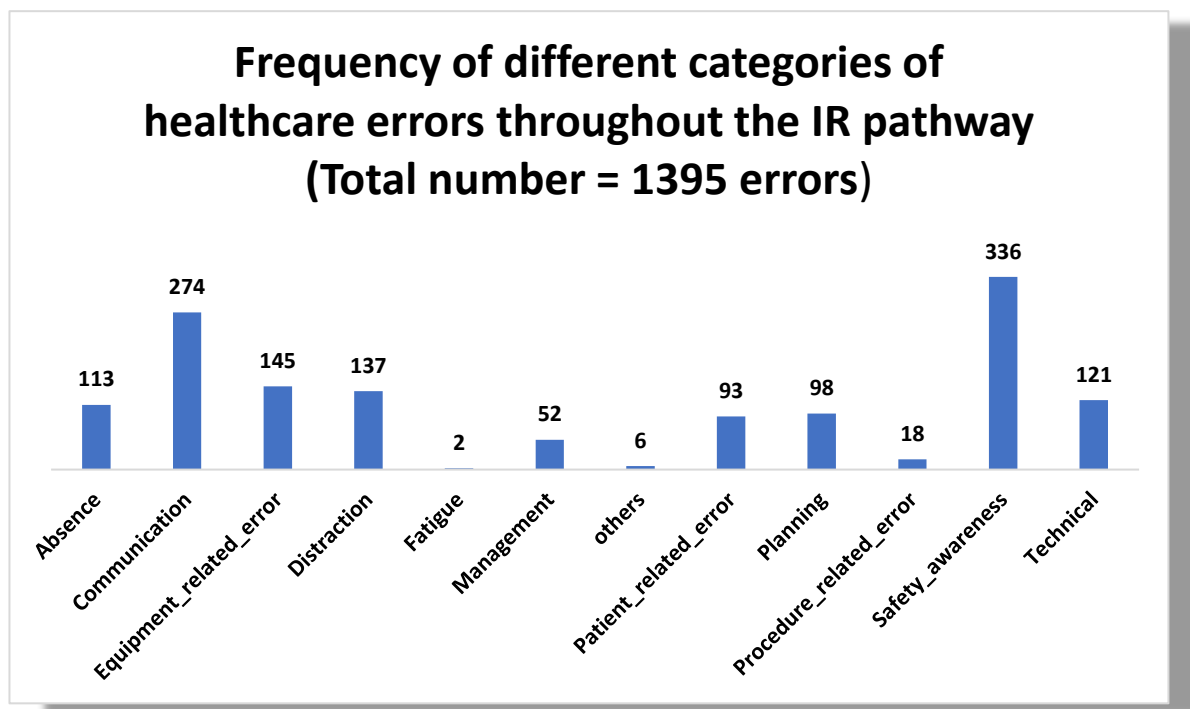


Figure 7.7 Shows the frequency of different healthcare errors throughout the IR pathway (Total number = 1395 errors)

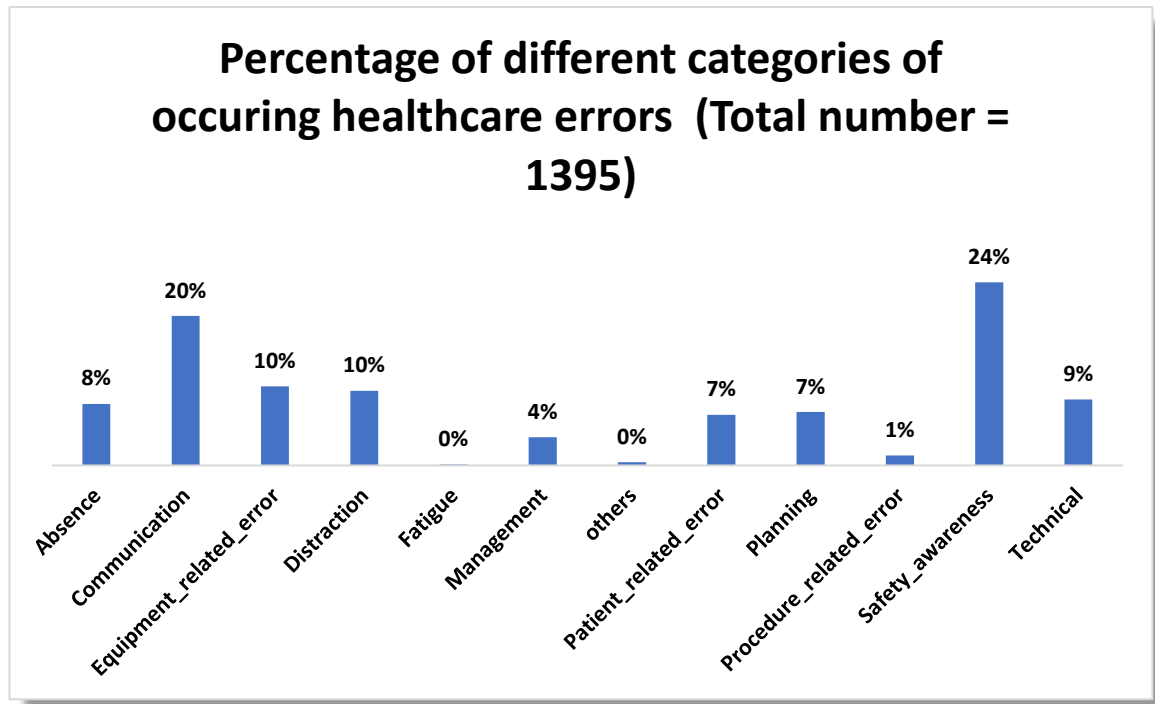
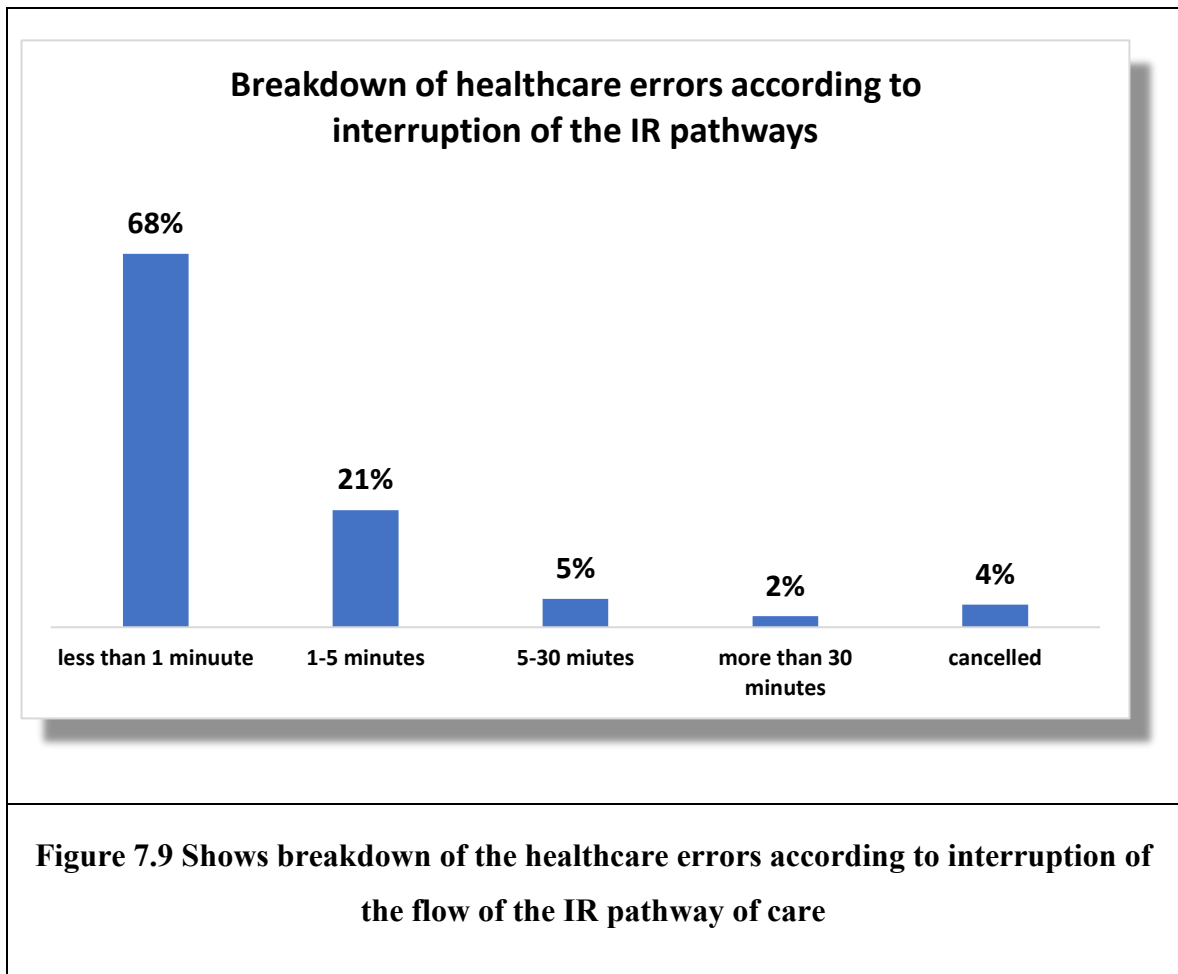


Figure 7.8 Shows the percentage of different healthcare errors throughout the IR pathway (Total number = 1395 errors)

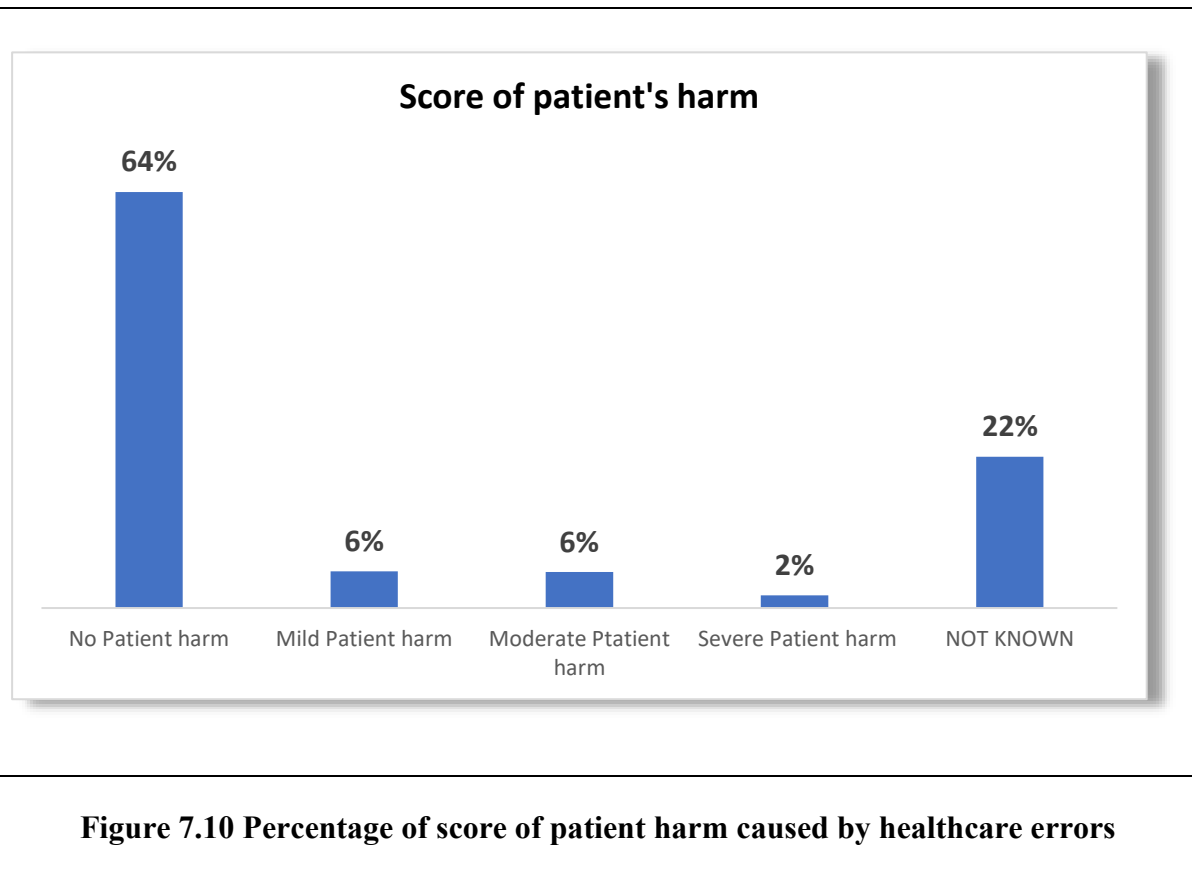
Interruption Time caused by Healthcare Errors

Most of the healthcare errors caused a delay of less than 1 minute at a rate of 68% followed by a mild delay of 1-5 minutes (21%), moderate delay of 5-30 minutes (5%) and severe delay of more than 30 minutes (2%). On the other hand, 4 % of the total number of the healthcare errors caused a procedure to be cancelled (Figure 7.9).



Severity of patient harm caused by healthcare errors.

The healthcare errors cause no patient harm in 64 % of time. The errors resulted or had a potential to cause mild, moderate, severe harm in 6 %, 6 % and 2 % of occasions respectively. However, in 22 % of occasions patient harm was not known (Figure 7.10).



Proportion of categories of healthcare errors that caused cancellation of IR procedures.

The most frequent healthcare error category that caused or contributed to cancellation of the IR procedures was communication error at a rate of 38% followed by planning at a rate of 31%. Patient-related error and management encountered at rates of 15% and 8% respectively (Figure 7.1).

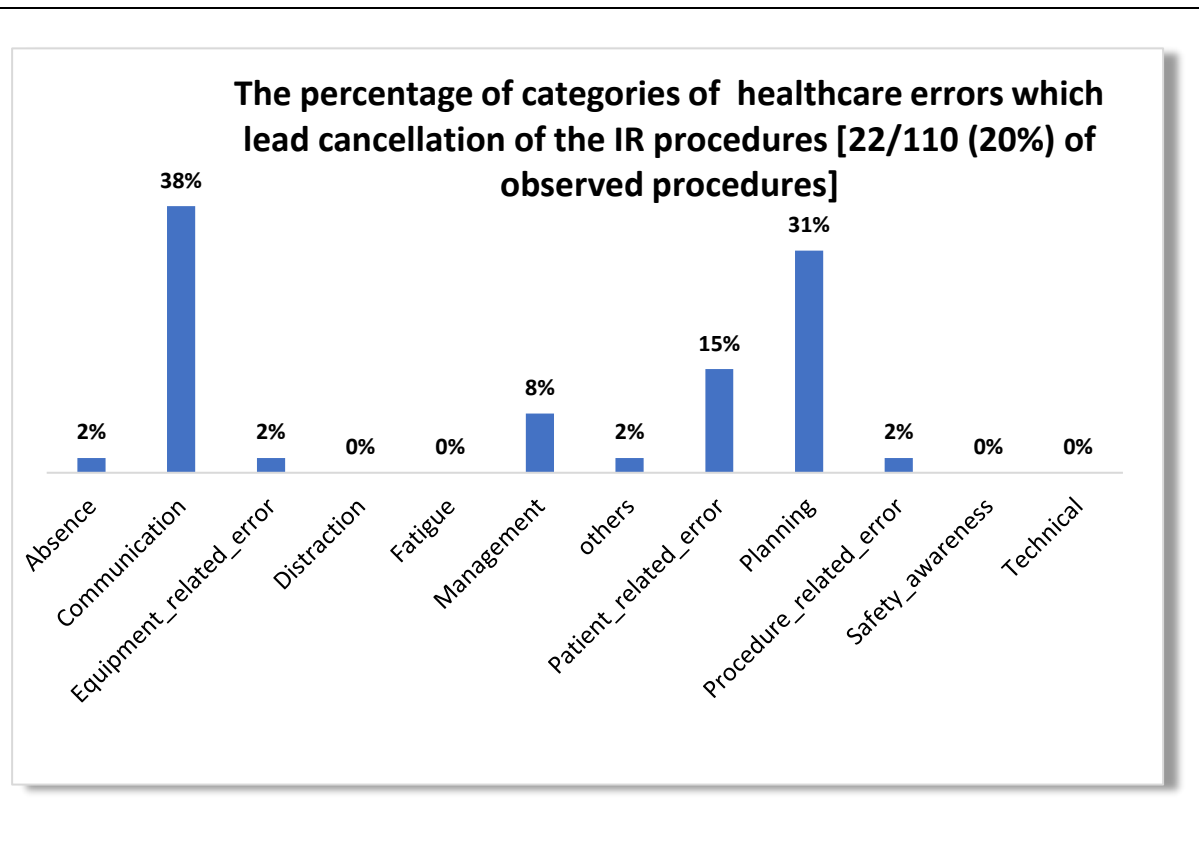
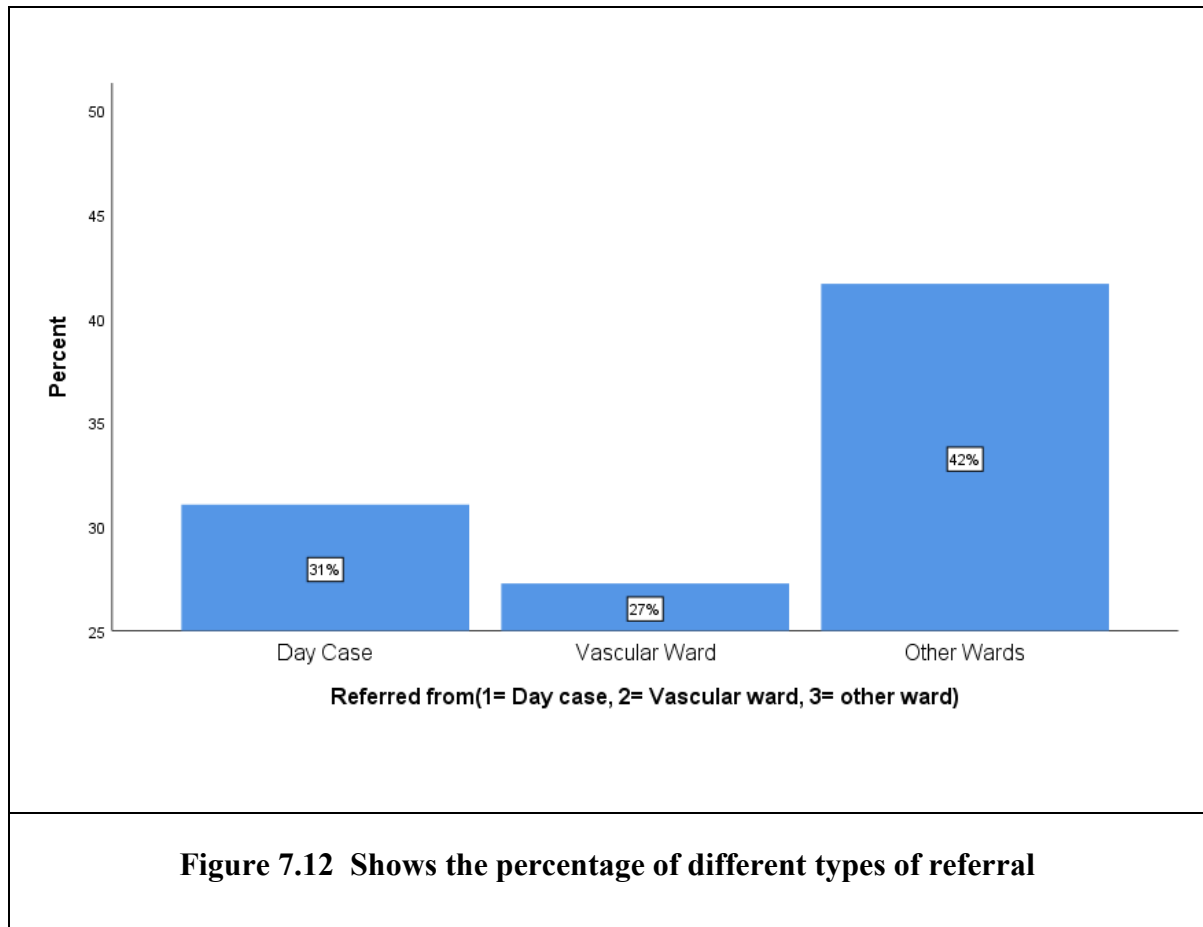


Figure 7.11 Shows the percentage of healthcare errors that caused cancellation of the observed IR procedures

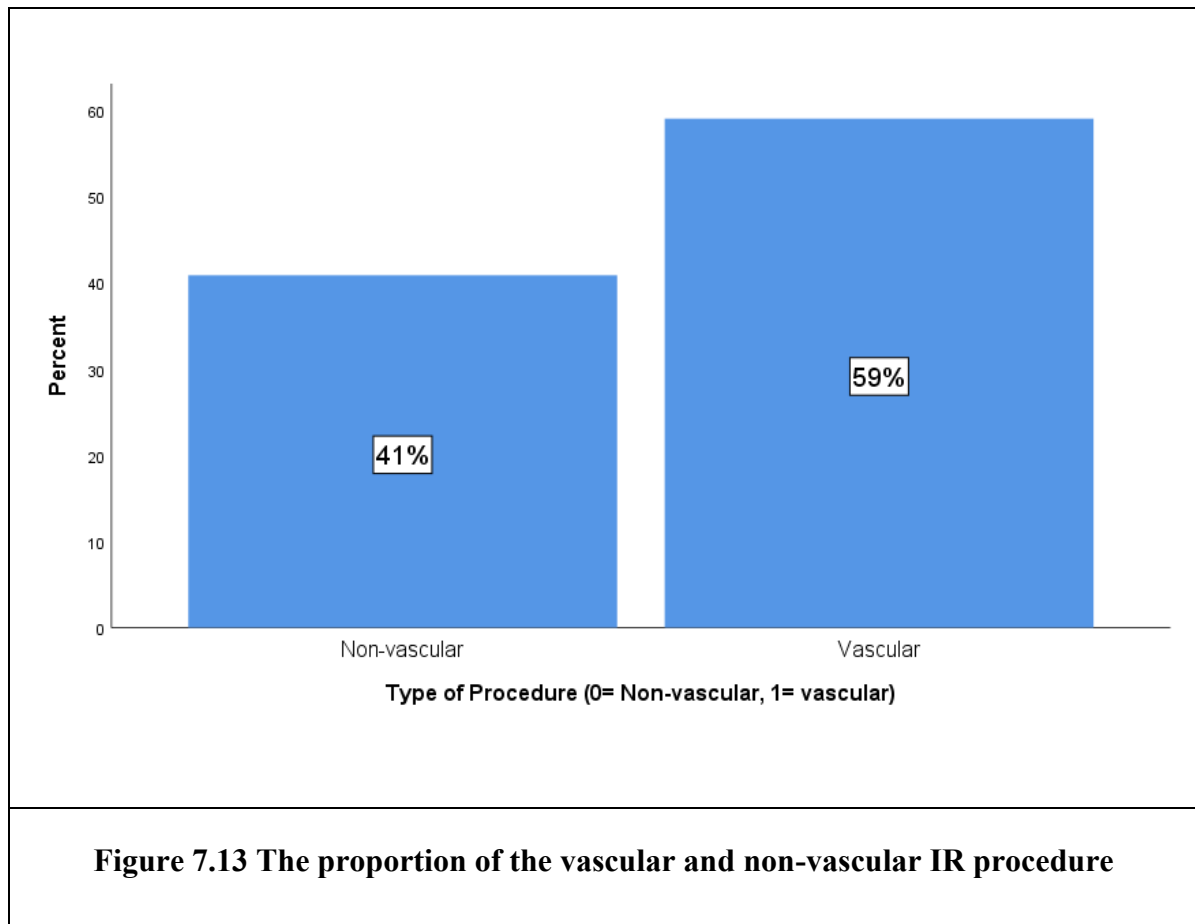
Types of Case Referrals to the IR Department

The highest rate of referral to the IR department in the studied population was from other wards (42%) followed by day cases (31%) and vascular ward (27%) (Figure 7.12).



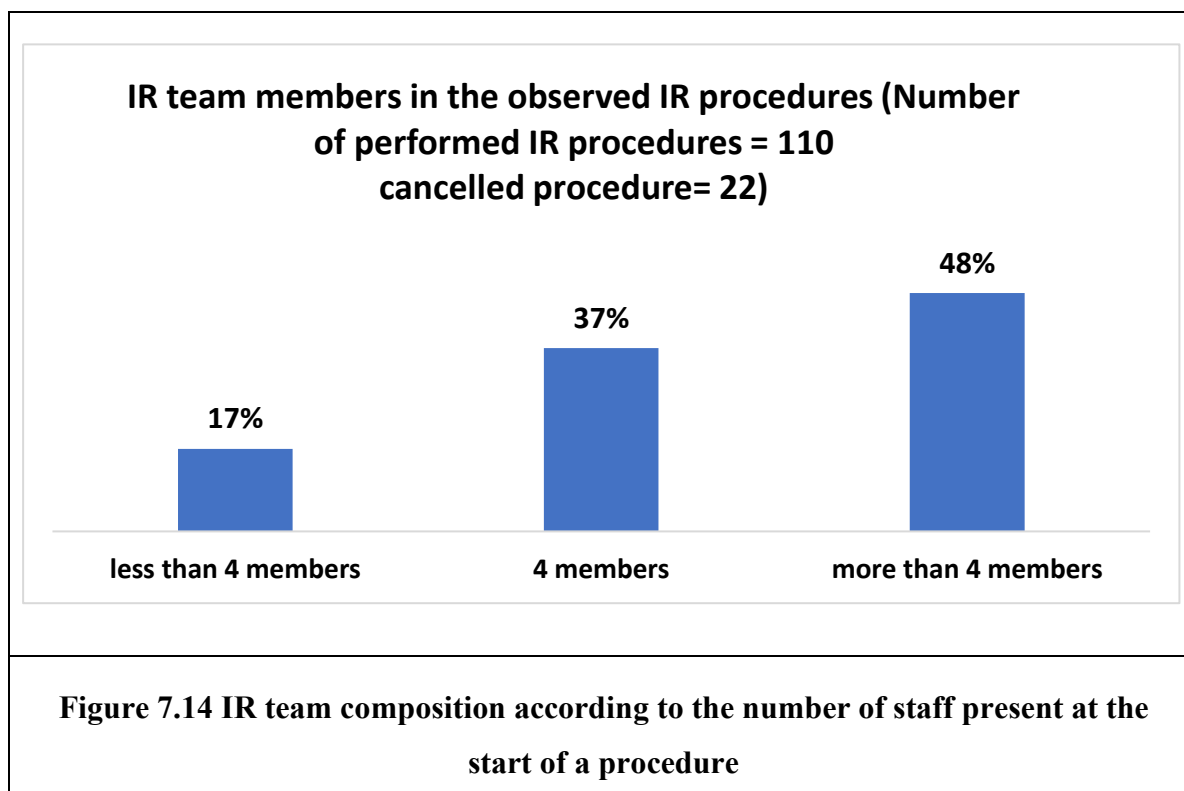
Types of the IR procedures

The vascular procedures constituted the most frequently performed procedures at a rate of 59% versus non-vascular procedures at a rate of 41% (Figure 7.13).



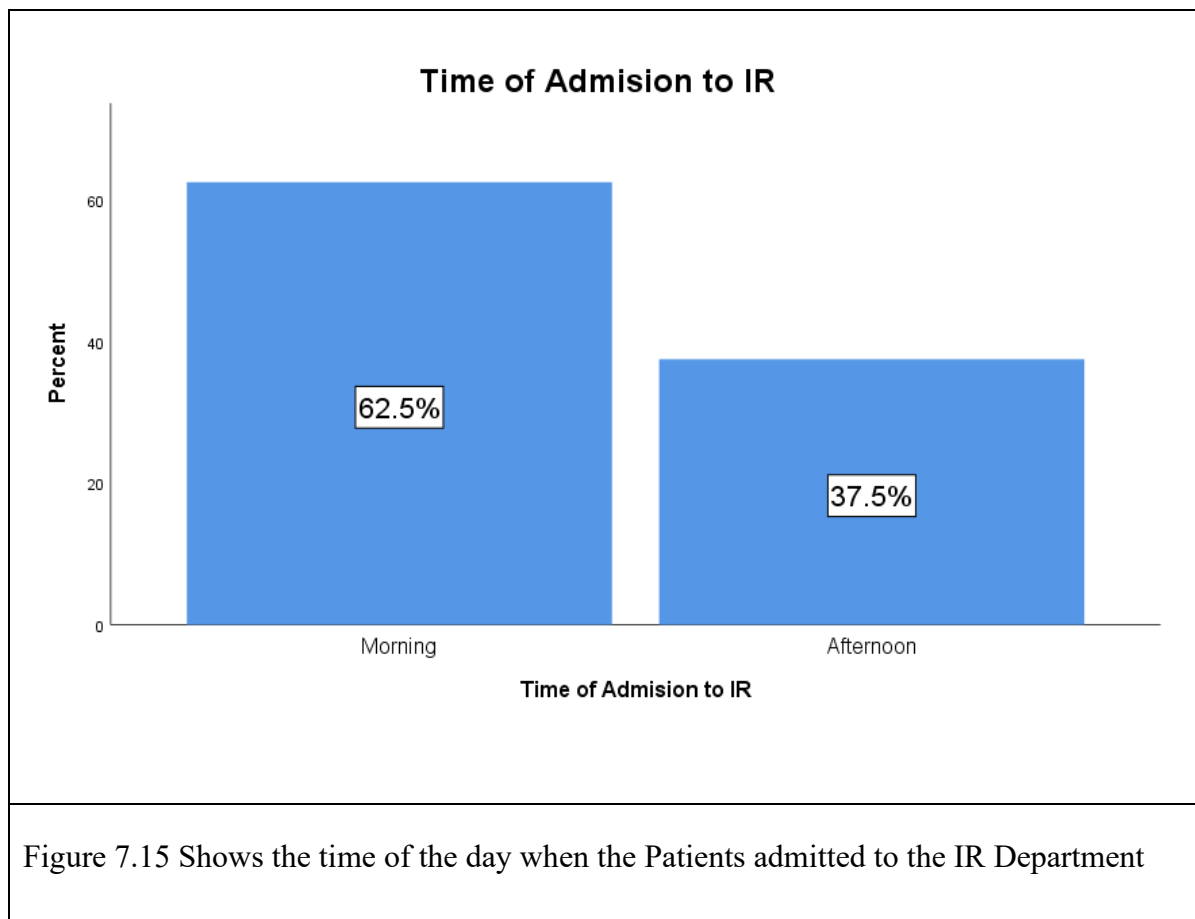
IR team number

The IR team composed of more than four members in 48% of procedures followed by teams of four members in 37% of cases. In contrast, in 17% of cases the IR team comprised of less than four members (Figure 7.14). There was no correlation between the number of IR team members and the total number of healthcare errors (Pearson coefficient value = 0.101, P value = 0.249).



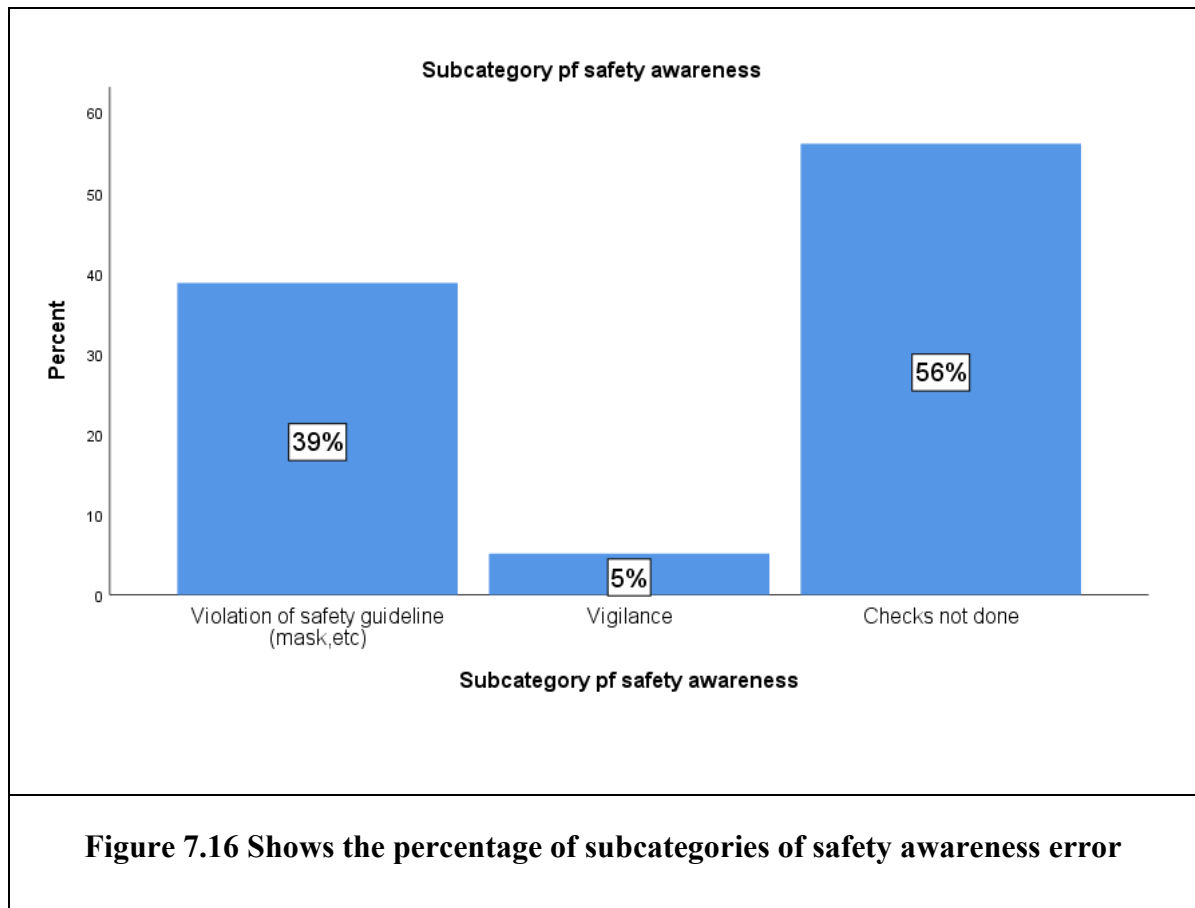
The beginning of the IR pathway and the time of the day

Most of the included IR pathways started in the morning at a rate of 62.5% compared to 37.5% in afternoon (Figure 7.15).



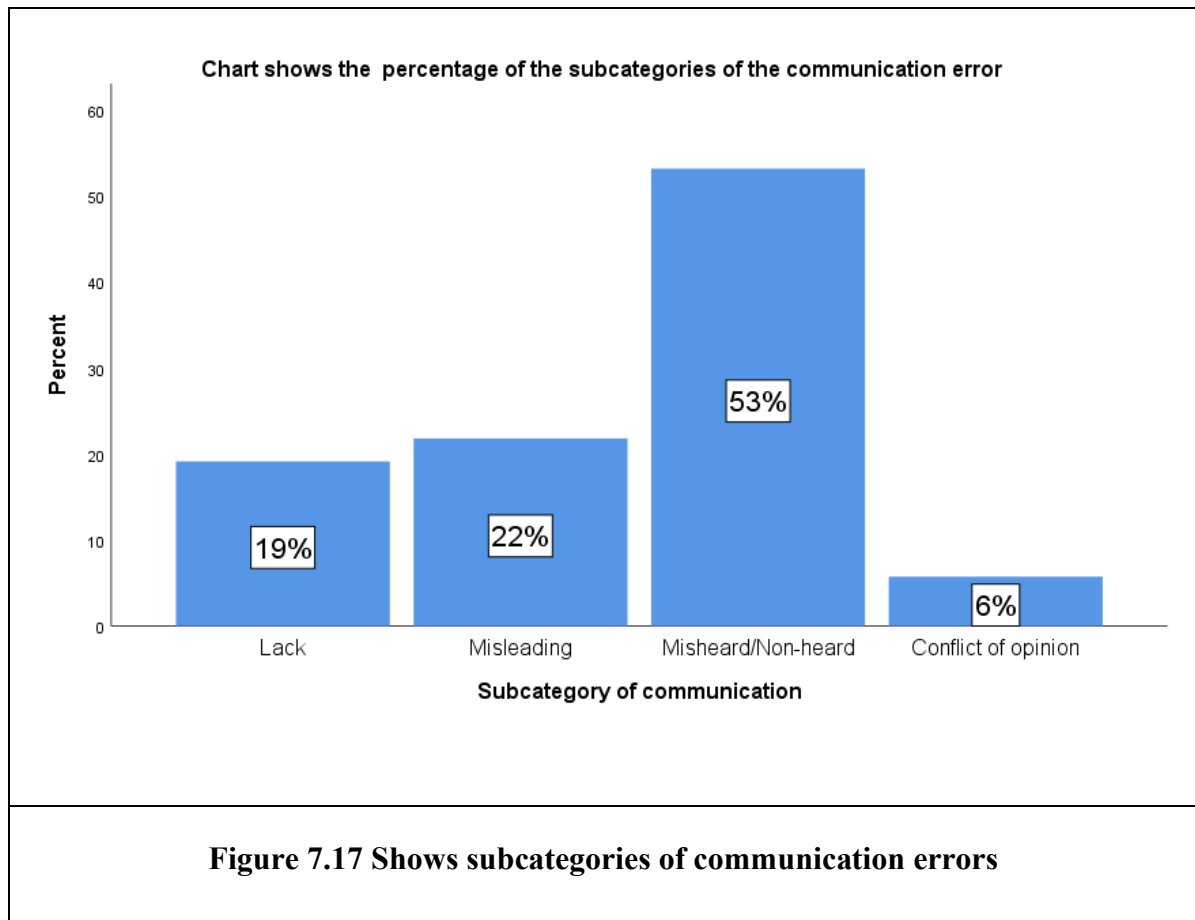
Subcategories of safety awareness error

The most frequent subcategories of safety awareness error were " Checks not done" which constituted 56% followed by " Violation (mask, etc)" _ 39% and " Vigilance or awareness error" _ 5 % (Figure 7.16).



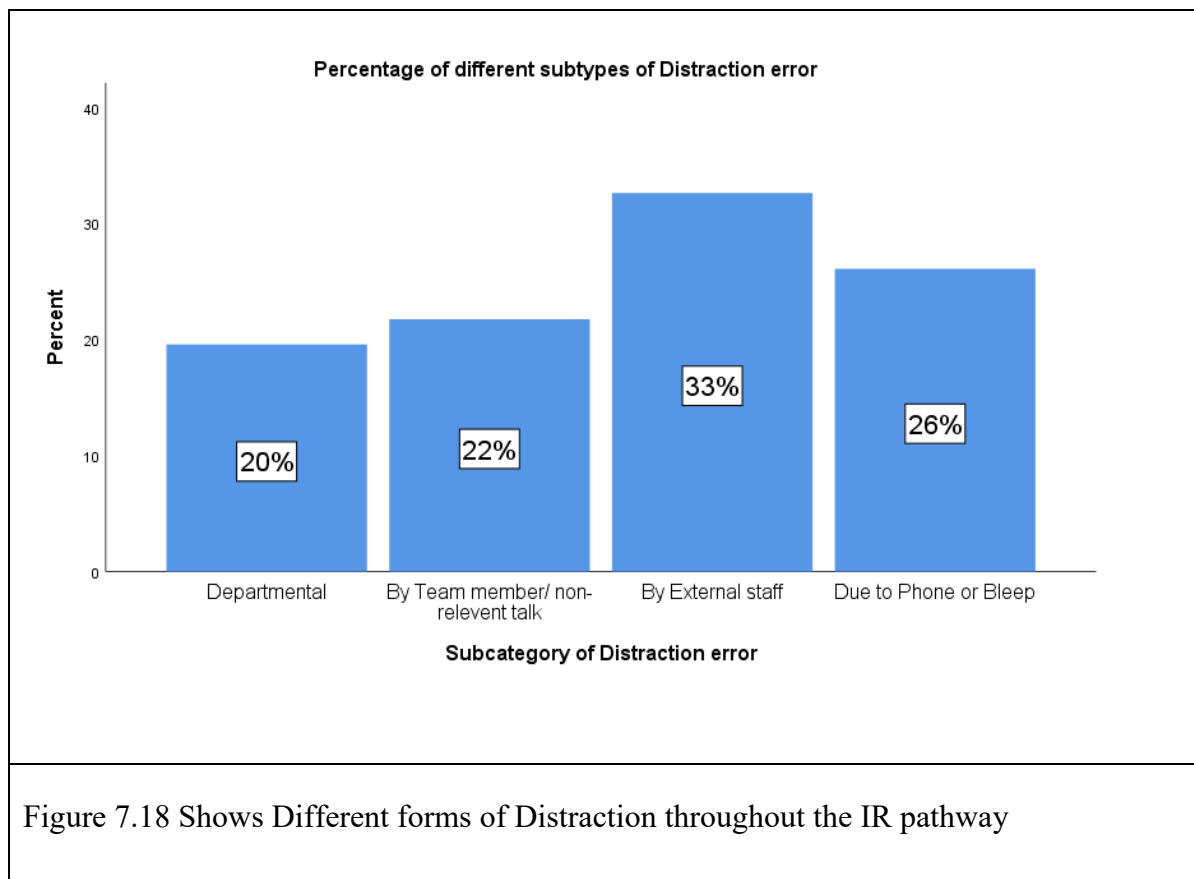
Subcategories of Communication error

The communication between different IR team members is misheard or non-heard in 53% of time while followed by misleading communication at a rate of 22% where there was no clear communication or request was delivered by the involved IR operating team member. In 19% of occasions, there was lack of communication. On the other hand, in 6% of occasions, there was a conflict of opinion among the IR team members (Figure 7.17).



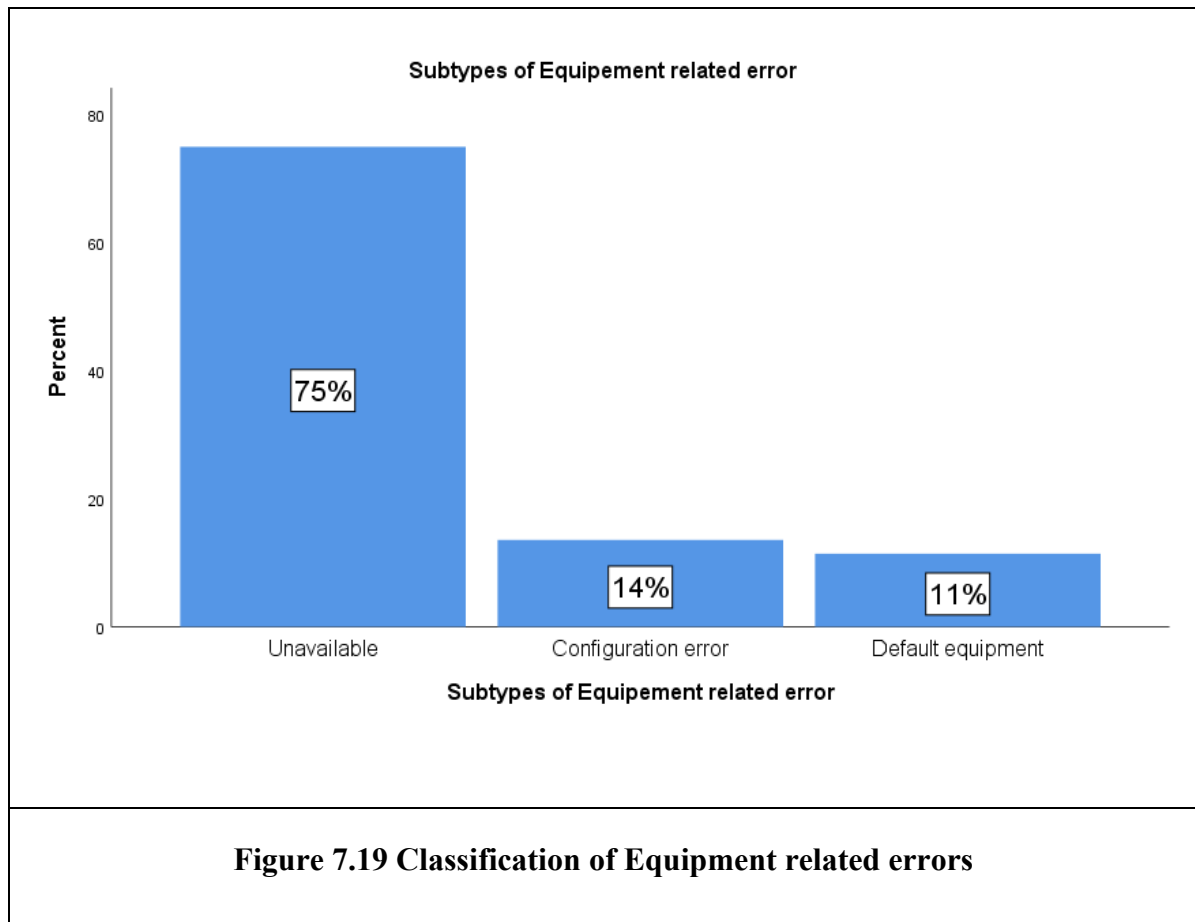
Different forms of Distraction throughout the IR pathway

The most frequent distraction to the IR team was from external staff with a percentage of 33% followed by distraction from phone ringing (26%) followed by irrelevant talks between team members themselves (22%). Distraction from departmental pressure to finish procedures quickly formed 20% of the total distraction (Figure 7.18).



Subcategories of Equipment-related errors

Equipment unavailability was the most frequent encountered subcategory which formed approximately 75%, followed by configuration error and default equipment at rates of approximately 14% and 11% respectively (Figure 7.19).



Difference in the mean total number of healthcare errors across the entire IR pathway among male and female groups of the study population

Using Independent samples T test, the distribution of mean total number of healthcare errors across the whole IR pathway of care is similar in the male and the female groups of the study population (P value = 0.312).

Difference between type of referral and the total number of healthcare errors

Using one-way ANOVA, the mean total number of healthcare errors is compared across different referrals, namely: day cases, cases referred from the vascular ward and those referred from the other wards.

The mean total number of healthcare errors was significantly different across these groups of referrals ($P = 0.007$). The mean total number of IR procedures referred from the vascular ward is 13.69 (Std. Deviation = 8.931) versus 8.41 (Std. Deviation = 6.189) for the day cases and 8.42 (Std. Deviation = 5.662) for the cases referred from the other wards. The mean difference between the cases referred from the vascular ward and the day cases is 5.280 which is statistically significant ($P, .003$). Similarly, the mean difference of the total number of healthcare errors of the cases referred from vascular wards and those referred from other wards was 5.276 which is statistically significant ($P, .001$). However, the mean total number of healthcare errors between day cases and cases referred from other wards was not statistically different (mean difference = -.004; P value, 1.000).

Distribution of the total number of healthcare errors across different degrees of case complexity

There was a significant difference in the total number of healthcare errors in the IR pathway across simple, moderate, and complex IR procedures ($P, 0.001$). The mean of the total number of healthcare errors in simple IR procedures was 6.79 (Std. Deviation = 3.912) versus 10.51 (Std. Deviation = 7.766) in moderately complexity procedures versus 12.28 (Std. Deviation = 8.179) in complex procedures.

The mean difference between moderate and simple IR procedures was statistically significant (measuring 3.727; $P = .042$). The mean difference between complex and simple IR procedures was even larger (measuring 5.493; $P < 0.000$). However, there was no statistically significant difference between complex and moderate IR procedures (mean difference = 1.766; $P = 0.472$).

The difference in the total number of healthcare errors across the entire IR pathway by different team member groups.

Using Pearson Correlation test, the mean total number of healthcare errors is correlated with the number of IR team members. There was no correlation between the number of IR team members and the mean total number of healthcare errors in the IR pathway ($P = 0.082$).

Difference between the mean total number of healthcare according to the time of admission to the IR department

Although the mean of the total number of healthcare errors in the entire IR pathway of care is slightly higher in patients who were admitted in the afternoon (11.13; Std Deviation: 7.347) than those who were admitted in the morning (10.13; Std Deviation: 7.133), the result was not statistically significant, $t(118) = -0.735$, $p = 0.464$.

Correlation between length of intraoperative IR procedures and the mean total number of healthcare errors across the entire IR pathway

There was a moderately positive correlation between the length of the IR procedure and the mean total number of healthcare error across the entire IR pathway: (Pearson Correlation coefficient = .523, $p < 0.001$).

Correlation between length of whole IR pathway and the Total number of healthcare errors across the entire IR pathway

There was a moderate positive correlation between the length of the whole IR pathway and the mean total number of healthcare error across the entire IR pathway (Pearson Correlation coefficient = 470, $P = \text{less than } 0.001$) (Spearman's rho Correlation Coefficient = .476, $p = \text{less than } 0.001$).

Predictors factors for the healthcare errors

Using multilinear regression model, the relationship between the dependant variable (mean total number of healthcare errors in the entire IR pathway) was studied with the following independent variables, namely: Age, gender, number of IR members, referred from (day case, vascular, other wards) and number of IR team members.

Only the following factors could predict the number of healthcare errors: type of the procedures (vascular, non-vascular) and the degree of case complexity (simple, moderate, complex), and type of IR procedures (elective, urgent, ITU). Twelve percent of the increase in the total number of healthcare errors were predicted by vascular procedures ($P = <0.001$). Fifteen percent of the increase in the number of the healthcare errors were predicted by change in the complexity of the IR procedures from simple to moderate to difficult ($P \text{ value} = 0.028$).

7.8 Discussion:

The need to study the healthcare errors across the whole IR pathway.

This study reports a detailed analysis of healthcare errors within the entire pathway of care of IR procedures from the point of admission of patients to the IR department to the point of their discharge from the IR department. According to the knowledge of the author of this thesis, this is the first study of its type that evaluate the entire IR pathway including the preoperative, intraoperative and the post-operative period.

Most of the reviewed studies only focused on one stage of patient's journey which was intraoperative (Catchpole et al., 2006a) (ALBAYETI et al., 2011), (Morbi et al., 2012) . It has been highlighted that the intra-operative period might represent the most critical period during surgical journeys, therefore is the most fertile land on which healthcare errors thrive. In a large retrospective study on more than thirty thousand randomly selected case notes from fifty-one randomly selected acute hospitals in the USA, more than 16 percent of the total rate of adverse events occurred in vascular surgery, surpassing other surgical specialties (Brennan et al., 1991).

The complete pre- intra- and the post-operative period of care had not been studied previously to know the proportion of the healthcare errors across the whole patient's journey. In a previous systematic review to evaluate communication and information exchange among team members in the field of surgery and anaesthesia, Nagpal et al. (2010) found thirty-eight studies dealing with this topic. However, none of these studies researched the whole care process neither in surgery nor in anaesthesia (Nagpal et al., 2010b). The review went on to state that communication transfer in the intraoperative stage has been investigated in many studies (Lingard et al., 2004a, Undre et al., 2006, Awad et al., 2005), while there was only one study highlighted the communication breakdown across the pre- intra- and postoperative stages of surgical process. This particular study was an after event study evaluating 400 surgical malpractice claims (Greenberg et al., 2007). Therefore, the need to study the whole aspect of medical care, specifically, surgical care has been stressed upon (Nagpal et al., 2010b, ALBAYETI et al., 2011).

The current study evaluates the IR pathway of care across the preprocedure preparation and planning through to the intra-procedural phase to the post-procedural care. It shows that the healthcare errors across the IR specialty are frequent. This agrees with the literature that reports

safety in IR and vascular surgery (ALBAYETI et al., 2011, Morbi et al., 2012, Koetser et al., 2013, Lutjeboer et al., 2015).

As IR specialism is a dynamic specialty that shares many features with other surgical disciplines, it would be reasonable to compare it to surgery in terms of the associated challenges and healthcare errors. It has been reinforced that healthcare errors are more frequent in surgical specialties than other specialties in hospitals across the globe. The startling statistics from the report of Institute of Medicine "To Err Is Human: Building a safer Health System" revealed that most of the errors occur in hospitals in those settings where higher technical complexity processes occur such as vascular surgery or neurosurgery. High errors rates including those which lead to serious complications occur mostly in operating rooms. This is presumably because of dynamic and complex events that occur in a short but complex environment involving interaction of different teams to deliver a safe care to patients (Institute of Medicine Committee on Quality of Health Care, 2000, Greenberg et al., 2007, Undre et al., 2006).

Healthcare errors in elective versus urgent versus intensive treatment unit (ITU) procedures

Not only does the current study highlights the landscape of healthcare errors in elective procedures but also it explores the rate of these errors in other pathways namely urgent and ITU referrals. In our sample, care has been taken to include more urgent and ITU patients to allow comparison among these different groups. However, the elective IR procedures were still comprised the highest proportion compared to the urgent and the ITU IR procedures. This result is in line with a previous study in which elective and semi-elective IR procedures were evaluated (Koetser et al., 2013). It is not surprising that elective IR procedures are the most encountered procedures in real life as they reflect the nature of IR specialism which provide minimally invasive alternative to open surgical procedures in many cases.

The prevalence of urgent interventional radiology (IR) procedures among all performed IR procedures varies depending on the healthcare setting, location, and patient population. According to the knowledge of the author of this thesis, there is no specific percentage available to represent the entire world or the UK, as the data may vary significantly between different hospitals and regions.

Elective IR procedures tend to be more common than urgent procedures, as they include a wide range of minimally invasive interventions for various conditions. Urgent IR procedures, as the name indicates, while less common, are critical for addressing acute and life-threatening situations. The exact prevalence of urgent IR procedures in a specific location will depend on factors such as the local patient population, healthcare infrastructure, and availability of IR specialists.

Interestingly, the rate of healthcare errors across the elective, urgent and ITU procedures in the current study is not statistically different. Even when adjusting for the case complexity. This could be explained by the fact that there were more complex cases in elective IR procedures than urgent procedure, which had more simple cases. There is no data in the literature, according to the knowledge of the author of this thesis, to compare difference in the rate of healthcare errors in elective, urgent and ITU patient in the IR specialty.

This finding could highlight other important factors such as team dynamics, logistics or technical factors in determining the procedural flow and outcome. Team structure and communication are important factor in operating room. If any of the members of the surgical or operating team does not feel engaged or part of the team, they may falsely assume the amount of duty or responsibility across the different team hierarchy. In a previous study by Gawande et al., (1999), 70 percent of the communication breakdown was secondary to communication failure among the surgical teams (Gawande, (1999). Other studies also reinforced the team dynamic as important factor for a successful outcome (Tan et al., 2006, Haynes et al., 2009a)

Healthcare errors and the phase of IR

Most of the healthcare errors in this study occurred in the intraoperative period (86%) followed by preoperative (9.5%) and post-operative period (4%) respectively. It is apparent that the intraoperative period is critical and shows a complex and high level of interactions among team members themselves and with the procedure and its requirement.

In a systematic review on the incidence of adverse events in hospitalised patients, it is found that the operative adverse events constitute the largest share of the total adverse events (de

Vries et al., 2008) . Previous studies highlighted similar results (Vincent et al., 2001, Wilson et al., 1999, Wilson et al., 1995).

However, the pre- and post-operative period in the journey of the patients are important too. Although 9.5 % of the observed total number of healthcare errors took place in the preoperative period, this would have been more if root cause analysis of all the healthcare errors was made. However, the study is not designed to analyse the root cause of each error. In a systematic review about the operative room safety, it is found that the preoperative and post-operative period are as important as the intraoperative period in terms of safety issues. The preoperative inefficient communications are regarded as root causes for many intraoperative adverse events (Poore et al., 2012) . In another retrospective study about the wrong site and wrong procedure, between 1300 and 2700 cases were found to have either wrong sites operated upon or wrong person being treated or near miss each year in the United states, all of which had root cause errors emerged from the preoperative planning (Seiden and Barach, 2006).

All the healthcare errors which led to cancellation of the IR procedures were in the preoperative phase. As 20% of the observed procedures in the current study were cancelled (22/110), the impact of this stage on the whole IR pathway is considered significant. Communication and planning were the most frequent errors which caused or contributed to cancellation of the IR procedures at a rate of 38% and 31% respectively. Although planning is not the most frequent error if we count all the occurring healthcare errors, it is the second most common error that has a detrimental impact on procedural flow. Communication error on the other hand remains the most effective failure that has been amongst the most frequent non-technical errors in this study. This agrees with the previous studies in IR and other surgical specialties (Nagpal et al., 2010b, ALBAYETI et al., 2011, Morbi et al., 2012, Koetser et al., 2013, Lutjeboer et al., 2015). In the current study, 274 (20%) communication errors were recorded which forms two communication error per IR pathway. This concurs with the results of a previous study in paediatric cardia surgery, in which 1.95 coordination_ communication error was encountered per operation (Catchpole et al., 2006a)

Preventability of Healthcare errors

In this study, most of the errors across the IR pathway are preventable by the current standard of practice. More than fifty percent of adverse events are judged to be preventable in hospitalised patients in Australia (Wilson et al., 1995). Similar rates of preventable errors are found in other studies (Morbi et al., 2012) (ALBAYETI et al., 2011, Hu et al., 2012).

To work out how to reduce these errors, it is true that it is not required to acquire a complex level of training or a long period of being in practice to get experience neither is required to attend training courses or sitting professional exams or by reading long textbooks. These errors may be reduced by engaging all the team members to share the responsibility to make decisions about the planning part of each procedure. This can be performed by establishing a dynamic team where the members understand each other to maintain no or minimum level of team tension or miscommunication. Technology might play a role in standardising some tasks or reminding people of the essential safety issues throughout the IR pathway.

It is important to build functional and effective teams to reduce procedural inefficiencies and hence improve patient safety. One way is to have frequent team training to improve the non-technical skills and to practice how to function as a one building block. In a study on 160 surgical procedures across ten specialties, team familiarity, intraoperative distractions and miscommunication were studied. The researchers found that the longer the time team practice together and the more familiar they are with each other the smaller number of surgical miscommunications and therefore a better patient safety. Miscommunication in surgery was responsible for the loss of one third of specific information regarding the surgical procedures. (Gillespie et al., 2012). Armour Forse et al. (2011) found that training team will increase the operative staff performance and they stressed on the continuous maintenance of a good team training to sustain a high operative room performance.

Rate of healthcare errors

A total of 1395 healthcare errors recorded in 132 IR pathway with a total of 373 hours and 5 minutes of observation time was reported in this study. The mean total number of errors per IR pathway is 10.57 [Std. Deviation = 10.006] versus 10.96 [Std. Deviation = 9.707] per procedure.

These figures are comparable to the previous studies. In a previous observational study to analyse failures and safety issues in vascular and endovascular procedures in our institute, sixty-six procedures (worth of 251 hour of observation) were observed. They found a total of 1145 failures, with a median rate of 5.7 errors /h in endovascular procedures with a higher rate in endovascular phase of combined procedures (9.6/h) (ALBAYETI et al., 2011). In another study by our group in vascular IR, a total of fifty-five cases were observed in the preintervention phase. Before intervention, 1197 potential failures were recorded which deemed to produce 2040 errors with a potential failure rate of 18.8 per hour (Morbi et al., 2012) . Other studies found comparable results (Mason et al., 2013) (Koetser et al., 2013, Lutjeboer et al., 2015). In a study on surgical interruptions and their severity with their relationship to patient safety, the rate of interruption of the operative team was 9.82 per hour (Antoniadis et al., 2014). Similar results were found in other studies (Barach et al., 2008).

Categories of Healthcare Errors Throughout the IR Pathway

There were twelve major categories of healthcare errors encountered in this study. The most frequent error was safety awareness at a rate of 24% followed by communication error, equipment-related errors, and distraction at rates of 20% and 10 % and 10% respectively.

This pattern of errors can be found in the literature both in interventional radiology and other surgical specialties. Morbi et al, (2012) found that most of the errors in vascular IR are non-technical such as planning errors, staff absence, equipment, unavailability of equipment, communication, and lack of safety awareness. ALBAYETI et al, (2011) found that non-technical failures constitute the most failures occur in open vascular or combined open and endovascular procedures. Among these errors, equipment-related errors and communication produced the highest rate of failures at rates of 23.5% and 21% respectively.

In our study, the rate of safety awareness forms the highest among all the other errors followed by communication errors. One explanation might be that all the subtypes of safety awareness errors such as checks not done, safety violation (not wearing masks, etc), vigilance, or fault resolution error are grouped under the umbrella of safety awareness. Furthermore, safety violation by not wearing masks constituted a significant proportion of these errors where each member of the IR team counted upon an error by not wearing mask or safety caps. It is unknown how this safety awareness error was reported in other studies which might account for the difference in the rate of reporting this error. However, the communication and equipment-

related errors are still frequent which agrees with the literature. Planning errors in the study by Morbi et al, (2012) forms the highest rate among other errors. This could be explained by different methodology used to categorise errors by a retrospective looking at the ethnographic field notes by more senior assessors. Error recording and contemplation is different when it is reported live by an observer compared to a retrospective analysis by different assessors. The senior assessors might attribute more errors to planning and this is true if we look at the root cause of these errors. In other words, there could be an element of planning failure in every and each healthcare error. Senior doctors tend to think "outside the box" and show greater awareness of the latent factors contributing to error (Khan and Arsanious, 2018).

Technical errors are less frequent in the current study forming only 9% of the total number of healthcare errors. A similar result was reported in the previous studies (ALBAYETI et al., 2011, Morbi et al., 2012, Mason et al., 2013, Catchpole et al., 2006a, Ugur et al., 2016).

Score of severity of patient's harm from the healthcare errors across the IR pathway

Most of the observed healthcare errors in this study cause no harm (64%). Only 2 % of the healthcare errors cause or has the potential to cause major harm. Minor and moderate severity errors encounter 6% each. This is in harmony with the previous literature (Brennan et al., 1991) (Catchpole et al., 2007a) (ALBAYETI et al., 2011, Mason et al., 2013, Morbi et al., 2012). However, there is a considerable percentage of errors (22%), in which severity of patient harm could not be determined. This could be secondary to the perception of medical error is being subjective and depends on several factors, among which are seniority of the observer and the clinical context or scenario in which the error occurs (Khan and Arsanious, 2018). In a prospective study on 213 equally distributed anonymously assessed medical students, junior doctors and consultants to see how various level of seniority might influence the perception of medical errors, a significant difference was found in 3 out of 8 scenarios between the medical students and the consultants (Khan and Arsanious, 2018).

Association of the total number of healthcare errors with different variables

There was no difference in the total number of healthcare errors in the IR pathway among males and females. Furthermore, there was no correlation between the age of sampled

population and the total number of healthcare errors. This is similar to the finding of the previous studies performed in IR and surgery alike (ALBAYETI et al., 2011), (Morbi et al., 2012), (Mason et al., 2013), (Brennan et al., 1991) , (Wilson et al., 1995). This indicates that the outcome of the IR procedures in terms of healthcare errors relies on other factors rather than patient's demographic characteristics.

One of the variables that has a significant association with the total healthcare errors is the case complexity. There was a significant higher number of healthcare errors in complex cases than in simple procedures [mean difference = 7.42 (Std. Error 1.937), P value = .001]. While there is a slightly higher rate of healthcare errors in IR procedures with a moderate degree of complexity than simple procedures [mean difference = 5.35 (Std. Error 2.128), P value = .046], there was no statistically significant difference between the mean total healthcare errors between the complex and the moderate procedures [mean difference = 2.07 (Std. Error 2.101), P value = .615].

This agrees with the conclusion of the previous studies. Morbi et al., (2012) found that increasing the degree of complexity of cases seem to lead to an increase in the total number of healthcare errors. However, they found a weak but positive correlation between case complexity and the number of failures in the vascular IR procedures. Al-BAYETI et al., (2011) compared open and endovascular procedures and found more errors in the endovascular procedures which are assumed to be more complex than the open procedures in terms of multiple team involvement and more complex tools which are used.

The IR procedures in this study were performed by experienced IR teams, in which the IR consultants were experienced, and each one of them had more than 7 years of experience after finishing training as IR consultants. Therefore, they could judge the complexity of the observed IR procedures based on the characteristics of the procedures and the patients and based on the context of the case. The question of the complexity of the cases was checked with the attending IR consultant after they finished each procedure. This was to make sure that all the factors were accounted for including the challenging anatomy of some patients or physiologic performance of the treated patients plus the other factors such as equipment unavailability which led the IR team to get around this problem to finish the case.

There was a moderately positive correlation between the length of the IR procedure and the mean total number of healthcare error across the entire IR pathway: (Pearson Correlation

coefficient = .523, $p = < 0.001$). This is in line with the previous literature (ALBAYETI et al., 2011) (Morbi et al., 2012). It has been reported that lengthy and complex surgical operations tend to experience a higher rate of minor errors. This is likely due to increasing burden on the operating team which increases the probability of making mistakes (Cook and Woods, 1994, Catchpole and McCulloch, 2010).

What are the most predicting factors that impact the total number of healthcare errors in the entire IR pathway?

The total number of healthcare errors is predicted by the category of IR (non-vascular, vascular) and by the degree of case complexity (simple, moderate, complex).

Vascular procedures usually involve usage of various IR tools as most of the time the procedures become more unexpected as it is not always possible to find similar vascular anatomy in different patients. Furthermore, vascular procedures were significantly longer than non-vascular procedures. Al-Bayati et al., (2011) reported a higher number of failure in combined open-endovascular procedures than open vascular procedure despite the duration of the former procedures was a slightly shorter than the latter ones. They postulated that the endovascular phase of these procedures involved introduction of more equipment, some of which are new, or unavailable leading to other types of delay or inefficiencies. Also, communication among multidisciplinary team require a different level of management of these personnel, which often contains communication breakdown and failure. Therefore, they reported that communication and equipment errors in this endovascular phase alone constituted 50% of the total failures (ALBAYETI et al., 2011).

Furthermore, complex procedures in our study associated with longer procedures and hence higher number of healthcare errors. This is in line with the previous studies (Brennan et al., 1991, Catchpole et al., 2006a, de Vries et al., 2008), (Morbi et al., 2012)

7.9 Limitations

There are limitations of this study that need to be acknowledged. Firstly, this is a one centre observation study which was performed in a tertiary vascular setting. It is prudent to compare

different settings in which IR specialism exist such as district hospitals to see if the findings of the study are consistent. Future studies would be invited to investigate this area.

Secondly, the number of the studied procedures are small owing to the difficulty of assessing the whole IR pathway which might extends sometimes to over several hours. This makes reproducibility of this type of study challenging. However, this was particularly the area that this designed for to get a wholistic insight about the whole IR pathway from the start to the end rather than having a snapshot of a part of the pathway. Using a validated error- checking tool_ the FERERI tool made the process easier as there was no need to analyse the ethnographic field notes by other assessors to extract potential errors as was the cases in the previous studies in this field (ALBAYETI et al., 2011, Morbi et al., 2012)

Although the observer tried to be unbiased in collecting and interpreting events as the observer was not part of the team that was observed and has no affiliation or conflict of interest that might influence the results, there is might still be an element of human observation bias. This might be decreased in future studies by combining direct observation with videotaping the operative room or the studied pathway to be assessed by at least two trained observers to allow for better understanding the context of the errors to categorise them and to determine the possible underlying root causes.

Finally, the Hawthorne effect needs to be considered in any observation study involving observing people performing their day-to-day tasks. This is defined as change in behaviour of observed people (McCarney et al., 2007b). However, the observed IR team has been involved in many other observational studies as the hospital setting is a big tertiary vascular unit and teaching hospital. This might make practicing teams less influenced by observation.

It has been found that the use of WHO checklist contains many flaws, especially during the timeout period (Rydenfalt et al., 2013). Furthermore, many safety check errors were believed to be related to the WHO checklist implementation itself. Therefore, it would be interesting to know in more details how the WHO checklist is implemented during IR procedures.

7.10 Conclusion

This study is the first analysis of the entire IR pathway across the preprocedure, intra-procedure, and post-procedure stages. Also, it is the first study of its kind to evaluate the elective, urgent and ITU IR procedures. It is emerged from the findings of this study that the

healthcare errors are frequent across the IR pathway of care at a similar proportion among elective, urgent and ITU IR patients. However, non-technical errors such as safety awareness errors, communication, and equipment related errors are regarded as the most occurring error across the entire IR pathway of care which need to be addressed in any future intervention.

Chapter Eight: Assessing the WHO Checklist for Radiological Intervention before and after new task allocation.

8.1 Introduction

Safety checks has been appreciated by experts and has been adhered to in some high-risk industries, including aviation (2006) (Federal Aviation Administration, 2006) (Evans et al., 2007) (Clay-Williams and Colligan, 2015). The World Health Organization (WHO) established the World Alliance in 2004 to improve patient safety. In the first phase of their programme, they focused on infection associated with healthcare. Then, in the second phase of their programme, they aimed to introduce the concept of "safe surgery". This has resulted in the development of "safe surgery saves life" project, which involved the development and application of a 19-item checklist (Figure 8.1 below) in reducing complication and mortality associated with Surgery. The checklist is called the WHO checklist. Eight different teaching hospitals piloted this checklist across the globe in 2007. It had resulted in a reduction of the rate of death from 1.5% to 0.8% and inpatient complication from 11% to 7 ($P < 0.001$). The researchers used six main characteristics that needed to be adhered to by the operative team namely, checking and documenting airway status, use of pulse oximetry at the time of anaesthesia initiation, presence of two peripheral intravenous lines or a central venous line before incision and administration of prophylactic antibiotics before earlier than 60 minutes from the first incision, checking the patient's ID, the site and the name of the procedure just before the incision, and lastly sponge count at the end of the procedure. The implementation of the WHO checklist increased adherence to those six main items from 34.2% at the baseline to 56.7% ($P < 0.001$).

Interestingly, this study did not measure the compliance of the operative team to the other items of the checklist such as team- introduction by name and role, briefings, and debriefings. However, they mentioned that the implementation of the checklist required these positive behaviours. (Haynes et al., 2009b).

The WHO checklist has been implemented and documented in all operative procedures of all surgical subspecialties in the UK as this has been made obligatory since 15th January 2009 by the National Patient Safety Agency (Vats et al., 2010). The Royal College of Radiologists (RCR) and the National Patient Safety Agency (NPSA) endorsed this checklist and issued a

modified checklist for use in all interventional radiology procedures since 2010 (RCR, 2012). This is called the WHO checklist for radiological intervention (Figure 8.2).

All the phases of the WHO checklist, including the time-out, are essential to be completed as they should be (Rydenfalt et al., 2013). The time-out phase is the phase in which all the team members introduce themselves, share the critical steps of the procedure and raise any concern they have. It is the time-out phase which allows setting up communication between surgical team members. The time-out phase could influence patient safety practice by decreasing medical errors and preventing adverse events (Rydenfalt et al., 2013).

However, the previous literature in Surgery demonstrates a non-consistent implementation of the WHO checklist in Surgery and the IR (Lingard et al., 2008) (Puttick et al., 2016) and (Ariyanayagam et al., 2019). The most ignored or under-implemented phase of the WHO checklist is the time-out phase (Rydenfalt et al., 2013) . Although there is no study in IR to address different phases of the WHO checklist such as time out, the WHO checklist as a whole seemed to be not enough to mitigate for the common errors occurring in this specialty (Morbi et al., 2012). Morbi et al., 2012 conducted a study in the vascular IR (VIR) to look at errors and inefficiencies that occur in the VIR, They interviewed the IR team and asked their opinion about the efficiency of the WHO checklist for Radiology Intervention. The IR team believed that the WHO this checklist is not efficient to address the requirement of the IR procedures in terms of equipment and communication needs. Nevertheless, they admitted that the WHO checklist could be useful in Surgery (Morbi et al., 2012).

As mentioned previously, practices such as team introductions, briefings or debriefings were not checked for by Haynes et al., (2009) in their benchmark study to develop the WHO checklist (Lingard et al., 2004a). However, since then many studies in the surgical environment have highlighted different aspects of communication and information transfer within the operative room related to the WHO checklist compliance (Vats et al., 2010) (Bethune et al., 2011) (Fourcade et al., 2012, Fudickar et al., 2012, RCR, 2012) (Rydenfalt et al., 2013), and (Bergs et al., 2014).

There has been no observational study to analyse the WHO checklist in detail in the IR speciality, especially different parts of the checklist and compare them with the healthcare errors that occur in the intraoperative stage.

Furthermore, there has been attempts in the past to increase the adherence and the compliance of the IR team to the WHO checklist for radiology intervention (Puttick et al., 2016). However, there has been no data about delegation of the process of the WHO checklist for radiology intervention initiation and completion to the attending IR consultant or the main performing IR doctor.

In this study, beside exploring the different aspects of the WHO checklist for radiology intervention, an intervention has been proposed to mitigate the inconsistencies that occurred during the WHO checklist implementation. The department of Interventional Radiology at St Mary's Hospital made the initiation and the completion of the WHO checklist the responsibility of the IR consultant in charge who should make sure that every element of the checklist is get completed. In this project, we are going to examine the efficacy of this intervention.

Surgical Safety Checklist			World Health Organization	Patient Safety A World Alliance for Safer Health Care
Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist and surgeon)	Before patient leaves operating room (with nurse, anaesthetist and surgeon)		
Has the patient confirmed his/her identity, site, procedure, and consent? ☐ Yes	☐ Confirm all team members have introduced themselves by name and role.	Nurse Verbally Confirms:		
Is the site marked? ☐ Yes ☐ Not applicable	☐ Confirm the patient's name, procedure, and where the incision will be made.	☐ The name of the procedure		
Is the anaesthesia machine and medication check complete? ☐ Yes	Has antibiotic prophylaxis been given within the last 60 minutes? ☐ Yes ☐ Not applicable	☐ Completion of instrument, sponge and needle counts		
Is the pulse oximeter on the patient and functioning? ☐ Yes	Anticipated Critical Events	☐ Specimen labelling (read specimen labels aloud, including patient name)		
Does the patient have a:	To Surgeon:	☐ Whether there are any equipment problems to be addressed		
Known allergy? ☐ No ☐ Yes	☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss?	To Surgeon, Anaesthetist and Nurse:		
Difficult airway or aspiration risk? ☐ No ☐ Yes, and equipment/assistance available	To Anaesthetist: ☐ Are there any patient-specific concerns?	☐ What are the key concerns for recovery and management of this patient?		
Risk of >500ml blood loss (7ml/kg in children)? ☐ No ☐ Yes, and two IVs/central access and fluids planned	To Nursing Team: ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns?			
	Is essential imaging displayed? ☐ Yes ☐ Not applicable			
This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.			Revised 1 / 2009	© WHO, 2009

Figure 8.1 Shows the WHO checklist in Surgery

WHO Surgical Safety Checklist: for Radiological Interventions ONLY

(adapted from the WHO Surgical Safety Checklist)



THE ROYAL COLLEGE OF RADIOLOGISTS



National Patient Safety Agency
National Reporting and Learning Service

SIGN IN (To be read out loud)

Before giving anaesthetic (local or general)

Have all team members introduced themselves by name and role?
☐ Yes

All team members verbally confirm:

- ☐ What is the patient's name?
- ☐ What procedure, site and position are planned?

If general anaesthetic given the two questions above should be moved to the beginning of TIME OUT

Has the patient confirmed his/her identity, site, procedure and consent?
☐ Yes

Has essential imaging been reviewed?
☐ Yes ☐ N/A

Are all IRMER requirements met?
☐ Yes

Is the procedural site marked?
☐ Yes ☐ N/A

Is the anaesthesia machine/monitoring equipment and medication check complete?
☐ Yes ☐ N/A

Does the patient have a:
known allergy?
☐ No ☐ Yes

anticipated risk of >500ml blood loss (7ml/kg in children)?
☐ No ☐ Yes (and adequate IV access/fluids planned)

Have risk factors for bleeding and renal failure been checked?
☐ Yes ☐ N/A

Has Antibiotic prophylaxis been given?
☐ Yes ☐ N/A

Has VTE prophylaxis been undertaken?
☐ Yes ☐ N/A

Is the required equipment available and in date?
☐ Yes

Are there any critical or unexpected steps you want the team to know about?
☐ Yes ☐ N/A

ONLY IF GENERAL ANAESTHETIC IS GIVEN

TIME OUT (To be read out loud)

Before start of radiological intervention
(for example needle to skin)

Anticipated critical events

Anaesthetist (if present):

- ☐ Is the anaesthetic machine check complete?

Does the patient have a difficult airway/aspiration risk?
☐ Yes ☐ N/A

- ☐ Are there any patient-specific concerns?
- ☐ What is the patient's ASA grade?
- ☐ What monitoring equipment and other specific levels of support are required, for example blood?

Registered practitioner/HCA:

- ☐ Are there any equipment issues or concerns?

Has the surgical site infection (SSI) bundle been undertaken?
☐ Yes ☐ N/A

- Antibiotic prophylaxis
- Patient warming
- Hair removal
- Glycaemic control

SIGN OUT (To be read out loud)

Before any member of the team leaves the room

Registered Practitioner/HCA verbally confirms with the team:

- ☐ Has the name and side of the procedure been recorded?
- ☐ Have all pieces of invasive equipment used been accounted for?
- ☐ Have any implanted devices been recorded?
- ☐ Have the specimens been labelled (including with patient's name)?
- ☐ Have any equipment problems been identified that need to be addressed?

Radiologist, Anaesthetist and Registered Practitioner:

- ☐ Have the instructions for post procedural care for this patient been agreed?

Remember to scan onto CRIS
or record checklist has been undertaken

PATIENT DETAILS

Last name:

First name:

Date of birth:

NHS Number:

Date of Procedure:

*If the NHS Number is not immediately available, a temporary number should be used until it is

**The checklist is for
Radiology Interventions ONLY**

This modified checklist must not be used for other surgical procedures.

www.nrls.npsa.nhs.uk

© National Patient Safety Agency 2010. Copyright and other intellectual property rights in this material belong to the NPSA and all rights are reserved. The NPSA authorises UK healthcare organisations to reproduce this material for educational and non-commercial use.

Ref: 1121 March 2010

Figure 8.2 Shows the WHO checklist for Radiological Intervention.

8.2 Aim of the study

The main aim of this study is to analyse the WHO checklist for Radiology Interventions to see the compliance of the IR team before and after intervention. Furthermore, to explore the relationship between the WHO checklist and the rate of the healthcare errors in the intraoperative phase of the IR procedures both in the pre- and post-intervention phase.

The study aims to answer the following questions:

- Are all essential checks of the WHO checklist for radiology interventions completed as they should be?
- Which phase of the checklist has the most flaws?
- What is the frequency and types of the error categories specific to the WHO checklist?
- Comparison of the rate of the mean total healthcare errors before and after intervention.
- Is there any correlation between the compliance to the items of the WHO checklist and the total number of intraoperative healthcare errors in the pre- and post-intervention phases.
- Correlation between the degree of the WHO checklist completion and the severity of the occurring healthcare errors in the intraoperative phase.

Parts of the WHO checklist for Radiological Interventions

The WHO checklist for Radiological interventions as can be seen in Figure 8.2 is composed of three phases, namely: Sign in, time out and sign out. All these phases are to be read aloud.

Sign in.

Similar to Surgery, the sign in starts before induction of anaesthesia when the patient is awake (WHO, 2008) (RCR, 2012). However, the sign-in in IR procedures is slightly different from Surgery. In Surgery, the conductor of the checklist (usually a nurse) and an anaesthetist are enough to be present with the patient to complete this phase (Figure 8.1). However, all the IR team members need to be present for this phase to complete the WHO checklist. Therefore, technically, the sign-in and the time out phase is combined here (Figure 8.2).

A coordinator (in the department chosen for study _ a circulating nurse for example) volunteers to read out loudly the items of this part starting from letting each member of the IR team including any student or observers to introduce themselves by name and role. The introduction step is important to make everyone feels that they are involved and to introduce themselves at least if they are new. Sometimes the coordinator, especially if the team are well known to each other, might say "Are all the team members known to each other?" (WHO, 2008).

Essential steps include " the patients confirm their identity, the procedure and their explicit consent" to make sure that both the patient and the treating team are on the same page.

Among essential checks is to make sure that all the connected machines to the patient are working well, such as oximetry and monitor. Checks for medication needed, including antibiotics within 60 minutes from the start of the procedure, anticoagulation prophylaxes, and analgesics. All the necessary blood tests are reviewed and are up to dates, such as the coagulation profile or renal function test. All the needed equipment is ready and by the side before starting the procedure to avoid delay or inability to complete the procedure. Any loss of blood more than 500 ml needs to be counted for and addressed. Any concern or critical or unusual steps the primary operator_ the IR consultant needs to inform the team about should be discussed here before the start of the procedure (Haynes et al., 2009a) .

These steps should not be too much disruptive if performed professionally. However, during the sign-in, the team must be in a pause. No other activities such as draping or scrubbing, must be performed. Not only does this pause allow the IR team to prevent missing important details about the case but also motivate the team to focus on the necessary communication and the required tasks to accomplish the procedure safely.

Time out

As it is seen in figure 8.2, the time out phase is a separate phase in IR and is only used when general anaesthesia is performed. The time-out phase is combined with the sign-in phase. The time-out means a pause. The IR team need to complete these phases before any needle injection for local or regional anaesthesia. During the time-out, all the IT team members need to pause and do not do other activities. Each member needs to introduce himself or herself by telling their names and role clearly and loudly enough so as all the IR room attendance hear it. All the critical steps of the procedure need to be discussed. All the checks and the requirements of the

procedure including site, side, and access point (if applicable), infection, glycaemic and thrombosis prophylactic check. Also, the check whether the patient is warm enough and whether there is enough necessary equipment is needed to be cleared in these phases. If the procedure requires general anaesthesia, the anaesthetic checks will be added, such as airways check (Figure 8.2).

Sign-out

This phase is performed when the IR team are still present in the Angio suite after the procedure is finished. During this part, a member of the IR team confirms the name of the patient the site, the side, the procedure's name, the equipment used, and any implanted devices are documented. Not only this, but any equipment fault should also be documented to get fixed or replaced before the next procedure. The leading operator, usually the consultant IR, should convey the main advice and recommendation about the post-procedure care to the IR nurse and the relevant staff for a safe handover (RCR, 2012).

8.2.1 What is defined as good compliance to the WHO checklist for Radiology Intervention?

The WHO, NPSA and the RCR use a guide for completing an ideal WHO checklist (WHO, 2008) (RCR, 2012). Any deviation from this is regarded as an error.

An example of a proper WHO checklist would be: "All the IR team members are present inside the angiography room before starting a procedure, while one of the team members volunteer to read out loudly the items of the checklist starting from the sign-in phase. All the team members must pause and stop doing any other activity, including scrubbing, or preparing the equipment while the WHO check being readout. No part of the checklist should be skipped unless it is irrelevant to the procedure, for example, general anaesthesia questions.

8.3 Material and Methods

The WHO checklist-process for Radiology Interventions studied in 109 IR procedures. Two cohorts of patients were studied: Fifty-five patients were observed from 03/11/2015 to 21/06/2016 prior to the WHO task allocation to IR consultants/ Fellow. Another 54 patients were observed from 27/07/2022 to 24/11/2022 after WHO task list allocation to IR consultant/Fellow. The FERERI error capture tool, which was developed and validated in chapter 5 and 6 of this thesis respectively was used to record the different items of the WHO checklist for radiology intervention (please refer to chapter 5 and 6 of this thesis for further details about the FERERI tool).

8.3.1 Data collection

All the WHO checklist procedures performed by the IR team were observed by a single observer_ the author of this thesis. The observer did not interfere if there was any inadequacy in the process of the WHO checklist execution. If no WHO checklist was done, this was regarded as a failure. The following scenarios were regarded as error as well: If any of the items of the checklists were omitted such as antibiotic prophylaxis not done within 60 minutes from the local anaesthesia start, or if there was no full pause for the time-out, or any staff member absence during the sign-in/ time-out phase, or staff leaving before the sign-out phase.

The data were collected by using a validated FERERI tool (see chapter 6). The data then was transferred into a master Microsoft spreadsheet, from which it was transferred into an SPSS statistical programme (Statistical Package for Social Science, version 26). All the categorical variables were coded. The essential adherence to the WHO checklist was checked by using the "0" if the checklist was "not done or inadequately performed" and "1" if it was performed adequately. The essential check was considered adequate if all the items of Table 8.2 were checked adequately. The essential checklist adherence was adapted from previous studies performed in general Surgery and the guidelines of WHO and the RCR (Haynes et al., 2009a) (WHO, 2008, RCR, 2012).

8.3.2 Intervention

The IR team attended a short training session (2 hours) conducted by the safety group of our hospital (St Marys Hospital_ Imperial College London) in which all the aspects of a good compliance to the WHO checklist for radiology intervention were taught. The outcome of this training session was to allocate the task of the initiation and the completion of the WHO checklist for radiology intervention to the attending IR consultant or the performing IR registrar or the IR fellow. This was to ensure that all team members are adhered to the recommendations. This new task allocation was to make sure that the process of the WHO checklist completion is transparent to eliminate blurriness of who is going to be responsible to initiate and complete this safety checklist.

8.3.3 Setting:

The study is conducted at the IR department of St Mary's Hospital/ Imperial College London NHS trust, which is a tertiary vascular and IR centre. The IR team of this department are trained and have experience in performing various types of IR procedures from simple to complex procedures. The IR team are quite familiar with the environment where they get observed by researchers. They have taken part in numerous research studies ranging from participation in different quality improvement surveys where they have been regularly observed in different types of research.

8.3.4 Patients

Any adult patient aged 18 years or older who were booked by the IR department to undergo an IR procedure were included.

8.3.5 Procedures

- **Inclusion Criteria:**

All the IR procedures which were purely performed by the IR team were included.

- **Exclusion Criteria:**

Any procedure which is jointly performed by other teams such as EVAR (Endovascular Abdominal Aortic Aneurysmal Repair), which is jointly performed by the vascular surgery team. The reason is to keep homogeneity of the study population and to exclude confounding factors.

8.3.6 Definition of healthcare errors in this study.

The healthcare errors throughout this thesis are defined as "acts of omission or commission in planning or execution that contribute or could contribute to unintended results" (Grober and Bohnen, 2005).

8.3.7 Definition of degree of severity of healthcare errors used in this study.

Using the data from the literature (Catchpole, 2010, ALBAYETI et al., 2011, Morbi et al., 2012, Mason et al., 2013) with the previous studies in the previous chapters of this study (see chapter 3, 4 and 6), a classification healthcare errors according to their degree of severity is performed (see Table 7.2).

Table 8.1 Definition of minor, moderate, major healthcare errors and errors-caused cancellation used in this study with examples	
Terms	Definition
Minor Healthcare errors	Any errors that cause no pause to the IR pathway or procedure or a pause for up to 5 minutes or cause no or minor patient harm or no need to resolve or easy to resolve. Examples: In a lumbar puncture procedure: Communication error occurred under the subcategory “Misleading” where the IR Consultant asked the radiographer for AP (anterolateral) projection when she meant lateral. This error did cause only several seconds pause of the procedure without patient harm. The error is easily fixed. In a procedure called Hickman line insertion, while the IR consultant tried to locate the vessel for the puncture site “The ultrasound machine switched off suddenly as the wire unplugged because the machine was too far from the wall socket. The CN changed the location of the plug”. This error causes a pause of less than a minute and did not cause any patient damage. In a procedure called Iliac Angiography with angioplasty there was an Equipment_ related error under the subcategory “Unavailable” in which the circulating nurse had to leave room to obtain a particular stent not available in the IR Angio-room. This error caused a pause for less than a minute with no potential to cause patient harm. The resolution was easy.
Moderate Healthcare errors	Any errors that cause pause to the IR pathway or procedure or a pause between 5- 30 minutes or cause moderate patient harm or moderately difficult to resolve. Examples: In a lower limb angioplasty procedure, there was a communication error under the subcategory of “non-heard misheard”, The IR consultant requested a 180cm long Terumo wire, but the CN opened a 150cm long wire and IR consultant had to replace it again after deployment into the target artery. This error is regarded as moderate as it caused a wasted time of more than 5minutes but less than 30 minutes. Also, it had still a potential to harm the patient as the wrong stent was actually deployed into the targeted artery when realised it is short. Although the error could have been easily fixed had the circulating nurse communicated well with the IR consultant. In a procedure which was “Left antegrade lower limb angioplasty” there was a planning error that caused a delay of 25 minutes. The context of the error was as follow: “While the team finished the procedure and transferred the patient back on to his bed the IR consultant called the IR fellow to do a diagnostic angiography run for the whole left leg. Therefore, the IR team had to transfer the patient back on the angio-room table and do another angiography run. In another IR procedure_ IVC filter insertion, the IR Consultant was absent as the consultant was outside seeing another patient in the ultrasound room. The patient was on the operative table and the IR team had to wait for the IR consultant for 20 minutes to start the procedure. Although there was no patient harm in this case, but the pause was more than the time window for a minor error.
Major healthcare errors	Any errors that cause a pause to the IR pathway or procedure for more than 30 minutes or cause severe patient harm, such as bleeding for example, or very difficult to resolve. Examples: The patient’s position was not straight, and the IR team could not figure out the reason, so while the needle was in the artery of the puncture site, they manoeuvred the patient to get a straight position which would pose a safety hazard as this might cause bleeding of the punctured artery”. In a liver biopsy procedure, the box of dry ice samples contained two tube samples for two different patients and the referring ward staff who handed over this box to the IR nurses did not

	mention that there are two separate tube samples for two different patients. The IR nurse did a check and just found out the name on the tube does not match with the name of the patient before handing over the tube sample to the IR operative team to transfer the liver biopsy sample. This was rectified and the correct sample tube handed over ultimately”. In an IR procedure_ femoral line insertion, the referring ward nurse did not check whether the patient has allergy to any medication. However, during clerking of the patient by the IR nurse in the preoperative stage, the stated he is allergic to some antibiotic without knowing the name of it. The main category of the error is safety awareness” and the subcategory is “checks not done”.
Errors led to cancellation of the scheduled IR procedure	Any error, because of which the IR procedure was cancelled. Examples: A prostate artery Embolisation procedure was cancelled because there were two other long complex cases namely Endovascular aortic aneurysm repair (EVAR) and Thoracic endovascular aortic aneurysm repair (TEVAR) booked on the same day and there was only one IR consultant available in the I department on that day without IR assistant doctor”. This failure is considered secondary to a planning error in which no proper planning was made when IR procedures were booked by the IR department. When booking IR procedures, the complexity and the projected length of each procedure should be considered to make the list feasible as well as the IR team availability on that day. Also, this failure could be secondary to management error under the subcategory of “personnel”. An Angioplasty procedure of the right lower limb was cancelled because of lack of communication between the appointment team of the referring ward and the patient. The patient did not turn up for his appointment. There should have been a better communication with the patient at different stages after booking had been made to ensure the patient is compliant or to allocate the slot to another patient in advance if that was not the case. Although this error could be labelled patient-related error as well with a subcategory “compliance”. A procedure for” Iliac artery stenting” was cancelled because there was no bed available in the destination ward. This was regarded as both planning error and lack of communication error.

Table 8.2 The Essential safety measures that were needed for adherence to the WHO checklist for Radiology Interventions		
Verbal confirmation of the identity of the patient	Yes ()	No ()
The side, site and the procedure name are checked.	Yes ()	No ()
Putting the patient on a monitor to check vital signs including the pulse oximetry before initiation the WHO checklist	Yes ()	No ()
The presence of at least one peripheral intravenous catheters or a central venous catheter before injection of the local anaesthesia	Yes ()	No ()
The check of the estimated blood loss of 500 ml or more	Yes ()	No ()
Verbal confirmation of administration of prophylactic antibiotics within 60 minutes before incision or (NA in case of pre-existing infection for example) Checking for Allergy	Yes () Yes ()	No () No ()
Checking Equipment issue	Yes ()	No ()
Checking Glycaemic control	Yes ()	No ()
Labelling All specimen including patient's ID	Yes ()	No ()
Adapted from (WHO, 2008) (Haynes et al., 2009a), and (RCR, 2012)		

Table 8.3 Surrogate measures of compliance		
Pause of the team during Sign-in/ time-out phase	Yes ()	No ()
Equipment checks	Yes ()	No ()
briefings, and debriefings	Yes ()	No ()
Adapted from (Haynes et al., 2009a) and (RCR, 2012).		

8.3.8 Outcome to measure

- Recording adherence of the IR team of the essential criteria mentioned in (Table 8.2).
- Recording adherence to the surrogate criteria which are in the (Table 8.3).
- Phases of the WHO checklist in which the failures occurred, namely sign-in/time-out and sign out.
- The exact occurring failures during the WHO checklist implementation (Table 8.4).
- Correlation between the mean total number of healthcare errors in the IR procedures and the adherence to the WHO checklist.
- The difference in the mean total number of healthcare errors in the pre- and post-intervention phases.

Table 8.4 Categories of the WHO-checklist-related Errors
1= team did not pause during sign-in (or talking, scrubbing, or not all the members present). 2= No sign in done. 3= Parts of sign in skip. 4= No sign-out done/ or inadequate. 5= No error. 6= No WHO check done at all.

		Faraidoon Rawf: 1= Not performed at all 2= Performed but inadequate 3= Properly Performed		Faraidoon Rawf: 1= Sign in 2= Time out 3= Sign out 4= No error 5= All phases		Faraidoon Rawf: 1= Team did not pause during sign in (or talking, scrubbing, or not all the members present etc). 2= No sign in done 3= Parts of sign in skipped 4= No signout done/ or inadequate 5= No error 6= No WHO check done	
				During which Phase of Checklist Error occurred?	What was the error		
Date		Procedure	WHO checklist			Comment	
03 November 2015	1	IVC FILTER REMOVAL	2	3	4	No WHO checklist signout done	
03 November 2015	2	U/S guided drainage of left Subphrenic collection	2	3	4	Procedure finished at 14:27 No signout WHO	

Figure 8.3 A screenshot of the Master Microsoft Excel sheet with all the data codes

8.3.8.1 Statistical studies used.

Using statistical Package for Social Science (SPSS) version 25, percentages, or frequencies of demographics of the study population were calculated using descriptive statistics. Furthermore, various characteristics of the WHO checklist were studied.

Using Chi square tests, the association of the mean total number of healthcare errors in the intra-procedural phase of the IR procedures was examined with the degree of WHO checklist completion before and after intervention. The strength of the association between these variables was assessed using Cramer's V coefficient with a value of 0 meant no association versus perfect association for a value of 1.

Using independent Mann Whitney U test, the distribution of the mean total number of healthcare errors in the intraoperative IR procedures was compared in the pre- and post-intervention groups. Using Kruskal Wallis test, the association.

To study the difference in the mean total healthcare errors among the subgroups of degree of completion of the WHO checklist, independent-Samples Kruskal-Wallis test was conducted. A p value of 0.05 or less was considered statistically significant throughout this thesis.

8.4 Results

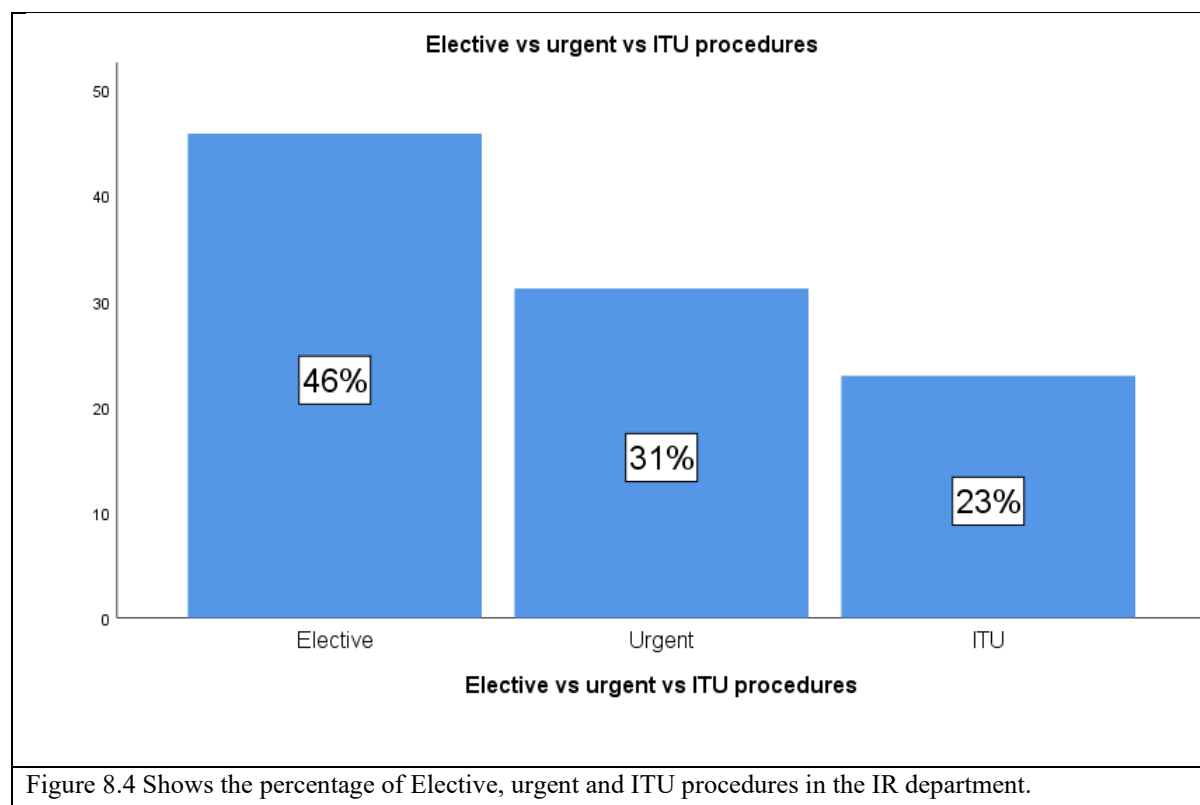
A trained observer (the author of this thesis) observed 109 consecutive IR procedures, fifty-five patients before intervention followed by 54 patients after intervention.

8.4.1 Patients' demographics and other parameters.

The median age of the patients in the study samples was 63-year-old [Std. Deviation 16.482], Range = 75 (18_93). Out of these 109 patients, 57 (52.3%) were male versus 52 (47.7%) were females. The mean duration of the IR procedures was 61.60 minutes.

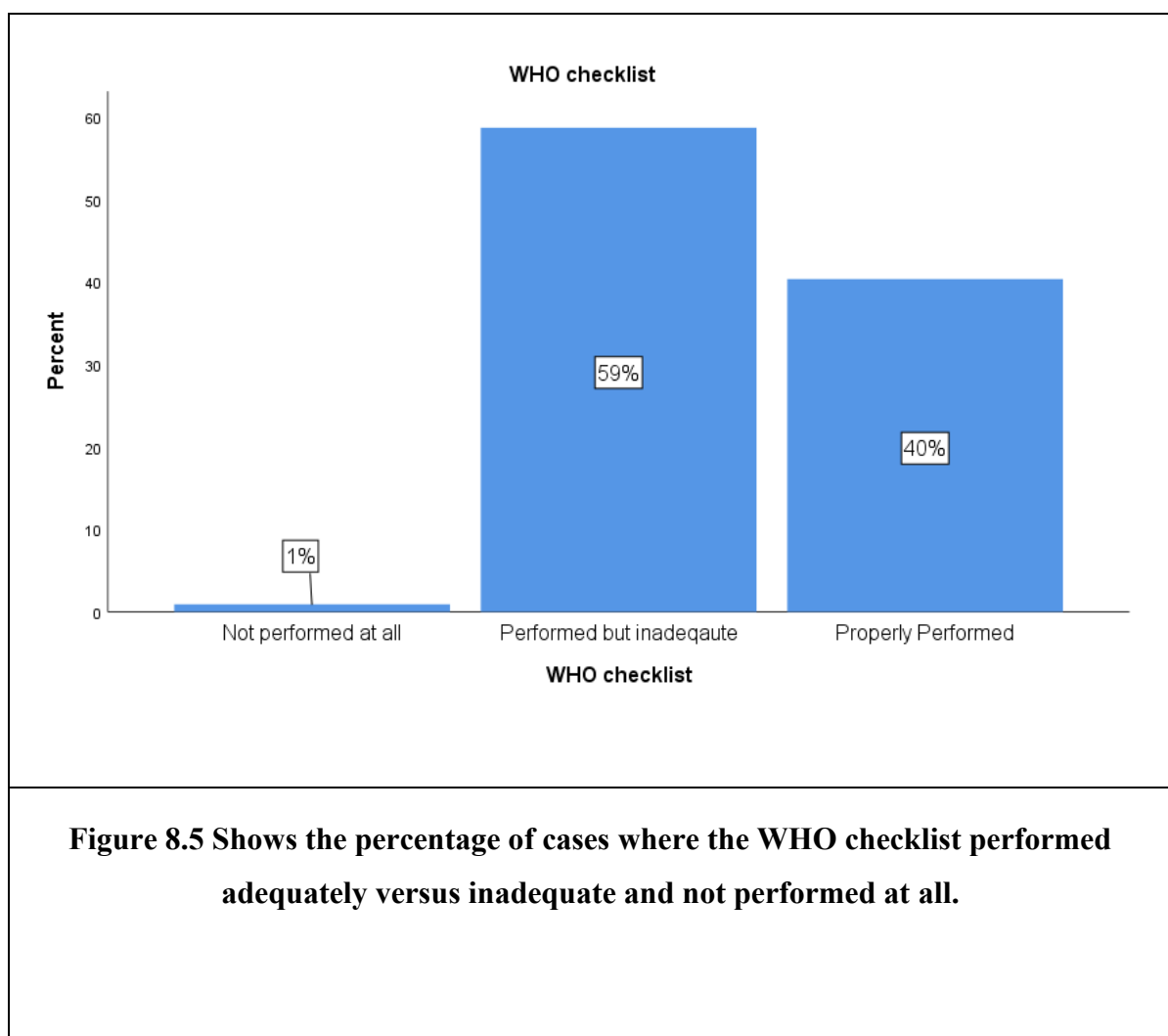
Elective procedures were the highest performed IR procedures at a frequency of 50 (46%) followed by Urgent procedures 34 (31%) and ITU procedures 25 (23%) respectively.

Referral from other wards comprised the highest proportion of the IR procedures at a rate of 46 (42.2 %) followed by Vascular Ward 32 (29.4 %) and day cases 31 (28.4). Out of the total number of the IR procedures, 68 (62.4%) of them were vascular versus 41 (37.6%) non-vascular procedures.



8.4.2 WHO checklist characteristics

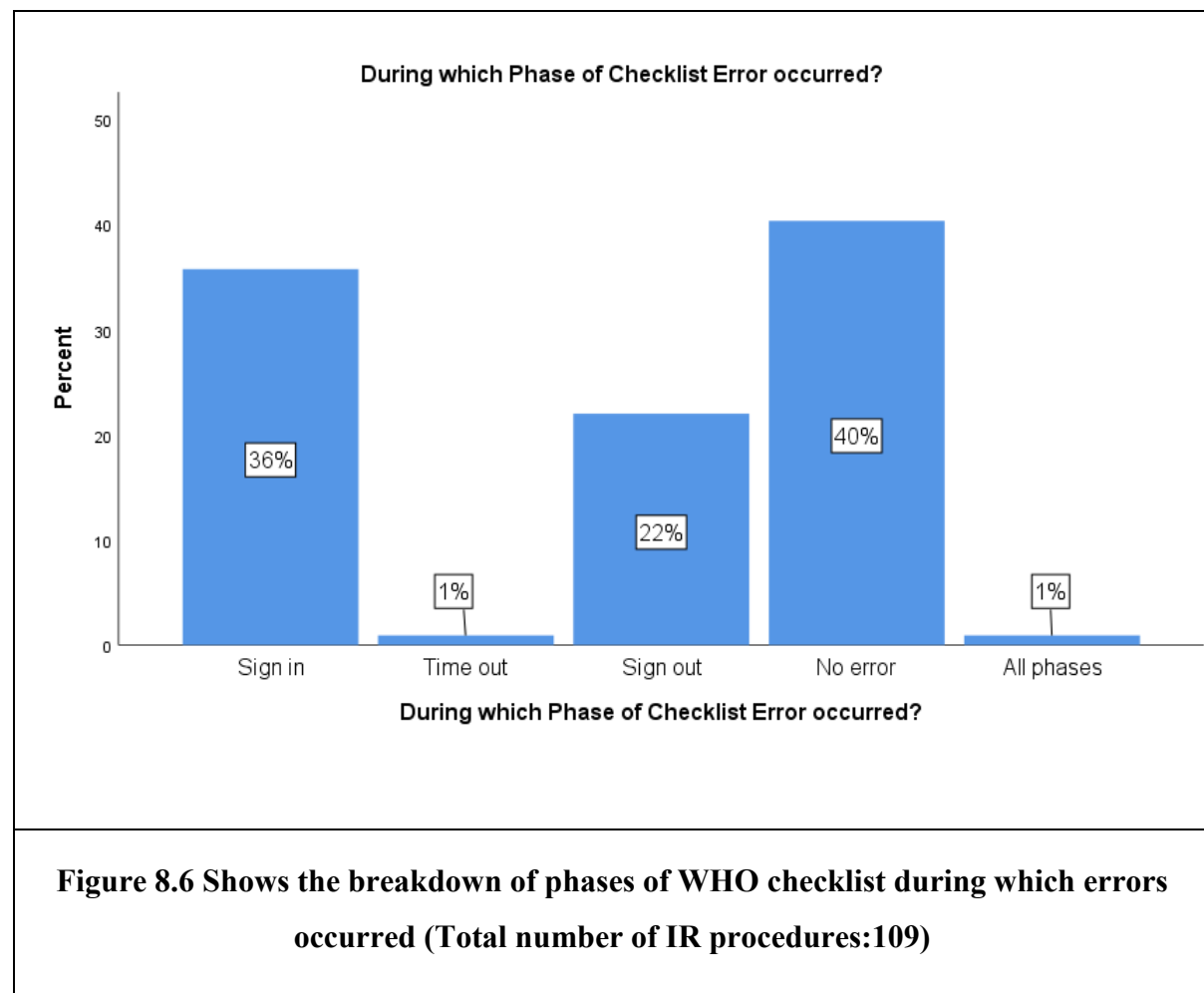
In 99% of the cases, the WHO checklist for Radiology intervention were initiated compared to only 1% of cases, in which they were not performed at all. In 59% of cases, the WHO checklist was performed inadequately, while in 40% of cases they were performed properly (Figure 8.5).



The case in which no WHO checklist was performed at all was an Naso-jejunal tube insertion on a 50-year-old female patient who was referred from the GI ward to perform this procedure urgently. The WHO checklist was deemed not necessary by the performing IR fellow.

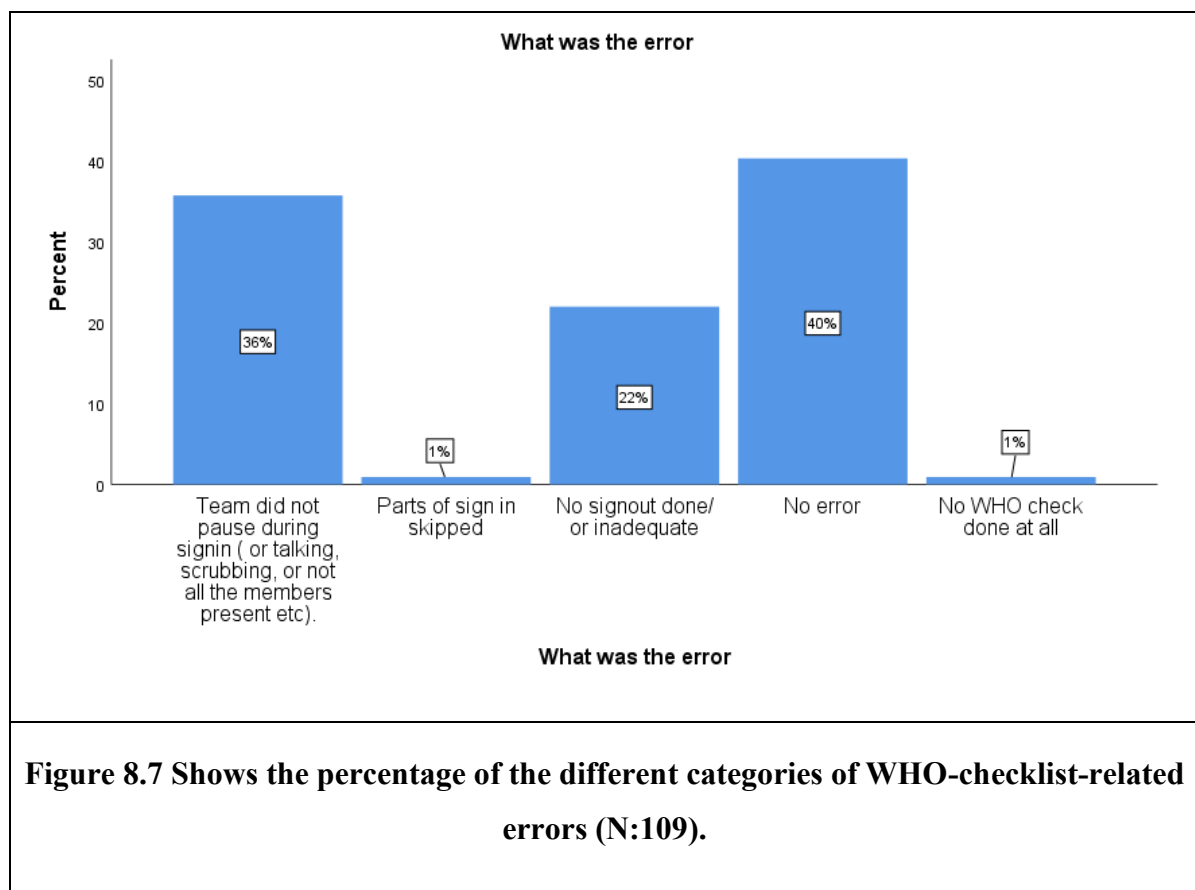
8.4.3 During which phase of the WHO checklist healthcare errors occurred?

Out of the total 109 WHO checklists, 44 (40%) were properly performed throughout all phases. From the other 60% of the procedures, 39 (36%) contained errors in the sign-in phase versus 24 (22%) in the sign-out, 1 (1%) in the time-out phase and 1(1%) in all phases (Figure 8.6).



8.4.4 Category of errors occurred during the WHO checklist.

In 44 (40%) of cases, no error related to the WHO checklist was recorded. Out of the remainder 60% of cases, 39 (36%) of the cases were recorded in which the IR team did not pause during the sign-in phase. For example, the team were scrubbing or engaging in irrelevant talk or involving in other activities related to the case preparation while the WHO checklist was read aloud, or it happened that one or more member of the IR team were not present at the time when the WHO checklist was read out. In the other 24 (22%) of cases, no sign-out or inadequate sign-out was performed by the team. WHO checklist was not done at all or part of it was skipped in the 2 (1%) of the cases. (Figure 8.7).



8.4.5 Comparison of the mean total number of healthcare errors pre- and post-intervention

The mean total number of healthcare errors before intervention was 14.35 [Std. Deviation 10.603] versus 7.74 [Std. Deviation 7.367] after intervention. Using Independent Samples Mann-Whitney U Test, the mean total number of healthcare errors was significantly lower after intervention (P value is <001).

8.4.6 Comparison of the severity of the healthcare errors in the observed IR procedures pre- and post- intervention

The frequency (percentage) of the severity of the healthcare errors during the intra-operative phase of the IR procedures pre- and post- intervention before intervention were as follows: Errors with no patient harm decreased from 38 (69%) to 22 (41%), those with mild Patient harm decreased from 12 (22%) to 3 (6%), those with moderate patient harm from 2 (4%) to 1 (2%) (Figure 8.8).

However, those severe Patient harm increased from 0 (0%) to 1 (2%) and those with the harm is not known increased from 3 (5%) to 27 (50%).

A Chi-square test of independence was performed to examine the association between the severity of healthcare errors before and after introducing the intervention by the IR department. The analysis revealed a significant association between the variables, [Pearson Chi-Square = 30.193 (4), p-value < .001].

Additionally, we wanted to measure effect size by knowing the strength of the association between the severity of the healthcare errors in before and after-intervention situation. The strength of the association between these variables was assessed using Cramer's V coefficient. The obtained value of [Cramer's V coefficient was .526, P, <.001] which indicated moderate to strong association between the severity of the healthcare errors.

In summary, the results indicate a moderate to strong association between the "before and after intervention" and "severity of healthcare errors" variables, and this association is statistically significant. Table 8.5 demonstrates some example of the healthcare errors which were discovered and fixed via the implementation of the WHO checklist.

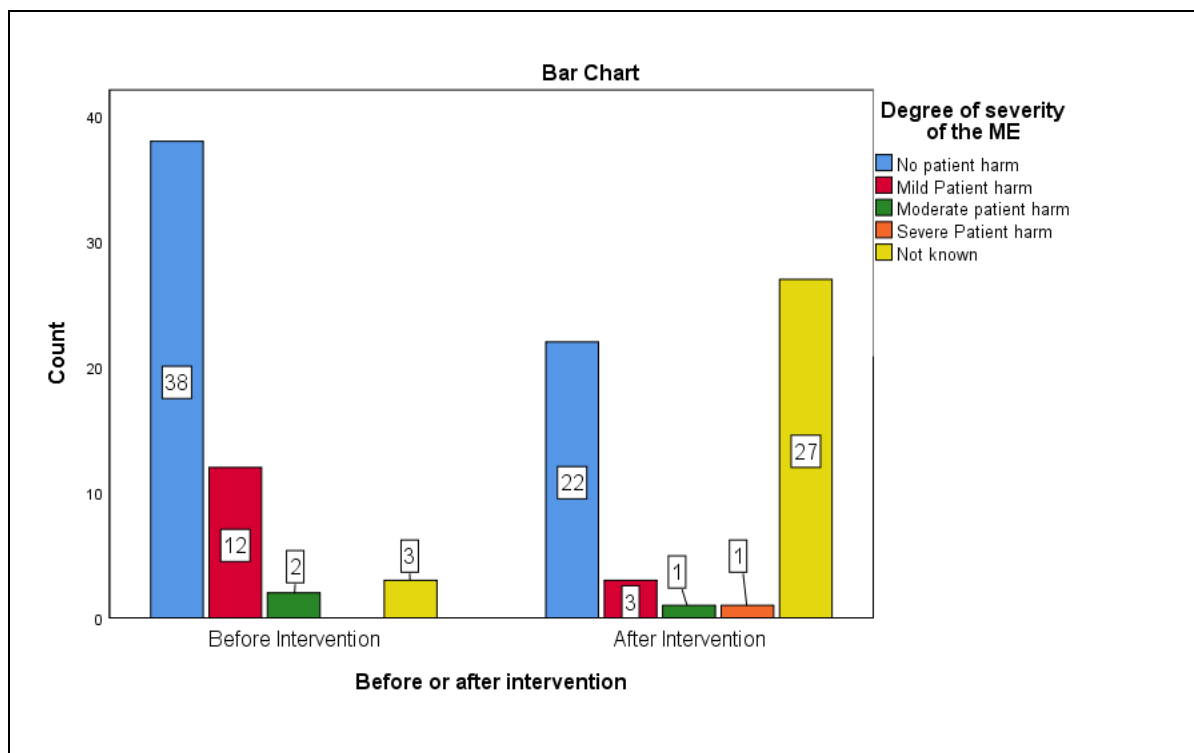


Figure 8.8 Shows the frequency of the severity of the healthcare errors in the intra-operative phase of the IR procedure pre- and post-intervention

Table 8.5 Shows examples in which the WHO checklist allowed fixing some errors

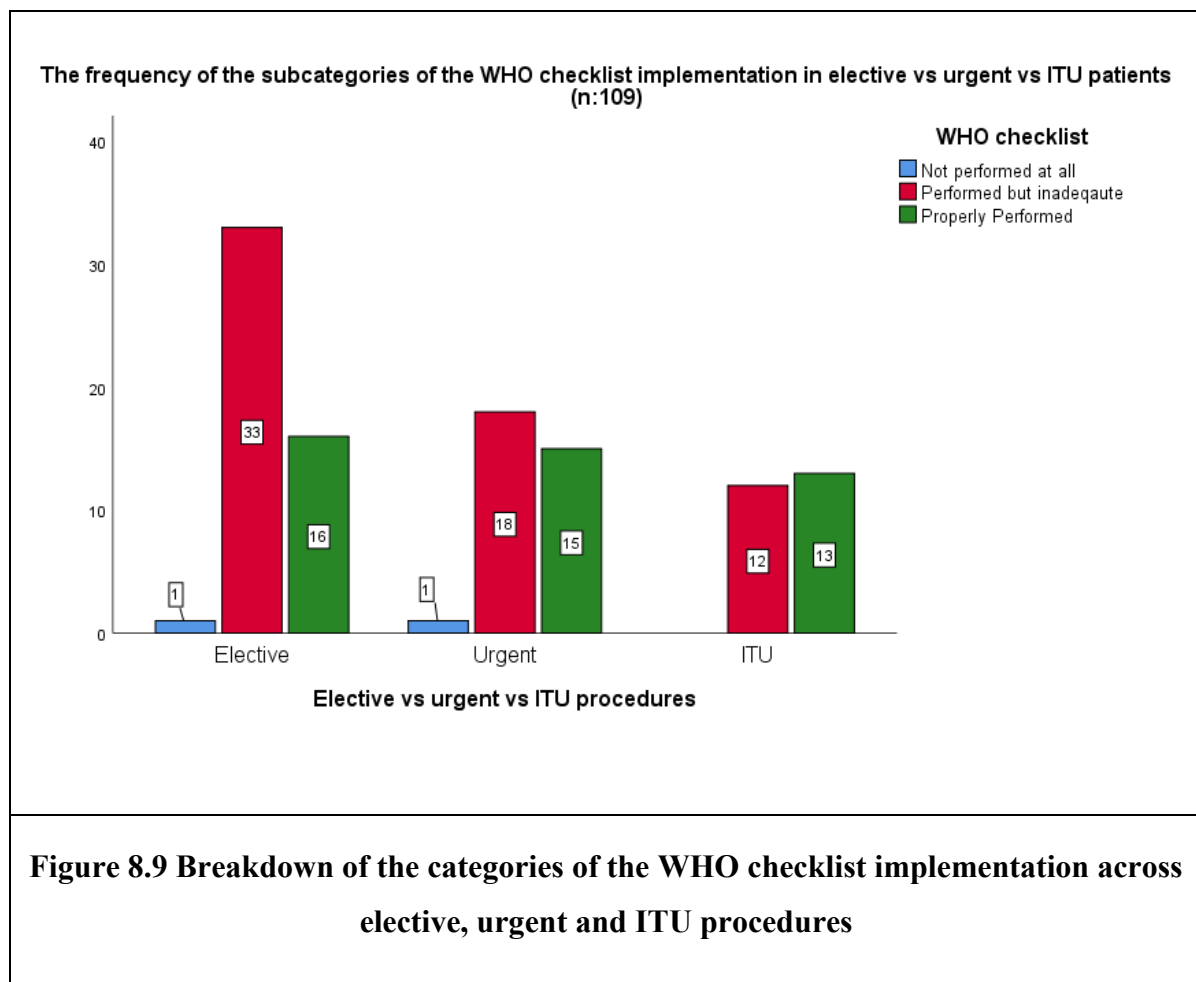
In an angioplasty procedure, during WHO checklist for radiology intervention the team fixed the incorrect C-arm position of the fluoroscopy machine after checking it with the RDG.

During the sign-in phase of a WHO checklist process in a TIPS (Trans jugular Porto-systemic shunt) procedure on an ITU patient on 10/08/2022, the IR team found that there was no consent form on the system with no request on the system for the procedure. So, the anaesthetic and the referring team arranged for a new consent form with the IR consultant.

In an angioplasty of the right lower limb on 15/09/2022, the IR team changed the sedation plan after they discovered during the WHO checklist review that the patient's blood pressure was high.

8.4.7 The distribution of the subcategories of the WHO checklist implementation according to the type of the IR procedures

Using, Chi-Square tests, the association of the degree of implementation of the WHO checklist was examined across elective, urgent and ITU IR procedures. The analysis revealed no statistical difference [Chi-Square tests value (df) = 3.653 (4), P, 0.455]. The frequency of different subcategories of the WHO checklist procedure is shown in (Figure 8.9).



8.4.8 Association between the total number of healthcare errors in the intraoperative phase and the implementation of the WHO checklist by the IR team

Mean- total- number of healthcare errors in cases when the WHO checklist was performed adequately is compared to cases when the checklist was inadequately performed and cases when the WHO checklist was not performed at all. Using the Independent-Samples Kruskal-Wallis test, this difference was measured. There was a statistically significant difference in the mean total number of healthcare errors in the intra-procedure phase across the subcategories of the WHO checklist [Kruskal-Wallis $H = 12.545$ (degree of freedom = 2), (P-value = 0.002)].

8.4.9 The difference in the implementation of the WHO checklist in different team group number

By performing the Independent-Samples Kruskal-Wallis Test, no difference was found across different WHO checklist group with different numbers of the team members. In other words, having a larger or smaller number team does not mean better or worse WHO checklist implementation (P-value = 0.901).

8.4.10 Comparison of the degree of implementation of the WHO checklist in pre- and post-intervention phase

Using Chi-Square Tests, the association of the implementation of the Who checklist was compared in the two cohorts of IR procedures: before and after intervention. A statistically significant association was found [Pearson Chi-Square = 45.518 (2), p-value < .001].

Additionally, we wanted to measure the effect size by knowing the strength of the association between the degree of implementation of the WHO checklist before and after-intervention. Cramer's V coefficient was used which revealed moderate to strong association between these variables [Cramer's V coefficient was .660 P, <.001].

The number of WHO checklist procedures which was inadequately performed decreased from forty-nine pre- intervention to 14 post-intervention, while the number of properly performed WHO checklists increased from 5 in the pre-intervention cohort to 39 post-intervention. On the other hand, one IR procedure was found in the post-intervention in which no WHO procedure was performed at all (Figure 8.5).

8.4.11 Association between the degree of implementation of the WHO checklist and the duration of the IR procedures

Using Kruskal Wallis test, the median total time of the IR procedures was the same across different subcategories of the WHO checklist implementation (P, 0.848).

8.5 Discussion

Implementing checklists and briefings have shown to enhance safety and decrease flaws in many risky sectors including healthcare (Evans et al., 2007) (Lingard et al., 2005) (Hales and Pronovost, 2006) (Lingard et al., 2008) (Haynes et al., 2009a).

As described in the methodology section, a new intervention has been implemented by the department of the IR in the studied hospitals (Hospitals under Imperial College London NHS trusts). Officially allocating the task of initiating, implementing, and assuring compliance with the WHO checklist to the attending IR consultant or the performing IR fellow was studied to see its impact on the rate of the healthcare errors related to the WHO checklist and in general.

The current study demonstrates a statistically significant decrease in the rate of the healthcare errors from 14.35 [Std. Deviation 10.603] before intervention to 7.74 [Std. Deviation 7.367] after intervention ($P, <001$). The study also shows a significant increase in the rate of adherence of the IR team to the WHO checklist after introduction of a simple intervention, which involved assigning the initiation and the completion of the WHO checklist to the attending IR consultant or the performing IR doctor. This is to ensure that the checklist is consistently completed by the leading practitioner of the IR team. This initiation has been made compulsory by the IR department to all IR consultants or the main IR doctor in any IR procedure. This agrees with the literature in this area (Puttick et al., 2016).

This is the first study of its kind according to the knowledge of the author of this thesis which examines a simple, yet a new intervention and its impact on the outcome of the WHO process and the occurring healthcare errors through the intraoperative phase of the IR procedures.

It has been stressed previously that limited data in the literature is available which explore the impact of the WHO checklist for radiology intervention on day-to-day practice or to improve patient safety (Alexander et al., 2021). In their systematic review about checklists for image-guided interventions, Alexander et al., (2021) only found two studies among the sixteen retrieved studies which reported the outcome measures after checklist implementation, one of which was only a survey.

In this survey study, Fargen et al. created an Endovascular Safety Checklist which is composed of twenty items _modified from the WHO surgical safety checklist and implemented it in their interventional neuroradiology department. They conducted a before-and-after checklist

survey to evaluate the effect of the checklist on patient safety. 71 and 60 procedures were included before and after the checklist respectively. Staff members reported 35.2% near-miss adverse events before the checklist which statistically significantly decreased to 10.0% after the checklist ($P = 0.001$) (Fargen et al., 2013).

In the other study, Corso et al., (2014) recorded a decrease in the rate of the complications by using a time-out checklist but had too few complications to allow any conclusions to be drawn (Corso et al., 2014).

There is evidence to suggest that adverse events or even a single never event incident is mostly caused by many underlying factors, usually a mixture of unsafe systems (An example of which would be unorganised procedure list) combined with unsafe behaviours (an example would be disregard or disrespect towards junior or less ranked staff). Both groups of factors lead to a compromise in the adherence to the safety checklist process_ such as WHO checklist for surgery or radiology intervention (NHS_England, 2014). This suggests that leadership within the team is required to prevent unsafe behaviours.

Previous research examined barriers to an optimum adherence to the safety checklists in IR specialism. One of the important highlighted barriers was lack of leadership. In other words, there was no team member who had been assigned by the IR department to take the responsibility of promoting, organising the process of WHO checklist completion. One of the proposed solutions to increase the uptake of the safety checks by staff is the introduction of a safety champion, who promotes and enables an accurate safety check completion (Puttick et al., 2016).

However, it is not clear whether this safety champion role is a fixed role assigned to a specific person in the IR team or an alternating role assigned on rotation. Also, there is no indication as to which job role the safety champion was assigned to. As pointed out earlier in the previous paragraph that one of the root causes that hinder a proper delivery of a safety checklist is unsafe behaviour where junior staff are not listened to as should be or even ignored.

Therefore, arguably there are two important factors that need consideration in assigning a person to initiate the safety checklist in the IR department. Firstly, there should be a fixed job role to whom the delegation of the safety check initiation and completion be assigned. Secondly, this job role should be at least at the centre of the IR team from a hierarchical point of view. For example, the IR consultant role or the main performing IR doctor would be responsible to

initiate the safety check for all the IR procedures. By this, we make sure that all the steps of IR procedures are well accounted for when reading out the safety checklist. It is the IR consultant who knows exactly what steps are required in specific cases.

The rate of initiation of the WHO checklist in the current study is high measuring 99%. This is in line with the published data. The RCR- Audit, which was performed in 2016, showed a 98% compliance rate compared to 94% in 2012 (RCR, 2012).

There was only one case, in which no checklist was performed which was a "NASO-JEJUNAL TUBE INSERTION". This procedure is a non-vascular simple procedure (based on the judgment of the performing IR doctor) which demonstrates three healthcare errors in the intraoperative phase. The duration of the procedure was 13 minutes and finished successfully. This procedure was performed by an IR fellow who deemed completing the WHO checklist unnecessary for this case.

The 2016 version of the RCR audit supports the finding of the current study and reveals that there is generally low compliance to perform the WHO checklists in short procedures, primarily if they are not performed in the IR suite. There is an overwhelming perception that these procedures are of minimal risk categories and adding the WHO checklist will only decrease the flow of the procedures (RCR, 2012) (Ariyanayagam et al., 2019). Another explanation as to why the checklist did not take place is that the leading operator was a trainee IR fellow who might have lacked the necessary leadership skills to motivate the team to perform the checklist. Lack of compliance to safety checklists are recognised in the literature (de Vries et al., 2009, Fourcade et al., 2012, Puttick et al., 2016). Puttick et al. (2016) identified six barriers to safety checklist uptake, among which are lack of leadership where no team member is assigned to take the lead to enhance the completion of the safety check and make sure is documented in every case.

Another barrier to endorse safety checklist is an attitude towards and perception of staff of the safety checklist. Some staff feel that the checklist was only adding bureaucracy and unnecessary tasks to their ones (Morbi et al., 2012) (Puttick et al., 2016).

Although the essential safety adherence is met in almost all cases, the current study highlights several quality features that need attention. In 59% of cases, the WHO checklist was performed inadequately versus 40% of cases they were performed properly. This agrees with the previous studies. Checklist completion rate varied from 28 to 100% in studies conducted in the IR

specialty ((Alexander et al., 2021)). (Alexander et al., 2021) Similar results have been reported in the surgical literature (Rydenfält et al., 2013).

Using Chi-Square Tests, the association of the implementation of the Who checklist was compared in the two cohorts of IR procedures: before and after intervention. A statistically significant improvement in the degree of WHO checklist completion is found after intervention. The number of WHO checklist procedures which was inadequately performed decreased from forty-nine pre- intervention to fourteen post-intervention, while the number of properly performed WHO checklists increased from 5 in the pre-intervention cohort to 39 post-intervention. [Chi-Square = 45.518 (2), p-value < .001]. This suggests that reverting barriers which hinder compliance towards the safety checks would lead to change in culture and hence improvement in the checklist completion. Understanding the barriers that cause safety check compromise and fixing them help to increase the rate of the compliance to the safety checks (Puttick et al., 2016).

In the current study, 60% of WHO checklist procedures demonstrated problems, 36% of which were in the sign-in phase. The IR team did not pause for the sign-in time-out part. They were either scrubbing or engaging in irrelevant talk or involving in other activities related to the case preparation while the WHO checklist was read aloud. In the other 22% of cases, no sign-out or inadequate sign-out was performed by the team. This finding agrees with the literature (Braaf et al., 2013). It is important to note that the sign-in phase of the WHO checklist for radiology intervention includes the time-out phase as well if the procedure is performed under local anaesthesia. This support the perception that individual subprocesses are not always completed. In an observational study in Surgery, twenty-four surgical procedures were video recorded to examine the compliance of the operational staff to the WHO checklist. Although the overall compliance with the checklist was 96%, the compliance to individual items were only 54% (Rydenfält et al., 2013).

A narrative example from a previous study in Surgery showing how much important information would be lost or essential steps of a surgical procedure would otherwise have been missed if a full pause for a time-out is not done .*"The other team members (first surgeon, anaesthetist nurse and theatre nurse) initiate the time-out, whereas the second surgeon gets dressed in sterile clothing. The second surgeon did not participate in the time-out and his/her attention appears to be elsewhere. The others did not appear to wait for the second surgeon to get dressed before the time-out was initiated. Whereas the first surgeon and anaesthetist go*

through the patient 's medication, the theatre nurse asks the assistant nurse for adhesive tape" (Rydenfalt et al., 2013). The question is, can this attitude or behaviour be allowed or compromised for if the operating team are experienced and know what the procedure steps and requirements are? Shall we be concerned about this non-crucial matter while the IR team, such as the consultant or the other team members, still partially engage in answering the questions raised by the checklist coordinator?

However, for a checklist to achieve its goal, all the items must be implemented and accomplished without deviation. This statement should not be confused with adaptation and modification of the checklist to meet specific safety requirement in each surgical subspecialty such as IR (2008, 2012). When it is said modification or adaptation of the WHO checklist, it is encouraged to meet the local aims, it does not mean to deviate from the core element of the checklist and the essential method of practising this valuable tool. Similarly, completing the items of the checklist should not be just a bleak and boring addition to meet the departmental or statutory regulatory obligation. Instead, the checklist should be a real safety practice that adds invaluable input to the procedures and a mainstay station in which operational staff communicate with each other and raise any concern before any safety issue or near miss. (WHO, 2008) (Lingard et al., 2005).

Not only did the intervention decreased the WHO-checklist-related errors but also it did decrease the mean total healthcare errors in the intra-procedure phase of the IR pathway. This intervention has enhanced planning of the steps and the required equipment for the procedures and improved communication among the IR team. The previous studies emphasized that a proper implementation of the safety checklists can enhance communication and improve patient safety in general (Haynes et al., 2009a) (Alexander et al., 2021); (Ferorelli et al., 2021).

It was previously unclear whether adding the WHO checklist into the IR practice can have a significant impact on specific types of healthcare errors such as communication or equipment errors. A previous study in IR interviewed the operational staff about their perception of the influence of the WHO checklist in IR procedures and whether it could be modified to decrease the preventable errors. It was perceived that the WHO checklist did not help to enhance communication among the IR team and did not help to understand the equipment required in these procedures. Although the IR staff admitted its usefulness in Surgery, they did not think it did improve efficiency in the IR field (Morbi et al., 2012).

However, not only does the checklist remind the operating team to adhere to critical tasks that need to be accomplished to prevent near miss, but also it is considered a planning tool to drive the procedure. This planning part of the checklist is mentioned in the time -out phase where the IR consultant should enlighten the team about the main steps of the procedure and any challenge or possible deviation from the norm might face them (Rydenfalt et al., 2013). Therefore, completing all the phases of the checklist should enhance better planning and ultimately, an improvement in the number of healthcare errors.

There are some limitations in the current study which need to be acknowledged. An inherited limitation accompanying observational studies is observational bias. Being an observer who was not belonged to the IR team, or be an employee of the hospital, could mitigate this limitation. Future studies should invest in having two or more observers to measure the interrater variability, which increases the reliability and validity of these observations.

Another bias is the Hawthorne effect which needs to be accounted for where an observed team change their behaviour when being observed. This effect can be mitigated as the IR team in the study setting has a long-time experience in being observed in different other research projects.

It is not known that the finding of this study can be generalised to other settings or hospitals, and it would be prudent to conduct multicentre studies to allow generalisation of the results. Further research is needed to explore this.

8.6 Conclusion

This study shows that a simple intervention of assigning the responsibility of initiation and completion of the WHO checklist for radiology intervention to the attending IR consultant or the main performing IR doctor is an effective way to increase the rate of the compliance of the IR team to complete items of the checklist. It also decreased the overall rate of the healthcare errors in the intra-procedure phase of the IR pathway.

Chapter Nine: Enhancing Communication among IR and Vascular Surgery Teams in Image-guided-Procedure Pathways by developing and using a Mobile Application Technology

9.1 Introduction

Recently, various industries including healthcare has shown serious interest in adopting and integrating mobile applications (apps). The implementation of these software technology into healthcare environment has demonstrated significant potential for enhancing communication, improving workflow efficacy, and eventually enhancing patient management and safety. The medical field, including surgery and interventional radiology (IR) are among those subspecialties to show this trend (Mobasheri et al., 2015).

This chapter sheds a light on the literature about using mobile apps in medicine and surgery, specifically the field of IR, and identifies the potential gaps and possible opportunities to promote mobile apps to improve communication and ultimately patient safety.

There has been a wide exploration of the mobile apps in medicine, with numerous studies demonstrating their impact on miscellaneous areas such as monitoring of patients, remote clinic consultations, and education. In a systematic review, Jarvis et al., (2023) found twenty articles about the use of mobile apps in plastic surgery. They concluded that mobile apps in plastic surgery are getting popular among doctors and patients alike acting as rich resource for patients, trainer, and consultant plastic surgeons. These apps can act as bridges facilitating communication between surgeons and patients. For instance, they reported some studies in which patients experienced improved post-surgical period after using mobile apps. These apps can enhance education for the trainee and could facilities marketing and advertisement for these clinics. Most o (Jarvis et al., 2023). Other studies explored the benefits of these apps in the care of diabetes where the patients reported improved adherence to the medication leading to both physical and psychological improvement after using these apps for certain amount of time (Steinert et al., 2017).

A systematic review about the use of mobile apps in surgical education revealed that most of the surgical trainees used mobile apps as resources for their teaching materials (Dickinson

and Bass, 2020). In another systematic review on the use of app technology in the surgical care, the authors reported a wide range of apps which have been used across the surgical practice from the preoperative preparation to the postoperative care. They highlighted the potential of these mobile apps in enhancing the surgical care (Mobasher et al., 2015).

Interventional radiology is considered one of the versatile and rapidly developing specialty which utilise imaging in performing minimum invasive procedures. This specialty provides services not only for their direct access patients, but also for a wide range of other specialties through elective or urgent referral pathways (Lutjeboer et al., 2015). It is arguable that utilisation of mobile apps can streamline communication within the IR department and beyond. Furthermore, using mobile apps might have the potential to increase efficiency of the IR settings and enhance patient safety. However, unlike medicine and surgery, there is scarcity of literature or trials that explore the use of mobile apps in the era of IR and its influence on communication and safety of patients. To the knowledge of the author of this thesis, there is no study in the literature to assess the use of mobile apps in IR specialty to enhance communication among the teams and to improve patient safety.

The literature supports the positive role of enhanced communication in healthcare system, especially in complex multidisciplinary practices such as IR. Poor communication and information transfer failures within the IR teams and among other healthcare settings can result in adverse events, harm patients and unfavourable outcome. (Lingard et al., 2004a), (Lingard et al., 2008), (Catchpole et al., 2007b) (ALBAYETI et al., 2011), (Morbi et al., 2012), (Koetser et al., 2013), (Lutjeboer et al., 2015). Therefore, there is an obvious need to fix the existing gap in communication in healthcare setting and expedite collaboration among IR teams and beyond to streamline an effective care and enhance patient safety.

9.2 Aim

The principal aim of this study is to create a mobile app designed to bring the IR teams and the vascular surgery teams together to enhance communication and teamwork among them. By implementing mobile technology, the app allows these teams to improve patient safety by decreasing healthcare errors and facilitate care within and beyond the IR department. Furthermore, seamless communication among the IR teams and other teams such as vascular surgery teams will be expedited by the app to secure efficient and safe care with improved task allocations to enhance effective treatment delivered to patients.

9.3 Methodology

A mixed method study model was used which included designing and developing a mobile app, followed by a pilot cross sectional questionnaire study to evaluate usability, and effectiveness to enhance communication and improve patient safety.

The design and the development of a mobile app_ FARADION (FAst RADiology InterventiON)

Microsoft Power Apps was used as a platform, in which FARADION was designed and created. Microsoft Power Apps is one of the tools that has been developed by Microsoft company within Microsoft 365 environment. It is a user-friendly, yet a robust developer tool to design and develop any app by mainly utilising built in drag and drop functions.

The app was created to incorporate features and functions aimed at specific elements of patient care, namely patient's visualisation, communication among teams and task management. The app design put into consideration the previous requirements and the gaps of communication found in the previous chapters of this thesis. Furthermore, the gathered requirements of the IR teams through informal meeting and discussion were put into consideration to ensure the app contains functionalities that can address these needs.

All the design and workflow of the App was performed by the author of this thesis. However, some functionalities of the buttons of the App required coding which was created by an App developer. The App consists of the frontend, which demonstrates the user platform where all the functionalities and the visuals of the App are located. Furthermore, the App requires a backend data storage to store data into and retrieve data from. The backend is composed of several SharePoint lists which are files which were created by the author of this thesis with the advice from a PowerApp developer hired for this purpose.

9.3.1.1 Content of the FARADION mobile app

The App contains a home screen which includes three buttons (tasks, patient information, and communication), each of which navigates the user into another screen (Figure 9.1).

1. Patients information screens

By clicking patients information button, another screen will open called patients information screen as shown in (Figure 9.2). The names of the patients are fictitious and presented for the sake of demonstration. In this screen the lists of patients will appear and in front of each patient there is a progress bar aimed at showing the status of the patient's preparation to their image-guided procedures. This progress bar is responsive and will change by changing the required checklist on these patients. In addition to the functionality of the progress bar, there are four icons in front of each patient appear in the left side of the screen. One of these icons is the checklist icon from which twenty-six checklists are assessed by the IR teams to result in 100% progress bar status. The colour of the progress bar is meant to change from dark red when there is no task conducted to green when all the tasks were completed. The checklist screen can be seen in (Figure 9.3). In this figure, it was shown that after completing more task for the dummy patient named "Lorum Ipsum" the progress bar changed from 5 in (Figure 9.2) to 10 in (Figure 9.3). It is worthwhile that only choices "Yes, or No" in the checklist options will add percentage to the progress bar which means that these checklists are either completed or are not applicable in case of "NA".

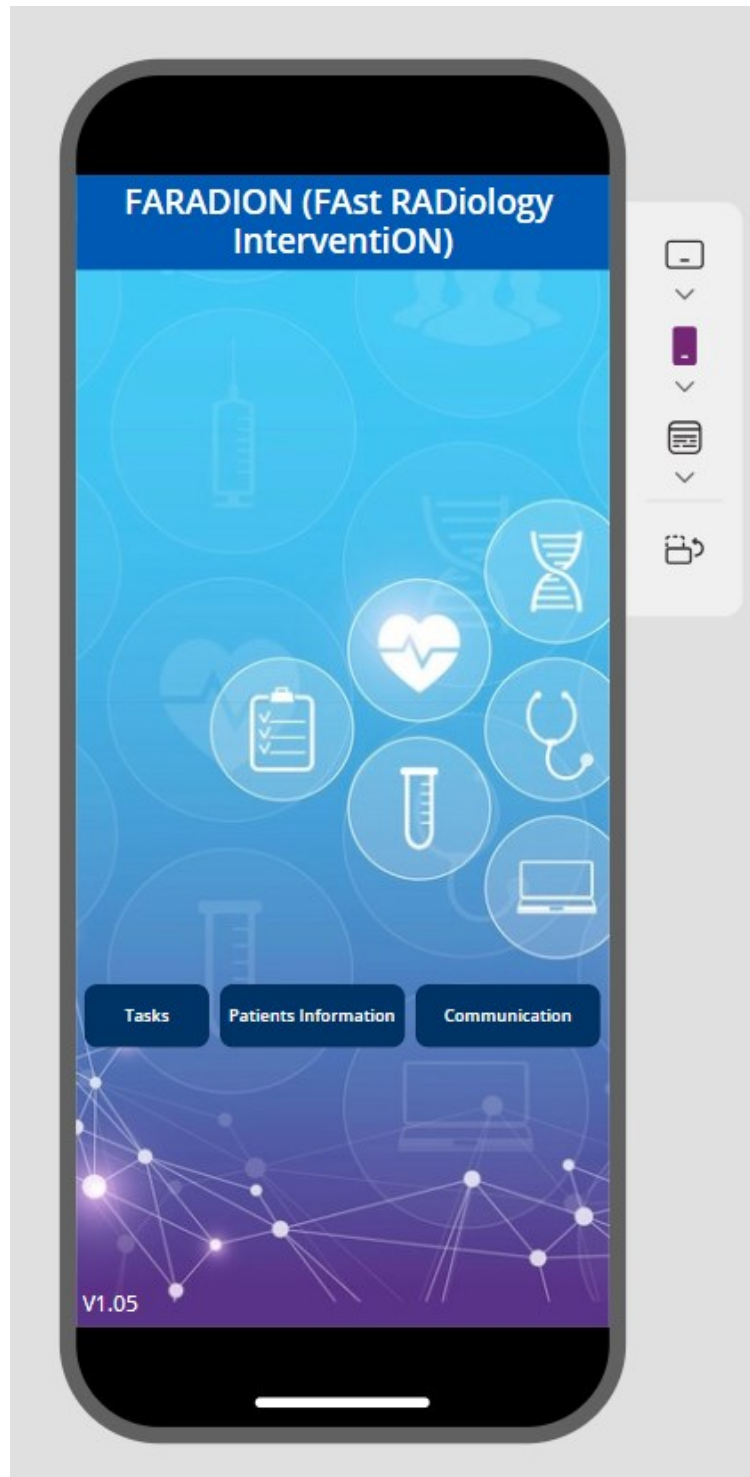


Figure 9.1 The Home screen of the app for iPhone 12 pro screen (the size is slightly decreased for demonstration)



Figure 9.2 Shows the patients information screen.



Figure 9.3 Shows the required checklist for each patient which affect the movement of the progress bar on the previous screen.

2. Task screens

By clicking the main task screen another screen will open which shows all tasks (complete and incomplete). These tasks can be moved from incomplete lists to complete list by clicking on the toggle button in front of each task. The tasks are coloured and labelled according to their priority by three colour like traffic lights: red denotes, amber and green denoting high, medium, and low priority tasks respectively (Figure 9.4). New tasks can be added by clicking the (+) sign on the left side of the screen.

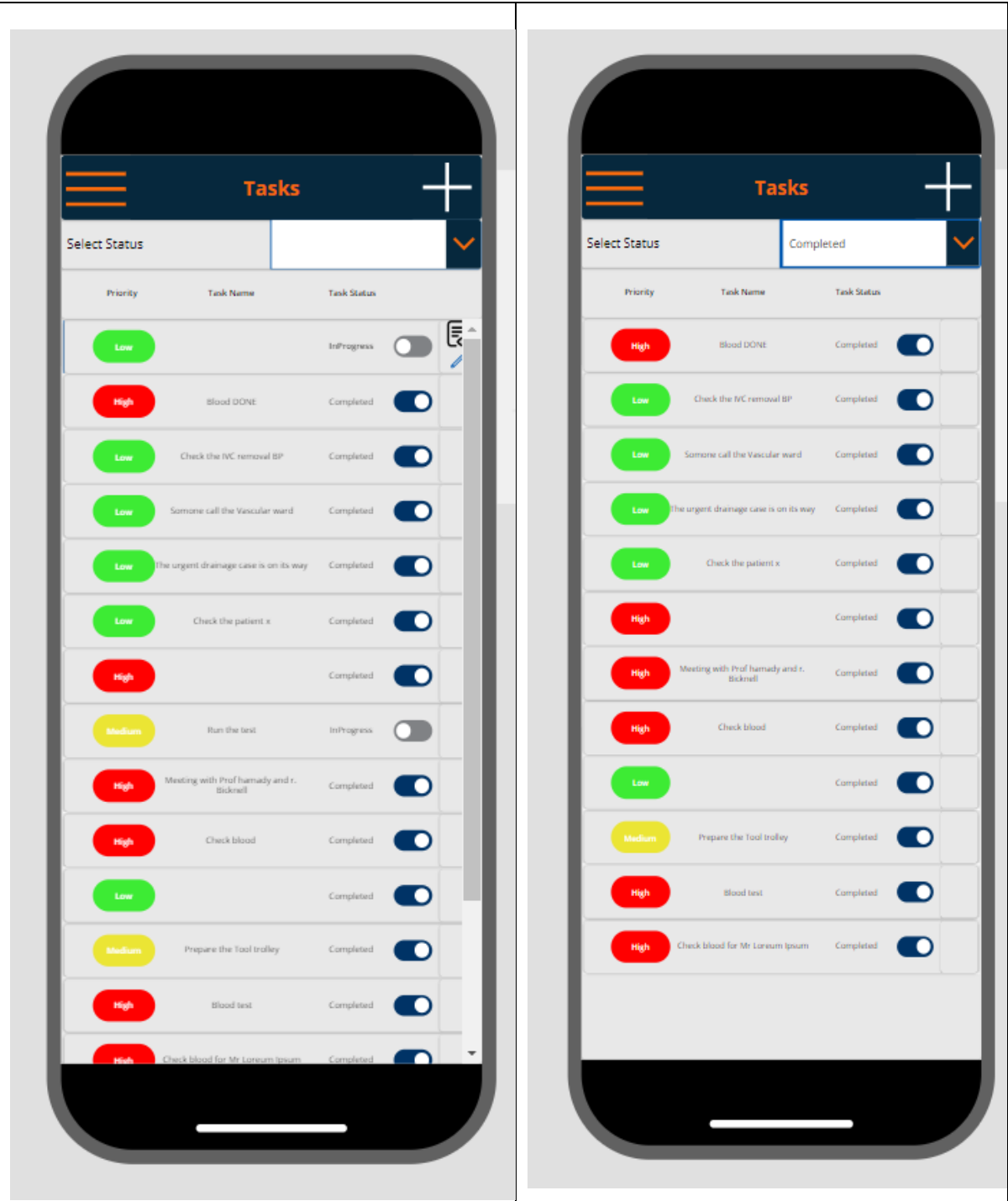


Figure 9.4 Shows the task screen (all tasks on the left side of the screen versus completed tasks on the right side of the screen)

3. Communication screen

Different types of communications can be created and shared by the users of the app, namely: text messages, voice messages, pictures (including the option of capturing picture from mobile phones or uploading pictures from the gallery of the phone) and attaching documents or files (Figure 9.5).

9.3.1.2 How to access the app

As this app was created by using the Power Apps platform of Microsoft 365 software, it can only be accessed if the user can have access to Microsoft 365 and has permission to use the app by the owner (the author of this thesis). The owner of the app can send invitation to the intended users by different ways. One of the ways is to export the package of the app along with the data source of the app that store all the information of the app to the intended user in a zip file. Then the user needs to open the Power app platform and import this package attached from the zip folder. As the app has three components, each of which are essential to run the app, all the components need to be transferred before the end user can use the app.

The three components are: The front end which is the user platform that were shown on the previous pictures of the app. The connector files which allow data to be transferred back and forth from the front to the back end and vice versa. The last component is the database which contains all the data from which the app can run. These data will build up each time the app is used as more data will be created by the users and stored into the database.

The app can also be integrated into Microsoft Teams to allow more functionalities and more access.

Three video demonstrations were made to briefly show some of the usability and functionalities. These videos can be accessed through the following links:

1. https://1drv.ms/v/s!Aln_RqiaxlpfgvI04uR_XVOpuYXXtA?e=cB4sN3
2. https://1drv.ms/v/s!Aln_RqiaxlpfgvI1tFzqMnpk2EEzeQ?e=Oaa0Qh
3. https://1drv.ms/v/s!Aln_RqiaxlpfgvIzaOsXD4JNdhsrA?e=axvgWB

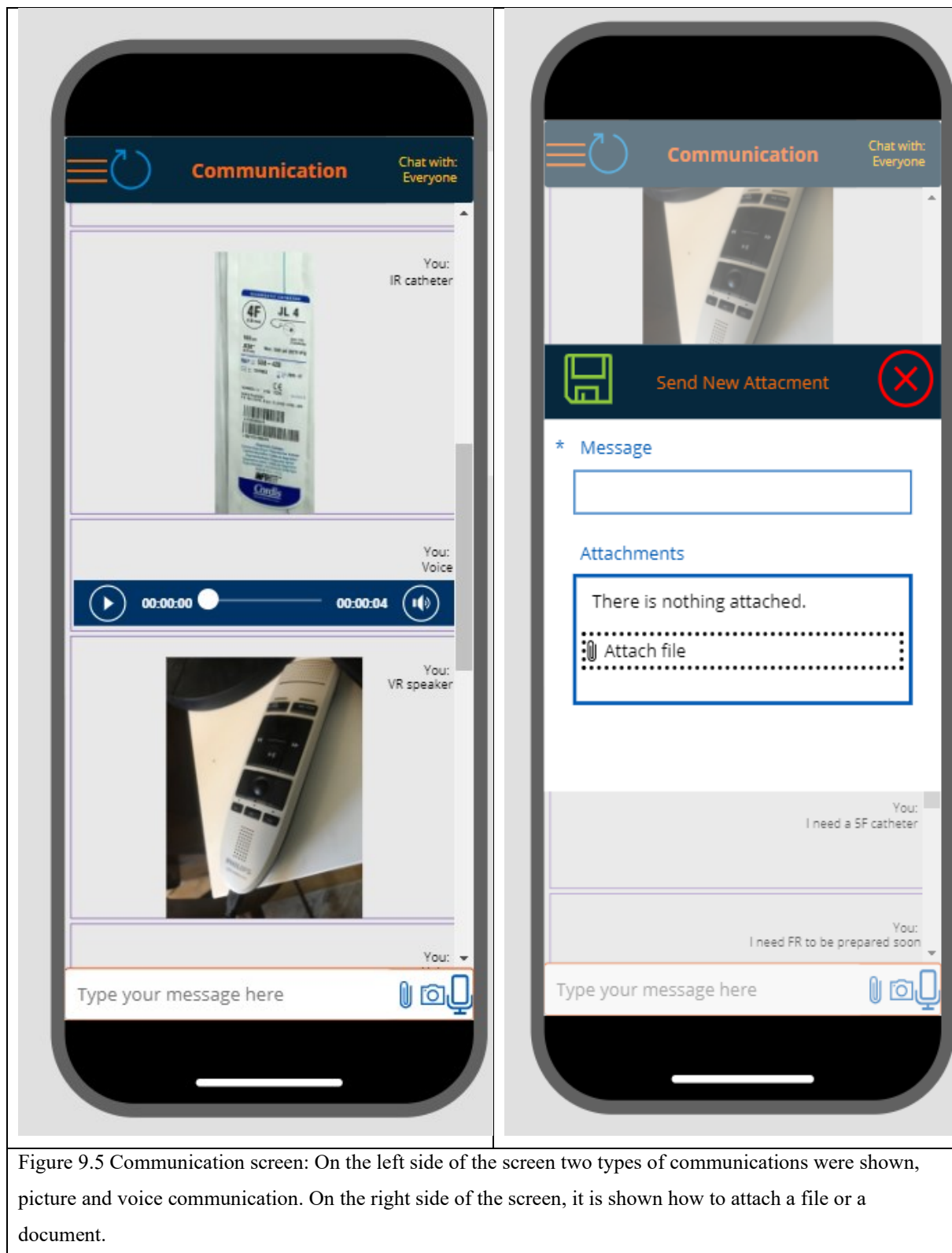


Figure 9.5 Communication screen: On the left side of the screen two types of communications were shown, picture and voice communication. On the right side of the screen, it is shown how to attach a file or a document.

9.3.1.3 The back end of the FARADION mobile app

The back end of the App is composed of several lists called SharePoint lists in which all the information entered to the App will be stored there which can be retrieved and showed from the App. The lists of the SharePoints must exactly match those within the App down to even spelling match of the words. The following figures show some of the lists of the back end of the FARADION App (see Figure 9.6, Figure 9.7, Figure 9.8, and Figure 9.9).

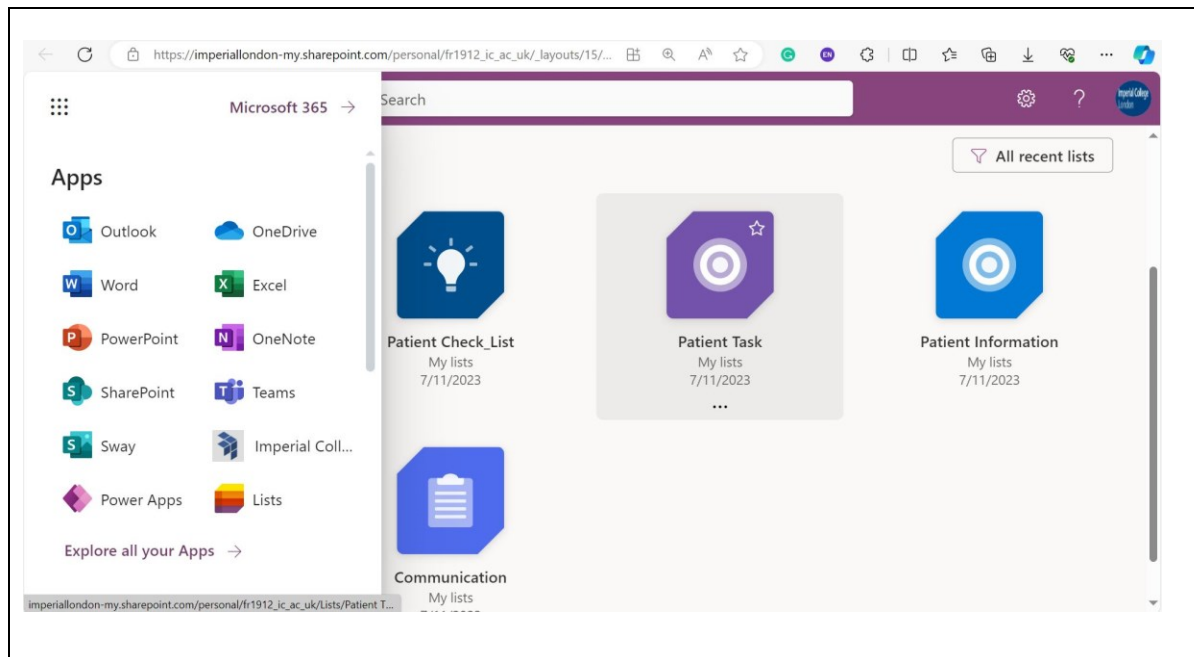


Figure 9.6 Demonstrates the Power SharePoint lists of the FARADION App in Microsoft 365

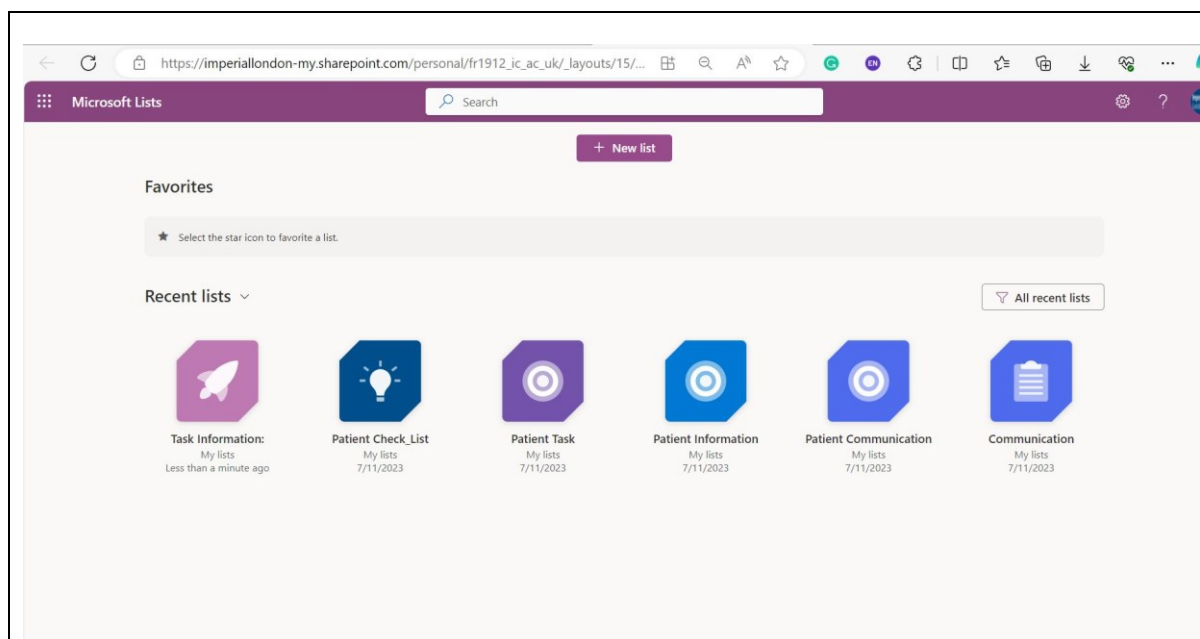


Figure 9.7 Demonstrates the Power SharePoint lists of the FARADION App in Microsoft 365

Title	First Name	Surname	Date of Bi...	Date of A...	Time of A...	Ty...	Ur...	Doctor As...	Blood Res...	Br...
Mr	Faraldoon	Rawf	11/5/1975	7/6/2023	7/7/2023	day case	Elective	Department of Surge	and others	New
Mrs	Alia	M	1/16/1957	7/8/2023		inpatient	Urgent			
Ms	Joanne	Bell	5/1/1940	7/6/2023		inpatient	Elective			Intermitt
Mr	Lorum	Ipsium	6/4/1996	7/6/2023		day case	Urgent		Platelets	Urgent
Mr	B	R	8/6/2013			day case	Elective			Abdomin
Untitled	Bahast	R				day case				pain, fev
Untitled	Aryas	R	7/3/2007	7/10/2023		day case	Urgent		Platelets	and rigor

Figure 9.8 Shows Patient Information list

Microsoft Lists

Search

+ Add new item Edit in grid view Undo Share Export Automate Integrate Manage access

My lists Task Information... ☆ ☺

Filter View All Items

Title	Task Name	Due Date	Assigned To	Task Status	Task Priority	Visibility
Untitled				Completed	Low	Everyone
Title	Blood DONE	7/6/2023 12:00 AM		Completed	High	Everyone
Title	Check the IVC removal BP			Completed	Low	Individual
Title	Somone call the Vascular ward	7/6/2023 1:03 AM		Completed	Low	Everyone
Title	The urgent drainage case is on its way	7/6/2023 1:20 AM		Completed	Low	Everyone
Title	Check the patient x	7/11/2023 4:00 PM		Completed	Low	Everyone
Title				Completed	High	Everyone
Title	Run the test			Completed	Medium	Everyone
Title	Meeting with Prof hamady and r.	7/6/2023 7:00 AM		Completed	High	Everyone

Figure 9.9 Demonstrates Task Information list

Presentation of the mobile app to the participants of the questionnaire study:

Prior to the pilot questionnaire study, several meetings through Microsoft Teams meeting were conducted with the participants to introduce and explain the features and functionalities of the mobile app. During those meetings, the participants were provided with an overview of the app's purpose, navigation, and how different features can be utilised. Additionally, face-to-face meetings were conducted with some other members who were unable to attend the Microsoft Teams meetings, ensuring that all participants had a comprehensive understanding of the app.

Ethical considerations

No ethical committee approval was deemed necessary as the study did not involve collecting data from or about patients. Furthermore, the questionnaire study was anonymous where no participant's ID was asked in the questionnaire. Furthermore, care was taken to preserve confidentiality of the responses by pooling the responses into larger aggregate files for analysis. However, from the start of the questionnaire study, informed consent was obtained from the participants prior to their participation the study.

Pilot cross sectional questionnaire study

The aim of this pilot questionnaire study was to assess the usability, effectiveness, and impact of the designed mobile app on communication, collaboration, and patient safety.

The targeted participants and the hospitals:

The participants included members of the IR team, such as IR nurses, radiographers, and IR doctors, as well as other teams involved in the patient care, such as vascular surgery nurses and doctors. Two hospitals were selected from which the participants were invited to take part in the study: Imperial College Teaching Hospitals NHS Trust (a tertiary teaching hospital) and the St Helens and Knowsley Teaching Hospitals NHS Trust (a district hospital located in Merseyside_ Northwest of England).

Sample size:

The sample size was decided based on feasibility and obtainability of participants.

Questionnaire Design:

An online software_ Qualtrics Imperial was used to create a structured questionnaire to evaluate the perceptions and the responses of the participants regarding different aspects of the developed mobile app. These aspects were ease of use, ability to enhance communication and collaboration among the IR and the vascular teams, impact on task allocation and management, impact on medical errors and patient safety and whether the app can be recommended to be implemented by the hospitals in the future.

Each statement was followed by scoring on a 5-points Likert-scale from 0 to 5, where 0 represented " Strongly Disagree" and five represented "Strongly Agree." The questionnaire also provided an opportunity to add comments, feedback suggestions.

Data Collection and Analysis:

Data collection was performed by administering the questionnaire to the targeted participants. The questionnaires were analysed using descriptive statistics to show the demographics of the participants and different agreement levels. Internal reliability was measured using Cronbach's Alpha reliability test. Quantitative data were analysed to see the proportion of the scoring of the different aspects of the app by the participants. Statistical tests were performed using SPSS statistical tests (Statistical Package for Social Sciences) version 25.

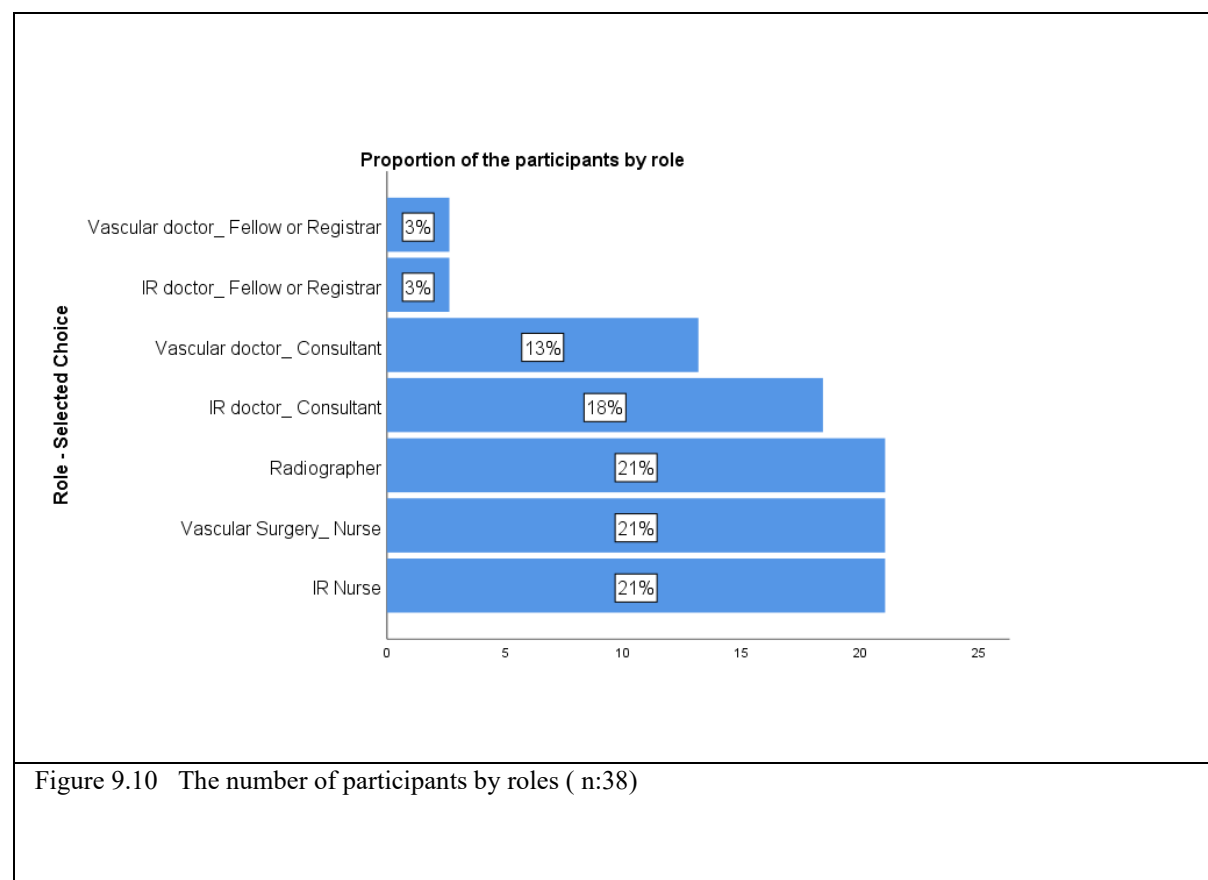
Qualitative data were collected by collecting the feedback and suggestions made by the participants in the provided free text box at the end of each questionnaire. This method aimed at exploring deeper insights of the participants from their experience and knowledge about the app and its impact on communication and patient safety. These qualitative data will be assessed by conducting theme analysis to explore common themes emerged from the ideas and feedback of the participants.

9.4 Results

Demographics of the participants

Invitations by emails, WhatsApp message and face to face of sixty potential participants were made from IR doctors, IR nurses, Radiographers, Vascular doctors, and Vascular nurses. 38 (63.3%) responses were completed the questionnaire as follows: 8 (21%) IR doctors (7 IR consultants and 1 IR Fellow or Registrar), 8 (21%) IR Nurses, 8 Radiographers (21%), 6 (16%) Vascular doctors (5 vascular Consultants and 1 Vascular doctor_ Fellow or Registrar) and 8 (21%) Vascular Surgery_ Nurses. The percentage of the participants are shown in (Figure 9.10).

The largest proportion of the participants (53%) have 6–10-year experience in their current role followed by those who have 11-20 years of experience (29%). 1–5-year experience group formed 18% (Figure 9.11). The participants from the Northwest of England formed 58% versus 42% from London (Figure 9.12).



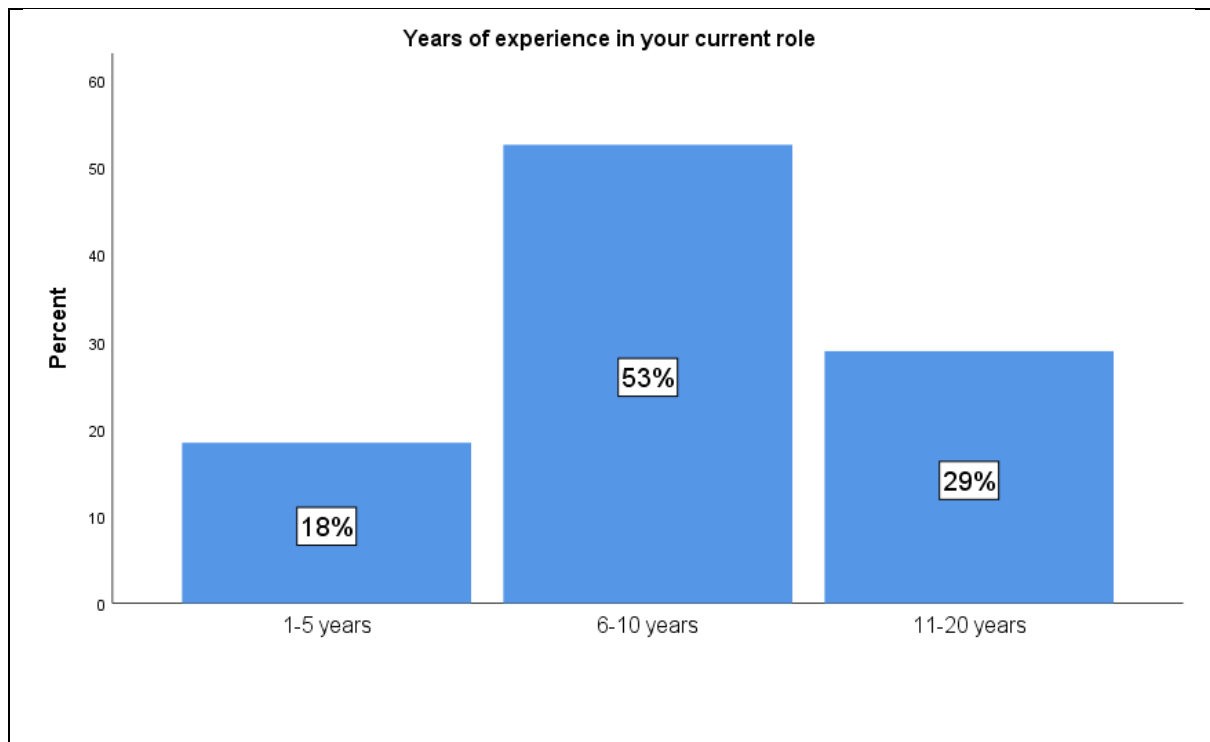
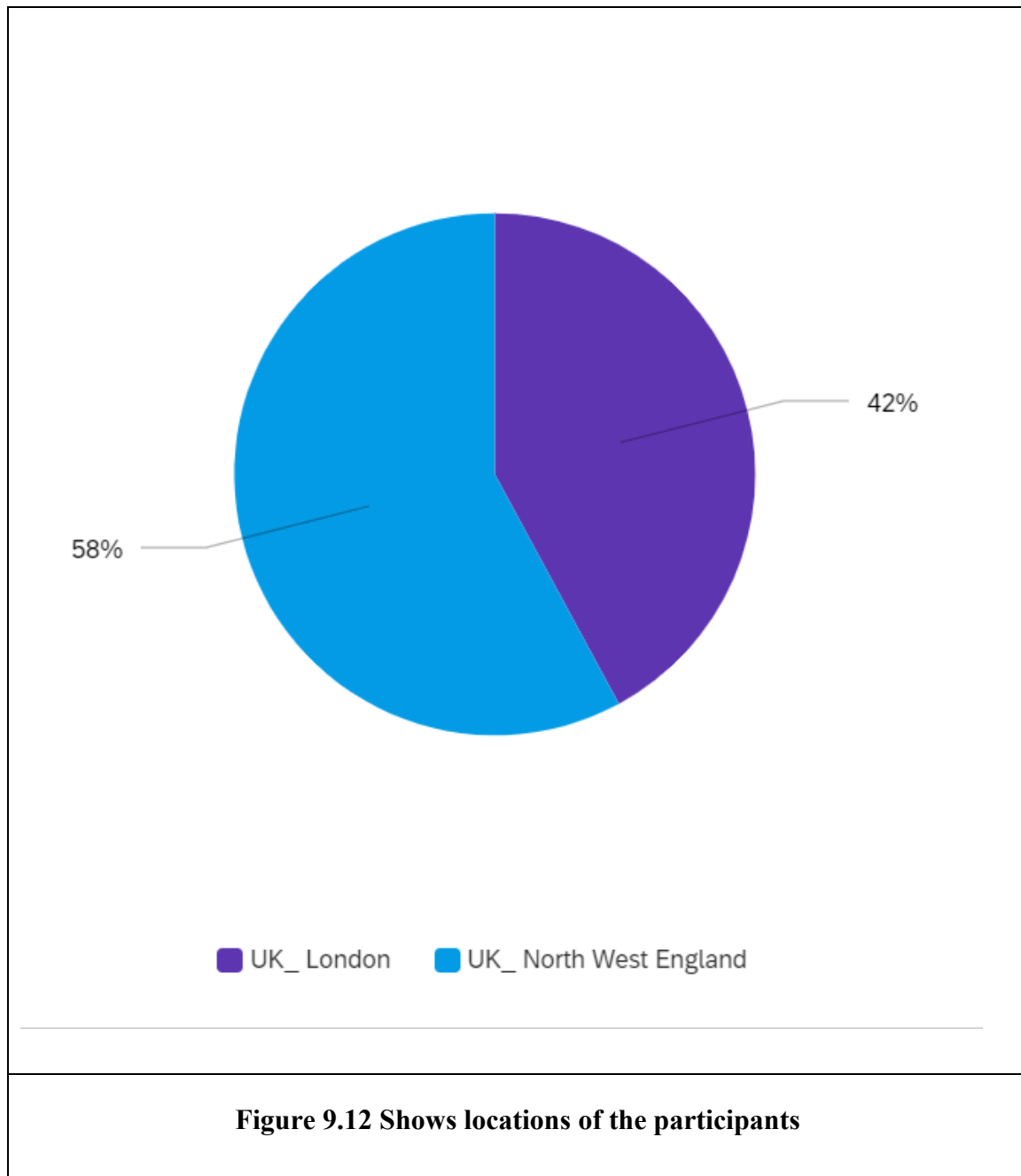


Figure 9.11 Bar chart shows the proportion of the experience of the participants



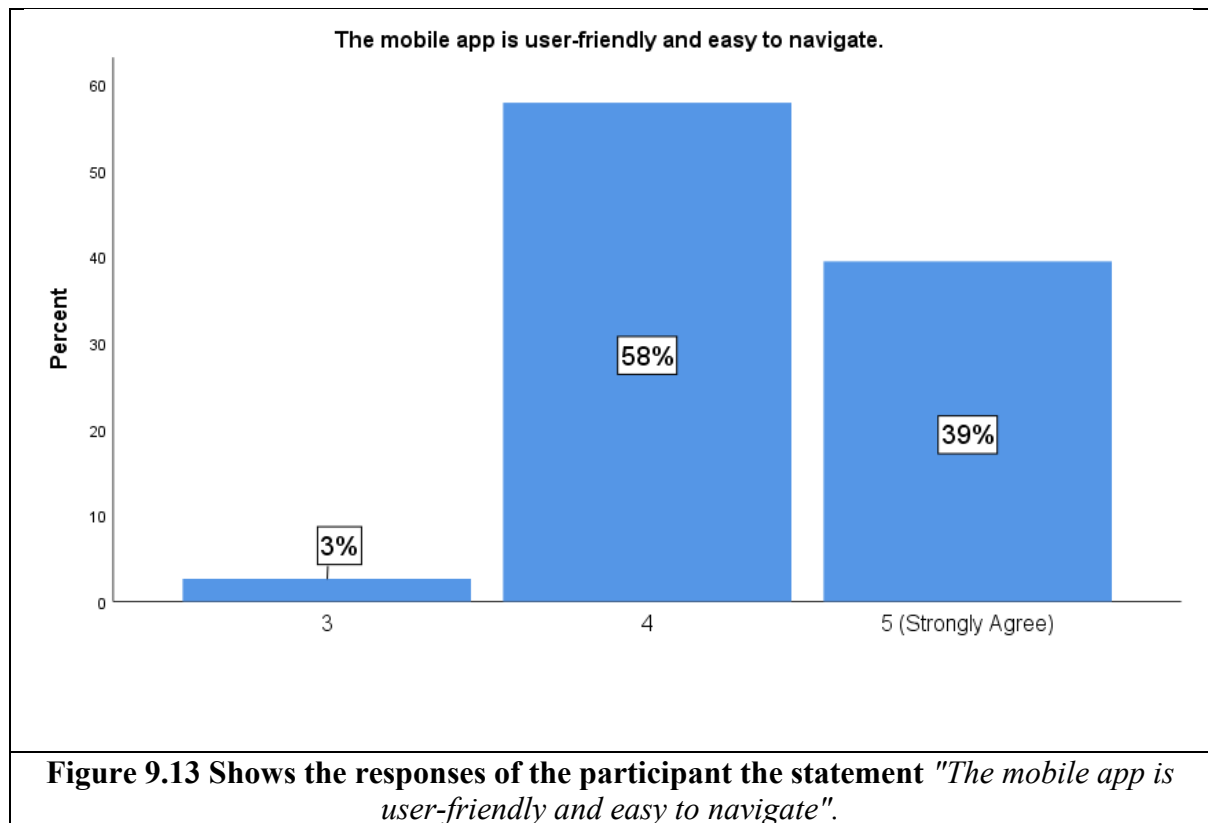
9.4.1 Internal scale reliability

Using Cronbach's Alpha reliability test, a good internal reliability is found among the items of the questionnaire [Cronbach's Alpha coefficient value =.735].

9.4.2 The ratings of the participants of the different aspects of the mobile app

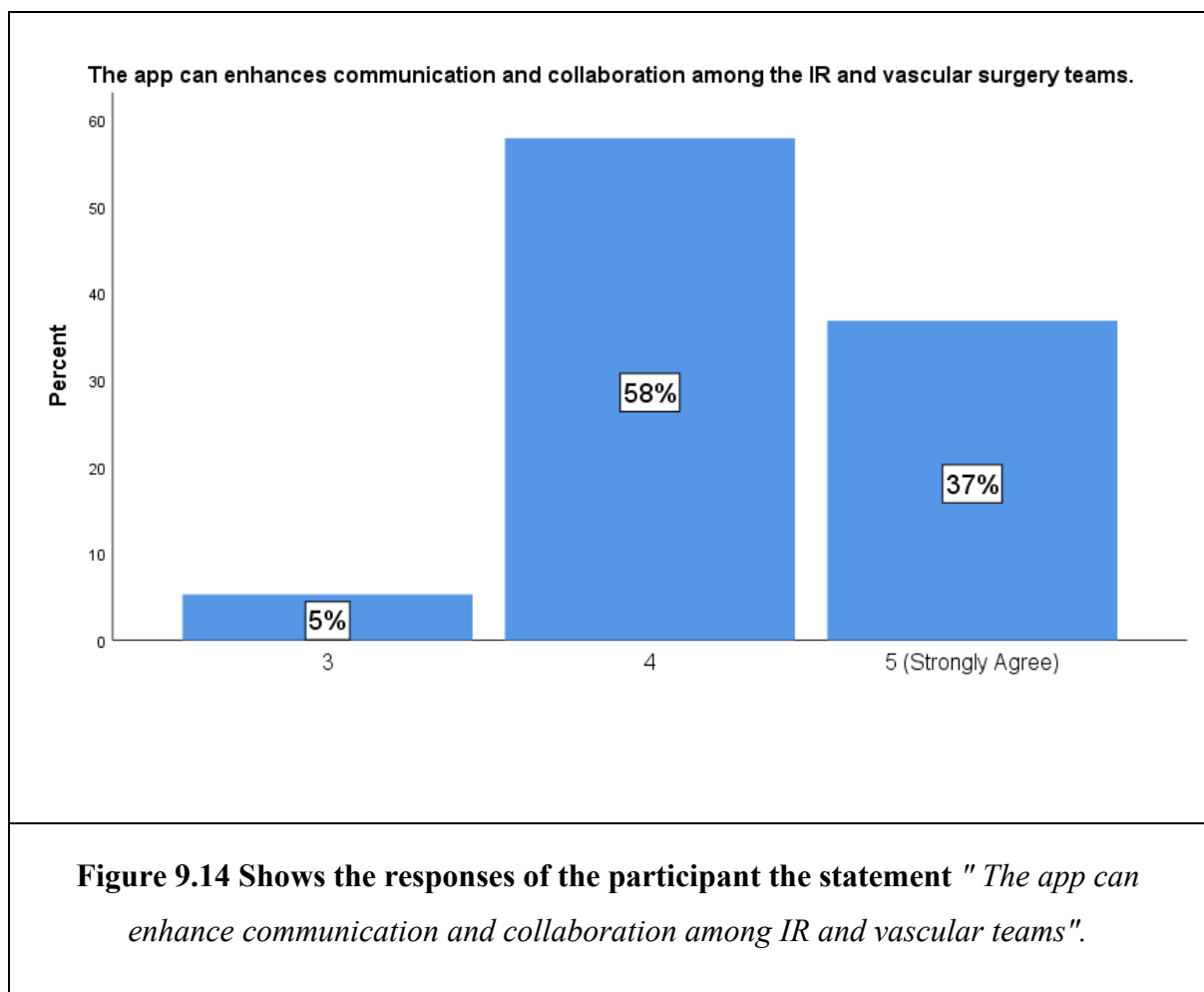
9.4.2.1 The statement "*The app is user-friendly and easy to navigate*".

Most of the participants [22 (58%)] agreed that the app is user-friendly and easy to navigate, and they rated the app 4 out of 5, while 15 individuals (39%) strongly agreed about the above statement (Figure 9.13).



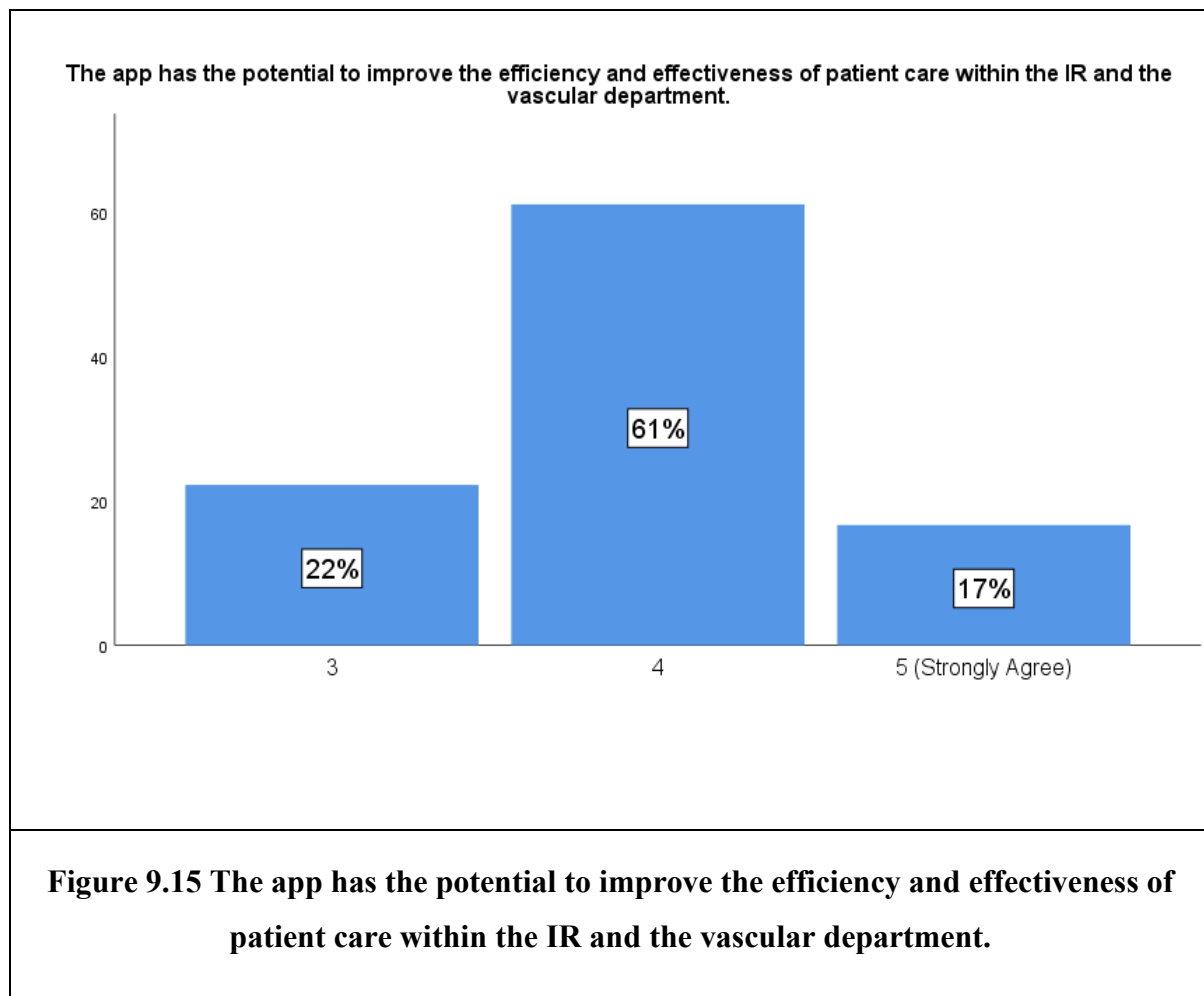
9.4.2.2 Responses to the statement " *The app can enhance communication and collaboration among the IR and vascular surgery teams.*"

A small percentage (5%) of the participants showed a low level of agreement with this statement. However, a large proportion of the participants (58%) found that the app has the potential to enhance communication and collaboration, providing a score of 4/5. Furthermore, 14 (37%) of the participants strongly agreed with the above statement, giving 5/5 score (Figure 9.14).



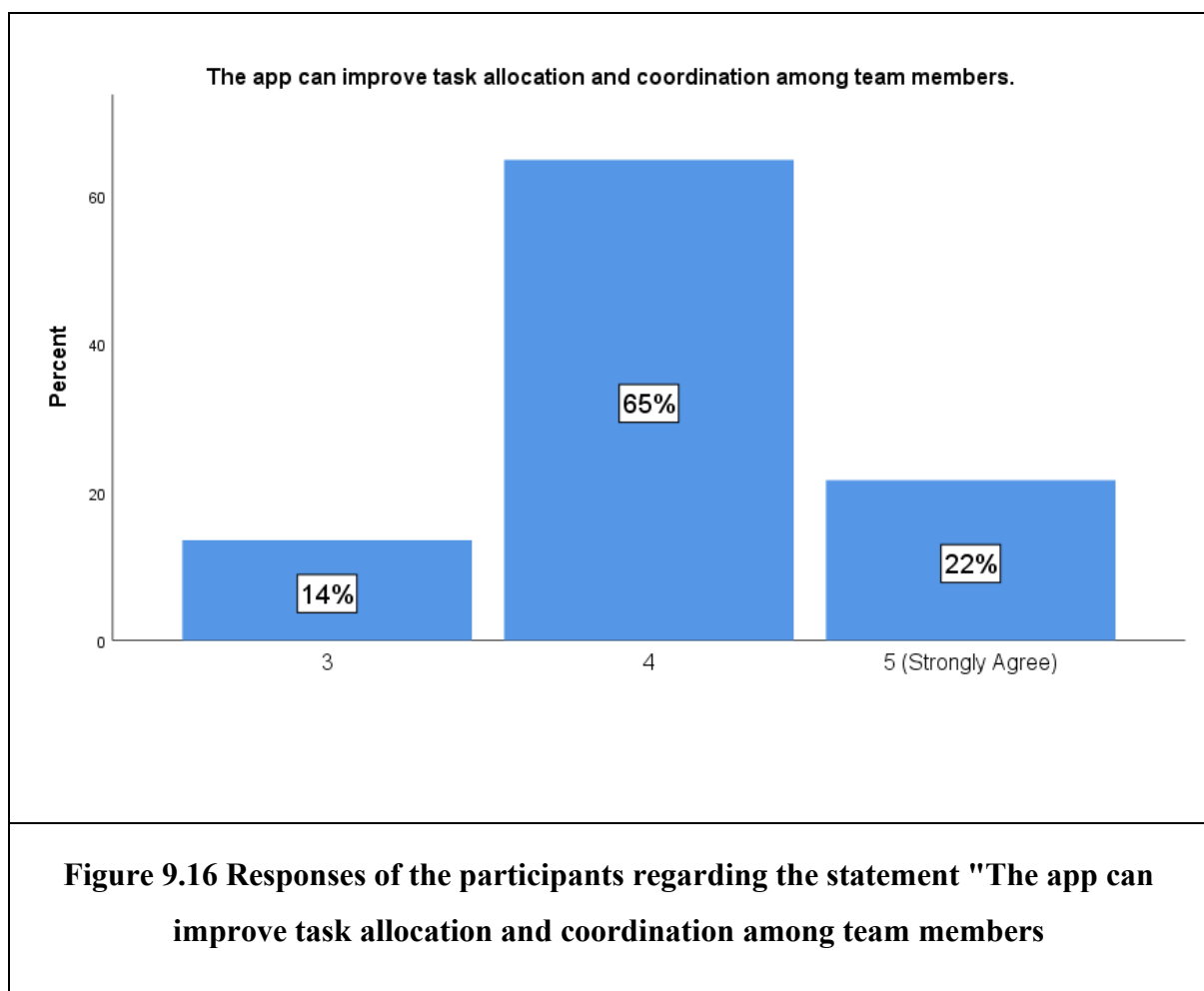
9.4.2.3 responses to the statement *"The app has the potential to improve the efficiency and effectiveness of patient care within the IR and vascular departments."*

Most participants (61%) rated four-fifths in regards of the potential of the app to improve the efficiency of and effectiveness of patient care within the IR and the vascular departments. Another 17% provided a score of 5 out of five, strongly agreeing with the above statement. It is noted that 22% of individuals showed a moderate degree of agreement (a score of 3/5) about the same. Generally, the findings suggest that the app perceived to have the potential to boost efficiency and effective of patient care within the above-mentioned departments (Figure 9.15).



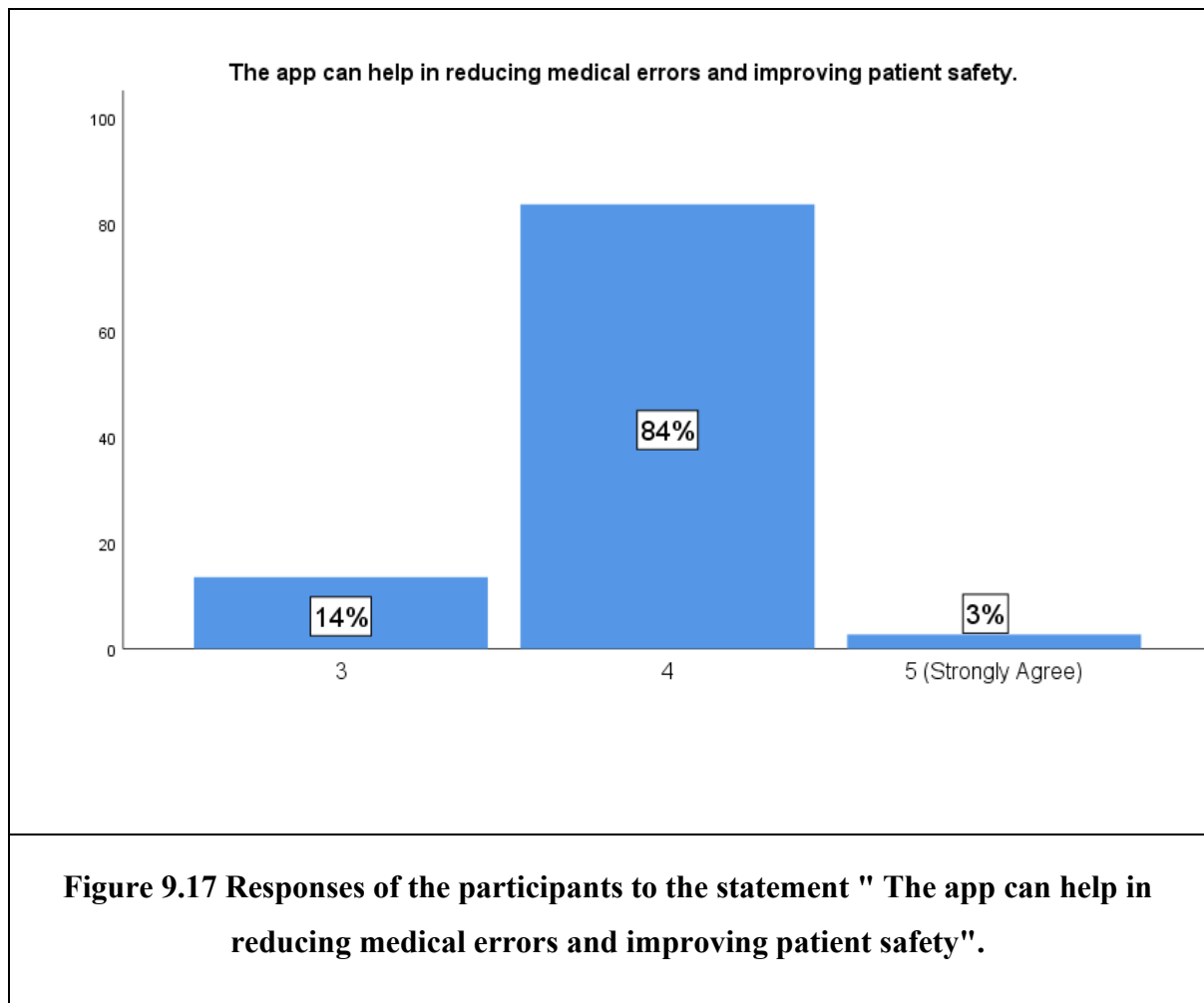
9.4.2.4 Responses to the statement "*The app can improve task allocation and coordination among team members.*"

Again, the majority (65%) of the healthcare professionals participated in this questionnaire provided a high level of agreement with the above statement, providing a score 4 out of 5. In addition, eight participants (22%) provided scores of 5/5, which means a strong agreement. On the other hand, 14% of the participants showed a lower level of agreement, providing a score of 3 out of five. These findings indicate that the app can help in task allocation improvement from the participant's point of view, allowing for room for further improvement of the app to meet this target (Figure 9.16).



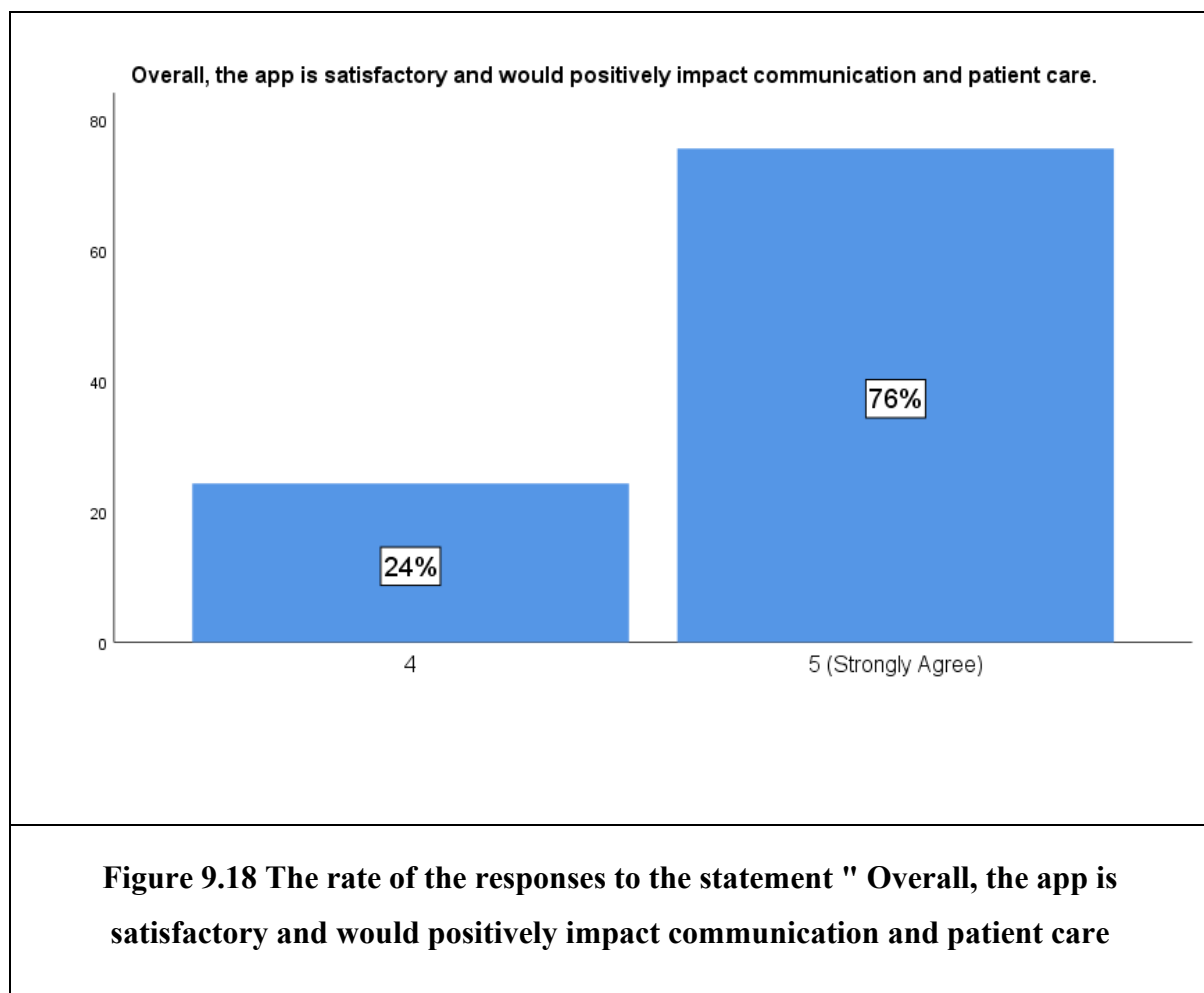
9.4.2.5 Responses to the statement *"The app can help in reducing medical errors and improving patient safety."*

A minority (14%) of participants rated the app three-fifths in terms of whether it helps in reducing medical errors and improving patient safety, suggesting a lower degree of agreement. In contrast, the majority of the participants (84%) agreed that the app can reduce medical errors (Figure 9.17).



9.4.2.6 Responses to the statement *"Overall, the app is satisfactory and would positively impact communication and patient care."*

28 (76%) participants of the total number of thirty-eight strongly agreed that the FARADION app is satisfactory in general and would positively impact communication and patient care. In addition, 9 (24%) provided a score of 4 out of five, suggesting an overall satisfaction with the above statement. These findings indicate the app is welcomed by the participants (Figure 9.18).



9.4.2.7 Responses to the statement *"I recommend my hospital to conduct a pilot implementation of the app."*

Again, 24% of the individuals strongly agreed with the above statement to recommend their hospital to conduct a pilot implementation of the app. In fact, most of the participants (74%) agreed about the above statement. In contrast, only one participant (3%) showed a lower level of agreement about this statement, giving a score of 3/5 (Figure 9.19).

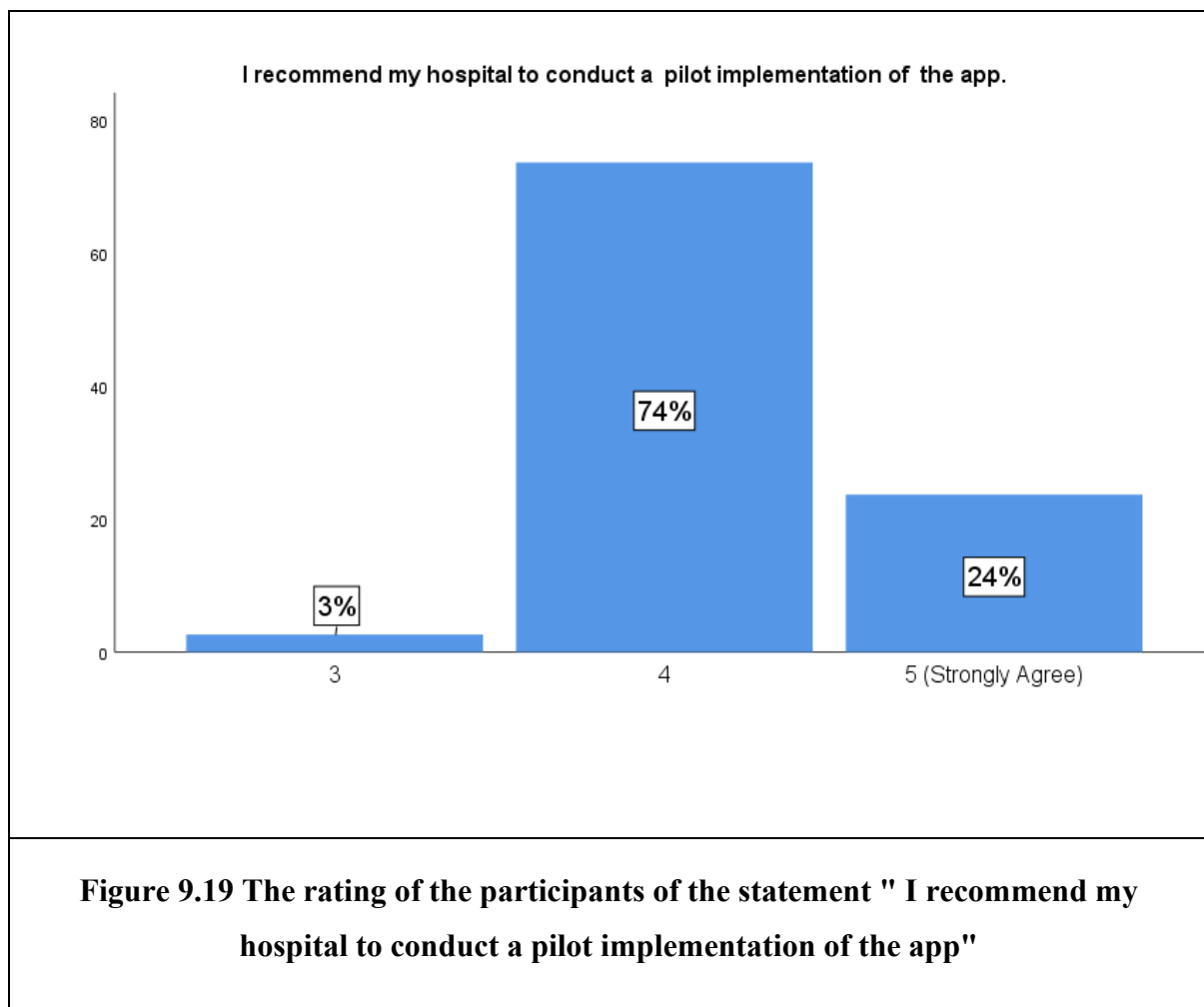


Table 9.1 The suggestions and the Feedback from the participants in their words.

The App needs to be tested on several patients to see it's efficacy.

Please include IRMER guidelines for the next version of the App.

Feel it would be beneficial if can be shared with main TCI ward to ensure all patients are prepped and any changes can be quickly highlighted.

Would be useful to share with our two main TCI wards.

It will be an asset to communication and efficiency in department.

The app is a good one, but we need some training before we can use it.

This app can bring teams together to focus on positive communication and efficient care.

It would have been amazing if it were integrated into the hospital's system so the data be kept safe and retrievable. Unlike, WhatsApp messages which violates the GDPR regulations.

Very user friendly and helpful app. Many thanks

IRMER regulation and other checks regarding the previous imaging would be helpful in the future versions of the app.

I suggest checks related to Anaesthesia to be included in the future. Overall, a very good app with lots of potential in vascular and IR setting.

Mobile app use in medicine is getting popular, and IR should align with this development.

Need to compare it to other interventions to see the effect on medical errors.

Connecting such gadgets with the in-house software can have more potential as the nurses do not need to double what they are doing. The feature of the progress of the patient's care is very good allowing better visualisation of our care.

Would have been good to cover the handover as well when revising the app for the future.

Incorporation of the list of equipment specific to each IR procedure filtered according to the attendant consultant would be useful in the future.

9.5 Discussion

Introduction and quantitative analysis of the results of the questionnaire

The current pilot study aimed to develop a mobile app_ FARADION by using power apps technology and assess its impact on communication, task management and patient care in the Interventional Radiology (IR) and the vascular surgery departments.

The current study showed a high degree of agreement and satisfaction among the participants in regards of the usability, effectiveness in enhancing communication and collaboration among these teams to improve patient safety. Most of the participants found that the app is easy to navigate through and can enhance effective communication among the IR and the vascular surgery teams. These findings align with the literature (Mobasheri et al., 2015), and (De La Cruz Monroy and Mosahebi, 2019). Furthermore, the participants thought that app could facilitate tasks allocation and efficiency among different teams which ultimately improve patient care and patient safety.

There are many studies that highlight the positive role of the mobile apps in the healthcare settings. A study by Dawes et al., (2021) showed the effectiveness of using mobile app in telemedicine to remotely monitor patients while they are at home after surgical operations. They highlighted that these apps can lead to fewer complications and fewer visits to emergency departments following surgery (Dawes et al., 2021). Similarly, De la Cruz Monroy and Mosahebi (2019) conducted a systematic review on the use of mobile app during the perioperative period of surgery, and they concluded that there is a positive impression among the surgical specialty about the use of mobile apps in the pre- and post-operative period. Nevertheless, they highlighted the needs of further studies in this era to explore the long term impact on the patient care and the sustainability of their usage (De La Cruz Monroy and Mosahebi, 2019). These studies beside my study indicate that the use of mobile apps in healthcare setting would positively impact the outcome and patient safety.

Qualitative feedback analysis

By analysing the feedback of the participants, several themes can be emerged:

Regulations and efficacy testing:

Some participants recommended assessing the app on sufficient sample of patients to evaluate its effectiveness in enhancing communication, streamlining tasks, and reducing medical errors. There was a request from the radiographers to include IRMER (Ionising Radiation in Medical Exposure Regulations) in the upcoming versions of the app to add inclusiveness to the app to the characteristics and the requirements of the radiographer specialty, which is an important part of the IR team. Some participants deemed checking of previous imaging and anaesthesia necessary in the future versions of the app.

Although there was a general recognition that the app has potential to meet its targets in the IR and the vascular surgery departments. However, some participants expressed their desire to compare the app with other types of interventions to reach consensus about the effectiveness of the app across the board.

Communication and Collaboration:

Participants thought that the app needs to be shared with the main TCI (TO Come In) ward to make sure efficient patient preparation is performed and immediate flagging of any change in their care or characteristics such as their blood tests or new signs or features of their disease.

However, the participants feel that the app is a valuable tool and asses to support positive communication and collaboration within the IR department and beyond.

Training and incorporation:

Some participants highlighted the need for getting some training into the use of the app to be familiar with the functionality and the intended aims of the app. This point suggests that the participants are aware of the safety aspects of integrating new technology or tool into their practice to make sure there is no gap in their knowledge that might negatively impact on their practice and patient safety.

Furthermore, participants expressed their desire to integrate the app into the hospital's current system to maintain security of data and adherence with the GDPR rules.

Overall, the participants appreciate the user-friendliness and practicality of the app.

Some participants suggested covering the handover in the future versions of the app. This suggests perception of the need to reach more areas of the patient care by the app.

Equipment and Procedure-specific requirements:

Participants expressed the desire to incorporate equipment lists into the app functionality to make it specific to each procedure and each attending consultant. This suggests that efficacy of the app is well perceived by the participants who project more comprehensive functionality to be integrated into the app to boost its efficacy.

Overall, the feedback from the participants highlights the engagement and the interest of those healthcare professionals with the idea of sing mobile apps in the IR and the vascular Surgery departments. It also confirms the positive perception of the value of the app in enhancing communication and collaboration, streamlining tasks and care across these departments, and improving patient safety.

Recommendations for future improvement and enhancement were mainly focused on integration and training, bringing more checks into the app and consideration of the current regulations such as IRMER and GDPR. There were also suggestions regarding incorporating new features into the app to enhance its usability and effectiveness.

The analysis of the qualitative data of this study agrees with the literature. In a systematic review by Van der Storm et al., (2023), several studies were found which explore the use of mobile apps on gastrointestinal surgery patients. They found that mobile apps have the potential to improve the overall care of these patients through enhancing communication among staff and between staff and patients, providing better training to the healthcare staff and also improving decision making (van der Storm et al., 2023).

In another questionnaire study asking the surgeons about their experience of the smart mobile phones during the COVID-19 pandemic, the researchers found that almost all the participants (99.5%) used their smart phones during the pandemic in relation to their profession. Texting, viewing, or taking medical pictures or videos in both emergency and elective settings. Most of these respondents (80%) rated the use of mobile phone for hospital-related works as important (Buabbas et al., 2021).

Limitations

There are some limitations of the current study which need to be acknowledged. The study was conducted on a limited sample of participants in two hospitals_ a tertiary hospital namely the Imperial College Teaching Hospitals NHS Trust and a general district hospital, the St Helens, and Knowsley Teaching Hospitals NHS Trust. This might have been because of the availability and inclination of participation from the invited participants. This limited sample may limit generalisability of the results and the conclusions from this study into wider population of healthcare professionals and hospitals across the UK. Therefore, caution should be taken in generalising the results to other hospitals or healthcare settings.

Another limitation is the type of the study which is a cross sectional self-response questionnaire study which exposes the results to reporting bias or subjective biases owing to personal preference or memory issues. Furthermore, only five groups of healthcare professionals were targeted to participate in this pilot study. It would be prudent in the future studies to target a wider population of the healthcare roles to reach more consensus about these perceptions about the current mobile app_ FARADION.

Another remedy would be testing the app objectively by integrating it into the hospital's system and implementing a pilot study before and after app usage to assess the rate of medical errors and the rate of the compliance to checklists and other aspects of care among the IR and the vascular surgery teams. This is done after passing regulatory filters such as GDPR and local research ethical committees.

Generalisability and future study directions:

Although the results of this pilot study are valuable in providing insights about the use of mobile apps in hospital settings, further research is needed on larger samples and wider groups of people across more hospitals and settings to boost common ground perception and robustness of the conclusions. Future studies should also investigate other aspects of assessing this app by conducting observational longitudinal studies to measure indicators of patient safety such as team adherence or medical error identification in pre- and post-intervention-based studies. This would allow assessment of other dimensions of the app usage and efficacy.

9.6 Conclusion

To the knowledge of the author of this thesis, this study is the first study that involved designing, developing, and evaluating a mobile app in the IR specialism. This method is an innovative way of assessing the impact of a mobile app on communication, task efficiency and patient safety. This pilot study demonstrates the potential of this app to improve communication and collaboration among multidisciplinary teams to enhance patient safety and to decrease healthcare errors.

However, the limitations of the current study need to be considered in attempting to generalise the results to wider healthcare community and healthcare settings. Future studies should focus on assessing more samples and wider healthcare populations and settings and assessing other outcomes by implementing the app directly into day-to-day practice after passing regulation filters.

In summary, utilisation of technology such mobile apps in medicine, surgery and IR have shown potential to improve patient safety.

Bibliography

2006. The aviation safety system.

ADACHI, W. & LODOLCE, A. E. 2005. Use of failure mode and effects analysis in improving the safety of i.v. drug administration. *Am J Health Syst Pharm*, 62, 917-20.

ALBAYETI, M., GOHEL, M., PATEL, S., RIGA, C., CHESHIRE, N. & BICKNELL, C. 2011. IDENTIFICATION OF PATIENT SAFETY IMPROVEMENT TARGETS IN SUCCESSFUL VASCULAR AND ENDOVASCULAR PROCEDURES: ANALYSIS OF 251 HOURS OF COMPLEX ARTERIAL SURGERY. *EUR J VASC ENDOVASCULAR SURG*, 795E802.

ALEXANDER, H. C., MCLAUGHLIN, S. J., THOMAS, R. H. & MERRY, A. F. 2021. Checklists for image-guided interventions: a systematic review. *Br J Radiol*, 94, 20200980.

ANGLE, J. F., NEMCEK, A. A., JR., COHEN, A. M., MILLER, D. L., GRASSI, C. J., D'AGOSTINO, H. R., KHAN, A. A., KUNDU, S., OSNIS, R. B., RAJAN, D. K., SCHWARTZBERG, M. S., SWAN, T. L., VEDANTHAM, S., WALLACE, M. J. & CARDELLA, J. F. 2008. Quality improvement guidelines for preventing wrong site, wrong procedure, and wrong person errors: application of the joint commission "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" to the practice of interventional radiology. *J Vasc Interv Radiol*, 19, 1145-51.

ANTONIADIS, S., PASSAUER-BAIERL, S., BASCHNEGGER, H. & WEIGL, M. 2014. Identification and interference of intraoperative distractions and interruptions in operating rooms. *J Surg Res*, 188, 21-9.

ARIYANAYAGAM, T., DRINKWATER, K., COZENS, N., HOWLETT, D. & MALCOLM, P. 2019. UK national audit of safety checks for radiology interventions. *Br J Radiol*, 92, 20180637.

ARMOUR FORSE, R., BRAMBLE, J. D. & MCQUILLAN, R. 2011. Team training can improve operating room performance. *Surgery*, 150, 771-8.

AWAD, S. S., FAGAN, S. P., BELLOWES, C., ALBO, D., GREEN-RASHAD, B., DE LA GARZA, M. & BERGER, D. H. 2005. Bridging the communication gap in the operating room with medical team training. *Am J Surg*, 190, 770-4.

BARACH, P., JOHNSON, J., AHMAD A, A., GALVAN, C., BOGNAR, A. & DUNCAN, R. 2008. A prospective observational study of human factors, adverse events, and patient outcomes in surgery for pediatric cardiac disease. *J Thorac Cardiovasc Surg.*, 136, 1422e8.

- BARACH, P. & SMALL, S. D. 2000. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *Bmj*, 320, 759-63.
- BECQUEMIN, J. P., MAJEWSKI, M., FERMANI, N., MARZELLE, J., DESGRANDES, P., ALLAIRE, E. & ROUDOT-THORAVALL, F. 2008. Colon ischemia following abdominal aortic aneurysm repair in the era of endovascular abdominal aortic repair. *J Vasc Surg*, 47, 258-63; discussion 263.
- BERGS, J., HELLINGS, J., CLEEMPUT, I., ZUREL, Ö., DE TROYER, V., VAN HIEL, M., DEMEERE, J. L., CLAEYS, D. & VANDIJCK, D. 2014. Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. *British Journal of Surgery*, 101, 150-158.
- BETHUNE, R., SASIREKHA, G., SAHU, A., CAWTHORN, S. & PULLYBLANK, A. 2011. Use of briefings and debriefings as a tool in improving team work, efficiency, and communication in the operating theatre. *Postgrad Med J*, 87, 331-4.
- BRAAF, S., MANIAS, E. & RILEY, R. 2013. The 'time-out' procedure: an institutional ethnography of how it is conducted in actual clinical practice. *BMJ Qual Saf*, 22, 647-55.
- BRENNAN, T. A. & LEAPE, L. L. 1991. Adverse events, negligence in hospitalized patients: results from the Harvard Medical Practice Study. *Perspect Healthc Risk Manage*, 11, 2-8.
- BRENNAN, T. A., LEAPE, L. L., LAIRD, N. M., HEBERT, L., LOCALIO, A. R., LAWTHERS, A. G., NEWHOUSE, J. P., WEILER, P. C. & HIATT, H. H. 1991. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*, 324, 370-6.
- BROOKS, S. K., GREENBERG, N., WESSELY, S. & RUBIN, G. J. 2021. Factors affecting healthcare workers' compliance with social and behavioural infection control measures during emerging infectious disease outbreaks: rapid evidence review. *BMJ Open*, 11, e049857.
- BUABBAS, A. J., ALDOUSARI, S., AYED, A. K., SAFAR, M. & ALKANDARI, O. 2021. Usefulness of smartphone use among surgeons in clinical practice during the pandemic of COVID-19: a cross-sectional study. *BMC Medical Informatics and Decision Making*, 21, 198.
- BURGMEIER, J. 2002. Failure Mode and Effect Analysis: An Application in Reducing Risk in Blood Transfusion. *The Joint Commission Journal on Quality Improvement*, 28, 331-339.
- CARTHY, J. 2003. The role of structured observational research in health care. *Qual Saf Health Care*, 12, ii13e6.
- CATCHPOLE, K. 2010. Errors in the operating theatre--how to spot and stop them. *J Health Serv Res Policy*, 15 Suppl 1, 48-51.

- CATCHPOLE, K., GIDDINGS, A., DE LEVAL, M., PEEK, G., GODDEN, P. & UTLEY, M. 2006a. Identification of system failures in successful paediatric cardiac surgery. *Ergonomics*, 49, 567-588.
- CATCHPOLE, K. & MCCULLOCH, P. 2010. Human factors in critical care: towards standardized integrated human-centred systems of work. *Curr Opin Crit Care*, 16, 618-22.
- CATCHPOLE, K., MISHRA, A., HANDA, A. & MCCULLOCH, P. 2008. Teamwork and error in the operating room: analysis of skills and roles. *Ann Surg*, 247, 699-706.
- CATCHPOLE, K. & WIEGMANN, D. 2012. Understanding safety and performance in the cardiac operating room: from 'sharp end' to 'blunt end'. *BMJ Qual Saf*, 21, 807-9.
- CATCHPOLE, K. R., DE LEVAL, M. R., MCEWAN, A., PIGOTT, N., ELLIOTT, M. J., MCQUILLAN, A., MACDONALD, C. & GOLDMAN, A. J. 2007a. Patient handover from surgery to intensive care: using Formula 1 pit-stop and aviation models to improve safety and quality. *Paediatr Anaesth*, 17, 470-8.
- CATCHPOLE, K. R., GIDDINGS, A. E., DE LEVAL, M. R., PEEK, G. J., GODDEN, P. J., UTLEY, M., GALLIVAN, S., HIRST, G. & DALE, T. 2006b. Identification of systems failures in successful paediatric cardiac surgery. *Ergonomics*, 49, 567-88.
- CATCHPOLE, K. R., GIDDINGS, A. E., WILKINSON, M., HIRST, G., DALE, T. & DE LEVAL, M. R. 2007b. Improving patient safety by identifying latent failures in successful operations. *Surgery*, 142, 102-10.
- CHRISTIAN, C. K., GUSTAFSON, M. L., ROTH, E. M., SHERIDAN, T. B., GANDHI, T. K., DWYER, K., ZINNER, M. J. & DIERKS, M. M. 2006. A prospective study of patient safety in the operating room. *Surgery*, 139, 159-73.
- CLAVIEN, P. A., SANABRIA, J. R. & STRASBERG, S. M. 1992. Proposed classification of complications of surgery with examples of utility in cholecystectomy. *Surgery*, 111, 518-26.
- CLAY-WILLIAMS, R. & COLLIGAN, L. 2015. Back to basics: checklists in aviation and healthcare. *BMJ Quality & Safety*, 24, 428-431.
- COOK, R. I. & WOODS, D. D. 1994. Operating at the sharp end: The complexity of human error. *Human error in medicine*. Hillsdale, NJ, US: Lawrence Erlbaum Associates, Inc.
- CORSO, R., VACIRCA, F., PATELLI, C. & LENI, D. 2014. Use of "Time-Out" checklist in interventional radiology procedures as a tool to enhance patient safety. *Radiol Med*, 119, 828-34.
- DAWES, A. J., LIN, A. Y., VARGHESE, C., RUSSELL, M. M. & LIN, A. Y. 2021. Mobile health technology for remote home monitoring after surgery: a meta-analysis. *Br J Surg*, 108, 1304-1314.
- DE LA CRUZ MONROY, M. F. I. & MOSAHEBI, A. 2019. The Use of Smartphone Applications (Apps) for Enhancing Communication With Surgical Patients: A Systematic Review of the Literature. *Surg Innov*, 26, 244-259.

- DE LEVAL, M. R., CARTHEY, J., WRIGHT, D. J., FAREWELL, V. T. & REASON, J. T. 2000. Human factors and cardiac surgery: a multicenter study. *J Thorac Cardiovasc Surg*, 119, 661-72.
- DE VRIES, E. N., HOLLMANN, M. W., SMORENBURG, S. M., GOUMA, D. J. & BOERMEESTER, M. A. 2009. Development and validation of the SURgical PATient Safety System (SURPASS) checklist. *Qual Saf Health Care*, 18, 121-6.
- DE VRIES, E. N., RAMRATTAN, M. A., SMORENBURG, S. M., GOUMA, D. J. & BOERMEESTER, M. A. 2008. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*, 17, 216-23.
- DEGIRMENCI, T., GUNLUSOY, B., KOZACIOGLU, Z., ARSLAN, M., CEYLAN, Y., ORS, B. & MINARECI, S. 2013. Utilization of a modified Clavien Classification System in reporting complications after ultrasound-guided percutaneous nephrostomy tube placement: comparison to standard Society of Interventional Radiology practice guidelines. *Urology*, 81, 1161-7.
- DEROSIER, J., STALHANDSKE, E., BAGIAN, J. P. & NUDELL, T. 2002. Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System. *The Joint Commission Journal on Quality Improvement*, 28, 248-267.
- DICKINSON, K. J. & BASS, B. L. 2020. A Systematic Review of Educational Mobile-Applications (Apps) for Surgery Residents: Simulation and Beyond. *Journal of Surgical Education*, 77, 1244-1256.
- DINDO, D., DEMARTINES, N. & CLAVIEN, P. A. 2004. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg*, 240, 205-13.
- EVANS, B., GLENDON, A. I. & CREED, P. A. 2007. Development and initial validation of an Aviation Safety Climate Scale. *J Safety Res*, 38, 675-82.
- FARGEN, K. M., VELAT, G. J., LAWSON, M. F., FIRMENT, C. S., MOCCO, J. & HOH, B. L. 2013. Enhanced staff communication and reduced near-miss errors with a neurointerventional procedural checklist. *J Neurointerv Surg*, 5, 497-500.
- FEDERAL AVIATION ADMINISTRATION. 2006. *The aviation safety system* [Online]. Available: http://www.faa.gov/data_research/safety/ [Accessed 2016].
- FERORELLI, D., BENEVENTO, M., VIMERCATI, L., SPAGNOLO, L., DE MARIA, L., CAPUTI, A., ZOTTI, F., MANDARELLI, G., DELL'ERBA, A. & SOLARINO, B. 2021. Improving Healthcare Workers' Adherence to Surgical Safety Checklist: The Impact of a Short Training. *Front Public Health*, 9, 732707.
- FLETCHER, C. E. 1997. Failure mode and effects analysis. An interdisciplinary way to analyze and reduce medication errors. *J Nurs Adm*, 27, 19-26.
- FORD, J., HENDERSON, R. & O'HARE, D. 2014. The effects of Crew Resource Management (CRM) training on flight attendants' safety attitudes. *J Safety Res*, 48, 49-56.

- FOURCADE, A., BLACHE, J.-L., GRENIER, C., BOURGAIN, J.-L. & MINVIELLE, E. 2012. Barriers to staff adoption of a surgical safety checklist. *BMJ Quality & Safety*, 21, 191-197.
- FUDICKAR, A., HÖRLE, K., WILTFANG, J. & BEIN, B. 2012. The effect of the WHO Surgical Safety Checklist on complication rate and communication. *Dtsch Arztebl Int*, 109, 695-701.
- GABA, D. M., SINGER, S. J., SINAIKO, A. D., BOWEN, J. D. & CIAVARELLI, A. P. 2003. Differences in safety climate between hospital personnel and naval aviators. *Hum Factors*, 45, 173-85.
- GAWANDE, A. (1999). The incidence and nature of surgical adverse events in Colorado and Utah. *Surgery I.*, 26, 66-75.
- GILLESPIE, B. M., CHABOYER, W. & FAIRWEATHER, N. 2012. Interruptions and miscommunications in surgery: an observational study. *Aorn j*, 95, 576-90.
- GORE, D. C., POWELL, J. M., BAER, J. G., SEXTON, K. H., RICHARDSON, C. J., MARSHALL, D. R., CHINKES, D. L. & TOWNSEND, C. M., JR. 2010. Crew resource management improved perception of patient safety in the operating room. *Am J Med Qual*, 25, 60-3.
- GRADINCAK, D. J., YOUNG, N., JONES, Y., O'NEIL, D. & SINDHUSAKE, D. 2004. Risks of Outpatient Angiography and Interventional Procedures: A Prospective Study. *American Journal of Roentgenology*, 183, 377-381.
- GREENBERG, C. C., REGENBOGEN, S. E., STUDDERT, D. M., LIPSITZ, S. R., ROGERS, S. O., ZINNER, M. J. & GAWANDE, A. A. 2007. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg*, 204, 533-40.
- GROBER, E. D. & BOHNEN, J. M. A. 2005. Defining medical error. *Canadian journal of surgery. Journal canadien de chirurgie*, 48, 39-44.
- GULLAND, A. 2017. UK has best health system in developed world, US analysis concludes. *BMJ*, 358, j3442.
- GURM, H. S., SANZ-GUERRERO, J., JOHNSON, D. D., JENSEN, A., SETH, M., CHETCUTI, S. J., LALONDE, T., GREENBAUM, A., DIXON, S. R. & SHIH, A. 2016. Using simulation for teaching femoral arterial access: A multicentric collaboration. *Catheter Cardiovasc Interv*, 87, 376-80.
- HALDANE, V., DE FOO, C., ABDALLA, S. M., JUNG, A.-S., TAN, M., WU, S., CHUA, A., VERMA, M., SHRESTHA, P. & SINGH, S. 2021. Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries. *Nature Medicine*, 27, 964-980.
- HALES, B. M. & PRONOVOST, P. J. 2006. The checklist--a tool for error management and performance improvement. *J Crit Care*, 21, 231-5.

- HAMMER, G. P., DU PREL, J. B. & BLETTNER, M. 2009. Avoiding bias in observational studies: part 8 in a series of articles on evaluation of scientific publications. *Dtsch Arztebl Int*, 106, 664-8.
- HAYNES, A. B., WEISER, T. G., BERRY, W. R., LIPSITZ, S. R., BREIZAT, A.-H. S., DELLINGER, E. P., HERBOSA, T., JOSEPH, S., KIBATALA, P. L., LAPITAN, M. C. M., MERRY, A. F., MOORTHY, K., REZNICK, R. K., TAYLOR, B. & GAWANDE, A. A. 2009a. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *New England Journal of Medicine*, 360, 491-499.
- HAYNES, A. B., WEISER, T. G., BERRY, W. R., LIPSITZ, S. R., BREIZAT, A. H., DELLINGER, E. P., HERBOSA, T., JOSEPH, S., KIBATALA, P. L., LAPITAN, M. C., MERRY, A. F., MOORTHY, K., REZNICK, R. K., TAYLOR, B. & GAWANDE, A. A. 2009b. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*, 360, 491-9.
- HELMREICH, R. L., KLINECT, J. R. & JOHN, A. MODELS OF THREAT, ERROR, AND CRM IN FLIGHT OPERATIONS.
- HELMREICH, R. L., MERRITT, A. C. & WILHELM, J. A. 1999. The evolution of Crew Resource Management training in commercial aviation. *Int J Aviat Psychol*, 9, 19-32.
- HIGGINS, M. & HERPY, J. P. 2021a. Medical Error, Adverse Events, and Complications in Interventional Radiology: Liability or Opportunity? *Radiology*, 298, 275-283.
- HIGGINS, M. C. & HERPY, J. P. 2021b. Medical error, adverse events, and complications in interventional radiology: liability or opportunity? *Radiology*, 298, 275-283.
- HU, Y. Y., ARRIAGA, A. F., ROTH, E. M., PEYRE, S. E., CORSO, K. A., SWANSON, R. S., OSTEN, R. T., SCHMITT, P., BADER, A. M., ZINNER, M. J. & GREENBERG, C. C. 2012. Protecting patients from an unsafe system: the etiology and recovery of intraoperative deviations in care. *Ann Surg*, 256, 203-10.
- HULL, L., ARORA, S., KASSAB, E., KNEEBONE, R. & SEVDALIS, N. 2011. Observational teamwork assessment for surgery: content validation and tool refinement. *J Am Coll Surg*, 212, 234-243.e1-5.
- INSTITUTE OF MEDICINE COMMITTEE ON QUALITY OF HEALTH CARE, I. A. 2000. To Err Is Human Building a Safer Health System. In: KOHN, L. T., CORRIGAN, J. M. & DONALDSON, M. S. (eds.) *To Err is Human: Building a Safer Health System*. Washington (DC): National Academies Press (US)
- Copyright 2000 by the National Academy of Sciences. All rights reserved.
- JACQUES, J. 2012. *Greek medicine from Hippocrates to Galen : selected papers*, Leiden.Boston, Koninklijke Brill NV.
- JARVIS, N. R., JARVIS, T., MORRIS, B. E., VERHEY, E. M., REBECCA, A. M., HOWARD, M. A. & TEVEN, C. M. 2023. A Scoping Review of Mobile Apps in Plastic Surgery: Patient Care, Trainee Education, and Professional Development. *Plast Reconstr Surg Glob Open*, 11, e4943.

- JCAHO. 2002. *The Accreditation Guide for Hospitals* [Online]. Available: The Joint Commission www.jointcommission.org › media › tjc › topics-library [Accessed].
- JENSEN, R. S. & RAKOVAN, L. A. 1995. Proceedings of the Eighth International Symposium on Aviation Psychology, April 24-27, 1995. (*No Title*).
- JOINT_COMMISSION_RESOURCES 2010. Failure Mode And Effects Analysis in Health Care:: Proactive Risk Reduction. Joint Commission Resources.
- JONES, S. R., CARLEY, S. & HARRISON, M. 2003. An introduction to power and sample size estimation. *Emergency Medicine Journal*, 20, 453-458.
- KHALILZADEH, O., BAERLOCHER, M. O., SHYN, P. B., CONNOLLY, B. L., DEVANE, A. M., MORRIS, C. S., COHEN, A. M., MIDIA, M., THORNTON, R. H., GROSS, K., CAPLIN, D. M., AERON, G., MISRA, S., PATEL, N. H., WALKER, T. G., MARTINEZ-SALAZAR, G., SILBERZWEIG, J. E. & NIKOLIC, B. 2017. Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee. *J Vasc Interv Radiol*, 28, 1432-1437.e3.
- KHAN, I. & ARSANIOUS, M. 2018. Does the perception of severity of medical error differ between varying levels of clinical seniority? *Advances in medical education and practice*, 9, 443-452.
- KOETSER, I. C., DE VRIES, E. N., VAN DELDEN, O. M., SMORENBURG, S. M., BOERMEESTER, M. A. & VAN LIENDEN, K. P. 2013. A checklist to improve patient safety in interventional radiology. *Cardiovasc Intervent Radiol*, 36, 312-9.
- LANDSBERGER, H. A. 1958a. *Hawthorne revisited. Management and the worker: its critics, and developments in human relations in industry*, Cornell University in Ithaca, N.Y.
- LANDSBERGER, H. A. 1958b. Hawthorne revisited: management and the worker : its critics, and developments in human relations in industry. . *Ithaca, N.Y., Cornell University*.
- LEAPE, L. L. 1994. Error in medicine. *Jama*, 272, 1851-7.
- LEAPE, L. L. 2009. Errors in medicine. *Clin Chim Acta*, 404, 2-5.
- LEAPE, L. L., BRENNAN, T. A., LAIRD, N., LAWTHERS, A. G., LOCALIO, A. R., BARNES, B. A., HEBERT, L., NEWHOUSE, J. P., WEILER, P. C. & HIATT, H. 1991. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med*, 324, 377-84.
- LEAR, R., GODFREY, A. D., RIGA, C., NORTON, C., VINCENT, C. & BICKNELL, C. D. 2017. The Impact of System Factors on Quality and Safety in Arterial Surgery: A Systematic Review. *Eur J Vasc Endovasc Surg*, 54, 79-93.
- LEWIS, D. R., BULLBULIA, R. A., MURPHY, P., JONES, A. J., SMITH, F. C., BAIRD, R. N. & LAMONT, P. M. 1999. Vascular surgical intervention for complications of cardiovascular radiology: 13 years' experience in a single centre. *Ann R Coll Surg Engl*, 81, 23-6.

- LINGARD L, E. S., WHYTE S, REGEHR G, BAKER GR, REZNICK R, BOHNEN J, ORSER B, DORAN D, GROBER E. 2004. Communication failures in the operating room: an observational classification of recurrent types and effects. . *Qual Saf Health Care*, 13, 330-4. .
- LINGARD, L., ESPIN, S., RUBIN, B., WHYTE, S., COLMENARES, M., BAKER, G. R., DORAN, D., GROBER, E., ORSER, B., BOHNEN, J. & REZNICK, R. 2005. Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. *Qual Saf Health Care*, 14, 340-6.
- LINGARD, L., ESPIN, S., WHYTE, S., REGEHR, G., BAKER, G. R., REZNICK, R., BOHNEN, J., ORSER, B., DORAN, D. & GROBER, E. 2004a. Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care*, 13:, 330–334.
- LINGARD, L., ESPIN, S., WHYTE, S., REGEHR, G., BAKER, G. R., REZNICK, R., BOHNEN, J., ORSER, B., DORAN, D. & GROBER, E. 2004b. Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care*, 13, 330-4.
- LINGARD, L., REGEHR, G., ORSER, B., REZNICK, R., BAKER, G. R., DORAN, D., ESPIN, S., BOHNEN, J. & WHYTE, S. 2008. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. *Arch Surg*, 143, 12-7; discussion 18.
- LINGARD, L., REZNICK, R., ESPIN, S., REGEHR, G. & DEVITO, I. 2002. Team Communications in the Operating Room: Talk Patterns, Sites of Tension, and Implications for Novices. *Acad. Med.*, 77:232–237.
- LINKIN, D. R., SAUSMAN, C., SANTOS, L., LYONS, C., FOX, C., AUMILLER, L., ESTERHAI, J., PITTMAN, B. & LAUTENBACH, E. 2005. Applicability of Healthcare Failure Mode and Effects Analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clin Infect Dis*, 41, 1014-9.
- LUTJEBOER, J., BURGMANS, M. C., CHUNG, K. & VAN ERKEL, A. R. 2015. Impact on Patient Safety and Satisfaction of Implementation of an Outpatient Clinic in Interventional Radiology (IPSIPOLI-Study): A Quasi-Experimental Prospective Study. *Cardiovasc Intervent Radiol*, 38, 543-51.
- MAFELD, S., OREOPOULOS, G., MUSING, E. L. S., CHAN, T., JABERI, A. & RAJAN, D. 2020. Sources of Error in Interventional Radiology: How, Why, and When. *Can Assoc Radiol J*, 71, 518-527.
- MALEUX, G., KOOLEN, M. & HEYE, S. 2009. Complications after endovascular aneurysm repair. *Semin Intervent Radiol*, 26, 3-9.
- MANI, R. L., EISENBERG, R. L., MCDONALD, E. J., POLLOCK, J. A. & MANI 1978. Complications of catheter cerebral arteriography: analysis of 5,000 procedures. I. Criteria and incidence. *American Journal of Roentgenology*, 131, 861-865.
- MASON, S., KURUVILLA, S., RIGA, C., GOHEL MS, H., GOHEL, M., HAMADY, M., CHESHIRE, N. & BICKNELL, C. 2013. Design and validation of an error capture tool

for quality evaluation in the vascular and endovascular surgical theatre. *Eur J Vasc Endovasc Surg*, 45(3), 248-54.

MCCARNEY, R., WARNER, J., ILIFFE, S., VAN HASELEN, R., GRIFFIN, M. & FISHER, P. 2007a. The Hawthorne Effect: a randomised, controlled trial. *BMC Med Res Methodol*, 7, 30.

MCCARNEY, R., WARNER, J., ILIFFE, S., VAN HASLEN, R., GRIFFIN, M. & FISHER, P. 2007b. The Hawthorne Effect: a randomised, controlled trial. *BMC Medical Research Methodology*, 7:30.

MCNALLY, K. M., PAGE, M. A. & SUNDERLAND, V. B. 1997. Failure-mode and effects analysis in improving a drug distribution system. *Am J Health Syst Pharm*, 54, 171-7.

MELLOUK AID, K., TCHALA VIGNON ZOMAHOUN, H., SOULAYMANI, A., LEBASCLE, K., SILVERA, S., ASTAGNEAU, P. & MISSET, B. 2017. Mortality and infectious complications of therapeutic EndoVascular interventional radiology: a systematic and meta-analysis protocol. *Syst Rev*, 6, 89.

MISHRA, A., CATCHPOLE, K., DALE, T. & MCCULLOCH, P. 2008. The influence of non-technical performance on technical outcome in laparoscopic cholecystectomy. *Surg Endosc*, 22, 68-73.

MISHRA, A., CATCHPOLE, K. & MCCULLOCH, P. 2009. The Oxford NOTECHS System: reliability and validity of a tool for measuring teamwork behaviour in the operating theatre. *Qual Saf Health Care*, 18, 104-8.

MOBASHERI, M. H., JOHNSTON, M., SYED, U. M., KING, D. & DARZI, A. 2015. The uses of smartphones and tablet devices in surgery: A systematic review of the literature. *Surgery*, 158, 1352-1371.

MORBI, A. H. M., HAMADY, M. S., RIGA, C. V., KASHEF, E., PEARCH, B. J., VINCENT, C., MOORTHY, K., VATS, A., CHESHIRE, N. J. W. & BICKNELL, C. D. 2012. Reducing error and improving efficiency during Vascular interventional radiology: Implementation of a Preprocedural Team Rehearsal. *Radiology*, 264.

MOSER, R. H. 1956. Diseases of medical progress. *N Engl J Med*, 255, 606-14.

NAGPAL, K., VATS, A., AHMED, K., SMITH, A. B., SEVDALIS, N., JONANSSON, H., VINCENT, C. & MOORTHY, K. 2010a. A systematic quantitative assessment of risks associated with poor communication in surgical care. *Arch Surg*, 145, 582-8.

NAGPAL, K., VATS, A., LAMB, B., ASHRAFIAN, H., SEVDALIS, N., VINCENT, C. & MOORTHY, K. 2010b. Information transfer and communication in surgery: a systematic review. *Ann Surg*, 252, 225-39.

NHS_ENGLAND 2014. Standardise, educate, harmonise

Commissioning the conditions for

safer surgery

Report of the NHS England Never

Events Taskforce

In: ENGLAND, N. (ed.).

PARLIAMENT, T. U. K. 1998. Data Protection Act 1998.

PATEL, S. R., GOHEL, M. S., HAMADY, M., ALBAYATI, M. A., RIGA, C. V., CHESHIRE, N. J. W. & BICKNELL, C. D. 2012. Reducing Errors in Combined Open/Endovascular Arterial Procedures: Influence of a Structured Mental Rehearsal Before the Endovascular Phase. *Journal of Endovascular Therapy*, 19, 383-389.

PATTERSON, E. S., ROTH, E. M., WOODS, D. D., CHOW, R. & GOMES, J. O. 2004. Handoff strategies in settings with high consequences for failure: lessons for health care operations. *Int J Qual Health Care*, 16, 125-32.

POORE, S. O., SILLAH, N. M., MAHAJAN, A. Y. & GUTOWSKI, K. A. 2012. Patient safety in the operating room: I. Preoperative. *Plast Reconstr Surg*, 130, 1038-47.

PUTTICK, T., SPEIRS, A., GIBSON, M., TADJKARIMI, J. & AHMAD, F. 2016. Barriers to a safety checklist and methods to improve usage of the WHO safety checklist in interventional radiology. *BJR Case Rep*, 2, 20150128.

QUALITY_ONE INTERNATIONAL. *HFMEA* [Online]. Available: <https://quality-one.com/hfmea/> [Accessed 2019].

RCR. 2012. *Invasive Radiology Procedure Patient Safety Checklist* [Online]. Available: <https://www.rcr.ac.uk/audit/invasive-radiology-procedure-patient-safety-checklist> [Accessed].

REASON, J. 1990. The contribution of latent human failures to the breakdown of complex systems. *Philos Trans R Soc Lond B Biol Sci*, 327, 475-84.

REASON, J. 1995. Understanding adverse events: human factors. *Qual Health Care*, 4, 80-9.

REASON, J. 2000. Human error: models and management. *The Western journal of medicine*, 172, 393-396.

RYDENFALT, C., JOHANSSON, G., ODENRICK, P., AKERMAN, K. & LARSSON, P. A. 2013. Compliance with the WHO Surgical Safety Checklist: deviations and possible improvements. *Int J Qual Health Care*, 25, 182-7.

SAAD, W. E., WALLACE, M. J., WOJAK, J. C., KUNDU, S. & CARDELLA, J. F. 2010. Quality improvement guidelines for percutaneous transhepatic cholangiography, biliary drainage, and percutaneous cholecystostomy. *J Vasc Interv Radiol*, 21, 789-95.

SACKS, D., MCCLENNY, T. E., CARDELLA, J. F. & LEWIS, C. A. 2003. Society of Interventional Radiology clinical practice guidelines. *J Vasc Interv Radiol*, 14, S199-202.

- SCHALLER, G. B. & HEINRICH, B. 2011. *Field Notes on Science & Nature*, Harvard University Press, Biography & Autobiography.
- SCHNEIDER, H. 1996. Failure mode and effect analysis : FMEA from theory to execution. *Technometrics*, 38, 80-80.
- SEIDEN, S. C. & BARACH, P. 2006. Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events: Are They Preventable? *Archives of Surgery*, 141, 931-939.
- SEVDALIS, N., LYONS, M., HEALEY, A. N., UNDRE, S., DARZI, A. & VINCENT, C. A. 2009. Observational Teamwork Assessment for Surgery; Construct Validation With Expert Versus Novice Raters. (*Ann Surg* ;, 249:, 1047–1051.
- SEXTON, J. B., HELMREICH, R. L., NEILANDS, T. B., ROWAN, K., VELLA, K., BOYDEN, J., ROBERTS, P. R. & THOMAS, E. J. 2006a. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC Health Serv Res*, 6, 44.
- SEXTON, J. B., HOLZMUELLER, C. G., PRONOVOST, P. J., THOMAS, E. J., MCFERRAN, S., NUNES, J., THOMPSON, D. A., KNIGHT, A. P., PENNING, D. H. & FOX, H. E. 2006b. Variation in caregiver perceptions of teamwork climate in labor and delivery units. *J Perinatol*, 26, 463-70.
- SEXTON, J. B., THOMAS, E. J. & HELMREICH, R. L. 2000. Error, stress, and teamwork in medicine and aviation: cross sectional surveys. *BMJ (Clinical research ed.)*, 320, 745-749.
- SKEVINGTON, S. M., LANGDON, J. E. & GIDDINS, G. 2012. 'Skating on thin ice?' Consultant surgeon's contemporary experience of adverse surgical events. *Psychol Health Med*, 17, 1-16.
- SORRA, J., KHANNA, K., DYER, N., MARDON, R. & FAMOLARO, T. 2012. Exploring relationships between patient safety culture and patients' assessments of hospital care. *J Patient Saf*, 8, 131-9.
- SOUTHARD, P. B., KUMAR, S. & SOUTHARD, C. A. 2011. A Modified Delphi Methodology to Conduct a Failure Modes Effects Analysis: A Patient-Centric Effort in a Clinical Medical Laboratory. *Quality Management in Healthcare*, 20, 131-151.
- SRIVASTAV, A. K., SAINI, V., KUKKAR, V., RATHORE, M. S., KHADAYAT, S. & SAMUEL, A. J. 2022. Safeguarding from COVID-19: educating healthcare workers about the available protective equipment. *Journal of Public Health*, 30, 2133-2137.
- STEINERT, A., HAESNER, M. & STEINHAGEN-THIESSEN, E. 2017. [App-based self-monitoring in type 2 diabetes]. *Z Gerontol Geriatr*, 50, 516-523.
- SUVA, D., HALLER, G., LUBBEKE-WOLFF, A., MACHERET, F., KINDLER, V. & HOFFMEYER, P. 2014. [From aviation to surgery: the challenge of safety]. *Rev Med Suisse*, 10, 882-4.

- TAN, J. A., NAIK, V. N. & LINGARD, L. 2006. Exploring obstacles to proper timing of prophylactic antibiotics for surgical site infections. *Qual Saf Health Care*, 15, 32-8.
- THOMAS, E. & PETERSEN, L. 2003. Measuring errors and adverse events in health care. *J GEN INTERN MED*, 18, 61–67
- THOMAS, E., STUDDERT, D., BURSTIN, H., ORAV, E., ZEENA T, T. & WILLIAMS, E. 2000. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care*, 38, 261e71].
- THOMAS, E. J., SEXTON, J. B., NEILANDS, T. B., FRANKEL, A. & HELMREICH, R. L. 2005. The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units[ISRCTN85147255] [corrected]. *BMC Health Serv Res*, 5, 28.
- THOMAS, E. J., STUDDERT, D. M., NEWHOUSE, J. P., ZBAR, B. I., HOWARD, K. M., WILLIAMS, E. J. & BRENNAN, T. A. 1999. Costs of medical injuries in Utah and Colorado. *Inquiry*, 36, 255-64.
- TRIPEPI, G., JAGER, K. J., DEKKER, F. W. & ZOCCAL, C. 2010. Selection Bias and Information Bias in Clinical Research. *Nephron Clin Pract.*, 115, c94–c99.
- TUONG, B., SHNITZER, Z., PEHORA, C., CHOI, P., LEVINE, M., KRISHNAMURTHY, G., CHAIT, P., TEMPLE, M., JOHN, P., AMARAL, J. & CONNOLLY, B. 2009. The experience of conducting Mortality and Morbidity reviews in a pediatric interventional radiology service: a retrospective study. *J Vasc Interv Radiol*, 20, 77-86.
- UGUR, E., KARA, S., YILDIRIM, S. & AKBAL, E. 2016. Medical errors and patient safety in the operating room. *J Pak Med Assoc*, 66, 593-7.
- UNDRE, S., HEALEY, A. N., DARZI, A. & VINCENT, C. A. 2006. Observational assessment of surgical teamwork: a feasibility study. *World J Surg*, 30, 1774-83.
- USA, D. O. V. A. 2023. *VHA National Center for Patient Safety* [Online]. Available: <https://www.patientsafety.va.gov/professionals/onthejob/HFMEA.asp> [Accessed 22nd of June 2023].
- USA, M. O. D. O. T. 1949. Procedures for performing a failure mode effect and critical analysis.
- VACIRCA, A., FAGGIOLI, G., PINI, R., GALLITTO, E., MASCOLI, C., CACIOPPA, L. M., GARGIULO, M. & STELLA, A. 2019. The Outcome of Technical Intraoperative Complications Occurring in Standard Aortic Endovascular Repair. *Annals of Vascular Surgery*, 56, 153-162.
- VAN DER STORM, S. L., BEKTAŞ, M., BARSOM, E. Z. & SCHIJVEN, M. P. 2023. Mobile applications in gastrointestinal surgery: a systematic review. *Surgical Endoscopy*, 37, 4224 - 4248.
- VATS, A., VINCENT, C. A., NAGPAL, K., DAVIES, R. W., DARZI, A. & MOORTHY, K. 2010. Practical challenges of introducing WHO surgical checklist: UK pilot experience. *Bmj*, 340, b5433.

- VINCENT, C., MOORTHY, K., SARKER, S. K., CHANG, A. & DARZI, A. W. 2004. Systems approaches to surgical quality and safety: from concept to measurement. *Ann Surg*, 239, 475-82.
- VINCENT, C., NEALE, G. & WOLOSZYNOWYCH, M. 2001. Adverse events in British hospitals: preliminary retrospective record review. *Bmj*, 322, 517-9.
- WETTERNECK, T. B., SKIBINSKI, K. A., ROBERTS, T. L., KLEPPIN, S. M., SCHROEDER, M. E., ENLOE, M., ROUGH, S. S., HUNDT, A. S. & CARAYON, P. 2006. Using failure mode and effects analysis to plan implementation of smart i.v. pump technology. *Am J Health Syst Pharm*, 63, 1528-38.
- WHO. 2008. *IMPLEMENTATION MANUAL SURGICAL SAFETY CHECKLIST* [Online]. Available: https://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf?ua=1 [Accessed 2016].
- WIEGMANN, D. A., ELBARDISSI, A. W., DEARANI, J. A., DALY, R. C. & SUNDT, T. M., 3RD 2007. Disruptions in surgical flow and their relationship to surgical errors: an exploratory investigation. *Surgery*, 142, 658-65.
- WILLIS, G. 1992. Failure modes and effects analysis in clinical engineering. *J Clin Eng*, 17, 59-63.
- WILSON, R. M., HARRISON, B. T., GIBBERD, R. W. & HAMILTON, J. D. 1999. An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust*, 170, 411-5.
- WILSON, R. M., RUNCIMAN, W. B., GIBBERD, R. W., HARRISON, B. T., NEWBY, L. & HAMILTON, J. D. 1995. The Quality in Australian Health Care Study. *Med J Aust*, 163, 458-71.

List of Appendices

Appendix 1
Ethnographic field notes collected for chapter 3
Appendix 2 Copy of the initial questionnaire used in the pilot study of chapter 4. C:\Users\Default.DESKTOP-LD6JUI4\OneDrive - Imperial College London\Dr Rawf PhD materials\Thesis draft1\PhD Resubmission\Chapter 4\Cop of IR Questionnaire 2022 template.xlsx
Appendix 3 A link to the online questionnaire used in chapter 4. https://imperial.eu.qualtrics.com/jfe/form/SV_3EugjdS0PsBJrYG
Appendix 4 A link to access the questionnaire in chapter 9. https://imperial.eu.qualtrics.com/survey-builder/SV_78nLwnUGPcVjk7c/edit
Appendix 5 A link to the FERERI error capture tool https://imperiallondon-my.sharepoint.com/:x:/r/personal/fr1912_ic_ac_uk/Documents/Dr%20Rawf %20PhD%20materials/Thesis%20draft1/PhD%20Resubmission/Chapter%205/FERERI%20template.xlsx?d=w4e29e402b6334b8e878b9275e6c3dc97&csf=1&web=1&e=5ooZQb